

CHouston Journal of Health Law and Policy 2001

Symposium

*109 CAM [FNa1] FOR KIDS

Kathleen M. Boozang [FNaa1]

Copyright (c) 2001 Houston Journal of Health Law & Policy; Kathleen M. Boozang

The expectation of the two therapists--Connell Watkins, 54, a well-known expert on attachment disorders, and Julie Ponder, 40, who practice in Evergreen, outside Denver--was that as they pushed against Candace with sofa pillows from the outside to simulate contractions, she would fight her way out of the sheet, as if emerging from a womb, and form a close attachment with Ms. Newmaker. But the procedure went awry almost from the start, when Candace began pleading that she could not breathe, and said, "I'm going to die." The entire 70-minute ordeal was videotaped by the therapists and shown 11 days ago to their jury. The exchanges between the therapists and the girl were so striking that Mary and David Davis, her grandparents, who stood with Mr. Owens today, left the courtroom. On tape, Candace is often heard screaming and begging for air, to which one of the therapists is heard to respond, "Scream for your life." One told her that she must die to be reborn. Candace said, "You mean like you want me to die for real?" Ms. Ponder, who was on top of the girl, said, "Uh-huh." "Die right now and go to heaven?" Candace asked. "Go ahead and die right now," Ms. Ponder said. [FN1]

Introduction

On April 17, 2001, Colorado Governor Bill Owens signed a law that prohibits rebirthing. [FN2] The rebirthing procedure, which simulates emergence from the womb, was fatally employed by two psychologists treating a ten year-old girl with reactive attachment disorder: the child apparently had difficulty forming a loving bond with her adoptive mother. [FN3] Commenting on the case, Dr. Arthur Caplan suggested the futility of legislating against health care treatments because enforcement can be impossible. According to Caplan:

*110 If you try to micro-manage every cuckoo, cockamamie intervention that Americans can dream up, you are going to have a lawbook that will extend from one end of the continent to the other . . . everyone who believes in the therapy will find ten ways to circumvent it so that it doesn't meet what's on the lawbook. [FN4] American parents spend billions of dollars each year on complementary and alternative therapies for themselves, a phenomenon well-documented over the last decade. [FN5] Much less studied but equally captivating is the trend of employing alternative modalities for their children. [FN6] The net effect of parents' choice to use alternative modalities with their children is difficult to assess. As Dr. Caplan indicated, whether a legal response is appropriate is an even more complicated question. [FN7]

Parents, especially mothers, traditionally are the primary caretakers of their sick children and utilize a vast armamentarium of remedies from multitudinous sources to treat them. In most instances the children recover, whether treated with over-the-counter medicines or generations-old folk remedies. [FN8] We trust parents to make the decision when to take their sick children to a "professional healer" and rarely does society concern itself if parents infrequently

*111 use such professionals. Even less often does society interfere in the parents' selection process of these professionals. While these issues arises most starkly when parents refuse life-saving treatment for their children for religious reasons, or when parents must decide whether and how to treat conjoined twins, it becomes a more quotidian question with alternative medicine. Should society's complacency be disturbed by parents' excursions with their children, into non-biomedical therapies? This article will examine the ethical and legal issues surrounding complementary and alternative medicine (CAM) for children. [FN9]

In Part I, this article provides a brief survey of CAM and then explores how parents apply CAM to their children. Society's on-going fascination with CAM resembles a large, uncontrolled experiment with results that are frequently of no benefit, or worse, pose serious risk to children. Part II considers the legal parameters of parents' autonomy to make difficult or controversial health care decisions for their children. Although states clearly afford parents wide berth, parents' choices are not unfettered. However, the precise boundaries on parents' discretion are not well demarcated. [FN10] For example, state policies do not compel parents to obtain preventive care for their children, do not preclude parents from allowing children to engage in dangerous activities, and generally do not override parents' decisions that adversely affect the health or well-being of a child. To define the boundaries on parents' zone of privacy, this article analyzes those instances in which the state affirmatively limits parents' freedom to make choices for their children. The section also suggests guidance for physicians concerned about parents' use of potentially dangerous alternative products and procedures. In Part III, this article surveys and critiques the various legal approaches to the problems CAM poses for children's health. I conclude that we must continue to place high value on deference to parent decision-making in the child health care context. At the same time, we must recognize that an unidentified number of children are at uncertain (but real) risk from unproven CAM interventions. I *112 suggest that narrow limitations on parents' ability to subject their children to CAM therapies may be appropriate when there is serious risk of harm to children and no benefit. The approach suggested seeks to avoid both wholesale regulation of CAM and broad intrusion into parental prerogatives.

I. Identifying the Alternative Phenomenon

According to one CAM World Wide Web site, the trauma of birth or falling from a swing may ultimately be the source of "chronic conditions such as headache, earache, asthma, hyperactivity, learning disorders, eye, sinus, and allergy conditions, throat ailments, neck and shoulder conditions, and scoliosis (curvature of the spine)." [FN11] The solution: natural care, including manipulative therapy. [FN12]

Chiropractors, the founders of manipulative therapy, embrace the concept that most illness can be traced to misaligned or subluxated vertebrae and commend themselves as the principal caretakers of family health. [FN13] The International Chiropractors Association (ICA) "recommends the earliest possible evaluation, detection and correction of chiropractic lesions (subluxation) in children, especially infants, to maximize the potential for normal growth and development." [FN14] Children require this care, according to the ICA, to overcome the trauma many infants suffer during birth, including "traction, rotation and lateral flexion of the head relative to the thorax. ... It is also recognized that day-in, day-out trauma is a continual part of childhood life which can create spinal misalignment and aberrant motor function." [FN15] Few studies have been conducted on *113 chiropractic care for childhood maladies, [FN16] and none suggests that it is effective for childhood diseases. [FN17]

Many chiropractors, as well as some physicians and naturopaths, [FN18] integrate homeopathy into their practices for everything from colic, diaper rash, sore throats and ear aches, to diarrhea. [FN19] Homeopathy uses infinitesimal doses of natural substances that would induce the symptoms of the illness in a healthy person to cure the sick person, by triggering the body's natural healing mechanisms, or "vital force." [FN20] Of course, parents may give their children homeopathic remedies without involving any professional-- ingredients are available in most health food stores, and literature exists for self-tutoring in the homeopathic system. [FN21] Whether homeopathy works remains a rather controversial question because there are few biochemical explanations; thus, clinical trials continue. [FN22]

Understandably, parents of chronically and terminally ill children are the most tempted to pursue alternative modalities for their *114 children. Many of these CAM offerings are unproven and of uncertain value. For example, parents of children with Cerebral Palsy often consider using hyperbaric oxygen chamber therapy. [FN23]As many as fifty percent of asthmatic children have been reported to experiment with CAM. [FN24] Known beneficial CAM treatments include: acupuncture, ginkgo biloba, vitamin C, magnesium, and yoga. [FN25] Meanwhile, unproven CAM treatments include licorice root and reduction of salt intake; potentially harmful treatments include bee pollen, ephedra, and restriction of dairy intake. [FN26] Additionally, studies have demonstrated that seventy percent of children with juvenile arthritis are using unconventional remedies, some of which can be harmful. [FN27] Children with the Human Immunodeficiency Virus (HIV), autism, cancer, Down's Syndrome, diabetes, and eczema are all receptive audiences for alternative therapies, and many have suffered serious consequences from unproven treatments. [FN28]

While CAM can be used to treat present illness, many parents subscribe to alternative modalities for preventative care, sometimes dissenting from public health approaches. [FN29] This is most evident regarding*115 childhood immunization programs. [FN30] Some CAM proponents link the "autism epidemic" to compulsory vaccination programs and recommend that parents utilize the breakthrough technology known as "Electro-Dermal Screening" to identify children who will react adversely to vaccinations. [FN31] Another popular CAM recommendation is a regime of herbs to prepare the immune system to receive a vaccine. [FN32]

Many homeopaths and naturopaths choose not to encourage or even affirmatively discourage childhood immunization. [FN33] Chiropractors, who increasingly act as primary care providers, are historically suspicious of immunization and assert the following arguments: (1) the majority of disease for which vaccines are offered would have disappeared naturally; (2) disease has been eliminated by improved hygiene, sanitation, and nutrition rather than by vaccines; (3) vaccines are generally ineffective, with dangerous side effects; (4) vaccine programs exist to benefit the pharmaceutical companies that produce them; and (5) compulsory vaccine programs violate parents' freedom of choice. [FN34]

The risks of unproven alternative modalities can be significant. Reduced effectiveness of immunization programs may expose not only the children whose parents have "exercised choice," but also may risk a resurgence of diseases that have been largely (though not completely) eradicated. The injuries experienced by children using dietary supplements have probably received the most pervasive media attention. For example in 1988, "the American Association of *116 Poison Control Centers received almost 7,000 reports on supplements; sixty-four percent involved children who were younger than six years-old." [FN35] Unsurprising, the Office of Inspector General of the Department of Health and Human Services is preparing for registration of dietary supplements with the Food and Drug Administration. [FN36] The Inspector General recently expressed concerns about the poor labeling of products, the frequent inability to identify the manufacturer of food supplements, and the risks associated with many dietary supplements. [FN37]

Specialists in the care of children with juvenile arthritis relay concerns that include: (1) severe dietary restrictions "in children whose growth is already compromised by the chronic arthritis process;" [FN38] (2) the deleterious effects of unconventional steroid use; [FN39] and (3) the extraordinary expense some parents incur for CAM treatment, which may include travel to other countries. [FN40]

Moreover, physicians have reported several instances of missed diagnoses by chiropractors. [FN41] Recently, a twenty-eight month-old infant with severe mental retardation, spastic quadriplegia, and a seizure disorder was placed on megavitamin and megamineral therapy by a private nutrition consultant; the infant fatally overdosed from Magnesium Oxide. [FN42] As illustrated by *117 this case, parents generally have no way of knowing the correct doses of the "natural" products they should use to treat their children and should additionally be concerned about product adulteration. [FN43] A recent case report in Pediatrics discussed a young developmentally delayed boy of Indian descent whose mother, pressured by the family to strengthen his brain, treated him for four years with a Tibetan herbal vitamin imported from India. [FN44] The Ayurvedic product contained lead and mercury and the child suffered lead

poisoning. [FN45] Parents are not seeing these reports, often appearing in peer reviewed medical journals that even on the Internet require a paid subscription. The alternative providers whom parents consult are probably also unaware of such reports; or, if they are, do not share them.

It is impossible to capture all the alternatives available to parents interested in exploring every option for their children's health. [FN46] Easier to describe are the numbers of parents actually taking advantage of these innumerable resources. Few parents use unconventional therapies exclusively. Most parents combine what a physician recommends with multiple complementary therapies (about which they rarely tell their physician). [FN47] One Canadian study found that about eleven percent of children surveyed were receiving*118 complementary treatments, mostly for chronic conditions. [FN48] These treatments were provided by not only chiropractors and homeopaths, but also naturopaths and acupuncturists. [FN49] Unsurprising, these children's parents were more likely to use alternative medicine themselves. [FN50] Multiple studies report that parents elect alternative methods in an effort to avoid the side effects of pharmaceuticals, or because they believe that conventional medicine is not effective enough for their children's chronic conditions. [FN51] One author speculates that "the accuracy of the data underlying evidence-based therapies is frightening to patients, and contrasts poorly with the less precise--but less frightening-- information provided about most alternative therapies. Many patients are likely to regard 'absence of evidence of serious side effects' as equivalent to 'evidence of absence." '[FN52] As a result, children with chronic illnesses are more likely to seek care from unconventional providers. For example, an estimated fifty to seventy percent of children with cancer receive CAM care. [FN53]

Kathi J. Kemper, M.P.H., M.D. has conducted a number of studies designed to identify the most prevalent sources of alternative care for children in the United States today. One study found that almost all practitioners of homeopathy and naturopathy regularly treat children; however, only thirty percent of the homoeopaths and thirty-three percent of the naturopaths received formal pediatric training. [FN54] This same study raises serious doubts *119 about these practitioners' ability to diagnose serious childhood conditions and their willingness to refer emergent conditions to physicians. [FN55]

Despite the generally unproven nature of CAM, families generally perceive a benefit from its use and claim a "reduction of symptoms, emotional comfort, improvement of overall well-being, security of social support, and prevention of feelings of guilt from not having 'tried everything."' [FN56] Although some CAM benefits may be the placebo effect, it is unclear at what age children would begin to experience this benefit. [FN57] Moreover, at issue is whether physicians or alternative practitioners (even with parental consent) may ethically prescribe treatment solely for the placebo effect. [FN58]

In short, American parents are subjecting their children to an enormous experiment with alternative therapies. In many instances, the therapies the children are receiving would not even qualify for clinical research because they would not satisfy the test of clinical equipoise, which demands that "[t]here exists ... an honest, professional disagreement among expert clinicians about the preferred treatment." [FN59] In the vast majority of cases, however, little is lost or gained. Little is lost because in most cases the children receive effective conventional treatment simultaneously with the alternative modalities, which are likely to be ineffective. But little is gained in advancing our knowledge about the safety and efficacy of CAM because*120 most alternative care being rendered is beyond the reach of observation and study.

Nevertheless, an identifiable and growing subset of cases exist in which children are at risk of harm. [FN60] This harm can be directly from the alternative intervention itself, or indirectly from the conventional care the child received either too late or not at all. Additionally, parents may lose time and money on useless therapies or regret a bad decision made on their child's behalf. The question arises then whether parents should have the option to choose unproven alternatives to treat their children from the outset.

II. Legal Limitations on Parental Decision-Making

Society is generally reluctant to subject parental decision-making to state interference, whether such intervention comes from the Child Protective Service, teachers, or health care professionals. The balance is difficult to achieve. The state must weigh child safety, health, and well-being on one side with the preservation of the primacy of the family on the other. Nonetheless, parents do not have complete discretion over their children, as demonstrated by state legislation that regularly circumscribes family discretion either to protect the public at large or the safety of an individual. These state limitations on parental decision-making may be categorized into several broad groups. Each will be addressed in turn.

A. State Limitations on Children's Behavior

One set of state statutes designed to protect both children and society at large prohibits certain activities by adolescents, irrespective of parental consent. For example, states establish minimum ages at which minors may drive, [FN61] consume alcoholic beverages, [FN62] *121 and purchase cigarettes. [FN63] With respect to driving, the state provides parents with little discretion to make an independent decision that a child of thirteen, for example, may be sufficiently mature and skilled to drive. Similarly, the state does not ask the parents' perspective when it limits young people's access to cigarettes and alcohol. All of these activities are potentially life-threatening; yet, one could argue that appropriate driving and drinking can be beneficial activities.

B. Compelling Parental Behavior

All states have enacted public health and safety statutes which compel certain parental behavior aimed at achieving child safety. For example, many states require that children under a certain age and weight ride in car seats, be restrained by safety belts, or sit in the back seat of the car. [FN64] These laws made headlines recently when the United States Supreme Court upheld the arrest of a mother whose two children were riding in the front seat of her vehicle without any restraints. [FN65] Some states use the health system to implement these regulations by requiring that hospitals with maternity wards advise parents of laws governing children riding in automobiles. [FN66] *122 Additionally, many hospitals have state-funded programs to distribute child safety seats to indigent mothers upon discharge from the hospital with their children. [FN67] In a similar manner, states penalize parents who allow their children to ride bicycles without helmets. [FN68]

C. Parameters on Parental Choices

Parental consent cannot expand what a statute prohibits. Thus, there are situations in which the government may simply remove options from parents. For example, the federal Child Abuse and Neglect Prevention and Treatment Act [FN69] and attendant regulations limit parents' ability to withdraw treatment from a disabled infant with a life-threatening condition by defining certain actions as medical neglect. [FN70] Another federal regulation limits parents' choices regarding a child's participation as a research subject in a clinical trial. [FN71] Parents are not provided the opportunity to allow their children to participate in research that presents greater than minimal risk unless it is anticipated that the children themselves will directly benefit from the research. [FN72] Thus, the federal government draws the *123 parameters within which parents may operate by simply removing some choices from them. [FN73]

At the state level, legislatures have enacted statutes that circumscribe physicians' ability to perform certain medical procedures, under the threat of criminal liability. Female genital mutilation is the primary example. [FN74] Another example is the statute described in the introduction to this article, "Candace's Law." Colorado criminalized the "rebirthing" technique and named the law in the memory of Candace Newmaker, the young girl who died as a result of the procedure. [FN75] Candace's Law provides that parents may not consent to "physical, chemical, or mechanical restraint on behalf of a child," to be used for therapeutic rebirthing. [FN76] Finally, states sometimes limit parental autonomy by requiring state concurrence with the parents' decision before the procedure may occur. For

example, a court order is typically obtained before an incompetent minor is sterilized [FN77] or becomes an organ donor. [FN78]

*124 D. Mandating Medical Procedures without Regard to Parental Choice

There are a number of instances in which states mandate medical procedures, thereby preempting parental choice. The most common example is the widespread use of state-mandated vaccination. These prevention programs, which date back to the 1800s, were upheld against attacks of unconstitutionality at the beginning of the twentieth century. [FN79] Although states employ a variety of mechanisms to ensure that parents obtain vaccines for their children, it is ironic that the parents' consent is still sought when the vaccine is actually given.

Another sample of state-mandated preventative care is found with neonatal screening statutes. These laws generally do not require parental cooperation or consent, although exceptions may exist for parents whose religion prohibits such screening. [FN80] The purpose behind neonatal screening is to identify newborns with treatable diseases. Thus, parental qualms about such testing are secondary to the state's decision that such testing is in the best interest of the child, is necessary to facilitate commencement of treatment, or is important to identify environmental or other risks that may have caused the child harm. [FN81]

*125 E. State Intervention When Parents Make Unreasonable Health Decisions

According to Jennifer Rosato, J.D., Professor of Law at Brooklyn Law School, the common law precedent for state preemption of parents' medical decisions for their children "lacks guiding principles" and has an "unprincipled nature." [FN82] Parents' rights to decide are afforded Constitutional protection, [FN83] but are not unlimited, as courts engage in a "best interests of the child" analysis, weighing the benefits and risks of the proposed treatment in so doing. [FN84] In recent decades, this power has been integrated in child abuse and neglect statutes whereby the state intervenes on behalf of children whose parents either fail to provide proper medical care or make a medical decision with which the health care establishment and the state disagree. [FN85] Although uncommon, the state or health care provider may (even without parental consent or over parental objection) seek a court order to treat or not treat a child. [FN86] The most frequent cases involve parents whose religious beliefs prohibit the treatment at issue, such as Jehovah's Witnesses who object to blood transfusions or Christian Scientists who object to a wide variety of medical interventions. [FN87]

*126 Less frequent are cases involving non-religious disagreements over what is best for the child. Here, conflicts arise between parents who desire continued care and physicians who believe that treatment should be terminated. [FN88] In the worst cases, the state does not become aware that the parents have declined potentially life-saving medical care for their child until after the child's death, in which case the state intervention is a criminal prosecution that debates whether the parents were compelled to seek the life-saving care and whether the treatment would have indeed saved the life. [FN89] The states' power to compel treatment in these cases is unpredictable and inconsistent. Whether the state is notified at all depends upon many factors including: (1) whether the children have contact with conventional providers; (2) whether the providers disagree with the parents' decision strongly enough to involve the legal system; (3) whether the children are sufficiently mature to voice an opinion about the decision; and (4) probably, the parents' lifestyle.

III. CAM for Kids

Part II suggested that states have at least five methods to limit parental decision-making. These methods can also be used to regulate parental use of CAM for their children. For example, the state might prohibit practitioners from performing certain procedures on children, as illustrated by Candace's Law. The state may also prohibit certain kinds of alternative providers from treating children at all, or condition such treatment on a referral from a licensed physician. Aside from direct legislation, the government may also define the parameters of parents' choice by educating

parents about the risks of particular kinds of therapies, taking measures to improve the safety of the various alternative products available on the market, or providing physicians with better guidance about when parental*127 decisions to use CAM for their children are so unreasonable that the physicians should seek state intervention.

A. Prohibiting Certain Alternative Modalities for Children

Legislation such as Candace's Law is one way to limit parents' decision making power while responding to problems with CAM. It is not the public policy option of first choice, however. For example, it would be difficult to agree upon which CAM procedures are so egregious to justify a ban. Perhaps the only consensus would be for those procedures known to cause a child's death. [FN90] Even so, a legislative approach provides no guarantee of eliminating the most frequently practiced procedures that present potential harm to children. Legislative micro-management of health care is neither efficient nor effective because it lacks the systemic approach necessary to identify and eliminate the "worst practices" being used by any particular branch of CAM. Even in conventional medicine, we generally do not choose legislation as the means to monitor safety, efficacy or quality. [FN91]

B. Prohibiting CAM Providers Treating Children and Requiring Physician Referrals

Legitimate concerns exist about alternative providers' diagnostic abilities and willingness to refer sick children to physicians, especially when children require antibiotics. [FN92] However, evidence has not yet conclusively established that, in the aggregate, the therapies offered by CAM providers are good, bad, or even a risk for children. [FN93] Substantial reasons exist to hope that CAM may offer benefits--even if placebo. [FN94] A total prohibition on CAM providers *128 treating children would be over-inclusive; but, legislation could be more tailored by prohibiting CAM providers from diagnosing or treating children who do not have a referral from a licensed physician. Such legislation would be ideal for the chiropractic care of neonates.

Legislation requiring physician referrals for all childhood visits to CAM providers would be very difficult to enact; it would likely face tremendous opposition from CAM providers who may fear that their minor clientele would disappear. A narrower approach may be more palatable, such as requiring CAM practitioners to coordinate their care with physicians. Alternatively, states could require CAM providers treating children to register with the state each year and to describe their training, their patients, and the type of care they render.

Health insurance might be a more flexible medium than legislation to ensure that CAM providers do not treat children until they are diagnosed by and referred from a physician. Using health insurance would have a narrow impact, however, because most CAM therapies are not covered by health insurance. Moreover, parents could circumvent the diagnosis and referral requirements by simply paying out-of-pocket, which Americans are typically willing to do for CAM. [FN95]

C. Educate Parents About the Risks of Particular Kinds of Alternative Therapies

People who use CAM typically can be described as (1) those who are highly educated and do their own medical research; or (2) those who employ unconventional therapies because of religious or cultural traditions; or (3) those who hold deep and abiding distrust for the medical profession, pharmaceutical industry, and government. CAM users typically consult, but do not defer to, medical professionals. Any approach to educating parents must account for unique differences among CAM users, such as the resources consulted*129 to obtain information. Many parents rely heavily on the Internet for their information, which raises the very serious question of whether it is possible to regulate the veracity and quality of medical information posted. Parents of chronically ill children may be more receptive to information provided by disease-oriented charitable organizations, such as the American Cancer Society, because of perceptions that these organizations are reliable, open-minded, and not controlled by the government or physicians. [FN96]

D. Provide Guidance to Physicians About Unreasonable CAM Use

Physicians will continue to be the primary means by which the states become aware of parents placing their children at risk. Parents' medical choices may create risk because parents either decline conventional care for their children or they use an alternative that is potentially harmful. Narrow limitations on parents' ability to subject their children to CAM therapies may be appropriate but physicians should not seek state intervention unless the parental decision poses a serious risk of harm to the child with no benefit. [FN97]

In essence, the issue is when are parents' choices to use CAM unreasonable decisions for their children? Physicians frequently will be of the opinion (usually unsupported by any published evidence) that there is no therapeutic benefit to using a particular CAM intervention. [FN98] Parents who either self-prescribe CAM or utilize a CAM provider may not participate in studies that yield the potential benefit of better understanding of the therapy. The parents' satisfaction of "having tried everything" may be a short-lived benefit in the face of side-effects or cost and may not be sufficient if the intervention carries more than minimal risk. That being said, these frustrations would not rise to the level of being unreasonable. The law does not require parents to be good, to be right, or to refrain from harmless *130 acts directed at their children. [FN99] It is important to remember that this discussion assumes that a sincere disagreement between parents and physicians exists. Parents' insistence on using CAM may be tied to their own idiosyncratic beliefs about medicine, holistic healing, and religion. Nonetheless, the presumption remains that parents act in their children's best interest. Their decisions should be honored, except in the rarest circumstances.

If parents use CAM in healthy children for prevention or maintenance of overall well-being then such use may be a grave concern if there is a potential for serious risk. [FN100] Unlike organ transplantation, using CAM in healthy children may lead physicians to argue that no benefit will be achieved for anyone (except perhaps the parent whose decision prevailed). [FN101] At stake is a conflict between parent and physicians' values, beliefs, and questionable probabilities. The physician could be wrong about the lack of benefit or the potential for risk. The physician could be influenced by her own biases about alternative medicine. The physician could underestimate the importance of keeping an open mind during the therapeutic relationship and not insisting that the parents keep the child in conventional therapy. Still, it remains difficult to determine when and how physicians should intercede in CAM decisions. Where, for example, an Ayurvedic medicine is causing a child lead poisoning, the physician should exert significant pressure on the parents to discontinue the CAM therapy, perhaps even to the point of seeking official intervention. Similarly, where the parents are integrating CAM with conventional therapies to ameliorate symptoms (rather than cure the illness), the physician should accede to the parents' decision to use CAM, unless serious physical risk exists. [FN102]

*131 In very young children, the potential for placebo effect from CAM is uncertain; but, it should be a factor in the analysis if the alternative satisfies the family's cultural or religious expectations, or provides the parents some measure of control. Additional factors in this analysis include: (1) whether the alternative is being provided as the exclusive treatment; (2) whether efficacious treatments with tolerable side-effects exist; and (3) whether the alternative has been tested in adults with indications of efficacy. [FN103]

The analysis is potentially more complex if the alternative is being offered not as a therapy but rather as something that is ameliorative, though not curative. Physicians must consider whether the CAM modality involves risk (physical, psychological, social, or economic) or offers potential benefit, and how these compare. Benefit in this context requires definition. [FN104] Can placebo effect constitute sufficient benefit in the right circumstances? Is it sufficient benefit if the alternative modality is used because it satisfies cultural or religious expectations, or because the parents' have the psychological satisfaction of feeling some measure of control? Obviously important to the ethical analysis involving use of unproven approaches on children is the distinction among healthy children, disabled children, chronically ill children, terminally ill children, and children with minor ailments that will naturally abate or require antibiotics. Likewise, the child's age and ability to participate in the treatment discussion and decision is relevant.

Conclusion

The extraordinary proliferation of alternative providers, in many instances with the imprimatur of the state, makes it unlikely that they will be effectively precluded from practicing. Whether certain kinds of providers could be prohibited from (1) treating children, (2) only seeing children upon referral from a physician who has diagnosed the child, or (3) precluded from performing particular procedures on children, are all possibilities. Direct regulation of parents' use of alternative providers or modalities is also possible but seems impracticable. Intervention through child neglect proceedings initiated by physicians seems to have the greatest potential *132 but may have undesirable consequences. For example, more than insignificant reliance on physicians to prevent parents' use of alternative therapies would drive a wedge between the parents and the conventional provider. The parents will either discontinue conventional care altogether else refuse to disclose what CAM treatments the child is receiving.

It is necessary to identify the least threatening interventions available to the state to protect children who are being exposed to significant risks from CAM. States should focus first on ensuring the safety of the CAM treatments and providers available to children. All consumers would be better served if the states prevented dangerous, contaminated, or mislabeled products from being sold. All consumers would benefit from access to more reliable information about alternative modalities. This is especially true for information on the World Wide Web. [FN105] Second, states should focus their efforts on preventing fraud in the practice. States, through licensing authority, could assess providers performing harmful procedures on children and review the representations made to parents regarding the nature and effect of various CAM treatments.

States should recognize that parents and physicians will continue to disagree about treatment in CAM. Thus, states should assist physicians in understanding when parents' decisions can be circumvented. It becomes necessary to balance the parent and states' notions of what is best for the child. I suggest that the proper result is to permit state intervention if using CAM either for prevention or actual treatment places children in serious risk of harm with no apparent benefit.

[FNa1]. CAM is an abbreviation for complementary and alternative medicine.

[FNaa1]. LL.M., Yale University; J.D., Washington University; B.S., Boston College. Kathleen M. Boozang is the Associate Dean for Academics, the Director of the Health Law & Policy Program, and a Professor of Law at Seton Hall Law School in New Jersey.

[FN1]. Michael Janofsky, Girl's Death Brings Ban on Kind of Therapy, N.Y. Times, Apr. 18, 2001, at A14.

[FN2]. Candace's Law, 2001 Colo. Legis. Serv. Ch. 129 (H.B. 01-1238) (West) (amending Colo. Rev. Stat. § 2. 12-43-222 (1)(t)(II -III)).

[FN3]. Janofsky, supra note 1.

[FN4]. Janofsky, supra note 1.

[FN5]. Kathi J. Kemper et al., Holistic Pediatrics: A Research Agenda, in 103(4) Pediatrics 902, 902 (1999) [hereinafter Holistic Pediatrics] (noting that thirty-three to fifty percent of American adults use complementary and alternative medicine therapies); Deborah Dokken & Nancy Sydnor-Greenberg, Exploring Complementary and Alternative Medicine in Pediatrics: Parents and Professionals Working Together for New Understanding, 26 Pediatric Nursing 383, 388 (2000) (noting that in 1997 health consumers spent more than twenty-one billion dollars on alternative medicine with more than one-half out of pocket); see generally, Benjamin Druss & Robert A. Rosencheck, Association Between Use of Unconventional Therapies and Conventional Medical Services, 282 JAMA 651 (1999); David M. Eisenberg et al., Trends in Alternative Medicine Use in the United States, 1990-1997, 280 JAMA 1569 (1998); David M. Eisenberg et al., Unconventional Medicine in the United States--Prevalence, Cost, and Patterns of Use, 328 New

1 HOUJHLP 109 1 Hous. J. Health L. & Pol'y 109

Eng. J. Med. 246 (1993).

[FN6]. See Holistic Pediatrics, supra note 5, at 903 (explaining that an alternative modality is "any health care remedy or system not generally accepted in modern biomedicine or therapies that are offered in place of or as substitutes for conventional therapies ... [also defined as] unproven ... a term that may simply mean that a therapy has not yet undergone scientific scrutiny, but that frequently carries the connotation that the therapy has been disproved and should not be considered.").

[FN7]. Janofsky, supra note 1.

[FN8]. See Holistic Pediatrics, supra note 5, at 903 (defining folk remedies as "self-administered therapies that typically are provided within an identified cultural group. These include dietary therapies such as chicken soup for respiratory infections, 'cold' foods to treat 'hot' diseases, chamomile tea to treat colic, 'coining,' and religious or ritual healing practices"). See also Lee Pachter et al., Home-Based Therapies for the Common Cold Among European American and Ethnic Minority Families: The Interface Between Alternative/Complementary and Folk Medicine, in 152 Pediatric & Adolescent Med. 1083 (1998).

[FN9]. See Holistic Pediatrics, supra note 5 (defining "complementary medicine" as "care provided in conjunction with conventional medical care, such as patient support groups for those suffering with cancer. Support groups do not replace patients chemotherapy ... but help patients cope.").

[FN10]. Jennifer L. Rosato, <u>Using Bioethics Discourse to Determine When Parents Should Make Health Care Decisions for Their Children: Is Deference Justified?</u>, 73 Temp. L. Rev. 1, 2 (2000) [hereinafter Bioethics Discourse] (noting inconsistencies that exist in the law and that "[d]ecisions are determined by different standards, depending upon which law governs the issue.").

[FN11]. Productions for Children's Healing, Healing Your Child: Natural Healing Recognizes the Body's Unique Ability to Heal Under Proper Conditions, available at http://www.healingyourchild.com/pages/heal.html (last visited Feb. 19, 2001).

[FN12]. Id. See also International Chiropractors Association, ICA Policy Statements (explaining that manipulative therapy is the "directional thrust that sets a vertebra into motion with the intent to improve or correct vertebral malposition or to improve juxtaposition segmentally in relationship to its articular mates thus reducing or correcting the neuroforaminal/neural canal encroachment factors inherent in the chiropractic vertebral subluxation complex."), available at http://www.chiropractic.org/ica/policy.htm (last visited Apr. 3, 2001).

[FN13]. James B.Campbell et al., Chiropractors and Vaccination: A Historical Perspective 105(4) Pediatrics e43, e44 (2000) (explaining that chiropractic history is noted for early opposition to the "germ theory," which posits that microbes are the cause of disease).

[FN14]. International Chiropractors Association, ICA Policy Statements, available at http://www.chiropractic.org/ica/policy.htm (last visited Apr. 3, 2001).

[FN15]. Id.

[FN16]. Kathi J. Kemper, The Holistic Pediatrician 10 (1996).

[FN17]. See, e.g., Jeffrey Balon et al., A Comparison of Active and Simulated Chiropractic Manipulation As Adjunctive Treatment for Childhood Asthma, 339(15) New Eng. J. Med. 1013, 1013, 1019 (1998) (reporting the results

from a randomized, controlled trial of chiropractic spinal manipulation for children with mild or moderate asthma and noting that the treatment "provided no benefit ... the effect is more likely to have been a placebo effect or study (Hawthorne) effect").

[FN18]. Anne C.C. Lee & Kathi J. Kemper, Homeopathy and Naturopathy: Practice Characteristics and Pediatric Care, 154 Arch. Pediatric Adolescent. Med. 75, 77 (2000) (summarizing literature which suggests that ten to thirty-seven percent of chiropractors practice homeopathy, and noting that 2,500 to 4,000 professionals practice homeopathy in America, "a few hundred of whom are physicians").

[FN19]. Id. at 75 (explaining that homeopathy is based on two principles: similia similibus, which mandates that an illness can be treated by a substance that produces similar symptoms in a healthy person, and doses minimae, which mandates that more dilute substances are more powerful and therapeutic); id. at 77 (noting that practitioners prescribed nutritional supplements, nutrition plans, herbal therapies, phytotherapies, and relaxation techniques as homeopathic remedies for a wide array of ailments).

[FN20]. Edward H. Chapman, Homeopathy, in Essentials of Complementary and Alternative Medicine 472, 479-86 (Wayne Jonas & Jeffrey Levin, eds. 1999) (detailing that homeopaths seek to learn everything about the patient to enable treatment in the "totality" and develop individualized remedies).

[FN21]. Lee, supra note 18, at 78 (indicating that laypersons account for over half of the membership of the National Center for Homeopathy).

[FN22]. Clinical results in other countries are sufficiently positive to commend further study. See, e.g., Jennifer Jacobs et al., Treatment of Acute Childhood Diarrhea With Homeopathic Medicine: A Randomized Clinical Trial In Nicaragua, 93(5) Pediatrics 719, 719 (1994) (summarizing literature on clinical trials of homeopathy and reporting on trial of homeopathic treatment of acute childhood diarrhea as inconclusive, but sufficiently positive to warrant further trials).

[FN23]. Richard Neubauer et al., New Hope for Kids with Cerebral Palsy and Brain Injuries, (discussing that hyperbaric oxygen therapy (HBOT) makes oxygen available to tissues that are receiving an inadequate supply and indicating that "it will probably be ten to fifteen years before we really know the ultimate effect of hyperbaric oxygenation."), available at http:// www.alternativemedicine.com/digest/issue33/ 33044.shtml (last visited Feb. 29, 2001).

[FN24]. Kathi J. Kemper & Mitchell Lester, Alternative Asthma Therapies: An Evidence-Based Review, 16 Contemp. Pediatrics 162, 162 (1999) [hereinafter Alternative Asthma] (noting an Australian survey concluding that fifty-five percent of asthmatic children from one to six years old have used alternative therapy).

[FN25]. See generally id. at 165-74; Linda S. Spigelblatt, Alternative Medicine: Should It Be Used By Children?, Current Problems Pediatrics 180, 183 (1995) [hereinafter Alternative Medicine].

[FN26]. See generally Alternative Asthma, supra note 24, at 165-74. See also Kathi J. Kemper, Seven Herbs Every Pediatrician Should Know, 13(12) Contemp. Pediatrics 79, 81-86 (1996).

[FN27]. Taunton R. Southwood et al., Unconventional Remedies Used for Patients With Juvenile Arthritis, 85(2) Pediatrics 150, 150 (1990) (summarizing a study of fifty-three patients suffering from juvenile arthritis, and finding that thirty-seven children used one of eight different unconventional remedies--one of which was dietary restriction that brought one subject to life-threatening starvation).

[FN28]. See, e.g., Spigelblatt, supra note 25, at 183-85 (outlining different ailments, the reasons why those patients

1 HOUJHLP 109 1 Hous. J. Health L. & Pol'y 109

seek CAM treatments, and noting that "serious and even fatal complications can arise from manipulation in children," such as quadriplegia).

[FN29]. See, e.g., International Chiropractors Association, ICA Policy Statements (stating that the ICA "considers public water fluoridation to be possibly harmful and deprivation of the rights of citizens to be free from unwelcome mass medication."), at http://www.chiropractic.org/ica/policy.htm (last visited Apr. 3, 2001).

[FN30]. See id. (stating that "the ICA supports each individual's right to select his or her own health care and to be made aware of the possible adverse effects of vaccines upon the human body. ... In accordance with such principles ... the ICA is opposed to compulsory programs which infringe upon such rights.").

[FN31]. See, e.g., U.S. Autism Epidemic and Vaccinations: Are They Related?, available at http://www.alternativemedicine.com/whatshot/whatshot51.shtml (last visited Feb. 19, 2001). But see Sandra Blakeslee, No Evidence of Autism Link Is Seen in Vaccine, Study Says, N.Y. Times, Apr. 24, 2001, at A16.

[FN32]. See, e.g., Healthwell, at http://www.healthwell.com (last visited Feb. 27, 2001).

[FN33]. Jonathan Halper & Lawrence Berger, Naturopaths and Childhood Immunizations: Heterodoxy Among the Unorthodox, 68(3) Pediatrics 407, 408 (1981) (explaining that "[t]hrough optimal nutrition and hygienic practices, the need for vaccinations, in the minds of some naturopaths, could be totally obviated.").

[FN34]. Campbell et al., supra note 13, at e48-e53 (outlining seven different arguments and explaining the history behind the chiropractors' policy decision). Because chiropractors often serve as primary care pediatricians, the issue of vaccination is significant. Children's primary care providers are the most influential factor in parents' decision to immunize. See Bruce G. Gellin et al., Do Parents Understand Immunizations? A National Telephone Survey, 105 Pediatrics 1097 (2000).

[FN35]. Dokken, supra note 5, at 341.

[FN36]. Robert Pear, Tighter Rules Are Sought for Dietary Supplements, N.Y. Times, Apr. 17, 2001, at A10 (reporting that the Inspector General found that 100 million Americans use dietary supplements, that the industry grosses almost fifteen billion dollars each year, that thirty-two percent of dietary supplements did not have a named manufacturer, and that seventy-seven percent of the supplements did not have a sufficient product label).

[FN37]. Id.

[FN38]. Southwood et al., supra note 27, at 153.

[FN39]. Id. (noting that in 1983 the "estimated total cost of unconventional arthritis treatments in the United States alone was three billion dollars").

[FN40]. Id.

[FN41]. See, e.g., Yubal Shafrir, Quadriplegia After Chiropractic Manipulation in Infant Congenital Torticollis Caused by Spinal Cord Astrocytoma, 120 J. Pediatrics 266 (1992) (reporting on paraplegia resulting to four month-old infant whose tumor was undiagnosed by chiropractor who provided manipulation therapy); Victor D. Turow, Chiropractic for Children, 151 Arch. Pediatric & Adolescent Med. 527, 527 (1997) (reporting that an eighteen year-old man visited a chiropractor with lower back pain as a symptom, was prescribed orthotic lift and nutritional supplements, but was later found by physicians to have a necrotic retroperitoneal mass with apparent metastatic lesions in the kidneys,

1 HOUJHLP 109 1 Hous. J. Health L. & Pol'y 109

liver, and lungs that the chiropractor failed to diagnose).

[FN42]. John K. McGuire et al., Fatal Hypermagnesemia in a Child Treated With Megavitamin/Megamineral Therapy, 105(2) Pediatrics e18, e19 (2000) (explaining that the mother was directed to give 0.5 teaspoons of magnesium oxide four times per day and that the mother increased that to 0.5 tablespoons four times per day to expedite improvement).

[FN43]. See, e.g., Richard J. Ko, Adulterants in Asian Patent Medicines, 339 New Eng. J. Med. 847, 847 (1998) (reporting on study of 260 traditional Chinese medicines by the California Department of Health Services, which found that eighty-three contained "undeclared pharmaceuticals or heavy metals" (including Lead, Arsenic, and Mercury), and twenty-three contained "more than one adulterant"); Nancy R. Slifman et al., Contamination of Botanical Dietary Supplements by Digitalis Lanata, 330 New Eng. J. Med. 806 (1998) (describing two case studies of emergency room admissions resulting from ingestion of contaminated dietary supplements).

[FN44]. Cynthia Moore & Robert Adler, Herbal Vitamins: Lead Toxicity and Developmental Delay, 106 Pediatrics 600, 600 (2000).

[FN45]. Id. at 600-01 (explaining that the tablets contained lead, mercury, and arsenic in addition to the traditional vegetable and animal products and that the child ingested approximately sixty-three grams of lead over the four year period).

[FN46]. See American Academy of Pediatrics, Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness Or Disability, 107 Pediatrics 598, 598 (2001) (defining CAM as "a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historic period.").

[FN47]. Linda Spiegelblatt et al., The Use Of Alternative Medicine by Children, 94(6) Pediatrics 811, 812 (1994) [hereinafter Use of Alternative Medicine] (detailing a study wherein thirty percent of surveyed children used at least two forms of therapy for a condition and that "only one half of all parents informed the child's [physician] of the consultation").

[FN48]. Id. (concluding that of 2,055 questionnaires distributed, 208 children consulted one or more alternative medicine practitioners during the 1992 year).

[FN49]. Id. (noting that chiropractic, homeopathy, naturopathy, and acupuncture together accounted for eighty-four percent of alternative therapy: thirty-six percent of that figure was for chiropractors, and twenty-five percent of that figure was for homeopathy).

[FN50]. Id. at 813 (noting various correlations between parent and child use of alternative medicines).

[FN51]. Id. at 812. See also Alternative Asthma, supra note 24, at 164 (explaining that parents of asthmatic children are frustrated over the lack of a cure and fear side effects of steroids).

[FN52]. Stan F. Whitsett et al., Why Are Children with Cancer Being Exposed to Complementary Medicine?: Untested Therapies Are Not the Best Choice in the Face of Deadly Disease, 171 W. J. Med. 150, 151 (1999).

[FN53]. Kathi J. Kemper & Loongwood Herbal Task Force, Shark Cartilage, Cat's Claw, and Other Complementary Cancer Therapies, 16 Contemp. Pediatrics 101, 102 (1999) (explaining that the rates are particularly "high among

children who have had relapses" of cancer). See also Michael G. Sawyer et al., Children with Cancer: The Use of Alternative Therapies by Children With Cancer, 160 Med. J. Australia 320, 322 (1994) (indicating that excluding hypnotherapy, thirty-three percent of surveyed children with cancer use at least one alternative therapy; but, less than fifty percent of parents inform physicians of that choice).

[FN54]. Lee, supra note 18, at 78.

[FN55]. Id. at 79 (noting that only sixteen percent of homeopathic providers referred patients to physicians and stating that fifty-two percent held the degree of M.D. and that "homeopathic education varies considerably ... the median reported training ... was three years and ongoing, ranging from three weeks to twenty years.").

[FN56]. Robert C. Stern et al., Use of Nonmedical Treatment by Cystic Fibrosis Patients, 13 J. Adolescent Health 612, 614 (1992).

[FN57]. American Academy of Pediatrics, Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness Or Disability, 107 Pediatrics 598, 599 (2001) (stating, "some alternative therapies conceivably may have placebo effects, which confer additional therapeutic gain and enhanced quality of life"). But see A. Hrobjartsson & P.C. Gotzsche, Is the Placebo Powerless? An Analysis of Clinical Trials Comparing Placebo with No Treatment, 344(21) New Eng. J. Med., 1594-1602 (2001) (finding that placebos have no significant effect on objective outcomes but may have a minor impact in studies with subjective outcomes, and arguing that there is no use for placebos outside the clinical trial setting). For additional arguments regarding the placebo effect, see Kathleen M. Boozang, The Therapeutic Placebo (forthcoming 2002).

[FN58]. See generally Marshall Kapp, Placebo Therapy and the Law: Prescribe with Care, 8 Am. J.L. & Med. 371 (1983).

[FN59]. Charles Weijer, The Ethical Analysis of Risk, 28 J. Law, Med. & Ethics 344, 354 (2000), citing K.M. Taylor et al., Physicians' Reasons for Not Entering Eligible Patients in a Randomized Clinical Trial of Surgery for Breast Cancer, 310 New Eng. J. Med. 1363-67 (1984).

[FN60]. See supra notes 35-45 and accompanying text.

[FN61]. See, e.g., Tex. Trans. Code § 521.029(a)(1) (Vernon 1999) (stating, "a person who enters this state as a new resident may operate a motor vehicle in this state for no more than thirty days after the date on which the person enters this state if the person is sixteen years of age or older ...").

[FN62]. See, e.g., Tex. Alco. Bev. Code § 1.03 (Vernon 1999) (stating, "this code is an exercise of the police power of the state for the protection of the welfare, health, peace, temperance, and safety of the people of this state."); id. at § 106.01 (stating, "in this code 'minor' means a person under twenty-one years of age."); id. at § 106.04(a) (stating, "a minor commits an offense if he consumes an alcoholic beverage.").

[FN63]. See, e.g., <u>Tex. Health & Safety Code § 161.082(a)(1)</u> (Vernon 1999) (stating, "a person commits an offense if the person, with criminal negligence: sells, gives, or causes to be sold or given a cigarette or tobacco product to someone who is younger than eighteen years of age ...").

[FN64]. See, e.g., Tex. Transp. Code § 545.412 (Vernon 1999) (stating that an individual is required to secure a child under two years of age in a safety seat and a child between two and four years of age in either a safety seat or by seat belt when the motor vehicle is in operation); Conn. Gen. Stat. § 14-100(c)(1) (1987) (stating that operators of motor vehicles shall secure passengers four years of age or older and under sixteen years with a seat safety belt); Conn. Gen. Stat. § 14-100(d) (1987) (stating that individuals transporting children under the age of four years weighing less than

forty pounds are required to use an approved child restraint system and seat belts or restraint systems for children four years old weighing forty pounds or more); <u>Idaho Code § 49-672 (1)</u> (Michie 1998) (stating that children under four years of age weighing less than forty pounds traveling in a car with seat belts must be secured in a car safety seat, however if all seat belts are occupied, the child must be in the back seat of the vehicle).

[FN65]. Atwater v. Lago Vista, 532 U.S. 318 (2001) (presenting a 42 U.S.C. § 1983 action by a Texas motorist against city, police chief, and arresting officer after she was arrested for failing to fasten her children in seat belts while driving without a license; the Supreme Court affirmed the Fifth Circuit's holding in 195 F.3d 242 (1999) and concluded that the arrest did not violate the motorist's Fourth Amendment rights).

[FN66]. See generally Judith Talty et al., Implementing a Comprehensive Child Restraint Program in a Pediatric Hospital: An Effective Model, 26 Pediatric Nursing 619, 620 (2000) (explaining that "incorporating child passenger safety and education and child safety seats into the hospital environment can positively impact the health and safety of young children and foster safe transportation practices by families"). See also 1996 Conn. Acts 96-257 § 4(a).

[FN67]. Talty, supra note 66 (noting that patients can obtain a child restraint system or safety seat from the hospital through a purchase plan, loan program or as an item under the patient's material services and that "[i]f a family is unable to afford a child restraint, vouchers for a free seat are available through a fund administered by the Social Services Department.").

[FN68]. See, e.g., Ala. Code § 32-5A-285 (2000) (stating that a parent or guardian will be subject to a fifty dollar fine for a child's fourth offense of riding a bicycle without helmet protection); Del. Code Ann. tit. 21 § 4198L(a), (b) (2000) (stating that if a person under the age of sixteen rides a bicycle without wearing a helmet then the individual's guardian is subject to a fine).

[FN69]. Child Abuse and Neglect Prevention and Treatment, 45 C.F.R. § 1340.15(b)(1-2) (2001) (explaining that medical neglect includes "the withholding of medically indicated treatment from a disabled infant with a life-threatening condition" and defining "withholding" as the "failure to respond ... by providing ... appropriate nutrition, hydration, and medication ... which in the treating physician's ... reasonable medical judgment will ... be effective in ameliorating or correcting all such conditions ...").

[FN70]. Id. at § 1340.15(b)(1) (defining the term medical neglect as "the failure to provide adequate medical care" such as nutrition, hydration, and medication and indicating that exceptions to neglect would arise if the infant is "chronically comatose" if the treatment would "prolong dying" or if the treatment would be "virtually futile").

[FN71]. See generally 45 C.F.R. § 46.404 (2000) (explaining that the Department of Health and Human Services will "conduct or fund research in which the [Institutional Review Board (IRB)] finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in section 46.408").

[FN72]. 45 C.F.R. § 46.405 (2000) (stating that the experiment must be "likely to contribute to the subject's well-being" and the Institutional Review Board (IRB) must find that "the risk is justified by the anticipated benefit to the subjects ... the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches ... and adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians ...").

[FN73]. But see Jennifer Rosato, The Ethics of Clinical Trials: A Child's View, 29 J. L. Med. Ethics 362, 369-71 (2000) [hereinafter Ethics of Clinical Trials] (delineating situations in which an Institutional Review Board should be able to override the parental permission requirement for a neonates, infants and young children where the treatment subject to the research represents the standard of care).

[FN74]. See, e.g., 720 III. Comp. Stat. 5/12-34 (2001) (mandating that "whoever knowingly circumcises, excises, or infibulates, in whole or in part" female genitalia, regardless if the minor or parent consented to the procedure, is subject to a felony charge).

[FN75]. Candace's Law, 2001 Colo. Legis, Serv. Ch. 129 (H.B. 01-1238) (amending Colo. Rev. Stat. § 2. 12-43-222 (1)(t)(II -III)) (stating that "a person licensed ... under this article is in violation of this article if such person has engaged in any of the following ... using or recommending rebirthing or any therapy technique that may be considered similar to rebirthing as a therapeutic treatment ... a parent or legal guardian may not consent to physical, chemical, or mechanical restraint on behalf of a child or ward.").

[FN76]. Id.

[FN77]. See, e.g., Ark. Code Ann. § 20-49-202(a) (Michie 1999) (indicating that a guardian or parent of an minor alleged incompetent, "may petition in the court for the sterilization... of an alleged incompetent."). See also In re K.M., 816 P.2d 71, 75 (Wash. App. 1991) (holding that K.M's guardian ad litem did not adversely represent K.M's interest in her fundamental right to procreate thus the trial court erred "by failing to appoint independent counsel for K.M." and the order for sterilization should be reversed and remanded for a new hearing).

[FN78]. See, e.g., Conn. Gen. Stat. § 45a-677(e) (1999) (mandating that "a plenary or limited guardian of the mentally retarded person shall not have the power or authority ... to consent on behalf of the ward to an abortion or removal of a body organ, except in accordance with applicable statutory procedures when necessary to preserve the life or prevent serious impairment of the physical or mental health of the respondent"). See also Hart v. Brown, 289 A.2d 386, 391 (Conn. Super. Ct. 1972) (finding that "natural parents of a minor should have a right to give their consent to an isograft kidney transplantation procedure when their motivation and reasoning are favorably reviewed by a community representation which includes a court of equity").

[FN79]. See generally Timothy J. Aspinwall, <u>Religious Exemptions to Childhood Immunization Statutes: Reaching for a More Optimal Balance Between Religious Freedom and Public Health, 29 Loy. U. Chi. L.J. 109, 117 (1997) (tracing the early Supreme Court vaccination jurisprudence back to <u>Jacobson v. Massachusetts, 197 U.S. 11 (1905)</u>, in which the Court affirmed "the criminal conviction of a man who refused to accept a legislatively mandated smallpox immunization," despite appellant's Fourteenth Amendment Due Process and Equal Protection Clauses arguments).</u>

[FN80]. See generally The New York State Task Force on Life and the Law, Genetic Testing and Screening in the Age of Genomic Medicine 151 (2000). Parental consent is not mandated for neonatal screening in all states except Maryland and Wyoming. Id., citing E.H. Hiller et al., Public Participation in Medical Policy Making and the Status of Consumer Autonomy: The Example of Newborn Screening Programs in the United States, 87 Am. J. Pub. Health 1283 (1997). Religious objections to screening are allowed under thirty-three state programs whereas seventeen programs permit parental refusal to newborn screening for religious and personal reasons. Id. Where parental refusal is permissible, only thirteen states inform parents of the screening program and provide educational information before testing. Id.

[FN81]. See, e.g., Tex. Health & Safety Code §§ 33.011(a), 33.012(a) (Vernon 1999) (providing that "the physician attending a newborn child or the person attending the delivery of a newborn child that is not attended by a physician shall subject the child to screening tests approved by the department for phenylketonuria, other heritable diseases, and hypothyroidism ..." and "screening tests may not be administered to a newborn child whose parents, managing conservator, or guardian objects on the ground that the tests conflict with the religious tenets or practices of an organized church of which they are adherents.").

[FN82]. Bioethics Discourse, supra note 10, at 5.

[FN83]. Id. at 6.

[FN84]. Id. at 10.

[FN85]. See, e.g., Colo. Rev. Stat. § 18-6-401(1)(a) (2000) (stating that "a person commits child abuse if such person causes an injury to a child's ... health, or permits a child to be unreasonably placed in a situation that poses a threat of injury to the child's ... health, or engages in a continued pattern of conduct that results in malnourishment, [or] lack of proper medical care ...").

[FN86]. See Bioethics Discourse, supra note 10, at 25-26 (explaining that "[m]ost cases involving parents' denial of medical treatment are treated as ordinary medical neglect cases. The parents' denial of treatment is brought to the attention of the local child protective services office (usually by the health care provider), and an action then is brought in family court or its equivalent to determine whether the child has been neglected. A finding of neglect usually necessitates an order of treatment. If treatment is ordered, a guardian may be appointed to ensure that the ordered treatment has been administered.").

[FN87]. See, e.g., Commonwealth v. Twitchell, 617 N.E.2d 609, 613 (Mass. 1993) (providing an example of Christian Scientist parents who used "spiritual treatment" exclusively to treat their infant son suffering from a perforation in his bowl caused by Meckel's Diverticulum; the infant died from peritonitis and the state charged the parents with involuntary manslaughter but the state Supreme Judicial Court reversed all lower court decisions finding that the parents were not afforded the opportunity to present an affirmative defense as to their religion).

[FN88]. See, e.g., In re Baby K., 16 F.3d 590, 592 (4th Cir. 1994) (providing an example of a lawsuit brought by a mother against a hospital under the federal Emergency Medical Treatment and Active Labor Act (EMTALA) for failing to provide mechanical respiration for her newborn with anencephaly, and finding that the hospital had a "duty to render stabilizing treatment under EMTALA"); In re Jane Doe, 418 S.E.2d 3, 13 (Ga. 1992) (providing an example of a child with degenerating brain stem who was on a respirator when the mother requested removal of life support measures while the father refused, and holding that "because the father revoked consent, the trial court correctly determined the hospital could not enter a DNR order" and the child would be kept alive on life-support indefinitely).

[FN89]. See, e.g., Twitchell, 617 N.E.2d at 613.

[FN90]. Even an untoward outcome such as death does not suggest that the alternative is bad. For example, a beneficial alternative can be incompetently performed.

[FN91]. See generally William J. Curren et al., Health Care Law and Ethics 1190-1222 (5th ed. 1998) (detailing that hospitals are required to comply with state licensure but that private accreditation is the dominate form of quality control through the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO)); id. at 314-414 (detailing that medical malpractice is a tort involving many considerations including a multitude of standards of care and factors pertaining to expert witness testimony).

[FN92]. See Lee, supra note 18, at 79 (noting that only sixteen percent of surveyed homeopathic providers refer patients to physicians).

[FN93]. See Holistic Pediatrics, supra note 5 (calling for more research to understand "how the use of CAM affects adherence with mainstream medical recommendations and vice versa...").

[FN94]. American Academy of Pediatrics, Counseling Families Who Choose Complementary and Alternative Med-

icine for Their Child With Chronic Illness Or Disability, 107 Pediatrics 598, 599 (2001) (stating, "some alternative therapies conceivably may have placebo effects, which confer additional therapeutic gain and enhanced quality of life").

[FN95]. Milbank Memorial Fund, Enhancing the Accountability of Alternative Medicine (January 1998) (stating that "[m]ost CAM treatments (chiropractic is a notable exception) are not reimbursed by health plans or insurance companies; they are usually paid for by the patient. Although the charge for a single visit may be lower than one to an MD-DO, often the treatment requires more visits before it is completed. Since 1996, however, a number of managed care organizations on the West Coast have begun to offer some type of CAM coverage as an option."), available at http://www.milbank.org/mraltmed.html (last visited Apr. 3, 2001).

[FN96]. See, e.g., American Cancer Society, Alternative and Complementary Therapy (educating browsers about the difference between evidence-based medicine and CAM and recommending that patients discuss options with physicians which may include: aromatherapy, biofeedback, meditation, and yoga), at http://www.cancer.org/alt_therapy/index.html (last visited Jun. 2, 2001).

[FN97]. This discussion assumes that the child is not capable of assent or consent, thereby focusing exclusively on parental consent.

[FN98]. See Alternative Medicine, supra note 25, at 186 (calling for pediatricians to have an attitude that is "open and nonjudgmental" and "despite a physician's own reservations about condoning unproved treatments" they should not "denigrate parents' attempts to seek help for their child").

[FN99]. See generally Leonard H. Glantz, Research with Children, 24 Am J.L. & Med. 213, 219-20 (1998).

[FN100]. Charles Weijer explains that "the proper ethical analysis of risk requires that both the magnitude of the harm and its probability of occurring be considered." Weijer, supra note 59, at 345-46.

[FN101]. See, e.g., <u>Hart v. Brown 289 A.2d 386, 389 (Conn. Super. Ct. 1972)</u> (providing the case of a kidney transplant from one minor, twin child to the other wherein the court balanced the interests and rights of all parties and noted, "[a] psychiatrist who examined the donor gave testimony that the donor has a strong identification with her twin sister. He also testified that if the expected successful results are achieved they would be of immense benefit to the donor in that the donor would be better off in a family that was happy than in a family that was distressed and in that it would be a very great loss to the donor if the donee were to die from her illness.").

[FN102]. This is so even in the face of serious social or economic risk. Intervention due to psychological risk would depend upon the circumstances. See generally Weijer, supra note 59, at 345-46.

[FN103]. See Ethics of Clinical Trials, supra note 73, at 369-71.

[FN104]. In the clinical research setting, the analysis focuses on the sufficiency of potential therapeutic benefit versus the potential to contribute to an understanding of safety and efficacy. Weijer, supra note 59, at 352. No potential exists in the context herein discussed for this kind of non-therapeutic benefit.

[FN105]. See H. Juhling McClung et al., The Internet as a Source for Current Patient Information, 101(6) Pediatrics e2 (1998) (surveying sixty World Wide Web documents on how to treat children's acute diarrhea and concluding that only twenty percent of the sites conformed to current American Academy of Pediatrics guidelines for management).

1 Hous. J. Health L. & Pol'y 109

END OF DOCUMENT