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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION FOUR

RIC SCHIFF et al., Plaintiffs and Appellants, v. MICHAEL PRADOS, Defendant and Respondent.	A087171 (San Francisco County Super. Ct. No. 982109)

A doctor's obligation to obtain a patient's informed consent to medical treatment includes "a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each." (*Cobbs v. Grant* (1972) 8 Cal.3d 229, 243.) We hold that, as a matter of law, a treatment that cannot legally be administered in this state is not "available" within the meaning of this rule, and thus that a physician cannot be held liable for failing to disclose the existence of such a treatment.

I. BACKGROUND

This appeal arises in a wrongful death action filed against Dr. Michael Prados and others including the Regents (Regents) of the University of California at San Francisco (UCSF) by Ric and Paula Schiff, the parents of Crystin Schiff, who died at the age of six, two and one half years after she was diagnosed with a brain tumor. There are two theories of liability: negligence in the provision of Crystin's medical treatment; and failure to obtain the Schiffs' informed consent to her treatment. This appeal is limited to the informed consent issue, and is taken by the Schiffs from the judgment in favor of Dr. Prados on that issue after his motion for summary judgment was granted.

Crystin was admitted to UCSF on January 22, 1993, with a malignant rhabdoid tumor, a rare and aggressive form of cancer, in her brain and around her spinal cord. Dr.

Prados is the head of UCSF's neuro-oncology (brain tumor) service and moderator of its neuro-oncology tumor board. UCSF is one of the most prominent brain cancer treatment centers in the world, and one of the few national hospitals to have a neuro-oncology tumor board. The board is comprised of physicians from various medical disciplines involved in the diagnosis and treatment of cancer. The patient's oncologist presents the facts of the case to the tumor board members, who attempt to arrive at a consensus as to the best course of treatment. The tumor board members have no direct patient contact; the patient's oncologist acts as a conduit and conveys the board's thinking to the patient.

Crystin had surgery on the tumor on January 25, 1993. Although most of the tumor mass was removed, residual tumor remained in the brain and around the spinal cord. Dr. Prados states that when Crystin's case was discussed by the neuro-oncology tumor board, he advised that he had not treated her type of tumor, and recommended contacting doctors he knew in other states who had experience with such tumors. Dr. Prados indicates that several possible treatment options were discussed during the conferences, including aggressive chemotherapy and radiation, and that he expressed concern over the potential toxicity of that course of treatment.

Mr. Schiff testifies that only two options were presented after Crystin's oncologist, Dr. Byron Smith, consulted with the tumor board following Crystin's surgery: having her undergo intensive chemotherapy and radiation, or "taking her home and letting her die." According to a February 1, 1993, UCSF Department of Radiation Oncology report signed by radiologists Wara and Scholz, they discussed Crystin's "poor prognosis" with the Schiffs, and recommended that she receive aggressive chemotherapy and radiation. The note states that short-term risks, including sepsis and the possibility of death, as well as long-term risks, including loss of I.Q. and stature, were explained to the Schiffs, and that the Schiffs wished to proceed with the therapy.

Mr. Schiff states that, in their conversations with Dr. Wara, he and Mrs. Schiff "both made it clear we were interested in knowing the benefits and risks of the proposed treatment, and knowing of any alternative treatment or options that might possibly be advantageous to our daughter." Dr. Wara told him that he "proposed to administer an aggressive dose [of radiation], but that it would not kill her. He said that there was a 15%

chance he could cure her." Dr. Wara "assured [Mr. Schiff] that the radiation therapy would likely extend Crystin's life." The Schiffs understood that radiation and chemotherapy would be very difficult for Crystin, and they asked Dr. Smith to look into other options, and to ask the tumor board about all possible therapies. Dr. Smith advised that none of the physicians he consulted, including Dr. Prados, knew of any appropriate alternative treatments. Dr. Smith had "no doubt" that the proposed chemotherapy and radiation treatment would not cure Crystin, but noted that there were clinical cancer studies in progress, and felt that given the rapid advances in medical science something beneficial to Crystin might be developed if her life could be extended.

Some residual tumor remained after Crystin's chemotherapy and radiation was completed in April or May of 1993. Toward the end of that period, the Schiffs began doing independent research and read of antineoplaston treatment for cancer offered by Dr. Stanislaw Burzynski.[1] Dr. Smith was unfamiliar with Dr. Burzynski's treatment, and urged the Schiffs to consult Dr. Prados. Mr. Schiff recalls that when he met with Dr. Prados in July of 1993, Dr. Prados was adamantly opposed to Dr. Burzynski's treatment. Dr. Prados had testified against Dr. Burzynski in court, and thought that antineoplastons were toxic and ineffective. They discussed alternatives Dr. Prados regarded as preferable

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[1] The previous year, a federal appellate court had written: "Stanislaw Burzynski is a physician and researcher located in Houston, Texas. He advocates an unconventional therapy for the treatment of cancer using substances distilled from human urine which he has named 'antineoplastons.' According to Dr. Burzynski, when injected into the body, antineoplastons 'reprogram' cancer cells to function normally. The Burzynski Research Institute, Inc. (BRI) is a research facility founded by Dr. Burzynski that engages in antineoplaston research and treatment. Dr. Burzynski and his institute have received national television exposure on such shows as '20/20' and 'Sally Jesse Raphael.' [¶] He also has received attention from federal and state regulatory authorities. In 1983, the Food and Drug Administration barred Dr. Burzynski from interstate transactions involving antineoplaston treatments. The National Cancer Institute and the Office of Technology Assessment of the United States Congress both have issued critical reports of the treatment. In 1988, the Texas Department of Health ordered Dr. Burzynski to cease and desist treating cancer patients with antineoplaston therapy absent FDA new drug or investigational drug approval." (*Burzynski v. Aetna Life Ins. Co.* (5th Cir. 1992) 967 F.2d 1063, 1064; see also *Trustees of the Northwest Laundry v. Burzynski* (5th Cir. 1994) 27 F.3d 153, 155 [describing antineoplastons as an "unorthodox" cancer treatment]; *State Bd. of Med. Examiners v. Burzynski* (Tex. App. 1996) 917 S.W.2d 365, 366 [same].)

options, including Crystin's participation in clinical trials. Mr. Schiff states that Dr. Prados explained Phases I, II and III of clinical trials, indicating that "we don't really know what the outcome[s] of these medicines are. We are experimenting with them to see."[2]

Mr. Schiff took Crystin to Dr. Burzynski's Houston, Texas clinic in August of 1993, and decided during the visit to begin Crystin on antineoplaston treatment. Mr. Schiff and Crystin remained in Houston for eight or ten days, and then returned home to California with a supply of antineoplastons, which were administered to Crystin intravenously. After Crystin and Mr. Schiff returned from Houston, a relative there obtained antineoplastons from Dr. Burzynski's clinic and mailed them to the Schiffs in California.

The Schiffs understood that Crystin's antineoplaston treatment was not approved by the FDA, that the State of Texas was prosecuting Dr. Burzynski or trying to take away his license, and that Dr. Burzynski could not legally transport antineoplastons across state lines. At the time, a federal injunction prohibited Dr. Burzynski from distributing antineoplastons in interstate commerce, but did not prevent their distribution in Texas. The Texas State Board of Medical Examiners had filed a disciplinary action against Dr. Burzynski in 1988 alleging that his use of antineoplastons violated Texas statutes, but

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[2] These trials precede FDA approval of a drug for marketing. (See Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process* (2000) 3 N.Y.U. J. Legis. & Pub. Pol'y 295, 304-306 [hereafter Greenberg].) Phase I trials are generally conducted on a small number of healthy volunteer subjects, and "are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." (FDA Center for Drug Evaluation and Research, The CDER Handbook (1998) p. 8 [hereafter CDER Handbook].) Phase 2 trials, which usually involve several hundred people, are "early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition." (*Ibid.*) Phase 3 trials are "expanded controlled and uncontrolled trials" on several hundred to several thousand people "to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug." (*Id.* at pp. 8-9.)

hearings in the Texas case did not begin until May of 1993, and the administrative law judge had not yet rendered a decision when Crystin went to Dr. Burzynski's clinic.

Mr. Schiff acknowledges that, during his investigation of antineoplastons, he found that others besides Dr. Prados, including the American Medical Association and the American Cancer Society, were critical of Dr. Burzynski and his treatment. Although many people called Dr. Burzynski a "fraud," Mr. Schiff, a police officer with fraud investigation experience, received favorable reports from Dr. Burzynski's patients. Mr. Schiff states that a number of considerations were material to his decision to have Crystin treated with antineoplastons, including: (1) most patients with rhabdoid brain tumors survived only six months to one year after diagnosis; (2) there was no case in the medical literature of anyone having been cured of a metastasized rhabdoid brain tumor by the chemotherapy and radiation treatment Crystin received; (3) there was evidence that antineoplastons had been effective in treating brain tumors; (4) the FDA had authorized Dr. Burzynski to conduct trials of antineoplastons as an investigational drug in clinical studies of some cancers and in special exception cases; and (5) Phase 2 clinical trials of certain antineoplastons were in the process of being established.

Dr. Burzynski testifies that he did not begin conducting FDA approved Phase 2 clinical trials until April of 1994; before then, his "Phase 2" trials "were done outside of the FDA jurisdiction." Dr. Burzynski states that in September 1993, shortly after Crystin's visit to the clinic, the FDA accepted an investigational new drug application (IND) authorizing him as principal investigator to conduct trials at his clinic of antineoplastons in children with brain tumors.[3] He further states that he received a "special exception" from the FDA on October 4, 1993, authorizing him to treat Crystin's brain tumor with intravenous antineoplastons.[4] However, it took several more months

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[3] IND's are required before clinical trials begin. (CDER Handbook, *supra*, p. 13.) The FDA "monitors the study design and conduct of clinical trials to ensure that people in the trials are not exposed to unnecessary risks." (*Id.* at p. 7.)

[4] The "special exception" Crystin received is described in the record as an exemption for "compassionate use." Compassionate use exemptions are "granted on a case-by-case basis pursuant to the request of a patient's primary care physician," and are "oriented to the end of treatment rather than to the end of clinical research." (Greenberg, *supra*, 3

and pressure from members of Congress solicited by the Schiffs before the FDA approved a treatment protocol for Crystin. Dr. Burzynski wrote Dr. Smith on March 30, 1994, stating that the protocol had been approved, and thus that Dr. Smith could be appointed as a co-investigator for Crystin's antineoplaston treatment. Dr. Smith testifies that he did not believe that antineoplastons would be effective, but agreed "for humanitarian purposes" to monitor Crystin's treatment as co-investigator because it would reduce the costs of the treatment to the Schiffs, and make it unnecessary for Crystin to travel to Houston.

In March 1994, the administrative law judge in the Texas disciplinary proceeding ruled that Dr. Burzynski's use of antineoplastons was lawful in Texas. In August 1994, the Texas Board of Medical Examiners rejected that decision, ruled that Dr. Burzynski's use of antineoplastons without FDA approval violated Texas law, and ordered him to treat patients only under an FDA IND or special exception. Dr. Burzynski sued to overturn the Board's order and obtained an injunction against its enforcement.

Crystin continued on antineoplaston treatment until December 2, 1994, when she appeared to be cancer free. When she was taken off antineoplastons she deteriorated rapidly, and an MRI confirmed that the brain tumor had reappeared. Mr. Schiff indicates that every doctor with whom they consulted at that point, including Dr. Prados, recommended against resumption of Dr. Burzynski's treatment. Mr. Schiff states that Dr. Prados recommended that other chemotherapies in Phase 1, 2, or 3 clinical trials be considered in lieu of antineoplastons. The Schiffs elected to put Crystin back on antineoplastons near the end of December 1994. Subsequent tests showed that her tumor had completely regressed.

Crystin died on July 29, 1995. The immediate cause of death was aspiration pneumonia brought on by radiation necrosis; an autopsy showed no evidence of any

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N.Y.U. J. Legis. & Pub. Pol'y at p. 316.) "The FDA typically grants those requests that indicate that 'a manufacturer [is] willing to supply the drug, a physician [is] willing to prescribe it, a patient [is] willing to give informed consent, and [there is] some basis for believing that the treatment [is] not an outright fraud or poison.'" (Note, *The Catch-22 for Persons With AIDS: To Have or Not to Have Easy Access to Experimental Therapies and Early Approval for New Drugs* (1995) 69 So.Cal. L.Rev. 105, 119.)

residual or recurrent malignant rhabdoid tumor. In Dr. Prados's view, Crystin's "profound neurological deterioration" at the time of her death "likely result[ed] from effects of the aggressive radiation treatments she had earlier undergone, possibly combined with chemotherapy effects, and/or the potential unknown effects of the antineoplaston treatment." The Schiffs have presented expert testimony that Crystin's death was caused by excessive radiation, that antineoplastons cured her cancer, and that she would not have died if she had been treated with antineoplastons instead of the radiation and chemotherapy she received.

After a hearing in February 1995, a Texas trial court overturned the Board of Medical Examiners' decision against Dr. Burzynski; the Board appealed from that decision. In November 1995, Dr. Burzynski was indicted by a federal grand jury on multiple counts of violating FDA rules and the injunction prohibiting shipment of antineoplastons across state lines, and on multiple counts of insurance/mail fraud. In February 1996, a Texas Court of Appeals reinstated the Medical Board's decision against Dr. Burzynski, concluding that Texas law did not authorize distribution of drugs that were not FDA-approved. (*State Bd. of Med. Examiners v. Burzynski*, *supra*, 917 S.W.2d at pp. 367-370.) Dr. Burzynski testifies that, later that same month, an FDA protocol was established to incorporate his patients who were then being "treated outside clinical trials" into a large Phase 2 study. All but one count of the federal indictment against Dr. Burzynski were eventually dismissed, and he was acquitted of the remaining count.

The Schiffs filed their complaint for Crystin's wrongful death against Dr. Prados and others in October 1996, alleging that Dr. Prados did not obtain their informed consent for Crystin's treatment because he failed to advise them of the antineoplaston treatment offered by Dr. Burzynski. Dr. Prados moved for summary judgment or summary adjudication, arguing among other things that he had met the standard of care, and that, as a matter of law, none of his acts or omissions during tumor board conferences created any duty of care to Crystin. The court denied the motion, finding that there were triable issues of fact as to whether, among other things, Dr. Prados had met the standard of care, and had breached a duty to provide the Schiffs with information about antineoplaston treatment.

Dr. Prados then moved for summary judgment, or summary adjudication of the duty issue, on the grounds: that antineoplaston treatment was unavailable because it had not been approved by the FDA when the Schiffs consented to Crystin's chemotherapy and radiation treatment; that he had no duty to inform the Schiffs of a treatment he did not recommend; and that he had no duty to obtain their informed consent because as a tumor board member he had no direct patient contact with them before they consented to Crystin's chemotherapy and radiation. The court granted the motion for summary judgment, finding that Dr. Prados had no duty to inform the Schiffs of antineoplastons because they had not been approved by the FDA for Crystin's treatment in January and February of 1993.

Dr. Julian Whitaker, a California licensed physician, and Dr. Carlos Fernandez, a physician licensed in Texas, have opined for the Schiffs that Dr. Prados breached the professional standard of care applicable in the circumstances by failing to inform the Schiffs of antineoplaston treatment as an alternative to the chemotherapy and radiation proposed for Crystin. Dr. Whitaker indicates that Dr. Prados's failure to disclose "the availability of antineoplastons" at tumor board discussions of Crystin's case "would be regarded by the average physician as morally offensive and unethical."

Dr. Prados states that "[i]n January 1993, there were many alternative treatments for cancer known to exist, including laetrile, vitamin C, immuno-augmentative therapy, coffee enemas, Chinese herbal medicines, and others." In his view, although "[a]ny patient is free to explore these potentialities," "[t]he standard of care does not require controversial and/or alternative methods which have not been subjected to scientific scrutiny, such as antineoplastons, to mandatorily fall within the range of options discussed during tumor board meetings." Dr. Prados has not cited lack of FDA approval as a reason for failing to mention antineoplastons as an option in Crystin's case.

Dr. Prados was aware of antineoplastons when Crystin's case was discussed by the tumor board. Dr. Burzynski wrote a letter to Dr. Prados in May 1991 about Dr. Prados's patient, Jeffrey Keller, who had received various treatments, including antineoplastons, after brain tumor surgery. In a June 1991 UCSF admission summary for Keller, Dr. Prados wrote that "[o]verall he has had a dramatic decrease in tumor volume since being

on the antineoplastins [*sic*]." Dr. Burzynski's May 1991 letter also referred to another of Dr. Prados's brain tumor patients, Pamela Winningham. The letter states that Winningham began antineoplaston treatment in May 1988, "went into complete remission" in January 1989, and had been "living a normal life" after her antineoplaston treatment was completed in January 1990. Dr. Prados acknowledges that "one adult patient of mine with quite a different type of tumor [than Crystin] with a much higher survival rate had undergone [antineoplaston] treatment, and may have been helped by it, although he later died."

Mr. Schiff has averred that, if he had been informed about antineoplastons, he would have elected to have Crystin treated with them rather than the chemotherapy and radiation she received.

II. DISCUSSION

"In *Cobbs v. Grant, supra,* 8 Cal.3d 229, the California Supreme Court held that a physician has a duty to disclose to a patient 'the available choices with respect to proposed therapy and . . . the dangers inherently and potentially involved in each.' (*Id*., at p. 243.) Under *Cobbs*, the scope of a physician's duty to disclose is measured by the amount of knowledge a patient needs in order to make an informed choice. (*Id*., at p. 245.) At minimum, a physician must disclose 'the potential of death or serious harm' known to be inherent in a given procedure and an explanation in lay terms of the complications that might occur. (*Id*., at p. 244; see also *Arato v. Avedon* [(1993) 5 Cal.4th 1172, 1190].) In addition to these 'minimal' disclosures, the physician must also reveal to the patient 'such additional information as a skilled practitioner of good standing would provide under similar circumstances.' (*Cobbs v. Grant, supra,* 8 Cal.3d at pp. 244-245, and quoted in *Arato v. Avedon*, *supra*, 5 Cal.4th at p. 1190.)" (*Spann v. Irwin Memorial Blood Centers* (1995) 34 Cal.App.4th 644, 656, fns. omitted.)

"With respect to . . . alternative treatments, under the doctrine of informed consent 'there is no general duty of disclosure with respect to *nonrecommended* procedures . . . .' (*Vandi v. Permanente Medical Group, Inc.* (1992) 7 Cal.App.4th 1064, 1071, italics added.) Instead, 'the failure to recommend a procedure must be addressed under ordinary medical negligence standards. [Citation.]' (*Id*., at p. 1070.) That is, a physician must

disclose alternative treatments only to the extent it is required 'for competent practice within the medical community.' (*Id*., at p. 1071.) The standard of care prevailing in the medical community must be established by expert testimony. (*Ibid*.)" (*Spann v. Irwin Memorial Blood Centers, supra,* 34 Cal.App.4th at p. 658.)

The Schiffs' experts have declared that the standard of care required a physician in Dr. Prados's position to disclose antineoplaston treatment as an alternative to the recommended chemotherapy and radiation, but whether or not those declarations would ordinarily create a triable issue, no such disclosure was required unless antineoplastons were an "available" treatment alternative in Crystin's case. Although the "availability" of an alternative treatment does not appear to have been litigated in any reported decision, many opinions have echoed the statement in *Cobbs v. Grant, supra*, 8 Cal.3d at p. 243, that the duty of disclosure extends only to "available choices." (*Arato v. Avedon, supra*, 5 Cal.4th at p. 1183; *Thor v. Superior Court* (1993) 5 Cal.4th 725, 738; *Truman v. Thomas* (1980) 27 Cal.3d 285, 291; *Warren v. Schecter* (1997) 57 Cal.App.4th 1189, 1200; *Spann v. Irwin Memorial Blood Centers, supra*, 34 Cal.App.4th at p. 656; *Jambazian v. Borden* (1994) 25 Cal.App.4th 836, 844; *Traxler v. Varady* (1993) 12 Cal.App.4th 1321, 1331.)

Dr. Prados contends that the "unavailability" of antineoplastons was established in *Smith v. Shalala* (D.D.C. 1996) 954 F.Supp. 1, but that case is distinguishable. The issue in *Smith v. Shalala* was whether a cancer patient could enjoin the FDA from prohibiting his receipt of antineoplaston treatment. The court rejected the plaintiff's contention that his constitutional rights were violated by the FDA's determination that, because he had not tried "an available, proven treatment for his illness," he did not qualify to participate in a clinical trial of antineoplastons (*Id.* at p. 4.) In response to the plaintiff's claim that he "had a fundamental right to 'choose among available medical treatments,'" the court explained that, because antineoplastons had "not been approved for general use by FDA" and had been approved "only for limited clinical trials under agency supervision," they were "not 'available' as a matter of law." (*Id.* at p. 3.) The latter statement, in context, meant only that use of antineoplastons was subject to FDA supervision. Since the court

was not addressing an issue of informed consent, its observations on the "availability" of antineoplastons are not pertinent here in any event.

The case that has come closest to addressing an availability issue is *Spann v. Irwin Memorial Blood Centers, supra,* 34 Cal.App.4th 644. In *Spann*, the plaintiff's decedent was infected with the HIV virus from transfusions of blood products (plasmapherisis) she received to treat a blood disease (TTP). The defendant blood bank allegedly failed to obtain the decedent's informed consent to the plasmapherisis treatment because it did not disclose steps that could have been taken to reduce the risk of infection, like a program to reduce the pool of donors from which the transfused blood products were obtained. The blood bank was not negligent for failing to offer such a program because none existed for TTP patients undergoing plasmapherisis at the time. (*Id.* at pp. 655, 658.) Although the ruling was not couched in terms of "availability," the court held that the blood bank "had no duty to 'disclose' a program which did not exist and which it had no professional duty to maintain." (*Id.* at p. 658.)

Here, unlike *Spann*, the alternative treatment in question did exist: one physician in Texas was administering antineoplastons. This case, however, presents the unusual situation where the alternative procedure—injection of antineoplastons into children with brain tumors—was outlawed by statute in California. Thus, we are called upon to determine whether a treatment that is illegal in this state is nonetheless an "available" alternative that a physician could be required to disclose in order to obtain a patient's informed consent.

Health and Safety Code section 109300 provides that the "sale, offering for 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 Section 505 of the federal Food, Drug and Cosmetic Act, or (2) there has been approved an application filed with the [Medical Board of California]

setting forth [specified information]."[5] Violating this prohibition is a crime. (§ 109370; *People v. Privitera* (1979) 23 Cal.3d 697, 701 [prosecution for conspiracy to distribute laetrile to cancer patients].)

This prohibition does "not apply to the use of any drug, medicine, compound, or device intended solely for legitimate and bona fide investigational purposes by experts qualified by scientific training and experience to investigate the safety and therapeutic value thereof unless the [State Department of Health Services] shall find that the drug, medicine, compound, or device is being used in diagnosis or treatment for compensation and profit. In order to qualify for an exemption under this section there shall be on file with the federal Department of Health, Education, and Welfare a current and unrevoked investigational new drug application issued pursuant to subdivision (i) of Section 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355(i)), or [alternative conditions are satisfied, including testing to establish that the drug may be safely administered, and a written filing with the Medical Board of California]." (§ 109325.)

The "legitimate state interest" expressed in these statutes (see *People v. Privitera, supra,* 23 Cal.3d at p. 705) is set forth in section 109250, which states in part: "Various persons in this state have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, whose representations are misleading to the public, with the result that large numbers of the public, relying on the representations, needlessly die of cancer, and substantial amounts of the savings of individuals and families relying on the representations are needlessly wasted. [¶] It is, therefore, in the public interest that the public be afforded full and accurate knowledge as to the facilities and methods for the diagnosis, treatment, and cure of cancer *available in this state* and that to that end there be provided means for testing and investigating the value or lack thereof of alleged cancer remedies, devices, drugs, or compounds, and informing the public of the facts

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[5] Unless otherwise indicated, all further statutory references are to the Health and Safety Code.

found, and protecting the public from misrepresentation in these matters." (Italics added.)

Under these statutes, a cancer drug is not legally "available in this state" unless: (1) the FDA has approved an application under section 505 of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) which permits the drug to be marketed (§ 109300; see 21 C.F.R. § 314.1, et seq. (2001)); or (2) at a minimum, a current and unrevoked IND is on file with the FDA pursuant to section 505(i) of the federal law (21 U.S.C. § 355(i)) which permits the drug to be clinically tested in humans (§ 109325; see 21 C.F.R. § 312.1, et seq. (2001)); or (3) specified alternative conditions, including filings with the Medical Board of California, are fulfilled (§§ 109300, 109325). There is no evidence in this case that there were any California Medical Board filings for antineoplastons when Crystin's post-surgical treatment was being considered, and antineoplastons were not approved by the FDA for marketing at the time. The only possible question would be whether a current and unrevoked IND was on file for the antineoplaston treatment Crystin required.

Dr. Burzynski states in a declaration: "I had been authorized since March 1989 by the FDA to treat patients clinically with antineoplastons provided that they were enrolled in a Phase II clinical trial or I obtained a special exception that allowed me to administer treatment that did not meet one or more of the requirements for acceptance into the trial. Thus, from the beginning of 1993, I had the opportunity to obtain from the FDA authorization to treat Crystin Schiff. If I were to have made an application for a special exception for Crystin Schiff in January 1993, it is more likely than not that the FDA would have quickly approved such an application . . . . [¶] When Crystin came to me as a patient, I initiated steps to obtain a special exception license by the FDA to treat her with antineoplastons. At the time of my request, the FDA had already accepted in September 1993 an . . . (IND) . . . that authorized me as the Principal Investigator to conduct clinical trials of antineoplastons in children with brain tumors at the Burzynski Clinic. Because this IND was more relevant to Crystin's case, I sought a special exception based on this IND. It would not have been possible to rely on this IND application prior to its acceptance by FDA in September 1993."

Dr. Burzynski's declaration suggests that there was an IND on file from March of 1989 under which Crystin's treatment with antineoplastons could have been authorized. However, that suggestion is untenable in light of Dr. Burzynski's previous deposition testimony and other evidence. (See *Jacobs v. Fire Ins. Exchange* (1995) 36 Cal.App.4th 1258, 1270 [court may disregard declaration prepared in connection with summary judgment motion that conflicts with declarant's deposition testimony]; *Preach v. Monter Rainbow* (1993) 12 Cal.App.4th 1441, 1451.) A March 1989 letter from the FDA to Dr. Burzynski indicates that the IND then on file was for investigation of the use of antineoplaston capsules for the treatment of advanced breast cancer. Dr. Burzynski confirmed in his deposition that Crystin's treatment could not have been authorized under this IND because she needed large doses of antineoplastons which were equivalent to hundreds of capsules and had to be administered intravenously:

"Q. So before August of '93 are you saying it would have been impossible for a patient to get a special exception? [¶] A. Not for intravenous treatment because we did not have any protocol yet approved for [sic] FDA for intravenous treatment. [¶] Q. I think it's the way the answer came out. Let me ask you basically the same question. [¶] Before August of 1993 it's your understanding that it would have been impossible for a patient to call for this special exception; is that right? [¶] A. With intravenous treatment. [¶] Q. Yes, sir. [¶] A. But it would be possible for special exception with capsules because this protocol had been approved already. [¶] Q. I see. [¶] Was Cryssie Schiff ever treated with capsules? [¶] A. No, she was treated with injections. [¶] Q. Why? [¶] A. Because of the dosage. Her tumor was very aggressive and required heavy dosages. If you would like to administer this orally with capsules, then corresponding dosage should be probably around few hundred capsules a day. So that's why it was administered intravenously. [¶] Q. So from a realistic standpoint, given the type of tumor she had, before August of '93 it was from a practical standpoint impossible for her to qualify for this special exception because you wouldn't have recommended capsules? [¶] A. That's right."

Thus, a minimum requirement for Crystin's lawful treatment with antineoplastons in California—a current and unrevoked IND on file permitting such treatment—was not

satisfied at the relevant time. Accordingly, the Schiffs have effectively conceded, both at oral argument on the summary judgment motion below and in their appellate briefs, that it would have been illegal to administer antineoplastons to Crystin in California when Dr. Prados allegedly should have disclosed the existence of that treatment. The Schiffs argue that Dr. Prados had a duty to advise them of antineoplastons because that treatment was available in Texas, not because it was available in California. Alternatively, the Schiffs argue that Dr. Prados "should have informed [them] about antineoplastons to give them the choice to investigate whether antineoplastons would become available in California through an FDA-approved clinical trial in time to save Crystin's life." The Schiffs observe that "within several months Crystin was able to get antineoplastons *with FDA approval*, but by that time she had already received lethal radiation treatment."

To rule that a physician may have a duty to disclose a treatment that is currently unavailable because the treatment might become available in the future would be to discard the availability requirement altogether. We acknowledge that the concept of meaningful choice is at the heart of the informed consent doctrine (*Cobbs v. Grant*, *supra*, 8 Cal.3d at p. 242; Schuck, *Rethinking Informed Consent* (1994) 103 Yale L.J. 899, 924), that informed consent is generally a jury question (*Arato v. Avedon*, *supra*, 5 Cal.4th at pp. 1184, 1186), and that informed consent cases are not ordinarily governed by "bright line" rules (*id.* at p. 1186). But we are not free to depart from the Supreme Court precedents that limit a physician's duty to disclose alternative treatments to those that are available. (*Auto Equity Sales, Inc.* v. *Superior Court* (1962) 57 Cal.2d 450, 455).

Nor are we free to ignore the lines the Legislature has drawn concerning available treatments. (See *Daum v. SpineCare Medical Group, Inc.* (1997) 52 Cal.App.4th 1285, 1305 [although the *Arato* court declined to prescribe specific disclosures to patients, courts must adhere to requirements imposed by the Legislature and the FDA for informed consent to participation in clinical trials].) The Legislature has specified the IND as a minimum prerequisite for the provision of a cancer treatment. An IND is typically preceded by years of pre-clinical research to develop data showing that a drug is reasonably safe for human testing. (CDER Handbook, *supra*, p. 7; Note, *Reform of the New Drug Approval Process* (1997) 49 Admin. L. Rev. 477, 484.) The IND requirement

thereby furthers the patient welfare goals of the cancer treatment laws. (§ 109250 [need "for testing and investigating the value or lack thereof of alleged cancer remedies" to avoid problems associated with unproven treatments].) That there was an IND on file permitting antineoplaston capsules to be administered to breast cancer patients did not necessarily establish that it was reasonably safe to give injections equivalent to hundreds of capsules to children with brain tumors.

The Schiffs' other argument for recognition of a duty in this case—that Dr. Prados was obligated to advise them of antineoplastons because that treatment was available in Texas—must also be rejected. A comparable argument failed in *Spencer By And Through Spencer v. Seikel* (Okla. 1987) 742 P.2d 1126. The plaintiff in *Spencer* consulted an Oklahoma physician for prenatal care. The fetus was diagnosed with a condition impairing brain development when the fetus was viable and could not, by Oklahoma statute, be aborted. After the child was born with brain damage, the mother sued the doctor on the theory that he had negligently failed to inform her that an abortion might have been available outside Oklahoma. The court agreed with the doctor that he had no duty to disclose information about an alternative treatment that was not legally available to the plaintiff in Oklahoma. The plaintiff was "correct in her assertion that physicians in Oklahoma are held to national standards of care but those standards do not impose upon physicians a duty to know or disclose the laws of other states which are contrary to laws in the state wherein they practice." (*Id.* at p. 1129.) "[I]nform[ing] patients of treatment alternatives not available in Oklahoma but available in other states is beyond what the law expects from physicians. Searching for legal alternatives is a job more suitable for lawyers." (*Ibid.*)

The merits of this reasoning are well illustrated here. When Crystin's treatment was being determined it was unclear whether Dr. Burzynski's use of antineoplastons was permissible under Texas law. The Texas Board of Medical Examiners had alleged that Dr. Burzynski's dispensing of antineoplastons without FDA approval violated a Texas statute, similar to section 109300, which provided that: "'[a] person shall not sell, deliver, offer for sale, hold for sale or give away any new drug unless . . . an application with respect thereto has been approved and the approval has not been withdrawn under

Section 505 of the federal Act.'" (*State Bd. of Med. Examiners v. Burzynski*, *supra*, 917 S.W.2d at p. 369.) Dr. Burzynski relied on another Texas statute, which provided that "[a] physician licensed to practice medicine under this Act may supply patients with any drugs, remedies, or clinical supplies as are necessary to meet the patients' immediate needs." (*Id.* at p. 368, italics omitted.) Initially an administrative law judge sided with Dr. Burzynski, then the Medical Board rejected that decision and "concluded that it is and always has been illegal for Dr. Burzynski to use his antineoplastons in Texas" (*id.* at p. 367), then a trial court sided with Dr. Burzynski, and then a Texas Court of Appeals finally resolved the matter in favor of the Board. The appellate court directed rendition of judgment consistent with the Board's decision because the statute on which Dr. Burzynski relied was only "intended to allow a physician to supply drugs to a patient in immediate need without violating the provisions of the Texas Pharmacy Act" (*id.* at p. 368) and did "not authorize physicians to dispense unauthorized drugs" (*ibid.*). (Accord, *Trustees of the Northwest Laundry v. Burzynski*, *supra*, 27 F.3d at p. 158.)

The protracted proceedings required to resolve the legality of antineoplaston treatment under Texas law demonstrate why Dr. Prados could not reasonably be held responsible for assessing the point. The Schiffs suggest that Dr. Prados cannot claim that antineoplastons were unavailable for Crystin's treatment because he knew of other brain tumor patients who had been treated with them. However, Dr. Prados could not have been expected to know whether the treatment those patients received was permitted by Texas law.

Moreover, even if Texas had allowed Crystin's treatment with antineoplastons, such treatment was, for legitimate policy reasons, outlawed in California. It would be contrary to the public policies reflected in our cancer treatment statutes to require a physician to discuss treatments those statutes proscribe. We note also that cancer drugs in FDA-approved clinical trials are not "unavailable" under our analysis. (§ 109325.) Thus, contrary to the Schiffs' suggestion at oral argument, our decision will not serve to discourage participation in such trials.

Accordingly, while we are mindful of the tragic loss the Schiffs have suffered, we are unable to endorse the duty they advocate.

The Schiffs' remaining argument, advanced without any authority, is that summary judgment cannot be granted on their informed consent claim against Dr. Prados because that claim is integral to their negligence case against the Regents for giving Crystin excessive radiation. The Schiffs object that if they are "forced to go to trial against the Regents without the informed-consent claim, the jury will not learn of the existence of the antineoplaston treatments, allowing the Regents to argue (falsely) that the radiation was not excessive because there existed no alternative treatment to kill the tumor." However, it is inappropriate to speculate about future evidentiary rulings in the litigation of claims not involved in this appeal. For present purposes, it is sufficient that "the summary judgment statute plainly contemplates circumstances in which one defendant is entitled to judgment even though others are not." (*24 Hour Fitness, Inc. v. Superior Court* (1998) 66 Cal.App.4th 1199, 1208.) Dr. Prados is entitled to summary judgment on the informed consent claim, and the negligence action against the Regents must be resolved on its own separate merits.

III. CONCLUSION

The judgment is affirmed.

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Kay, J.

We concur:

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Reardon, Acting P.J.

_____
Sepulveda, J.

Trial Court:	San Francisco Superior Court
Trial Judge:	Honorable David Garcia
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