

Chapter 59

Oncology Patients

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FAILURE TO DIAGNOSE CANCER

As a result of a failure to obtain an adequate history, a physician may not include the diagnosis of certain cancers in the differential diagnoses or may not give it proper consideration. Family and racial history is important in cancer screening and for obtaining proper tests in certain symptomatic patients.¹

Occupational exposure and social habits, such as alcoholism or smoking, significant x-ray exposure, or other radiation exposures, chemical exposure, and exposure of parents to certain drugs or carcinogens are important factors. Failure to inquire of these historical factors, warn of dangers, and give guidelines to the patient may be considered negligent.²

Overreliance on certain facts obtained in taking the medical history may be just as significant in certain cases as failure to take an adequate history. Failure to detect the clues of certain symptoms as related by the patient because of a history of “cancerphobia” has been a factor in certain failures to diagnose cancer cases.³

Physical Examination

Failure to perform a physical examination, performing an inadequate examination, overreliance on a negative examination, or failure to perform a follow-up examination may also lead to claims for failure to diagnose cancer. In the 1985 case of *Gorman v. LaSasso*,⁴ a Colorado jury awarded \$1 million to a woman in her thirties who complained about the presence of a lump in her breast for 6 months, which was not investigated until the fourth time she complained about it.

Referral and Testing

A physician has an affirmative duty to obtain or perform appropriate tests in the diagnosis of a suspected cancer. In *Barenbrugge v. Rich*,⁵ a gynecologist did not order a mammogram on his 28-year-old patient after she presented with a breast lump later proven cancerous. A 1985 Illinois jury returned a verdict for \$3 million in favor of the patient.

Failure of a physician to refer to another physician or specialist for a suspected cancer may also be a negligent act of omission. In the case of *O'Dell v. Chesney*,⁶ a doctor of chiropractic treated a 63-year-old man for rectal bleeding and diabetes for 2 years. He was held negligent for failing to refer the patient to a medical doctor after the plaintiff died from colorectal cancer.

Failure of a physician to read the test report or consultant's recommendations or to communicate the report or recommendations to the patient may be negligent. In *Mehalik v. Morvant*,⁷ a 42-year-old Louisiana woman was referred by her physician for a mammogram to evaluate a breast lump. Her physician told her that the mammogram report was negative, although the radiologist reported a suspicious mass and recommended follow-up monitoring. Relying on this report, she did not return for follow-up evaluation. A large breast cancer was confirmed later at biopsy, and the patient sued her physician for damages, with a resultant settlement.

Failure to repeat a test, perform indicated studies, or refer for biopsy when an initial test is negative may be negligent when clinical suspicion should be high that cancer may be present. A Massachusetts jury in the 1985 case *Brown v. Nash*⁸ awarded \$3 million to a woman because a surgeon failed to diagnose her breast cancer when he relied on a negative mammogram report, despite a changing physical abnormality noted in her breast. Relying on the false-negative report, he elected not to do a biopsy of an area later shown to be cancerous.

In *Glicklich v. Spievack*,⁹ another Massachusetts court awarded \$578,000 to a woman who was not referred by her primary care physician to a surgeon for a biopsy, even though he relied on a false-negative mammogram report and a negative needle biopsy of a breast lump later diagnosed as malignant.

Failure to Follow Recommended Protocol

The American Cancer Society and other professional specialty organizations have published guidelines for physicians, suggesting schedules or protocols for early cancer detection. Failure to follow these protocols is not

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necessarily negligent. However, it is common in litigation involving cancer diagnosis for attorneys to use compliance or noncompliance with published guidelines for health care, whether called “standards” or not, as evidence of the required standard of care. Box 59-1 shows the guidelines for cancer-related checkups recommended by the American Cancer Society.¹⁰

Delayed Diagnosis of Breast Cancer

Delayed diagnosis of breast cancer is the most frequent cause of litigation related to cancer. Analysis of medicolegal cases shows that breast cancer is involved in 36.7% of cases of delayed diagnosis of cancer.¹¹ An inordinate delay in the diagnosis of breast cancer may result in a worse prognosis than if there were no delay. Patients tend to perceive any delay in the diagnosis as decreasing their chance of survival.¹²

Haagensohn et al.¹³ found the following errors by physicians, which resulted in delay in the diagnosis of breast cancer:

1. Failure to examine a breast containing an obvious tumor while treating the patient for an unrelated disease.
2. Failure in palpation of the breast to recognize the tumor of which the patient is complaining.

Box 59-1. Guidelines for Cancer-Related Checkups

1. Health counseling and cancer checkup to include examination for cancers of the thyroid, testicles, prostate, ovaries, lymph nodes, and skin every 3 years after the age of 20 and every year after the age of 40.
2. Sigmoidoscopy after the age of 50 to include two normal examinations 1 year apart and then every 3 to 5 years.
3. Stool guaiac slide test every year after the age of 50.
4. Digital rectal examination every year after the age of 40.
5. In women:
 - a. Papanicolaou test every year after age 18 or before age 18 if sexually active. (After three consecutive normal examinations, test may be performed less frequently at physician's discretion.)
 - b. Pelvic examination every year after age 18 or before age 18 if sexually active.
 - c. Endometrial tissue sample at menopause in women at high risk with a history of infertility, obesity, failure to ovulate, abnormal uterine bleeding, or estrogen therapy.
 - d. Breast self-examination monthly after the age of 20.
 - e. Breast examination every 3 years between ages 20 and 40 and every year after the age of 40.
 - f. Mammography every 1 to 2 years between ages 40 and 49 and every year after the age of 50.

Data from American Cancer Society, *Survey of Physicians' Attitudes and Practices in Early Cancer Detection*, 35 CA 197–213 (1985); Woo, *Screening Procedures in the Asymptomatic Adult*, 254 J.A.M.A. 1480–1484 (1985); C. Metlin & C.R. Smart, *Breast Cancer Detection Guidelines for Women Ages 40 to 49 Years: Rationale for the American Cancer Society Reaffirmation of Recommendations*, CA-A Cancer J. for Clinicians 248–255 (1994); and A.M. Leitch et al., *American Cancer Society Guidelines for the Early Detection of Breast Cancer: Update 1997*, 47 CA-A Cancer J. for Clinicians 150–153 (1997).

3. Mistaking a cancer for a breast infection.
4. Wrongfully diagnosing a breast cancer as a benign lesion and failing to advise a biopsy or excision.
5. Disregarding a history of acute and sharp pain in the breast.
6. Disregarding a sign of retraction.
7. Failure to determine the cause of nipple discharge.
8. Relying on a normal aspiration biopsy.

Early treatment of breast cancer is sound practice because the success of treatment, such as surgery, chemotherapy, radiotherapy, and immunotherapy, is predicated on minimal tumor burden.¹⁴

PATHOLOGY REPORTS

The pathology report on a surgical specimen is one of the most important aspects of the clinical record. The pathological status of the tumor allows a determination of whether there is a malignancy, whether the neoplasm is cured, probably cured, or unlikely to be cured, as well as being an indicator for the type of future therapy and follow-up care.

Since the pathology results are so vital, the report should contain all the information needed by the attending physician(s) to make decisions. All information must be clearly stated in the pathology report. An incomplete report or error in the report may result in disastrous consequences to the patient. Although diagnostic decisions may be difficult for the pathologist, the clinician must rely on that pathology report for decision-making.

The Association of Directors of Anatomic and Surgical Pathology (ADASP) has formed several committees for the purpose of developing recommendations concerning the content of surgical pathology reports for various common malignant tumors.

RADIATION THERAPY

More than half of all cancer patients will ultimately need radiation therapy. The physician and the patient must weigh the benefits of therapy against the possible complications. Newer techniques have been developed with the use of the electron and proton beams to allow more accurate placement of the treatment with less damage to surrounding tissues.

Complications

Proper radiation may result in skin burns consisting of erythema (redness) or desquamation (dry or wet).¹⁵ Ulceration with necrosis may be seen with prolonged healing time and scar deformity. Permanent pulmonary fibrosis in the treatment field for cancer of the breast does occur at times. Development of radiation enteritis after treatment of intraabdominal malignancies is not unknown. Excessive radiation has been one source of litigation.

In *Duke v. Morphis*,¹⁶ radon seeds were implanted in the supraclavicular area for treatment of a malignancy. The patient suffered myelopathy and paralysis, blaming

the radiation treatment plan and the manner of supervision. The plaintiff was awarded \$266,700. In *Rudman v. Beth Israel Medical Center*,¹⁷ paralysis after radiation treatment of a head and neck cancer brought a \$2 million settlement. In *Barnes & Powers v. Hahnemann Medical College and Hospital*,¹⁸ a patient with cervical cancer was treated with radiation therapy and radium implants. After a radical hysterectomy she suffered radiation cystitis, vesicovaginal fistula, radiation fibrosis of the ileum, and radiation fibrosis of the vagina. Multiple further surgeries were necessary to correct these problems. The case was settled for an undisclosed amount.

CHEMOTHERAPY

Medical oncology is a changing field, and new chemotherapeutic agents and new combinations of agents are being investigated at a rapid pace. No other medical specialty handles extremely dangerous drugs on an almost daily basis. Many of the antineoplastic drugs are mutagenic, teratogenic, and carcinogenic in animals.¹⁹ Exposure to these agents can result in the appearance of mutagenic substances in the urine.²⁰ There have been reports of an increased incidence of acute myelogenous leukemia in patients treated with alkylating agents,²¹ and bladder cancer²² has been associated with the use of cyclophosphamide, especially in low doses over prolonged periods.

Chemotherapeutic agents can be fetotoxic and therefore potentially dangerous to health care personnel. Drugs that have been associated with fetal malformations include folate antagonists, 6-mercaptopurine, and alkylating agents,²³ as well as the MOPP (nitrogen mustard, vincristine, procarbazine, prednisone) treatment for Hodgkin's disease.²⁴ Personnel safety guidelines have been established to protect personnel who are mixing and administering antineoplastic drugs.²⁵

Complications

Hypersensitive reactions may occur with edema, rash, bronchospasm, diarrhea, and hypotension.²⁶ In *Lefler v. Yardumian*,²⁷ there was a leak of intravenous chemotherapy agents into the subcutaneous area of the arm. Tissue ulceration and damage to the tendons of the left hand occurred. Inadvertent overdose has been a source of litigation. In *Newman v. Geschke*,²⁸ a patient with throat cancer was given 12–15 mg of vincristine by the office nurse. This amount was 9 to 10 times the normal prescribed dosage. He developed neuropathies, bowel and bladder incontinence, weight loss, and alopecia and required 3 weeks of hospitalization. The case was settled for \$450,000.

GENETICS

But this disease seems to me to be no more divine than others. . . . Its origin is hereditary like that of other diseases. . . . What is to hinder it from happening that where the father and mother were subject to this disease, certain of their offspring should be affected also?

Hippocrates, *On the Sacred Disease*

Cancer	Chromosome	Gene
Breast and ovarian cancer	BRCA1	17q21
Breast cancer	BRCA2	13q12-13
Li-Fraumeni syndrome/SBLA	p53	17p13
Lynch syndrome/HNPCC	MSH2	2p
Melanoma	MLM	9p21
Medullary thyroid	RET	10q11.2
Neurofibromatosis	NF1	17q11.2
Retinoblastoma	RB1	13q14
Turcot's syndrome		
Predominance of glioblastoma	PMS2	7p22
Multiform	MLH1 3	p21.3-23
Predominance of cerebellar medulloblastoma	APC	5q21
Familial adenomatous polyposis	APC	Distal to 5'
Hereditary flat adenoma syndrome	APC	Proximal to 5'
von Hippel-Lindau disease	VHLS	3p25
Wilms' tumor	WT1	11p13

HNPCC, Hereditary nonpolyposis colorectal cancer; SBLA, sarcoma, breast and brain tumors, leukemia, laryngeal and lung cancer, and adrenal cortical carcinoma.

Table 59-1 Genes associated with hereditary cancers

The recent rapid evolution of genetics in cancer research has provided physicians with the means of identifying individuals and their family members who are at high risk for developing cancer. Ethical, legal, and social implications of genetic abnormalities have become the medical community's new challenge.²⁹ Some of the genes associated with hereditary cancers are listed in Table 59-1.

MOLECULAR GENETIC TESTING

Genetic testing is not perfectly predictive. The absence of a mutation does not mean cancer will not occur. There is no substantial proof that screening for genetic defects leads to increased longevity.

Disclosure of results may be potentially psychologically distressing information. There is a need for counseling on reproductive choices if a gene with fatal consequences is potentially going to be passed to a child. There is the problem of patient privacy versus relatives' need to know as well as the problem of patient autonomy versus the duty to warn third parties of potential harm. A potential for discrimination exists by employers or medical, life, and disability insurers.

Chromosomes

The chromosome is divided into the short (petit) or p arm and the long or q arm. The regions and bands are numbered, proceeding from the proximal arm (near the centromere) to the distal arm (near the telomere). The region is the first number and the band the second number. For example, 1q23 = chromosome 1, q = long arm, 2 = region, 3 = band. Genetic abnormalities can be

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deletion (terminal or interstitial), duplication, mutation, transposition, or rearrangements (pericentric inversion, paracentric inversion).

Breast Cancer Risk Assessment

There are features of familial breast cancer that can aid physicians in recognizing individuals who are at high risk because of inheritance of a breast cancer susceptibility gene.^{30,31} The following individuals may have a high probability for mutations in BRCA1 or BRCA2:

1. Single affected relative with:
 - a. Breast cancer <30 years of age.
 - b. Ovarian cancer <30 years of age.
2. Sister pairs:
 - a. Breast cancer <50 years of age; breast cancer <50 years of age.
 - b. Breast cancer <50 years of age; ovarian cancer <60 years of age.
 - c. Ovarian cancer <60 years of age; ovarian cancer at any age.
3. Families:
 - a. Breast cancer only, >3 cases diagnosed <60 years of age.
 - b. >2 with breast cancer and >1 with ovarian cancer.

BRCA1 is responsible for 28% of breast cancers under age 30 and 5% under age 50, 40–60% risk of breast cancer by age 60, and 10–49% risk of ovarian cancer by age 60. BRCA2 is associated with female and male breast cancers, has less ovarian cancer than BRCA1, and is associated with other cancers such as upper gastrointestinal (UGI), prostate, colon, brain, leukemia, lymphoma, and gliomas.

Prevention Options and Early Detection

Breast cancer prevention options include:

1. Prophylactic mastectomy: 95–98% effective.
2. Chemoprevention:
 - a. Tamoxifen.
 - b. Vitamins?
 - c. Retinoids.

Ovarian cancer surveillance and early detection strategies include:

1. Transvaginal ultrasound.
2. Clinical pelvic examination.
3. CA 125 tumor marker.

Ovarian cancer prevention options include:

1. Prophylactic oophorectomy.
2. Chemoprevention (tamoxifen).
3. Oral contraceptives.

Familial Adenomatous Polyposis (FAP)

FAP is an autosomal dominant condition characterized by multiple polyps (>100) in the colon and rectum. Polyps appear in childhood and invariably undergo malignant transformations, usually by age 40. Extracolonic manifestations include osteomas, polyps in the distal stomach of antrum, the duodenum, the periampullary region, terminal ileum, and retinal pigment epithelium. Gardner's syndrome

includes soft tissue tumors (lipomas, desmoids, fibromas) and dental abnormalities.³² Risk assessment is from the family pedigree that includes sibling, parent, or children with the phenotype

Prevention

Prevention in high-risk individuals includes:

1. Colectomy.
2. Chemoprevention: Sulindac (nonsteroidal anti-inflammatory drug or NSAID).

Hereditary Nonpolyposis Colon Cancer

The Amsterdam criteria for diagnosis of hereditary non-polyposis colon cancer include:

1. Three or more relatives with histologically verified colorectal cancer, one of whom is a first-degree relative of the other two.
2. Colorectal cancer involving at least two generations.
3. One or more colorectal cancer cases diagnosed before the age of 45.
4. Exclusion of FAP.

DNA testing includes hMSH2, hMLH1, hPMS1, and hPMS2.

Prevention

Prevention in high-risk individuals includes:

1. Colonoscopy at age 20 to 30 years or 5 years younger than the youngest case in the family. Follow-up colonoscopy every 1–5 years.
2. Endometrial biopsy and pelvic ultrasonography in potentially affected women.

Multiple Endocrine Neoplasia Syndromes

Multiple endocrine neoplasia type I (MEN I) includes the triad of pituitary, pancreatic islet cell, and parathyroid tumors while multiple endocrine neoplasia type II (MEN II) involves tumors of the thyroid, adrenal medulla, and parathyroids. MEN IIa consists of medullary thyroid carcinoma, pheochromocytomas, and parathyroid hyperplasia while MEN IIb consists of ganglioneuromatosis, Marfanoid habitus, medullary thyroid carcinoma, pheochromocytomas, and rarely parathyroid hyperplasia. Every patient with medullary carcinoma of the thyroid and at-risk individuals should have genetic testing for possible germ line mutations in the RET proto-oncogene.³³

Familial Cancer Syndromes

Table 59-2 lists other familial cancer syndromes that are commonly seen.

DISCRIMINATION

Genetic discrimination is defined as “discrimination against an individual or against members of that individual's family solely because of real or perceived differences from the normal genome in the genetic constitution of

Syndrome	Gene	Locus
Wilms' tumor	WT1	11p13
	WT2	11p15.5
	WT3	
Renal cell carcinoma	RCC	3q14.2
Familial atypical mole and melanoma syndrome	CMM1	1p36
	CMM2	9p21
Basal cell nevus syndrome	PTC	9q22.3
Neurofibromatosis type 1	NF1	17q11.2
Neurofibromatosis type 2	NF2	22q12.2
Peutz-Jeghers syndrome	STK11	19p13.3
Prostate cancer, familial	PRCA1	10q25
	HPC1	1q24-25
Retinoblastoma	RB1	13q14
Von Hippel-Lindau disease	VHL	3p25-26

Table 59-2 Commonly seen familial cancer syndromes

that individual."³⁴ The fear exists in many individuals with or at risk of hereditary cancer that awareness of their status on the part of employers³⁵⁻³⁸ or life, disability, and health insurers^{36,39-41} could lead to termination of employment or insurance.

Federal Legislation

The Rehabilitation Act of 1973 (29 U.S. Code, §§701-796, 1982)³⁵ prohibits preemployment inquiry about health or disability, although employment may be conditioned upon passing a medical examination. It is limited to employers whose work is related to the federal government.

The Americans with Disability Act of 1990 (42 U.S. Code, §§12111-12201, 1990)⁴² has as its stated purpose to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities and to provide clear, strong, consistent, enforceable standards addressing discrimination against individuals with disabilities. The appendix to the regulations states that the definition of "physical or mental" impairment does not include "characteristic predisposition to illness or disease."³⁷ However, the legislative history of the act suggests that "genetic status" was to be in its purview.⁴³⁻⁴⁵ In a given circumstance in which discrimination is actually in question, there must be an actual example of discrimination, not the mere fear of it. It does not prohibit insurers or other health - benefit administrators from underwriting and classifying risks, presumably including genetic risks.⁴²

The Health Insurance Portability and Accountability Act of 1996 guarantees insurance to individuals who change jobs and prohibits companies from denying coverage for preexisting conditions. There are no benefits for the unemployed, for those who leave jobs to become self-employed, and those who have never been insured.

State Legislation

A number of states have passed regulations to limit discrimination on the basis of genetic traits.⁴⁶ These include

prohibition for health or disability insurance, inclusion in health welfare benefit plans, release of genetic information without written consent, performance of genetic information without written consent, and differential ratings, premium payments, or dividends in life insurance.

TASK FORCE ON GENETIC INFORMATION AND INSURANCE

The National Institutes of Health formed this task force in 1993⁴⁷ to establish the background facts and issues and to formulate recommendations as to how genetic information should be handled in relation to insurance. The following recommendations, limited to health insurance (not life or disability insurance), were made:

1. That genetic information bearing on health status, past, present, or future, should not serve as a basis for denying coverage or services.
2. Health systems should offer universal access to "basic" health services.
3. Genetic services should be integrated into the larger system, to include genetic counseling, testing, and treatment for individuals and families.
4. Costs of insurance to such individuals and families should not be affected by genetic data.
5. Access to services should not depend on employment status.
6. Access should depend on an individual's disclosure of genetic information.
7. Pending availability of universal coverage, measures should be taken to reduce discrimination, including a moratorium on the use of testing in underwriting by insurers.

SIGNIFICANT CASES

In *Katsbee v. Blue Cross/Blue Shield of Nebraska*,⁴⁸ the appellant, with a family history of breast and ovarian cancer, was diagnosed by her gynecologist on January 1990 in consultation with Dr. Henry T. Lynch (oncologic geneticist) as having a genetic condition known as breast-ovarian carcinoma syndrome. Prophylactic total abdominal hysterectomy and bilateral salpingo-oophorectomy was recommended. Preoperatively, the health insurance company refused to pay for the procedure, but the appellant proceeded with the surgery in November 1990. The appellant filed this action for breach of contract. The Supreme Court reversed the summary judgment in favor of the insurer, holding that the insured's breast-ovarian carcinoma syndrome was an "illness" defined as "bodily disorder" or "disease" within the meaning of the health insurance policy, notwithstanding the insurer's contention that the syndrome was merely predisposition to cancer. *Webster's Third International Dictionary* (1993) defines disease as "an impairment of the normal state of the living animal . . . many of its components that interrupt or modify the performance of the vital function . . . to inherit defects of the organism or to combinations of these factors."

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In *Pate v. Threlkel*,⁴⁹ the plaintiff's mother had been treated for medullary carcinoma of the thyroid, a genetically inheritable disease, in 1987. The plaintiff developed medullary carcinoma of the thyroid in 1990. The plaintiff alleged that the physicians knew or should have known of the genetic transferability of the disease, that the physicians owed a duty to warn her mother that her children should be tested for the disease, that her mother would have had her children tested had she been warned, and that her mother would have taken preventive action which would have made a cure more likely than not. The Florida Supreme Court held that the defendant physician had a duty to his patient's child to warn the patient that she had a hereditary form of thyroid cancer. The defendant was held liable for failure to inform his patient.

In *Safer v. Pack*,⁵⁰ the plaintiff's father had been treated for cancerous polyposis of the colon in 1956. In 1990 the plaintiff developed cancerous polyposis. The plaintiff alleged that the physician knew that cancerous polyposis was a hereditary disease, that the physician had a duty to warn those at risk, and such a warning would have allowed the plaintiff to avoid the worst consequences of the disease. The Appellate Court of New Jersey held that physicians have a duty to warn the patient and the patient's children if the parent's illness is genetically transmissible. Whether such a duty exists, extending beyond the physician and patient to include third parties, should be determined by the jury. A physician's conduct at a particular time is an issue for the trier of fact, not a matter of law.

There is some protection of the patient and family in requiring a physician to be aware of inheritable cancerous conditions and giving the physician the duty to warn the patient and possibly the children of the patient so that genetic testing can be performed. Counseling of patients allows the selection by at-risk individuals in the family to have early tests for the disease and/or prophylactic surgery, allowing a better chance of survival.

UNORTHODOX CANCER TREATMENTS

Despite persistent efforts to achieve early detection and exhaustive research aimed at developing effective treatment modalities, cancer continues to be a leading cause of death in the United States. Conventional cancer therapy includes surgery, chemotherapy, and radiation therapy in various combinations, depending on the nature and extent of disease involved in each particular case. Elaborate treatment protocols have been developed for virtually every stage of every type of cancer. These medical advances have undoubtedly resulted in increased survival or improved quality of life for some cancer patients. For many others, however, conventional cancer therapy has simply come to mean a sequence of painful, even disabling, experiences that does not in any way alter the inexorable course of the disease and does not make the patient more comfortable, productive, or fulfilled during the time that remains.

For many years, cancer victims have attempted to seek out whatever ray of hope may be offered, even in the form of treatment that the medical establishment finds to be unproven, ineffective, or even fraudulent. These include metabolic therapy, diet therapies, megavitamins, mental imagery applied for antitumor effect, and spiritual or faith healing.⁵¹ Despite recent technological advances in orthodox medical care, unorthodox cancer treatments are increasing in popularity.⁵²

Cancer victims, particularly those who are terminally ill, are vulnerable to exploitation because of their predicament. Desperate for any glimmer of hope, they are easy prey for charlatans intent on financial gain. Traditionally, the law has protected those unable to protect themselves on the basis of *parens patriae*. This rationale has most frequently been applied to juveniles and the developmentally disabled.

However, the state's interest in protecting its citizens must be balanced against an individual's right to have control over his or her own body and to make decisions regarding his or her own medical care. Most cancer patients are adults in full control of their mental faculties, which distinguishes them from other citizens the state seeks to protect under the *parens patriae* rationale.

It is this basic conflict between the state's interest in the health and welfare of its citizens and the right of the individual to make decisions affecting his or her health that has confronted legislatures and courts attempting to deal with the problem of unorthodox cancer treatments.

To date, this conflict has not been resolved uniformly. Considerable variation currently exists among the various states with regard to regulation of unorthodox cancer treatment. Interestingly, where there has been legislative action, most legislatures have granted the individual some measure of freedom in selecting cancer treatment that is unproven. In most states that have acted legislatively, however, this freedom is not unlimited. When courts have considered the subject of unorthodox cancer treatment, they have focused more on the state's right to regulate the lives of its citizens under the police power.

Legislative Approaches

The overwhelming majority of legislation dealing with unorthodox cancer treatment has concerned Laetrile (amygdalin). Nineteen states have enacted legislation authorizing the manufacture, sale, and distribution of Laetrile.⁵³ Other unorthodox cancer treatments that have received legislative protection include DMSO (dimethyl sulfoxide),⁵⁴ Gerovital H3 (procainamide hydrochloride with preservatives and stabilizers),⁵⁵ lily plant extract,⁵⁶ and prayer.⁵⁷

Most states that have legislatively authorized the use of Laetrile have placed concurrent restrictions on its accessibility. Twelve states require that the treatment be prescribed by a licensed physician.⁵⁸ Three states allow the use of Laetrile only as an adjunct to conventional medical therapy.⁵⁹ Many of the states that require a licensed physician's prescription of the unorthodox treatment also require that

the patient first sign a consent form indicating that the physician has explained that Laetrile or DMSO has not been proved to be effective in the treatment of cancer or other human diseases, that it has not been approved by the Food and Drug Administration for the treatment of cancer, that alternative therapies exist, and that the patient requests treatment with Laetrile or DMSO.⁶⁰

Several states have attempted to maintain a precarious balance between police power and individual rights by reserving the right to prohibit unconventional cancer treatment when it is found to be harmful as prescribed or administered in a formal hearing before the appropriate state board.⁶¹

The most sweeping exercise of police power has been enacted in California, where it is a crime to sell, deliver, prescribe, or administer any drug or device to be used in the diagnosis, treatment, alleviation, or cure of cancer that has not been approved by the designated federal agency or by the state board.⁶² As discussed later, the statute has been upheld by the California Supreme Court against a constitutional challenge based on the right of privacy.⁶³

Judicial Determination Regarding Unorthodox Cancer Therapy

The lack of uniformity among the states in regulating the use of unorthodox cancer treatments has created an environment in which patients who reside in states that do not authorize the manufacture, sale, or distribution of Laetrile or other unconventional therapies have attempted to obtain those substances from other states, or even from neighboring countries.⁶⁴ In several instances, patients have resorted to legal action in attempting to obtain Laetrile.

The most extensively litigated case has been *Rutherford v. United States*, which has generated eight federal court opinions,⁶⁵ including one from the U.S. Supreme Court.⁶⁶ The Supreme Court did not consider the right of privacy issue. It held that, under applicable statutory law, Laetrile was not a "safe and effective" drug, and therefore FDA approval was required before interstate distribution. The court felt that if an exception were to be made in the case of terminally ill cancer patients, that decision was for the legislature rather than the courts to make.⁶⁷

While *Rutherford* was being litigated, the California Supreme Court had occasion to consider the question of whether the state's police power could be used to restrict an individual's right of access to drugs of unproven effectiveness. *People v. Privitera*⁶⁸ involved prosecution of a physician and other individuals for conspiracy to sell and to prescribe an unapproved drug—Laetrile—intended for the alleviation or cure of cancer, in violation of applicable California statutory law.⁶⁹ The defendants appealed on the grounds that the statute was unconstitutional, and that the state and federal constitutional rights of privacy encompassed a right to obtain Laetrile.

The court, by a 5 to 2 majority, held that Laetrile was a drug of unproven efficacy and is not included in either the federal or state constitutional rights of privacy. The court further held that the statute prohibiting the prescription or

administration of any drug not approved by the FDA or state board was a permissible exercise of the state's police power because it bore a reasonable relationship to the achievement of the legitimate state interest in the health and safety of its citizens.⁷⁰

CONCLUSION

Despite a massive resource outlay directed at early detection and effective treatment of cancer, millions of cancer-related deaths are reported each year. Virtually none of the treatments labeled by orthodox medicine as ineffective has been the subject of well-controlled scientific studies.⁷¹ The scope of research must be broadened to include all modalities in which there appears to be substantial public interest.⁷² As a broader range of information becomes available, patients will be able to make more informed decisions regarding treatment. Although some states have enacted legislation allowing patients to obtain certain types of alternative cancer therapies, the majority of state legislatures remain silent on this issue. Diagnosis and treatment of cancer are governed by common law tort principles and the "loss of chance" doctrine.

Endnotes

1. Anderson, *Counseling Women on Familial Breast Cancer*, 37 *Cancer Bull.* 130-131 (1985).
2. Mills, *Prenatal Diethylstilbestrol and Vaginal Cancer in Offspring*, 229 *J.A.M.A.* 471-472 (1974).
3. *Burke v. United States*, No. M-84-425 (Md. 1984). In 1 *Med. Mal. Verdicts, Settlements and Experts* 9 (1985).
4. *Gorman v. LaSasso*, No. 83-CV-6311, Denver Dist. Ct. (Colo. 1983). In 1 *Med. Mal. Verdicts, Settlements and Experts* 17 (1985).
5. *Barenbrugge v. Rich*, No. 81L8949, Cook County Cir. Ct. (Ill. Oct. 25, 1984). In 2 *Med. Mal. Verdicts, Settlements and Experts* 17 (1986).
6. *O'Dell v. Chesney*, No. 118-496, Riverside County Ct. (Cal. Jan. 15, 1982).
7. *Mehalik v. Morvant*, No. 45173, Lafourche Parish Ct. (La. 1981) (Note: This case was settled on Dec. 9, 1985).
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52. *Id.*
53. Alaska Stat. 08.64.367; Ariz. Rev. Stat. Ann. 26-2452; Del. Code Ann. 16-4901-05; Fla. Stat. Ann. 500.1515 (West); Idaho Code 18-7301A; Ind. Code Ann. 16-8-8-1-7 (Burns); Kan. Stat. Ann. 65-6b; Ky. Rev. Stat. Ann. 311.950 (Baldwin); La. Rev. Stat. Ann. 40:676; Md. Code Ann. 18-301; Mont. Code Ann. 50-41-102; Nev. Rev. Stat. 585.495; N.J. Stat. Ann. 24: 6F-1 (West); N.D. Cent. Code 23-23.1; Okla. Stat. Ann. 63-2-313; Or. Rev. Stat. 689.535; Tex. Rev. Civ. Stat. Ann. 71, article 4476-5a; Wash. Rev. Code Ann. 70.54.1310; W. Va. Code 30-5-16a.
54. Fla. Stat. Ann. 499.035 (West); Kan. Stat. Ann. 65-679a; La. Rev. Stat. Ann. 40-1060 (West); Mont. Code Ann. 42-102; Okla. Stat. Ann. 363-2-313.12; Tex. Rev. Civ. Stat. Ann. 71, article 4476.5b.
55. Nev. Rev. Stat. 585.495.
56. Okla. Stat. Ann. 63-2-313.7 (West).
57. Colo. Rev. Stat. 12-30-113 (2).

58. Alaska, Delaware, Florida, Indiana, Maryland, Montana, Nevada, New Jersey, North Dakota, Oklahoma, Texas, and Washington.
59. Idaho, Indiana, and Oklahoma.
60. Arizona, Indiana, Louisiana, New Jersey, Oklahoma, Texas, and Washington.
61. Alaska, Colorado, Delaware, Louisiana, and Maryland.
62. California Health and Safety Code 1701.1 (West 1979).
63. *People v. Privitera*, 23 Cal. 3d 697, 153 Cal. Rptr. 431, 591 P. 2d 919 (1979).
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65. *Rutherford v. United States*, 399 F. Supp. 1208 (W.D. Okla. 1975), 542 F. 2d 1137 (10th Cir. 1976), 424 F. Supp. 105 (W.D. Okla. 1977), 429 F. Supp. 506 (W.D. Okla. 1977), 438 F. Supp. 1287 (W.D. Okla. 1977), 582 F. 2d 1234 (10th Cir. 1978), 616 F. 2d 455 (10th Cir. 1980).
66. *Rutherford*, 442 U.S. 544.
67. *Id.* at 559.
68. *People v. Privitera*, *supra* note 63. For a judicial decision that reached a different conclusion, see *Suenram v. Society of the Valley Hospital*, 155 N.J. Super. 593, 383 A. 2d 143 (1977). The *Suenram* court was not considering a statute, however, and in fact the New Jersey legislature authorized the use of Laetrile shortly after the court's opinion was rendered.
69. California Health and Safety Code 1707.1, which provides as follows: "The sale, offering of sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under 505 of the Federal Food, Drug and Cosmetic Act, or (2) there has been approved an application filed with the board setting forth: (a) Full reports of investigations have been made to show whether or not such a drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use; (b) A full list of the articles used as components of such drug, medicine, compound or device; (c) A full statement of the composition of such drug, medicine, compound or device; (d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packaging of such drug, medicine, or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation; (e) Such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and (f) Specimens of the labeling to be used for such drug, medicine, compound or device and advertising proposed to be used for such drug, medicine, compound or device."
70. *People v. Privitera*, 153 Cal. Rptr. 431, 433.
71. For an example of a well-controlled study of the effect of an "unorthodox" cancer treatment, see Johnston, *Clinical Effect of Coley's Toxin: I. A Controlled Study*, 21 *Cancer Chemotherapy Reports* (Aug. 1962).
72. *Supra* note 51.

