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SPECIAL ARTICLE

Pediatric Use of Complementary Therapies: Ethical and Policy Choices

Michael H. Cohen, JD, MBA*‡§; Kathi J. Kemper, MD, MPH¶; Laura Stevens, BA; Dean Hashimoto, JD, MD¶; and Joan Gilmour, LLB, JSD#

ABSTRACT. Objective. Many pediatricians and parents are beginning to integrate use of complementary and alternative medical (CAM) therapies with conventional care. This article addresses ethical and policy issues involving parental choices of CAM therapies for their children.

Methods. We conducted a literature search to assess existing law involving parental choice of CAM therapies for their children. We also selected a convenience sample of 18 states of varying sizes and geographic locations. In each state, we inquired within the Department of Health and Human Services whether staff were aware of (1) any internal policies concerning these issues or (2) any cases in the previous 5 years in which either (a) the state initiated proceedings against parents for using CAM therapies for their children or (b) the department received telephone calls or other information reporting abuse and neglect in this domain. We asked the American Academy of Pediatrics and the leading CAM professional organizations concerning any relevant, reported cases.

Results. Of the 18 state Departments of Health and Human Services departments surveyed, 6 reported being aware of cases in the previous 5 years. Of 9 reported cases in these 6 states, 3 involved restrictive dietary practices (eg, limiting children variably to a watermelon or raw foods diet), 1 involved dietary supplements, 3 involved children with terminal cancer, and 2 involved religious practices rather than CAM per se. None of the professional organizations surveyed had initiated proceedings or received telephone calls regarding abuse or neglect concerning parental use of CAM therapies.

Conclusions. Pediatric use of CAM therapies raises complex issues. Clinicians, hospitals, state agencies, courts, and professional organizations may benefit from a policy framework to help guide decision making.15 This article builds on our previous work by addressing pediatric review of parental concerns involving CAM therapies. We also summarize legal, regulatory, and professional developments regarding pediatric use of CAM therapies and offered a framework to guide clinical advising by pediatricians.15 We also summarized legal, regulatory, and professional developments that affect pediatric integration of CAM therapies and offered a framework to help guide clinical decision making. This article builds on our previous work by addressing pediatric review of parental choices involving CAM therapies for their children. Such choices raise novel and significant ethical and policy concerns at the interface of medicine and personal choice.

In a recent survey of 745 pediatricians, 87% reported being asked by a patient (or parent) about 1 or

ABBREVIATIONS. CAM, complementary and alternative medical; DHHS, Department of Health and Human Services; AAP, American Academy of Pediatrics; USFSMB, US Federation of State Medical Boards; FDA, Food and Drug Administration; AANP, American Association of Naturopathic Physicians.
more CAM therapies, and 83% desired additional information or education about CAM therapies.23 The most common patient queries (and the areas of greatest physician interest for future learning) concerned herbs such as echinacea or St Johns Wort and dietary supplements such as melatonin, fish oil, or megavitamins.23 Fewer pediatricians reported being asked recently about hypnosis, biofeedback, meditation, massage, or acupuncture.23 Most (73%) pediatricians agreed that “it is the role of pediatricians to provide patients/families with information about all potential treatment options for the patient’s condition,” and 54% agreed that “pediatricians should consider the use of all potential therapies, not just those of mainstream medicine, when treating patients.”23

However, few (if any) state statutes specifically address either integration of CAM therapies with conventional pediatric care or use of CAM therapies as substitutes for conventional care. Statutes in every state, however, do more generally address criminal “abuse and neglect” of children.15 Neither these statutes nor regulations and many judicial opinions identify whether or when use of or reliance on CAM therapies constitutes such abuse and/or neglect.15 The most analogous cases of abuse and neglect typically involve the neglect of conventional care in favor of prayer, whereas the integration of CAM therapies into conventional care can involve inclusion of a range of CAM therapies, including those at the borderland of medicine and spirituality.15,24-26

The uncertainty surrounding parental use of CAM therapies for children would be particularly acute in cases in which their children have serious, chronic, or life-threatening diseases (eg, cerebral palsy, cancer), exactly the kinds of situations in which use of CAM therapies is most common.2-13 The lack of definitive data regarding safety and efficacy of such therapies may lead to parental choices that are different from those of clinicians, complicating communication and shared decision making or even potentially jeopardizing the therapeutic relationship.27 The problem may be compounded further when CAM therapies are used as substitutes for conventional medical therapies. Indeed, the impetus for this project was a call to one of the authors from parents whose pediatrician had threatened to initiate criminal abuse and neglect proceedings because the parents had chosen to take their seriously ill children for supplemental visits to a practitioner of traditional oriental medicine. This experience suggests that pediatricians who counsel parents concerning use of CAM therapies face complex decisions and may stand to benefit from clarification and analysis of the dilemmas involved.

We therefore decided to research how state laws and agencies handle cases of parental use of CAM therapies for their children. Our aim was to assess whether a policy framework that builds in legal and ethical safeguards to balance clinical concerns, respect for autonomous family choices, and the best interest of the child exists or could be established.

METHODS

We received approval for this study from the Harvard Medical School Institutional Review Board. Our research methods for this investigation involved the following steps:

1. We searched LEXIS-NEXIS, a standard database of state statutes and judicial opinions, to assess existing law involving parental choice of CAM therapies for their children.

2. We selected a convenience sample of the 6 New England states and added 12 states of varying sizes and geographic locations for our survey (see Appendix 1). In each state, we began our inquiry with the relevant section within the state’s Department of Health and Human Services (DHHS) in charge of child welfare and abuse and neglect (eg, Child Welfare Bureau, Department of Children and Families, Child Protection Program, Child Protective Services). In each site, we asked for appropriate personnel who would know of policies and cases regarding state intervention for child abuse and neglect pertinent to CAM therapies use. We asked whether staff were aware of (1) any internal policies concerning these issues or (2) any cases in the previous 5 years in which either (a) the state initiated proceedings against parents for using CAM therapies for their children or (b) the department received telephone calls or other information reporting abuse and neglect in this domain. When we were referred to other personnel or another agency within the state’s department, we followed up accordingly, conducting an average of 3 to 6 calls in each agency.

3. We asked the American Academy of Pediatrics (AAP) and the leading CAM professional organizations for the most frequently licensed CAM professions (eg, chiropractic, acupuncture and traditional oriental medicine, massage therapy, naturopathy; see Appendix 2).

4. We drew on results of the information from steps 1 to 3, as well as the guidelines of the US Federation of State Medical Boards (USFMSB) concerning physician practices involving CAM therapies to create a legal and ethical policy framework that can be considered for implementation by the following stakeholders: (1) hospitals, (2) appropriate state agencies, and (3) organizations that are interested in crafting regulation that is responsive to these issues.

RESULTS

The 18 states that we surveyed are the 6 New England states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont; New York; New Jersey; Ohio; Maryland; South Carolina; Florida; Colorado; Oregon; Washington; California; Utah; and Minnesota. Of the 18 states, none had formal, stated policies concerning parental use of CAM therapies for their children. Two respondents reported that although no formal policies existed, they tended to follow the policies of associated hospitals. Social workers in 2 additional states responded that during staff training, they are told that some therapies, such as cupping or coining, may look like abuse because of the marks that they leave on the body but that such situations are not judged as abusive until the therapy is understood and investigated and real harm shown.

One respondent reported that the department allows parents to include CAM therapies as long as these do not adversely affect the health of the child. If questions arise concerning parental use of CAM therapies for a given child, then the department typically will engage a multidisciplinary team (composed of doctors, ethicists, and social workers) at a hospital within the state, one that is “open” to inclusion of CAM therapies, and determine whether the CAM practices being used are valid and do not interfere with conventional care. This process is “supposed to involve the family in a positive way.”
Of the 18 respondents, 6 states reported being aware of a total of 9 cases in the previous 5 years in which either (1) the state initiated proceedings against parents for using CAM therapies for their children or (2) the department received telephone calls or other information reporting child abuse and neglect in this domain. Of the 9 reported cases, 3 involved restrictive dietary practices (eg, limiting children variably to a watermelon or raw foods diet), 1 involved dietary supplements, 3 involved children with terminal cancer, and 2 involved religious practices rather than CAM per se. None of the cases involved chiropractic. More specific, 1 of the cases involving restrictive dietary practices related to a child who starved to death because the family was vegan and allowed consumption of only uncooked fruits, grains, and vegetables. One of the religious practices cases involved parents who allegedly kidnapped their 20-month-old son from a hospital and refused to feed their child “anything other than lettuce and watermelon, believing he is a ‘religious prophet.’” The parents were described as “religious cultists,” however, and not individuals who were interested in CAM therapies outside of a formal religious context.

In the cases involving cancer, 1 involved a 6-year-old child who was in a coma after experiencing complications from medulloblastoma. The parents won a temporary restraining order, preventing the hospital from removing life support, and believed intravenous dietary supplements would bring him back to life. The hospital staff reportedly threatened to report the parents to social services if the parents did anything that interfered with hospital policy. Another case involved a 12-year-old boy who received a diagnosis of Ewing’s sarcoma after an oral surgeon surgically removed a tumor from under his tongue. The family physicians recommended chemotherapy and radiation. The parents, after additional tests showed that the cancer had not spread anywhere and concerned about potential side effects of these treatments, decided to take the child to Dr Stanislaw Burzynski, the Texas researcher who uses controversial antineoplaston therapies. After the child reportedly missed 1 doctor’s appointment, a physician contacted the Division of Child and Family Services and filed a medical neglect claim. The judge ordered chemotherapy to begin, but the parents left the state, at which time the judge ordered the child to be placed in state custody and the state filed kidnapping charges against the parents. Negotiations followed in attempts to strike a deal between the parties. After this case, numerous child welfare bills were introduced into the state legislature, including a statute that required more stringent procedures before removing a child from a parent’s home (see Appendix 3).

One of our respondents referred to the case of a 4-year-old who had a diagnosis of brain cancer. His parents sought several CAM therapies, including treatment by Dr Burzynski, instead of chemotherapy and radiation. The Food and Drug Administration (FDA) prohibited the child from receiving Burzynski’s treatments for 18 months, finally allowing a “compassionate use exemption,” but only shortly before the boy’s death. The case fueled debate about the Access to Medical Treatment Act, a federal bill to allow patients access to non–FDA-approved therapies under certain circumstances (see Appendix 4).

To date, the AAP, the American Association of Massage Therapists, the American Association of Oriental Medicine, the National Center for Homeopathy, and the American Association of Naturopathic Physicians (AANP) have not initiated proceedings or received telephone calls regarding abuse or neglect concerning parental use of CAM therapies. According the AANP, there has never been a complaint filed against a licensed naturopathic physician involving a case with a child. However, AANP representatives did mention a case in which an unlicensed, self-proclaimed “naturopath” was convicted of manslaughter in North Carolina after the death of a 6-year-old girl who had diabetes and was taken off insulin.

**DISCUSSION**

Despite widespread concern about calamities when parents integrate CAM therapies and conventional care, only 9 cases were reported over 5 years in 18 states. Of these cases, several were truly alternative to necessary conventional medical care, in which parents were abandoning accepted, mainstream medical approaches, and others were following religious convictions in lieu of necessary medical care. Some of these cases resulted in changes in state law to allow parents greater autonomy in making health care choices for their children.

These data suggest that the outliers remain of concern but that the risks may be higher when CAM therapies are not incorporated sensibly into a conventional treatment plan. A fuller understanding of how to respond to parental interest in CAM therapies for their children requires knowledge of the structure of relevant law.

**Abuse and Neglect**

State statutes typically define child neglect in terms such as “the negligent treatment or the maltreatment of a child by a person responsible for the child’s welfare under circumstances indicating harm or threatened harm to the child’s health or welfare.” Such neglect can include omissions as well as actions. For example, Connecticut’s Department of Children and Families defines “medical neglect” as “1. The refusal or failure on the part of the person responsible for the child’s care to seek, obtain, and/or maintain those services for necessary medical, dental, or mental health care. 2. Withholding medically indicated treatment from disabled infants with life-threatening conditions.” These legal definitions do not specify whether or when use of CAM therapies instead of (or in addition to) conventional care might constitute child neglect.

At least 1 state has a statute noting that although unlicensed providers of CAM therapies are authorized to offer services under certain conditions (see Appendix 5), a “parent who obtains unlicensed
health care for the parent’s minor child is not relieved of the duty to seek necessary medical care consistent with the requirements of the general laws. Furthermore, “a complementary or alternative health care practitioner who provides services to a child” is still subject to the reporting provisions for abuse and neglect. The statute does not delineate when pediatric use of CAM therapies constitutes abuse or neglect; it merely states that using CAM therapies does not in itself exempt families from the legal obligation to seek “necessary” conventional care consistent with existing abuse and neglect statutes.

Most statutes specify a religious exemption for parents who choose not to seek medical care for their children because of religious beliefs. For example, Utah law provides that “a parent or guardian legitimately practicing religious beliefs and who, for that reason, does not provide specified medical treatment for a child, is not guilty of neglect.” Although many CAM practices (e.g., the use of special diets or fasting) in addition to prayer could be deemed to fall within the borderland between medicine and religion, most CAM therapies would not be tied to faith in a traditional religion or characterized as meeting this religious exemption.

All states have statutes that require physicians to report child abuse and neglect to law enforcement officials, yet there are few legal guidelines as to whether or when parental choices involving CAM therapies for their children constitute abuse and therefore trigger such reporting requirements. The cases reported above suggest a potential conflict between parental choices and the physicians’ determination that those choices prevented the child from receiving necessary medical care.

There have been few court cases concerning abuse and neglect involving pediatric use of CAM therapies, and the law is unsettled. Generally, courts have been reluctant to overrule parental choice of treatment, except in life-threatening clinical situations. A few courts have articulated respect for parental choices involving CAM therapies when supported by some medical authority, so long as the child’s life is not in danger and conventional care is not imminently necessary.

A pending legislative bill in Utah entitled “Medical Decisions of a Parent or Guardian” states, “A health care decision made by a child’s parent or guardian does not constitute severe child abuse or neglect unless the state or other party to the proceeding shows, by clear and convincing evidence, that the decision is not reasonable and prudent.” Furthermore, “[this bill] provides that a parent or guardian is not guilty of child abuse for selecting a treatment option for the medical condition of the parent’s or guardian’s child, if the treatment option is one that a reasonable parent or guardian would believe to be in the best interest of the child.” This bill can serve as a template for medical neglect and abuse standards involving parental choices and CAM in states where the standards are less clear or are ill-defined.

Malpractice and Discipline

Because pediatricians are subject to the legal and ethical reporting requirements relating to child abuse and neglect, a pediatrician who accessed to parental demands for CAM therapies may feel caught between the impetus to please patients, the prospect of malpractice liability if the CAM therapy fails, professional discipline for providing the requested therapy, and reporting of abuse and neglect by another pediatrician. Negotiating an evidence-based, family-centered outcome in such a charged context may be difficult.

Malpractice is defined as unskilful practice that fails to conform to a standard of care in the profession and thereby results in patient injury. It can be grounds for a civil lawsuit by an injured patient and/or in professional discipline by the state medical board. Some states regard departures from prevailing conventional medical norms as grounds for professional discipline, irrespective of patient harm, whereas in other states, new statutory language clarifies that use of CAM therapies does not in itself constitute disciplinary grounds.

The USFSM has issued model guidelines concerning physician use of CAM therapies, stating that merely using CAM therapies does not constitute grounds for discipline. The guidelines, however, require that the selected CAM therapies are likely to provide “a favorable risk/benefit ratio compared with other treatments for the same condition”, be “based on a reasonable expectation that it will result in a favorable patient outcome, including preventive practices”; and “be based on the expectation that a greater benefit will be achieved than that which can be expected with no treatment.” Even if evidence of either safety or efficacy is inconclusive, malpractice risks are lessened when the patient continues to be monitored, with the clinician ready to intervene when necessary.

A Proposed Policy Framework

Given the current ambiguity in legal rules concerning abuse and neglect and malpractice and discipline in the CAM arena, a policy framework may help clinicians, hospitals, state agencies, and professional organizations make decisions concerning integration of CAM therapies. Such a framework should balance parental autonomy interests and the state’s interest in protecting children against abuse and neglect. In light of both of the purposes and limitations of legal rules described above, we propose the following framework.

After taking a thorough history, including parental use of CAM therapies, physicians should

1. Determine whether (a) parents plan to abandon effective care when the child’s condition is serious or life-threatening or (b) use of the CAM therapy will otherwise divert the child from imminently necessary conventional treatment. If (a) or (b) is true, then reporting requirements that are pertinent to child abuse and neglect are likely triggered. However, if (a) the child’s condition is not serious or life-threatening or (b) parental choice of CAM therapies is not
Pediatric use of CAM therapies raises complex issues at the borderland of medicine, law, and public policy. Although some parental choices endanger preventing imminently necessary conventional treatment, then courts are likely to support parental choices.

2. Determine whether the CAM therapies selected are known to be unsafe and/or ineffective. If the CAM therapies selected are known to be unsafe or ineffective on the basis of the medical literature, then the pediatrician should avoid and discourage such approaches, and if parents persist and the child’s life is thereby endangered, then reporting and state action may be appropriate. However, assuming that (a) the clinical situation is not serious or life-threatening, (b) the patient’s CAM therapy will not divert attention away from imminently necessary medical care, and (c) the CAM therapy is not known to be unsafe or ineffective, the pediatrician may continue to monitor the patients while the parents try CAM therapies. If the physician is uncomfortable with this role, then, rather than abandon the patient, the pediatrician may wish to find another caregiver who is able to supervise care.

In general, the better the evidence of safety of the CAM treatment, the more appropriate to tolerate use of that therapy; in the absence of effective conventional treatments, the greater the evidence of efficacy for a CAM therapy, the more ethically appropriate it is to consider tolerating use of that therapy. However, subjecting a child to a serious risk, without sufficient evidence of benefit, for a therapy that most physicians consider dangerous or ineffective may trigger professional discipline and potential liability.

3. Ensure that the proper parties have consented to use of the CAM therapy. It is legally and ethically appropriate to discuss with the family the evidence for and against CAM therapies. Because the doctrine of informed consent legally and ethically requires disclosure of all therapies that are relevant to a treatment decision, ensuring consent (and shared decision making) in a family-centered approach is reasonable.

In line with this framework, state agencies that investigate complaints of child neglect relating to choice of CAM therapies should ensure, before intervening, that both questions 1 and 2 are answered affirmatively. This will help to ensure that interventions satisfy the legal definitions for child neglect, namely, the withholding of necessary medical care, and will not be based on bias or speculative fears concerning choices involving CAM therapies. Just as the new statutes, USFMB guidelines, and emerging legal scholarship clarify that clinical use of CAM therapies should not in itself constitute grounds for physician discipline, similarly, agencies should clarify in their policies and statements that parental inclusion of CAM therapies for their children in itself does not constitute child neglect.

In parallel with this development, hospitals should consider including these guidelines in their hospital policies to clarify the distinction between withholding of necessary medical care on one the hand and trying CAM therapies while continuing to monitor the patient on the other hand. If such clarifying policies had been in place, then some of the cases described above may have turned out differently, with negotiated exchanges between caregivers and families toward a more family-centered resolution.

In addition, implementing such policies institutionally would help clinical decision making. Pediatricians recognize that many patients use CAM therapies, do not feel comfortable discussing them, yet often desire additional information about them. Although additional education about CAM therapies could potentially increase this comfort level, clear hospital guidelines might further help pediatricians guide families concerning appropriate care boundaries.

Likewise, courts that evaluate cases may find this framework helpful in delineating when parents have crossed the line from freedom of choice to child neglect. Finally, state legislatures and Congress could reconsider the extent to which state and federal legislation respectively balances the ethical tradeoffs between paternalism and autonomy than current regulation.

Limitations

Our investigation had several limitations. First, we investigated only 18 states, and results may have differed in other states. Second is the lack of consistent expertise and knowledge across respondents; specifically, only a handful of DHHS staff reported having a central repository for information concerning abuse and neglect policies and cases. Most others had diffuse sources of information about abuse and neglect policies and cases within the state, for example, individual hospitals or individual social workers. In at least 1 state, we learned of relevant cases through interviews with a hospital to which DHHS referred us.

Some states collect case information at the county rather than at the state level. Even when states centralize information, they often track cases by criteria such as the age and gender of the child but not according to whether medical treatment was received (or not received) or the kind of treatment rendered. This system limits information about cases to interviewees’ memory.

Even when we followed through a chain of 3 to 6 referrals within the agency to the person identified as most likely to have relevant expertise and knowledge, we frequently would obtain a response such as, “I cannot think of any cases of this sort ever occurring or coming to our attention. I don’t think we have any policy specifically addressing CAM therapies, either.” Because these answers involved an affirmative denial of policies or cases, to the best of the interviewee’s knowledge, we chose to catalog these answers as “no” rather than “no response.” However, we catalogued a response such as “I’m not sure” as “no response,” and we followed up when the interviewee encouraged us to ask another source within the department.

CONCLUSION

Pediatric use of CAM therapies raises complex issues at the borderland of medicine, law, and public policy. Although some parental choices endanger
children, others simply clash with those of clinicians, raising differences in outlook, lifestyle, and health care preferences. In some cases, the hand of the state can fall where negotiated decisions may have been more appropriate. Clinicians, hospitals, state agencies, courts, and professional organizations may benefit from a policy framework to help guide decision making.

APPENDIX 1: LIST OF STATES CONTACTED

APPENDIX 2: LIST OF ORGANIZATIONS CONSULTED
American Academy of Pediatrics (Washington, DC), American Chiropractic Association, American Association of Oriental Medicine, American Association of Naturopathic Medicine, and National Center for Homeopathy.

APPENDIX 3: UTAH LEGISLATION
Utah Code s. 62A-4a-201: Rights of parents—Children’s rights—Interest and responsibility of state.

(1) (a) Courts have recognized a general presumption that it is in the best interest and welfare of a child to be raised under the care and supervision of his natural parents. A child’s need for a normal family life in a permanent home and for positive, nurturing family relationships will usually best be met by his natural parents. Additionally, the integrity of the family unit and the right of parents to conceive and raise their children have found protection in the due process clause of the Fourteenth Amendment to the United States Constitution. The right of a fit, competent parent to raise his [or her] child has long been protected by the laws and Constitution of this state and of the United States.

(b) It is the public policy of this state that parents retain the fundamental right and duty to exercise primary control over the care, supervision, upbringing, and education of their children who are in their custody.

(2) It is also the public policy of this state that children have the right to protection from abuse and neglect and that the state retains a compelling interest in investigating, prosecuting, and punishing abuse and neglect, as defined in this chapter, and in Title 78, Chapter 3a. Therefore, as a counterweight to parental rights, the state, as parens patriae, has an interest in and responsibility to protect children whose parents abuse them or do not adequately provide for their welfare. There are circumstances where a parent’s conduct or condition is a substantial departure from the norm and the parent is unable or unwilling to render safe and proper parental care and protection. Under those circumstances, the welfare and protection of children is the consideration of paramount importance.

(3) When the division intervenes on behalf of an abused, neglected, or dependent child, it shall take into account the child’s need for protection from immediate harm. Throughout its involvement, the division shall utilize the least intrusive means available to protect a child, in an effort to ensure that children are brought up in stable, permanent families, rather than in temporary foster placements under the supervision of the state.

(4) When circumstances within the family pose a threat to the child’s safety or welfare, the state’s interest in the child’s welfare is paramount to the rights of a parent. The division may obtain custody of the child for a planned period and place him in a safe environment, in accordance with the requirements of Title 78, Chapter 3a, Part 3, Abuse, Neglect, and Dependency Proceedings.

(5) In determining and making “reasonable efforts” with regard to a child, pursuant to the provisions of Section 62A-4a-203 and keeping with the presumptions described in Subsection (1), both the division’s and the court’s paramount concern shall be the child’s health, safety, and welfare.

(6) In cases where actual sexual abuse, abandonment, or serious physical abuse or neglect are involved, the state has no duty to make “reasonable efforts” or to, in any other way, attempt to maintain a child in his home, provide reunification services, or to attempt to rehabilitate the offending parent or parents. This Subsection (6) does not exempt the division from providing court-ordered services.

Utah Code s. 62A-4a-203: Removal of a child from his home—Reasonable efforts to maintain child in home—Exception—Reasonable efforts for reunification.

(1) Because removal of a child from his home may affect protected, constitutional rights of the parent, the division shall:

(a) when possible and appropriate, without danger to the child’s welfare, make reasonable efforts to prevent or eliminate the need for removal of a child from his home before placement in substitute care;

(b) determine if there is substantial cause to believe that a child has been or is in danger of abuse or neglect, in accordance with the guidelines described in Title 78, Chapter 3a, Part 3, Abuse, Neglect, and
Dependency Proceedings, before removing the child from his home; and
(c) when it is possible and appropriate, and in accordance with the limitations and requirements of Sections 78-3a-311 and 78-3a-312, make reasonable efforts to make it possible for a child in substitute care to return to his home.

(2) In determining the reasonableness of efforts needed to maintain a child in his home or to return a child to his home, in accordance with Subsection (1) (a) or (c), the child’s health, safety, and welfare shall be the paramount concern. Additionally, the division shall consider whether those services would be effective within a 6-month period and whether they would be likely to prevent reabuse or continued neglect of the child.

(3) When removal and placement in substitute care is necessary to protect a child, the “efforts” described in Subsections (1) and (2) would not be reasonable or appropriate and, therefore, should not be used.

(4) In cases where obvious sexual abuse, abandonment, or serious physical abuse or neglect are involved, the state has no duty to make “reasonable efforts” or to, in any other way, attempt to maintain a child in his home, provide reunification services, or to attempt to rehabilitate the offending parent or parents. This subsection does not exempt the division from providing court ordered services.

**APPENDIX 4: NAVARRO FDA PATIENT RIGHTS ACT**

The purpose of the bill is to “amend the Federal Food, Drug, and Cosmetic Act to restrict the authority of the Food and Drug Administration to issue clinical holds regarding investigational drugs or to deny patients expanded access to such drugs.” Specifically, the bill proposes to amend existing rules concerning (1) clinical holds on investigational new drugs and (2) expanded access to investigational new drugs, by allowing patients access to such drugs if, among other things, (a) “there is a comparable or satisfactory alternative therapy available for a patient who is receiving or will receive the drug as a clinical subject in the investigation” and (b) “the patient declares in writing that the patient is aware of the comparable or satisfactory alternative therapy, is aware of the risk involved in receiving the drug in the investigation, and chooses to receive the drug notwithstanding such risk and notwithstanding the comparable or satisfactory alternative therapy.”

**APPENDIX 5: LIST OF THERAPIES BY UNLICENSED HEALTH CARE PROVIDERS**

The Rhode Island statute defines “unlicensed health care practices” as “the broad domain of unlicensed healing methods and treatments, including, but not limited to: (i) acupressure; (ii) Alexander technique; (iii) aroma therapy; (iv) ayurveda; (v) cranial sacral therapy; (vi) crystal therapy; (vii) detoxification practices and therapies; (viii) energetic healing; (ix) rolling; (x) Gerson therapy and colostrum therapy; (xi) therapeutic touch; (xii) herbology or herbalism; (xiii) polarity therapy; (xiv) homeopathy; (xv) nondiagnostic iridology; (xvi) body work; (xvii) reiki; (xviii) mind-body healing practices; (ixx) naturopathy; and (xx) Qi Gong energy healing.” R.I. Gen. Laws § 23-74-1 (a).

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