



American Academy of Pediatrics



**Testimony of Moira Ann Szilagyi, MD, PhD, FAAP
on behalf of the American Academy of Pediatrics**

**House Ways and Means Subcommittee on Human
Resources hearing
Foster Children and Clinical Trials**

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Mr. Chairman, I am grateful for the opportunity to testify at this important hearing on children in foster care and clinical trials. My name is Dr. Moira Ann Szilagyi, and I am proud to speak on behalf of the 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists of the American Academy of Pediatrics. For the past 19 years, I have specialized in medical care and developmental issues of children in foster care. I am an associate professor of pediatrics at the University of Rochester Medical Center in Rochester, New York and Medical Director of the Monroe County Department of Health's Foster Care Pediatrics clinic. I also serve on the American Academy of Pediatrics' Committee on Early Childhood, Adoption and Dependent Care.

The Academy has a deep and abiding interest in the health care provided to children in the child welfare system. In fact, the Academy has published numerous policy statements, clinical guidelines, and studies regarding children in foster care, including a 170-page handbook for pediatricians on health care standards for children in foster care. I was proud to chair the District II Task Force on Health Care for Children in Foster Care, which authored that resource manual.

The 540,000 children in foster care comprise one of many vulnerable populations to which the Academy urges special attention in the provision of health care. Compared with children from the same socioeconomic background, children in foster care have much higher rates of serious emotional and behavioral problems, chronic physical disabilities, birth defects, developmental delays, and poor school achievement.¹ Typically, these conditions are chronic, under-identified, and under treated, and they have an ongoing impact on all aspects of their lives, even long after

these children and adolescents have left the foster care system.² As a result, children in foster care warrant special attention in all aspects of their health care.

One aspect in which children in foster care deserve particularly close and special consideration is their inclusion in clinical trials. It is the position of the American Academy of Pediatrics that drugs must be studied in children to determine their safety and efficacy in this age group. Indeed, the Academy considers it a *moral imperative* to formally study drugs in children so that they can enjoy equal access to existing, as well as new, therapeutic agents.³ Research participation is often beneficial to the participants, and may allow them access to care they could not otherwise receive. Therefore, children in foster care, as a population that tends to have a greater preponderance of special health care needs, should be afforded the same opportunities and access to safe and effective treatments. However, special consideration is necessary when allowing children in foster care who are in the care and custody of the state to take part in certain studies that may contain greater than minimal risk to the child.

The Academy has developed extensive guidelines and standards related to the ethical conduct of clinical trials involving children. The Academy also agrees with the Department of Health and Human Services' (HHS) regulations governing the inclusion of children in clinical research (CFR 45 Part 46, Subpart D). For the purposes of today's hearing, however, perhaps the most relevant standards deal with consent. Young children are, by definition, incapable of consenting to medical procedures. Consent must be given on their behalf by a parent, a legal guardian, or an individual or institution acting *in loco parentis* - that is, in the place of the parent.

The Academy's foster care handbook, *Fostering Health*, dedicates an entire chapter to medical consents for children and adolescents in foster care. States and localities have varying laws and detailed policies related to the ability of individuals involved in a child's care to consent to medical care or procedures. Many localities have convened multidisciplinary teams to determine what is in a child's best interest when confronted with complex health issues for children in their care. In general, legal guardianship remains with the birth parents (a term which includes legal guardians) unless a child is freed for adoption. There have certainly been cases when children who are in foster care are enrolled in clinical trials with the full consent of their birth parents. In certain cases when the birth parents are unavailable or uncooperative, agencies may approve or seek a court order for medical procedures - such as participation in clinical trials -- for which written consent is required and which are deemed to be in the best interests of the child. Once a child is freed for adoption, the state agency assumes sole responsibility for consenting for a child's medical care.⁵ In all cases, however, the overriding consideration must be the best interest of the child.

HHS regulations outline issues of consent: consent must be obtained from the adult acting legally on behalf of the child, and, when developmentally appropriate, the assent of the child must be gained prior to participation in any clinical trial. The question, then, for children in foster care is whether adequate safeguards are established when consent is obtained for trials that contain above minimal risk to the child, or when the research does not hold the prospect of providing direct medical benefit to the child him or herself. For children in the foster care system, an important safeguard is a special advocate who can help the foster family or state agency navigate medical issues, ensure that the child's medical care needs are being met, assist the child in

determining whether or not he or she should participate, and provide a source of continuity for the child and legal guardians throughout the duration of the study (section 46.409). Even in cases of less than minimal risk or studies with prospect of direct benefit, an advocate, while not required, could play an important role in the child's support system.

HHS regulations state - and the Academy concurs - that children in foster care should not be considered for studies which contain the prospect of greater than minimal risk and in which there is no direct benefit to the child him or herself (46.406-407). For these studies, it is only appropriate to consider using children in foster care under certain circumstances, such as if the research is related to their status as wards of the state. In other words, they should only be included when involvement of children in foster care is necessary since the research aims to answer a question related to conditions specifically affecting children in foster care. In these rare instances, it is imperative that an advocate be appointed to act on behalf of the child for the duration of the study to assist the child and foster family for the reasons stated above: to navigate medical issues, ensure that the child's medical care needs are being met, assist the child in determining whether to participate, and provide a source of continuity for the child and legal guardians throughout the duration of the study.

It is my understanding that the subcommittee is concerned by recent press reports about the participation of children in foster care in clinical trials of HIV drug treatments that began in the late 1980s. While attention has been paid specifically to these HIV drug trials, children in foster care have been known to participate in other types of clinical trials, including those focused on cancer treatment. My own professional experience includes a number of cases of HIV-positive

children in foster care in my community who received HIV multi-drug treatments during late 1980s and early 1990s. When our patients took these drug combinations, we saw a startling improvement in lifespan and quality of life. Before the introduction of these combination drugs, our HIV-positive foster children were literally wasting away before our eyes. There were some side effects with the drugs, but not that many. I recall one two-year-old child in particular who was literally dying. One year after receiving combination therapy, he was essentially undistinguishable from his healthy peers. He was able to go to preschool, live in a family instead of the hospital, and have hope for a longer life. He is still alive today and was adopted by his foster family.

Mr. Chairman, the decision to enroll a child in a clinical trial is never an easy one, even in a "traditional" family structure. While the headlines seem to suggest that children in foster care were somehow singled out as hapless guinea pigs, my experience indicates that children in foster care are actually less likely than other children to be considered for participation in a clinical trial. In fact, numerous barriers exist for children in foster care even to obtain routine health care and necessary services. Participation in a clinical trial, where care would be far more complex, is even less likely to occur.

The American Academy of Pediatrics believes that children in foster care deserve to be offered the same opportunities as other children to benefit from newer drugs and treatment protocols, especially when a child's condition is so grave that there are few options available to them. Indeed, it would be unethical to do otherwise and systematically deny access to clinical trials that could have saved the lives or vastly improved the health of critically ill children in foster care. It

is clear that children in foster care are a special population, and that they deserve additional protections when being considered for inclusion in clinical trials.

Mr. Chairman and Members of the Subcommittee, I deeply appreciate this opportunity to offer testimony on behalf of the American Academy of Pediatrics. I stand ready to answer any questions you may have, and I thank you for your commitment to the health of the children of our nation.

¹ Committee on Early Childhood, Adoption and Dependent Care. "Health Care of Young Children in Foster Care." *Pediatrics*, Vol. 109, No. 3, March 2002.

² Task Force on Health Care for Children in Foster Care. *Fostering Health: Health Care for Children in Foster Care*. 2nd ed. American Academy of Pediatrics, 2005.

³ Committee on Drugs. "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations." *Pediatrics*, Vol. 95, No. 2, February 1995.

⁴ Committee on Drugs. "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations." *Pediatrics*, Vol. 95, No. 2, February 1995.

⁵ Task Force on Health Care for Children in Foster Care. *Fostering Health: Health Care for Children in Foster Care*. 2nd ed. American Academy of Pediatrics, 2005.