

Chapter 10

Laws and Regulations Affecting Unconventional Cancer Treatments

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Laws and Regulations Affecting Unconventional Cancer Treatments

INTRODUCTION

Laws and regulations governing medical treatments are predicated on the idea that State and Federal Governments have a legitimate interest in protecting the health and safety of their citizens. At the same time, both State and Federal Governments have an interest in protecting individuals' rights of privacy in matters of their own health and welfare. Issues concerning the availability and use of unconventional cancer treatments illustrate some ways in which these two interests may conflict. In recent years, laws and regulations designed to protect patients from drugs, biologics, or other substances of unknown safety and efficacy have been challenged for limiting patients' access to unconventional cancer treatments, impinging on their "freedom of choice" in medical care. From the opposing point of view, that of "consumer protection," State laws permitting access to specific unconventional cancer treatments that otherwise would be illegal have been criticized for posing a public health hazard and for violating Federal requirements for uniform national drug standards. The effects of these opposing arguments on the use of unconventional cancer treatments is discussed in the first section of this chapter.

Though few are written with the specific intent of influencing the use of unconventional cancer treatments in the United States, many Federal and State laws and regulations ultimately do have a significant effect on the use of these treatments by restricting their availability, marketing, and advertising. The second part of this chapter examines the major Federal and State laws and regulations that affect the use of unconventional cancer treatments and the ways in which Federal and State agencies enforce them. Though these regulations may affect practitioners' activities (particularly practitioners who manufacture and distribute their own treatments), they are not directed solely at them. Laws that restrict availability are designed to ensure that drugs are both safe and effective, while laws that regulate marketing and advertising of products and services (not limited to medical treatments) are intended to prevent such crimes as mail fraud and false advertis-

ing. This **chapter examines those aspects of law that relate to the availability and marketing of** unconventional cancer treatments. Statutes that explicitly regulate the practice of medicine are discussed in chapter 11.

Instances where laws have been challenged in court and the activities that have led to prosecution of some practitioners have been highlighted. These cases rarely involve a single, self-contained issue and are very difficult to characterize into general categories. Both the effort to challenge, or even bypass, the intentions of the laws that prevent use of unconventional methods, and the efforts to effectively enforce the laws have evolved over the years as lawyers have devised different arguments to support claims. In addition, the decisions of the courts have sparked further innovation. Throughout this chapter and the next, court cases illustrate the evolution in this area of law.

CONSUMER PROTECTION V. "FREEDOM OF CHOICE" IN UNCONVENTIONAL CANCER TREATMENTS

The **forces acting to legally** restrain or **expand the availability of** unconventional cancer treatments in the United States can be divided generally into two opposing camps: advocates of "consumer **protection**" **and** advocates **of "freedom of choice"** in cancer treatment. Individuals in the former group basically favor the legal status quo. That is, they **support laws such as the Federal Food, Drug, and Cosmetic Act (FDCA), which requires substantial evidence of safety and efficacy of drugs before they may become widely available, evidence that does not currently exist for** unconventional cancer treatments. The latter group, objecting to the status quo, argue for patients' greater access to unconventional cancer treatments without restrictions.

The proponents of the consumer protection view reason that, based on the U.S. Constitution, State and Federal Governments have a responsibility to protect the health and safety of their citizens. This responsibility includes protecting people from un-

safe and ineffective drugs—the rationale and purpose of the FDCA. It is argued that the safety and efficacy requirements of FDCA are a rational extension of the government’s overall responsibilities to promote public health. In an early case that reached the U.S. Supreme Court involving the 1938 Food, Drug, and Cosmetic Act, Justice Frankfurter articulated the need for government regulation:

The purposes of this legislation . . . touch phases of the lives and health of people which, in normal circumstances of modern industrialism, are largely beyond self-protection. (913)

For unconventional cancer treatments, the rationale for consumer protection extends beyond simply protecting the public health and safety through the regulation of practitioners and treatments. It also includes protecting the public from inaccurate or fraudulent claims about treatments. For instance, the purpose of FDCA provisions that regulate packaging and advertising of prescription drugs is to protect consumers from false and inaccurate claims made for products.

The argument for ‘freedom of choice’ in medical care is based on the concept of an individual’s fundamental right of privacy. It is argued that this right prohibits governmental and private restraints on individual rights to make choices regarding treatments and therefore that individuals should be allowed to decide whether to use any treatment of their choosing: as stated by one ‘freedom of choice’ proponent, “the patient should be permitted to opt for treatment consistent with his views of higher quality of life. . .” (416). A parallel argument is made for a physician’s right and responsibility to provide medical care. It reasons that well-informed physicians, following their best judgment and having assessed the risks and benefits of a treatment, should be allowed to provide the care they deem best for their patients without outside interference (950).¹

Proponents of “freedom of choice” in medical care support implementation of a variety of mechanisms, ranging from State laws exempting certain unconventional cancer treatments from safety and efficacy requirements, to elimination of FDCA requirements for proof of both safety and efficacy of drugs distributed in interstate commerce, to an amendment to the U.S. Constitution that would guarantee “freedom of choice” in health care.

The main route by which the argument for open access to unconventional treatments has been pursued is through the courts, and it is in response to such court cases that the argument for consumer protection has been further developed. In State and Federal courts such questions as the right of privacy,² the right of parents to choose unconventional treatments for their children, and the ability of patients to take responsibility for their treatment decisions through informed consent (in a malpractice case), have been addressed. So far, no legal right has been established that would allow patients general access to unapproved drugs.³ The outcomes of the cases described below show that the straightforward argument for an absolute right to choose any treatment has not been upheld by the courts. In all the cases where the right of privacy in choosing medical treatments has been invoked, the issue of free choice has immediately been blurred by controversies over whether treatments have any demonstrated benefit. However, by addressing the issue of informed consent, the court leaves the door open for a patient to take on some responsibility for choosing an unconventional cancer treatment, broadening the legal interpretation of free choice.

Litigation Involving “Freedom of Choice” in Unconventional Cancer Treatments

In California, the right of privacy was addressed by the State Supreme Court in 1979, in a case

¹The legal restraints on physicians who offer unconventional cancer treatments are discussed in ch. 11, which deals directly with the Practice of medicine.

²The right of privacy generally encompasses various rights recognized as inherent in a free society, including a general right to be left alone and to be protected from governmental interference. It also includes the freedom of the individual to make fundamental choices involving the individual, his or her family, and relationships with others, except where such choices prove to be harmful to others and possibly oneself. Limitations on such fundamental rights are justified only by a compelling State interest. Although the Constitution does not explicitly mention the right of privacy, “zones of privacy” have been created by specific constitutional guarantees based on the Bill of Rights and on Amendments to the Constitution. The U.S. Supreme Court has created zones of privacy in areas such as marriage, procreation, contraception, abortion, family relationships, childrearing, and education. The right of privacy has been invoked in some cases involving medical decisionmaking, including the right to refuse treatment (as in the widely publicized *Quinlan* (441) and *Bowvia* (94a) cases).

³Such access is currently limited to unapproved drugs that are under an investigational new drug (IND) exemption, drugs brought from foreign countries for personal use, or to particular States where laws have been enacted to exempt certain unapproved drugs from safety and efficacy requirements.

involving a physician charged with violating the State's Health and Safety Code.⁴ In this case, the physician, James Privitera, had been convicted by a jury of a felony, conspiracy to sell or prescribe an unapproved drug (laetrile) to cancer patients. The verdict was appealed on the grounds that the statute was unconstitutional; Privitera's lawyers contended that the right to obtain laetrile is a fundamental right of privacy. The California Court of Appeals overturned the conviction because it found, among other things, that the State Health and Safety Code violates patients' rights to privacy under the California and U.S. Constitutions (716). When the State appealed the decision, the case went to the California Supreme Court, which found that the right to obtain drugs of unproven efficacy is not encompassed by the right of privacy embodied in either the State or Federal Constitutions.⁵⁶

In his argument for the right of privacy, Privitera relied heavily on cases, such as *Roe v. Wade*, **where the right to privacy in medical decisions was expanded by the courts' decisions. However, in its decision on the Privitera case, the court pointed out that *Roe v. Wade* established that the right of privacy in decisions pertaining to medical care is not absolute, noting that, "the lesson of *Roe v. Wade* for our case is that a requirement that a drug be certified effective for its intended use is a reasonable means to 'insure maximum safety for the patient' " (717). Having decided that the State's Health and Safety Code did not violate a fundamental right of privacy, the court concluded that, "section 1707.1 [of the statute] amply satisfies the applicable standard by bearing a reasonable relationship to the achievement of the legitimate state interest in the health and safety of its citizens" (717). Privitera was unsuccessful in an attempt to have the U.S. Supreme Court review the case (718).**

To date, the only Federal case testing the right of privacy in access to unapproved drugs for cancer treatment is *United States v. Rutherford*. Because every decision was appealed successfully by the

opposing parties, this case made its way to the U.S. Supreme Court. However, as it progressed through the Federal court system, new issues were brought into consideration, making it impossible to characterize it solely as a case about patients' rights of privacy in choosing their medical treatments.

Originally, Glen Rutherford, on behalf of a class of cancer patients, brought suit in Federal district court to stop FDA from prohibiting interstate shipment of laetrile. The court found the drug to be nontoxic and effective if given in the correct dosage, and permitted its limited purchase. The government appealed the decision. The U.S. Court of Appeals for the 10th Circuit upheld the lower court's injunction but directed the district court to remand the case to the Food and Drug Administration (FDA) for determination of whether laetrile was a 'new drug' (within the meaning of the FDCA) and, if so, whether it was exempted from the safety and effectiveness requirements by falling under either of two "grandfather" clauses. FDA's determination that laetrile was a new drug that did not fall under either grandfather clause brought the case back to the district court. The presiding judge concluded that FDA's determination was incorrect (he determined that the drug was grandfathered), and that by denying cancer patients access to laetrile, FDA was infringing on the constitutionally protected right of privacy. Again the decision was appealed. However, in its decision, the court of appeals did not address the lower court's ruling, but introduced anew issue: the court found that FDCA's standards for safety and efficacy had "no reasonable application" to terminally ill cancer patients and allowed terminally ill individuals to receive laetrile. FDA appealed the decision to the U.S. Supreme Court, which focused only on the issue of whether the safety and efficacy requirements applied to drugs for terminally ill patients. In a unanimous decision, the Supreme Court reversed the lower court's ruling by upholding the FDCA provision, and remanded the case to the lower court (918).⁷ The circuit court upheld the

⁴This code requires Federal or State approval of drugs used to treat cancer patients.

⁵The court's decision was split 5 to 2. The Chief Justice dissented, arguing that the constitutional right to privacy for both the patient and physician was violated. In a separate dissent another Justice expressed the opinion that the majority opinion condoned action that appeared to him to be cruel and inhuman treatment (717).

⁶Each court's decision to view this as a right to privacy issue or not determined the legal standard by which the court judged the statute. The Appeals court saw the right to choose any medical treatment as constitutionally protected and applied the compelling interest standard, which requires that the State have a compelling interest that overrides the right to privacy. The State Supreme Court, however, did not see it as a protected right and therefore applied the rational basis test, which requires that a statute bear "a reasonable relationship to the achievement of a legitimate state interest" (717).

⁷The Supreme Court did not address the right of privacy issue because that was not the basis of the appeals court decision, the subject of the appeal.

FDCA provision and dismissed the argument that the right of privacy extends to the use of unapproved drugs (920). A petition for a writ of certiorari, which would put the case before the court of appeals again, was denied by the Supreme Court (919).

Two court cases concerning the use of laetrile have addressed the issue of parents' rights to choose an unapproved treatment for their child, both of whom had cancers that, in all probability, were curable with appropriate mainstream treatment. In both cases, the State requested that courts declare the children wards of the State, arguing that the parents' actions constituted parental neglect. However, the circumstances surrounding the parents' decisions led the courts to different opinions (525,692). In Massachusetts, Chad Green, a 2-year-old boy with acute lymphocytic leukemia, was declared a ward of the State when his parents stopped his chemotherapy while he was in remission and put him on what they called a metabolic therapy (laetrile and a nutritional regimen). Though his parents had already left the State with Chad, the State Supreme Court upheld a court order requiring he receive State-supervised chemotherapy and cease taking the unapproved treatment. The court acknowledged that parents have natural rights that encompass a private family life, but viewed the child's well-being as an overriding interest. The court based its decision of what was in the child's best interest on strong medical evidence that the unconventional treatment was not improving the child's condition, while, until the parents stopped treatments, conventional treatment had controlled the leukemia. It found the nutritional therapy "useless and dangerous" (692). Chad Green died in Mexico shortly after his parents took him there for unconventional treatment (627).

A similar case in New York, *In re Hofbauer*, involved a 7-year-old boy, **Joey Hofbauer**, with **Hodgkins** disease. **Again the State tried to prevent the parents from continuing** to treat the child with **metabolic therapy (including laetrile) by pursuing a child neglect case. However, in this** case the **New York Court of Appeals found** that the **parents, who had found a licensed physician** to prescribe laetrile, **had not "failed** to exercise a minimum degree of care" (653) since they were following a recommended treatment that had "not been totally rejected by responsible medical authority" (439). In addition, the court found some evidence that the uncon-

ventional treatment might be effective, while there was also evidence that conventional treatment was failing (440). Joey Hofbauer died a few years later, in 1980. In both cases, how the courts weighed the evidence of effectiveness of the available treatments seems to have played more of a role in their decisions than the concern for a right to family privacy (692).

In a malpractice case that is still in the court system, another aspect of "freedom of choice" in unconventional cancer treatments was addressed: whether patients can assume the risk for the treatments they choose, thereby relieving practitioners of legal responsibility. In *Schneider v. Revici, Edith Schneider and her husband sued Emanuel Revici and the Institute of Applied Biology, Inc.*, for fraud and medical malpractice in connection with his use of unconventional treatments in treating Schneider's breast cancer. Before the trial began, the defendants tried to modify their answer to the charges "to include express assumption of risk as an affirmative defense" (786). The trial judge denied the motion. If the judge had allowed the motion, during the trial the defense would have argued that Edith Schneider had assumed the risk of her treatment by signing a release form. The jury found in favor of Mrs. Schneider only on the malpractice claim and awarded her and her husband \$1.05 million.⁸ Revici appealed the verdict, arguing, among other things, that the trial judge erred in not allowing express assumption of risk as a defense. The appeals court agreed, finding that express assumption of risk provided a complete defense. The case was remanded to the lower court for a jury to consider the issue of assumption of risk.

The appeals court's decision adds a new dimension to the argument for "freedom of choice" in medical care by expanding the potential of the patient to take on responsibility for treatment choice. In its opinion, the court specifically noted:

[W]e see no reason why a patient should not be allowed to make an informed decision to go outside currently approved medical methods in search of an unconventional treatment. While a patient should be encouraged to exercise care for his own safety, we believe that an informed decision to avoid surgery and conventional chemotherapy is within the patient's right "to determine what shall be done with his own body." (786)

⁸However, they also found that she was 50 percent negligent and reduced the award accordingly to \$525,000.

In the upcoming trial, the jury will have to decide whether the consent form signed by Mrs. Schneider constitutes an assumption of risk.

Summary

The cases **described above demonstrate** that the courts **generally have** not agreed with the arguments **put forth for “freedom of choice” in** unconventional cancer treatments. Though they are sympathetic to the plight of cancer patients, they see the laws, such as the FDCA, as both fulfilling Congress’ intent and playing a necessary role in protecting the public from unproven treatments that might not be safe or effective. *Schneider v. Revici* **has brought** a new issue to the forefront of this area of law that could have an impact on both patients’ and physicians’ attitudes toward these treatments by extending the potential for patients to take on more responsibility for their treatment choices, relieving the practitioner of some liability.

FEDERAL AND STATE REGULATION OF UNCONVENTIONAL TREATMENTS

Both **Federal and State Governments, through their appropriate agencies, are responsible for regulating the manufacturing, marketing, and advertising of drugs and the advertising of health products in general.**⁹ **At the Federal level, the Food and Drug Administration (FDA) is responsible for approving** new drugs **for** interstate commerce; stopping interstate marketing of adulterated, misbranded, or unapproved drugs¹⁰; and regulating advertising of prescription drugs, among other responsibilities. The Federal Trade Commission (FTC), along with FDA, is responsible for stopping false advertising of most products and services, including over-the-counter drugs, devices, and treatment regimens. The U.S. Postal Service (USPS) is responsible for protecting consumers from false and deceptive mail-order advertising. Regulation of intrastate commerce involving drugs unapproved by FDA falls under the jurisdiction of each State. In addition, States have their own laws about false advertising and health fraud. This section discusses how the Federal and

State Governments carry out their responsibilities in this area, describes their effect on unconventional cancer treatments, and, where possible, provides examples of relevant litigation arising from violations of the laws.

Federal Regulation of Manufacturing and Marketing of Drugs

FDA has regulatory authority over the manufacturing and marketing of food, drugs, devices, and cosmetics in order to ensure their safety and (in the case of drugs and devices) efficacy. The Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 321-393) authorizes FDA to prohibit the interstate marketing of unsafe or ineffective drugs (21 U.S.C. § 331), and provides for sanctions against manufacturers, distributors, or promoters who violate the terms of the FDCA (21 U.S.C. § 333). It does not include sanctions against patients who use these drugs. The FDCA requires that the safety and effectiveness of a drug be established before FDA grants formal approval for the drug to be shipped in interstate commerce. (See box 10-A for a description of how the safety and efficacy of drugs are established.) FDA determines whether a sponsor has shown “substantial evidence” of the safety and efficacy of a new drug it wishes to market, but is not responsible for carrying out investigations necessary to prove drug safety and efficacy (791).

FDA also has the authority to collect additional information on substances that are, or are suspected of being, marketed or promoted in violation of the FDCA. FDA can collect samples and conduct examinations and inspections of the substance in question; examine records to determine whether the substance has been marketed in interstate commerce; enter and inspect manufacturing sites and warehouses; refuse imported products that appear to violate the FDCA; and not@ manufacturers or promoters that they may be violating FDA regulations in time for them to make corrections voluntarily before FDA initiates legal or administrative proceedings (21 U.S.C. §372,373,374, and 381).

FDA regulations apply only to specific substances used in treatments, not to treatment regimens or practices. Among unconventional cancer treatments,

⁹The discussion of FDA authority applies generally to specific substances—drugs, biologics, and foods—for which medical claims can be made. It does not extend to psychological, behavioral, or spiritual techniques, or to general dietary regimens (except in some cases to specific *dietary* products).

¹⁰Unapproved drugs are drugs that have not been approved by FDA for marketing in the United States.

Box 10-A—HOW the Safety and Efficacy of New Drugs Is Established

Under the FDCA, the requirements for evidence of safety and efficacy (“effectiveness”) apply to those substances that FDA classifies as “new drugs.” A “new drug” is defined in part as:

any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. (21 U.S.C. § 321(p)(1))

A key provision of the statute specifies that a new drug cannot be approved, and therefore cannot be shipped in interstate commerce, until there is “substantial evidence” that it is safe and effective for its intended use. The term “substantial evidence” refers to evidence derived by:

adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. (21 U.S.C. § 355 (d))

Before initiating “well-controlled investigations” (as specified in the section of the statute quoted above), FDA requires that drugs be studied experimentally in animal systems; if the results of those tests fulfill FDA criteria, FDA allows the drug to proceed to a final stage of testing in specific clinical (human) trials. Any person or company wanting to conduct clinical research on an unapproved drug must submit an investigational new drug (IND) application to FDA. If the application contains sufficient detail to meet FDA’s requirements, the IND is allowed to proceed, exempting the sponsor from the FDCA prohibition against shipping unapproved drugs in interstate commerce for the study or studies specified in the IND, and ensures that FDA can monitor the clinical research process (474). Usually, a progression of clinical trials is required, culminating in large, randomized clinical trials.

The rationale for adequate and well-controlled trials set by the statute is one of consumer protection; it is meant to assure that a certain standard of evidence has been met for all new drugs. In a regulation promulgated by FDA (21 C.F.R. § 314.126(b)), an “adequate and well-controlled investigation” is defined as having the following characteristics:

- . it includes a clear statement of the objectives of the investigation and a summary of the proposed or actual methods of analysis in the protocol for the study and in the report of its results;
- . it uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect;
- . its method of selection of subjects provides adequate assurance that they have the disease or condition being studied;
- . its method of assigning patients to treatment and control groups minimizes bias;
- . measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data;
- . its methods of assessment of subjects’ response are well-defined and reliable; and
- . there is an analysis of the results of the study adequate to assess the effects of the drug.

the FDA regulations apply to pharmacologic agents (e.g., laetrile or Burzynski’s Antineoplastons), biologic agents (e.g., vaccines or the biologic products used in Immuno-Augmentative Therapy (IAT)), herbal preparations (e.g., the Essiac or Hoxsey tonics), and homeopathic preparations. Under the terms of the FDCA, drugs are defined as “articles,” including chemical or biological substances, ‘(other than food) intended to affect the structure or any function of the body of man’ and ‘intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man” (21 U.S.C. § 321(g)(1)) .11

Most other types of unconventional cancer treatment (e.g., **psychological and metaphysical approaches**, nutritional regimens) would not be considered drugs and therefore would not be subject to regulation under the FDCA as long as drug-type claims were not made for them.

Drugs manufactured, sold, or used in interstate commerce are **subject to FDA regulation. This includes drugs** that are **sold to patients who** then transport them across state lines or drugs whose components or packaging are produced in another State before sale to a patient (168). FDA’s authority

¹¹FDA examines product labels, promotional materials, advertisements, and oral representations to determine whether a substance is intended to be used therapeutically.

Anecdotal evidence from patients or physicians who have used the drug is not sufficient to exempt it from the new drug classification. As one judge explained:

...it is simply not enough to show that some people, even experts, have a belief in safety and effectiveness. A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea. To remove the aberrations in uniformity which can result from a well-staged ‘swearing match,’ the law requires more. Indeed, it has been heretofore held that the purpose of the normal inquiry is not to determine safety and effectiveness at all, but to ascertain the drug’s general reputation in the scientific community for such characteristics. It is certain that a conflicting reputation is insufficient to establish general recognition.

Therefore, what is required is more than belief, even by an expert; it is a general recognition based upon substantial scientific evidence as delineated in the regulatory guidelines. (910)

The standards of safety and effectiveness specified in the FDCA apply regardless of the type or severity of disease for which a drug is intended. However, depending on the benefits a drug provides and the severity of the condition being treated, different risks are acceptable; for all drugs, the risks must be balanced against the benefits derived from them. It is known and accepted that a number of drugs used to treat cancer have adverse effects so serious that they would not be acceptable in treating, e.g., self-limiting conditions or other non-life-threatening diseases.

Until 1988, use of drugs under INDs was limited to the patients involved in the clinical trial. In a rewrite of the IND regulation, a new provision, often referred to as “treatment IND,” was added. Under a treatment IND, patients with life-threatening or serious diseases may obtain certain drugs that have not yet been approved by FDA for marketing (474). The purpose of this rule is:

...to facilitate the availability of promising new drugs to desperately ill patients as early in the drug development process as possible, before general marketing begins, and to obtain additional data on the drug’s safety and effectiveness. (21 CFR § 312.34)

This new rule permits drugs that are in phase III trials (the final stage of clinical investigation before a new drug application is submitted), or sometimes phase II trials, to be available to patients with serious diseases or immediately life-threatening diseases who are not enrolled in a clinical trial. In these cases, FDA requires that there be a proper treatment protocol in place to obtain the treatment IND, which requires the collection of certain experimental data. FDA may deny the treatment IND if it decides that there is insufficient evidence for concluding that the drug may be effective or if the drug would expose the patient to an unreasonable risk.

Drugs are approved by FDA for the specific indications studied in the clinical trials. These indications appear on the package insert and are the only ones for which the product maybe labeled. Once a drug is approved by FDA, however, physicians are legally free to prescribe it for any medical conditions they wish.

also covers drugs **imported** into the **United States to be sold here. Drugs** that are **produced, packaged, sold, and used entirely** within a **given State** (from **components grown, synthesized, or manufactured** within that **State**) or **completely outside the country fall outside FDA’s** jurisdiction (168,791).¹²

FDA can also take action to stop the interstate distribution of unapproved substances used in unconventional cancer treatments if the substances are shown to be ‘adulterated’ or ‘misbranded. Under the FDCA, a drug is considered adulterated if it has not been made according to current good manufacturing practices or if its strength, purity, or quality falls below that which it is represented to have. A drug is ‘misbranded’ if its labeling contains unfounded claims or inadequate directions for use,

inadequate warnings of potential dangers, or inaccurate information about ‘the contents ‘of the product (279).

Enforcement of the FDCA

Violations of the FDCA requirements can lead to a variety of penalties, such as seizure and destruction of the drugs in question, injunctions to restrain further violations, and criminal penalties (e.g., fines and imprisonment) (21 U.S.C. §332,333, and 334). Violators of the FDCA may also be subject to penalties under the Criminal Fines Enforcement Act and the Comprehensive Crime Control Act (which amended Title 18 of the U.S. Code) authorizing fines of up to \$500,000 for corporate or organizational defendants and \$250,000 for individual defendants

¹²However, the FDA can coordinate with Customs and Immigration officials to control the importation of unapproved drugs into the United States.

(181). Cases of possible violation of the FDCA are reviewed by FDA attorneys, the U.S. Department of Justice, and by local U.S. Attorneys, who decide whether to proceed with civil or criminal action (168,791).

Litigation Involving the FDCA

Several cases involving unconventional cancer treatments have challenged specific provisions of the FDCA and the way in which FDA has carried them out. In other cases, practitioners who use unconventional methods have been charged with violating provisions of the FDCA. Examples of both types of case are given below.

The most intensive legal challenge to any provision of the FDCA was the *Rutherford case* (discussed **above**). When *Rutherford originally brought the case* to court **requesting the** injunction to prevent the FDA from prohibiting distribution of laetrile, he challenged the legality of FDA's actions. Later, after FDA determined that the drug fell under the FDCA requirements for new drugs and was not eligible to be exempted under a grandfather clause which would have exempted it from efficacy requirements, the district court found that FDA's interpretation infringed on a constitutionally protected right of privacy. When the case reached the U.S. Court of Appeals, that court did not address the statutory and constitutional issues on which the lower court ruled (that the drug was entitled to an exemption and that the law violated a constitutional right of privacy). The court of appeals did find, however, that the Act's standards of safety and effectiveness have no reasonable application to the terminally ill. This issue was also taken up by the U.S. Supreme Court. In a unanimous decision, the Supreme Court held that the FDCA contained no express exemption, nor did Congress intend there to be an implicit exemption, with respect to drugs used by the terminally ill. The "effectiveness" requirements of the Act applied equally to drugs used by terminally ill cancer patients, who are entitled to the same protections under the FDCA as other patients; this included the assurance that the drugs they use are safe and effective and that these drugs will not increase their pain and suffering (918).¹³ The Supreme Court remanded the case to the circuit court to resolve the statutory and constitutional issue brought up earlier.

This time, the **district court found** that the drug was not **exempt** from **FDCA requirements because of a grandfather clause and** that the **law did** not infringe on a constitutional right of privacy. The fact that the Supreme Court denied a request for a writ of certiorari that would reopen the issue before the appeals court indicates that the court agreed with the district court's decision (919). In the end, the courts upheld both the provisions of the FDCA and FDA's interpretation of them.

In a more recent case in Texas, Stanislaw Burzynski, M.D., the developer of Antineoplastons, and his patients, challenged parts of the FDCA in a countersuit against the government. Originally, in a civil action in 1983, FDA accused Burzynski of violating two provisions of the FDCA. Specifically, Burzynski was charged with selling his unconventional cancer treatment, Antineoplastons, in interstate commerce. In addition, the government sought to stop the manufacture and distribution of the treatment on the grounds that drugs were adulterated within the meaning of the Act, because the facility did not comply with FDA regulations concerning good manufacturing practices (912). The judge issued an injunction that granted most of FDA's requests. In particular, it ordered Burzynski to bring his facility up to FDA standards for good manufacturing procedures, but also ordered FDA to cooperate in an IND by acting promptly on a submission for approval. Burzynski was explicitly allowed to continue manufacturing and prescribing the drug in Texas. Two years later, in 1985, as part of a criminal investigation based on a referral from FDA, the Department of Justice searched the administrative offices of the Burzynski Research Institute. During the investigation, the government legally seized the patient-treatment records. Burzynski and some of his patients filed a counterclaim seeking return of the records, financial compensation for damages, and other relief. The district court dismissed these counterclaims. Burzynski and his patients appealed the decision to the Fifth Circuit Court of Appeals, but again the court found in favor of the government in regard to seizure of the records and most of the other counterclaims (911). The appellate court did agree that Burzynski and his patients were denied the opportunity for discovery, unfairly preventing them from supporting any counterclaim that might

¹³It has also been argued that seriously ill patients are entitled to even greater protection than less seriously ill patients since the serious **retie** of their illnesses may interfere with their ability to make informed decisions about using risky or unapproved drugs (902); and 21CFR § 56.111(b).

have entitled them to injunctive relief in order to stop the government from disseminating false information to outside parties (911). On this issue, the case was remanded for further proceedings and is still pending. In addition, in December 1987, the patients petitioned the Supreme Court for a writ of certiorari, which would have brought the lower court's decision up for reexamination. Their petition was denied (967).

In an earlier case, Andrew Ivy, a Chicago physician and promoter of Krebiozen, an unconventional cancer treatment popular in the 1950s, was indicted along with another physician and two manufacturers of Krebiozen, on forty-nine separate criminal charges, ranging from violations of the FDCA to conspiracy and mail fraud (937).¹⁴ Ivy countered by bringing suit against the Attorney General of the United States and the U.S. Attorney for the Northern District of Illinois seeking to enjoin them from proceeding against him. He requested instead that an impartial medical commission be appointed to conduct a clinical test of the drug (supervised by the court) to determine its efficacy in treating cancer. Ivy claimed that he could not receive a fair trial, with all the rights guaranteed by the Fifth and Sixth Amendments of the Constitution, if the trial proceeded. The judge ruled in favor of the State and Ivy appealed. The appeals court judge affirmed the lower court's decision, asserting that the criminal trial against Ivy, prior to an impartial test of the drug's effectiveness, would not violate Ivy's rights to a fair trial and due process. The judge noted that though 'resolution of the efficacy issue was beyond the intelligence and comprehension of the jury. . .mere complexity of the factual issues involved in a criminal case is not constitutional basis for precluding the trial' (452). The appeals court agreed with the district judge, who pointed out that juries are regularly required to decide issues not within their scope of knowledge or understanding. In such cases the expert witness is used to bridge the gap in knowledge.

Federal Regulation of Advertising

Three **Federal agencies, FDA, FTC, and USPS, are involved in regulating advertising claims made for health products. As discussed in the previous section, manufacturers and promoters of foods,**

drugs, devices, and cosmetics who make false claims for their products are in violation of the FDCA's misbranding provision. While FDA is primarily responsible for the accurate labeling of foods and drugs and for advertising of prescription drugs to professionals, FTC is primarily responsible for the consumer advertising of foods and over-the-counter drugs.¹⁵ Both FDA and FTC have jurisdiction over advertising of medical devices (791). The ways in which FTC and the Postal Service (which is responsible for monitoring mail order advertising) can regulate advertising claims for unconventional cancer treatments are discussed below.

Federal Trade Commission

FTC learns of potential problems with advertising, including ads for health-related products, through consumer complaints or through its own monitoring efforts. The Federal Trade Commission Act (FTCA) (15 U.S.C. § 41 *et seq.*), which authorizes FTC to **regulate advertising claims,** contains **both a general prohibition of unfair or deceptive acts or practices in or affecting commerce (15 U.S.C. § 45 (a)) and a provision that specifically prohibits the false or deceptive advertising of foods, drugs, devices, or cosmetics (15 U.S.C. § 52).** FTC is **authorized to stop advertisements if they** contain a representation or omission that would likely mislead reasonable consumers and that representation or omission is material (203). It is not necessary for FTC to show that deception has actually occurred or that an advertiser intended to deceive consumers (36,191).

FTC has several alternatives in enforcing the FTCA. In most false or deceptive advertising cases, FTC issues an administrative complaint against the advertiser. Following a hearing held before an administrative law judge, the Commission may issue a cease-and-desist order prohibiting future deceptive advertising (15 U.S.C. § 45(b)). FTC also has authority to seek preliminary and permanent injunctions from Federal district courts for violations of the FTCA (15 U.S.C. § 53). In cases where FTC has entered a cease-and-desist order against an advertiser, it may seek refunds or other restitutions for injured consumers from a State or Federal court, if it can be shown that the violations were fraudulent or dishonest (15 U.S.C. § 57(b)). FTC can also promulgate industry-wide guidelines and trade regu-

¹⁴After a very well-publicized trial that took over a year to complete, Ivy and his co-defendants were acquitted of all charges against them (915).

¹⁵FDA, however, does have jurisdiction over direct-to-consumer prescription drug advertising (181).

litation rules in response to widespread violations of the statute (15 U.S.C. § 57(a)).

If FTC seeks to initiate proceedings to obtain monetary civil penalties, it generally must go through the Department of Justice (15 U.S.C. § 5(a)). The FTC can seek civil penalties for violations of its trade regulation rules or of previous orders (15 U.S.C. § 45(l)-(m)).

Litigation Involving the FTCA—FTC has used its authority to stop false advertising of unconventional cancer treatments. In 1975, FTC sued Travel King, Inc., for false claims about its “psychic surgery” treatment for cancer and other disorders. The company advertised and sold trips to the Philippines where the treatment was performed. Following a trial, FTC ordered the company to stop selling its treatments. The company was also required to send a warning letter to consumers who requested information (857). In a more recent case, FTC obtained a preliminary injunction, stopping Pharmtech, the manufacturer of an unconventional nutritional treatment (“Daily Greens,” capsules containing vitamins, selenium, beta-carotene, and dehydrated vegetables) from advertising that its product could reduce the risk of developing certain types of cancer (283). In the ads, the promoters based their claims on findings in a report, *Diet, Nutrition, and Cancer*, published by the National Academy of Sciences. FTC argued successfully that the report did not substantiate the promoter’s claims and that the report stated that the findings did not apply to dietary supplements, such as Daily Greens. The court, agreeing with FTC’s contention that the promoter’s claims for this product were false, misleading, and deceptive, issued the preliminary injunction prohibiting advertisements containing these claims. In addition, Pharmtech signed a consent agreement prohibiting it from claiming, without substantiation, any health benefits for its products (724).

A similar case, brought against General Nutrition, Inc., was also concluded with a consent agreement (282). In 1984, General Nutrition was accused of making false and unsubstantiated claims about its products, in particular, one called “Healthy Greens.” The company implied that findings of the National Cancer Institute, and American Cancer Society, and the National Academy of Sciences in the Academy’s report, *Diet, Nutrition and Cancer*, **associated the product** with a reduction in cancer

incidence. In February 1989, the company signed a consent agreement obliging them, among other things, to refrain from implying that the findings of those organizations support a finding that the company’s products could reduce the risk of cancer; to stop advertising, packaging, promoting, or labeling its products as being able to cure, treat, prevent, or reduce the risk of disease in humans; and to pay \$200,000 each to the American Diabetes Association, American Cancer Society, and American Heart Association for the support of research. The order also prohibits the company from making false claims about any other products, putting specific restrictions on the claims that could be made in advertising, labeling, and packaging of certain products. In addition, General Nutrition must make available, upon request from FTC, all materials used for advertising and disseminating information about its products, and studies used as the basis for claims it makes about its products (442).

U.S. Postal Service

Unlike FTC, **which has very broad** authority, **USPS jurisdiction over false advertising is limited** to mail **order products (where money or property is sought through the mail) under the civil False Representation Statute (39 U.S.C. § 3005)**. The Postal Inspection Service investigates potential violations of section 3005. It reviews direct mail advertising, television commercials and a number of health and general publications for mail order health products for possible false claims. Another source of information is complaints from consumers and health professionals concerning such advertising.

Enforcement—Promoters who are investigated for false advertising through the mails have the right to an evidentiary hearing before an administrative law judge and may appeal any adverse decision to the USPS Judicial Officer, who then renders the final decision. Upon finding a violation under section 3005, the Judicial Officer may issue two orders: an order directing that all mail containing product orders addressed to the promoters be returned to the consumer and an order that the promoter cease and desist from similar advertising practices. Violations of cease-and-desist orders bring a \$10,000 a day penalty for each day of violation (463).

Administrative proceedings, however, are necessarily time-consuming and USPS cannot issue any remedial orders until the process concludes. Therefore, Congress gave USPS authority to seek from a

U.S. district court judge an injunction detaining the promoter's incoming mail while proceedings are pending (39 U.S.C. § 3007).

In those cases where the product poses a serious health hazard or the claim is blatantly false, the Inspector may decide to present the case to the U.S. Attorney for criminal prosecution in Federal court under the Mail Fraud Statute (18 U.S.C. § 1341). Under this statute, a person who uses the mail in a scheme to intentionally defraud consumers may be subject to up to \$1,000 in fines, up to 5 years in jail, or both, for each violation.

Litigation Brought by USPS—During the 6-month period from October 1, 1986 to March 31, 1987, the USPS concluded 34 civil actions dealing with claims for medical products and services (907). Some criminal cases have also been brought. In one recent civil case, promoters of what they call 35% “food grade” hydrogen peroxide (H₂O₂) were charged with misrepresenting their product as a cure for AIDS, cancer, alcoholism, Alzheimer's disease, and arthritis, among other diseases. In settling the case, the promoters agreed that the Judicial Officer could issue an order to stop their representing hydrogen peroxide as having a therapeutic effect on human disease and injury, unless claims could be supported by reliable and competent evidence (443).

Other Relevant Federal Statutes

There are several additional Federal criminal statutes that may affect the marketing and advertising of unconventional cancer treatments. Allegations of crimes are investigated and, if pursued, prosecuted by a U.S. Attorney where the crime allegedly occurred. They are usually based on either consumer complaints or recommendations of government agencies, such as FDA and FTC, who believe the crimes have been or are being committed.

The Federal wire fraud statute (18 U.S.C. § 1343) prohibits the use of telephone, radio, or television to make false representations for products and services in interstate or foreign commerce. Violation of this statute can lead to criminal penalties of fines up to \$1,000, imprisonment for up to five years, or both. In one case, a woman in Salt Lake City, Utah, operated an organization called “Western Health Research” and the “Western Research Center.” Patients who contacted her through a toll-free number were referred to a clinic in Mexico run by James Keller, and were given travel arrangements

and appointments at the clinic. The clinic was eventually closed **down by Mexican** authorities, and the woman in Utah was indicted for interstate wire fraud (568).

The Federal smuggling statute (18 U.S.C. § 545) prohibits unlawful introduction of products into the United States. Possession of such products alone is sufficient for conviction under this statute; in addition, any such products are confiscated by the Government. Penalties for violating this statute include fines, imprisonment for up to five years, or both. In one case, *United States v. Richardson, John Richardson, M.D., and three co-defendants (Ralph Bowman, his office manager, and Robert Bradford and Frank Salaman*, two **members of the Committee for Freedom of Choice in Cancer Therapy**) were **convicted of several crimes including conspiracy to smuggle laetrile** from a clinic in Mexico into the **United States (962). The defendants argued that FDA's classification of the drug, which prohibited its being brought** into the country, was an act of **governmental misconduct; they claimed their** actions were justified because laetrile was unavailable but necessary in the United States. Their conviction was upheld on appeal (917). Bradford was freed \$40,000, Richardson \$20,000, and Salaman and Bowman \$10,000 each (962).

The Federal conspiracy statute (18 U.S.C. § 371) prohibits “two or more persons [from] conspiring] to commit any offense against the United States, or to defraud the United States.” The statute authorizes fines up to \$10,000, imprisonment for up to 5 years, or both. There are several examples of litigation where practitioners have been charged with conspiracy in connection with their involvement with an unconventional cancer treatment. For example, the defendants in *United States v. Richardson* were **charged and convicted of conspiring** to possess **and distribute laetrile, and the defendants in United States v. Durovic (the Ivy case, see previous discussion)** were charged with, but not convicted of, conspiracy (915,917).

Several Federal criminal fraud statutes have been used in cases involving unconventional cancer treatments. These statutes make it a criminal offense to deliberately falsify and conceal facts from the Federal Government (18 U.S.C. § 1001) or to deliberately present false claims to any agency or department of the Federal Government (18 U.S.C. § 287). These two statutes have been invoked in

prosecutions concerning false statements on claims submitted to Medicare and Medicaid by practitioners (see ch. 9).

The Federal Racketeer Influenced and Corrupt Organizations (RICO) Act (18 U.S.C. § 1961-1968) classifies a variety of criminal offenses, including bribery and welfare fraud, as racketeering activity. To date, no unconventional practitioners have been convicted of offenses under RICO (79 l). One suit in the complicated legal battle of Burzynski and his patients versus Aetna involves a RICO suit. In December 1987, in response to an insurance claim from a cancer patient for reimbursement of the costs for Burzynski's treatment, Aetna Life Insurance Co. filed a counterclaim against Burzynski and the Burzynski Research Institute, alleging that Burzynski planned to defraud insurers and patients, and engaged in a pattern of racketeering activity by forwarding misleading and deceptive claims for insurance reimbursement (630). This case is still pending (631) (see ch. 9).

State Regulation of Manufacturing and Marketing of Drugs

While **Federal laws regulate the marketing and** advertising of some unconventional cancer treatments in interstate commerce, State laws extend regulation to commerce within States (intrastate commerce). In addition, some State laws explicitly regulate intrastate use and possession of particular unconventional treatments.

In addition to prescribing any approved drug or device, licensed physicians may legally "manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice" (21 USCA § 360 (a)). This means it is legal for physicians to prescribe treatments they manufacture that are unapproved by FDA, but only in the State in which they manufacture the treatments. It is illegal to transport unapproved drugs across State lines and laws pertaining to good manufacturing practices apply to physicians as well as to commercial medical manufacturers. However, treatments made from the patient's own tissues that are customized for each patient are not regulated under Federal or State laws; theoretically, this would include the Livingston-Wheeler autogenous vaccine (which is manufactured individually for each patient) (791). This section summarizes the scope of State regulation of marketing and advertising of

medical products and services **and discusses State laws that apply** specifically to unconventional cancer treatments.

State Food and Drug Laws

Following the **passage of the Federal FDCA in 1938 covering** interstate activities, it was proposed in 1940 that all States adopt a uniform food, drug, and cosmetic law in order to provide the same coverage for intrastate activities (56a). To date, 23 States have adopted the uniform law, in whole or in part, in State laws regulating the intrastate manufacture, promotion, labeling, and distribution of drugs and devices. The uniform law uses nearly identical definitions for adulteration and misbranding of drugs as the FDCA, so any State law based on the uniform law is likely to have similar provisions for dealing with these issues.

One difference between the uniform law and the FDCA, however, is that the uniform act includes a provision against false advertising, which at the Federal level is split between the FTC and FDA. Another difference is that nearly all of the States that have adopted some form of the uniform act have a provision in their food and drug law that prohibits public advertising of any treatment as effective against certain conditions, including cancer. It is argued that justification for this prohibition was based on the assumption that certain diseases should be treated only by professionals and that public advertising of treatments available directly to consumers could encourage patients to treat themselves without professional care (526).

State Regulation of Advertising

In addition to the advertising provisions of food and drug laws that some of the States have adopted, all States have laws prohibiting false advertising of products and services. These **State laws, whose provisions are similar** to those of the FTCA, are enforced **by each State's Attorney General**.

One recent case involved United Sciences of America, a company whose advertising claimed its nutritional treatment could help prevent cancer. The Attorneys General of Texas, California, and New York filed suit jointly, charging the company with false advertising under their States' false advertising laws by making improper claims. Initially, the company advised its distributors of the actions against it, including an injunction barring it from

marketing and shipping its **products** without appropriate correction and disclosure statements and barring it from making false claims. Several months later, the case was settled when the defendants, without admitting fault, agreed to pay \$35,000 to each State and refrain from making unproven and misleading statements about United Sciences products (68).

In another case, the State of California sued a company, Ancient Gold, also known as the Colostrum Research Foundation, for falsely representing that their product, colostrum, could inhibit the symptoms of cancer and other diseases. The company was sued in both criminal and civil State courts for violation of the State Food, Drug, and Cosmetic Act; the civil suit also sought an injunction to prevent the firm from making further false representations (85).

State Laws Pertaining to Cancer Treatment

In addition to State laws regulating intrastate commerce **of drugs, at least 30 States have passed laws pertaining** specifically to cancer, a few of which have provisions for regulating unconventional cancer treatments. Overall, these cancer laws provide for a variety of activities, including organizing and providing resources to combat the disease, establishing registries and advisory boards, and assisting patients in paying for cancer treatment (279). Some of these laws specify that cancer can be treated only by certain categories of licensed health professional. Others authorize the State health agency to approve cancer treatments before they can be used in the State (791).

The oldest and most comprehensive State cancer statute is California's (149). This statute established criteria for cancer treatments similar to those of the FDCA and provided a mechanism for informing the public about treatments that are considered to be unsafe or ineffective. This law also incorporated regulations making it illegal to use certain unconventional cancer treatments, including laetrile and the Hoxsey tonic, within the State. Under this statute, James Privitera, a medical doctor, and four co-defendants were convicted by a jury of conspiracy to sell and prescribe an unapproved drug, laetrile, for the alleviation or cure of cancer, a felony

(described above).¹⁶ **The law** authorizes the **State** health agency to issue cease-and-desist orders to those who violate the State cancer law (see, e.g., ch. 5, discussion of the case of Virginia C. Livingston, M.D.). Failure to comply with these orders can lead to injunctions against the promotion of the treatments and to criminal penalties against the promoters.

Legalization of Specific Unconventional Cancer Treatments Under State Laws

In contrast to State laws that prohibit the use of unconventional cancer treatments, several States have enacted laws that specifically *exempt certain* unconventional treatments from State drug regulation and from some aspects of medical practice acts. These laws only affect the intrastate use of the substances, so they do not conflict with the interstate provisions of the FDCA. They may conflict, however, with the safety and efficacy provisions of State food and drug laws and with the objectives of the uniform national drug standards. These exemptions have not been challenged in court (791).

One State offered the following rationale for its provision legalizing the use of laetrile in cancer treatment:

In a free society, people should be able to choose their own forms of treatment for disease as long as doing so does not expose them to harmful products. In other words, the safety of drugs needs to be assured by government but not necessarily the effectiveness of drugs. (665)

At present, at least 19 States have laws legalizing the prescription and intrastate sale of laetrile to cancer patients (2 other States had this provision but repealed it). Several States enacted (and later repealed) provisions legalizing the use of IAT. Many of these laws require certain types of informed consent or limit the use of the substance to physicians. Some of the statutes prohibit State licensing boards from disciplining physicians who prescribe laetrile. Other laws protect manufacturers from penalties associated with the manufacture or distribution of the substance.

¹⁶The defendants appealed the conviction on the grounds that the right of the patient to obtain, or the physician to prescribe, a treatment was ensured by the 14th Amendment to the U.S. Constitution. After being overturned by the appeals court, the conviction was affirmed by the California Supreme Court (see earlier discussion of case) (717).

SUMMARY

The laws and regulations discussed in this chapter fall into two categories. There are those that, at **both State and Federal levels, have** a major **impact** on the **availability of** unconventional cancer treatments because they determine whether a drug or treatment can be made available legally. Laws included in this category are the Federal FDCA, State Food and Drug laws, and Health and Safety Codes. These laws

are the focus of controversy for the opposing sides of consumer protection and “freedom of choice” in medical care. The other regulations discussed in this chapter play a secondary role by monitoring available treatments, their promoters, and to some extent practitioners who offer them. Though they too have an impact, their effect on the users and practitioners of unconventional cancer treatments is never likely to be at the center of this controversy.