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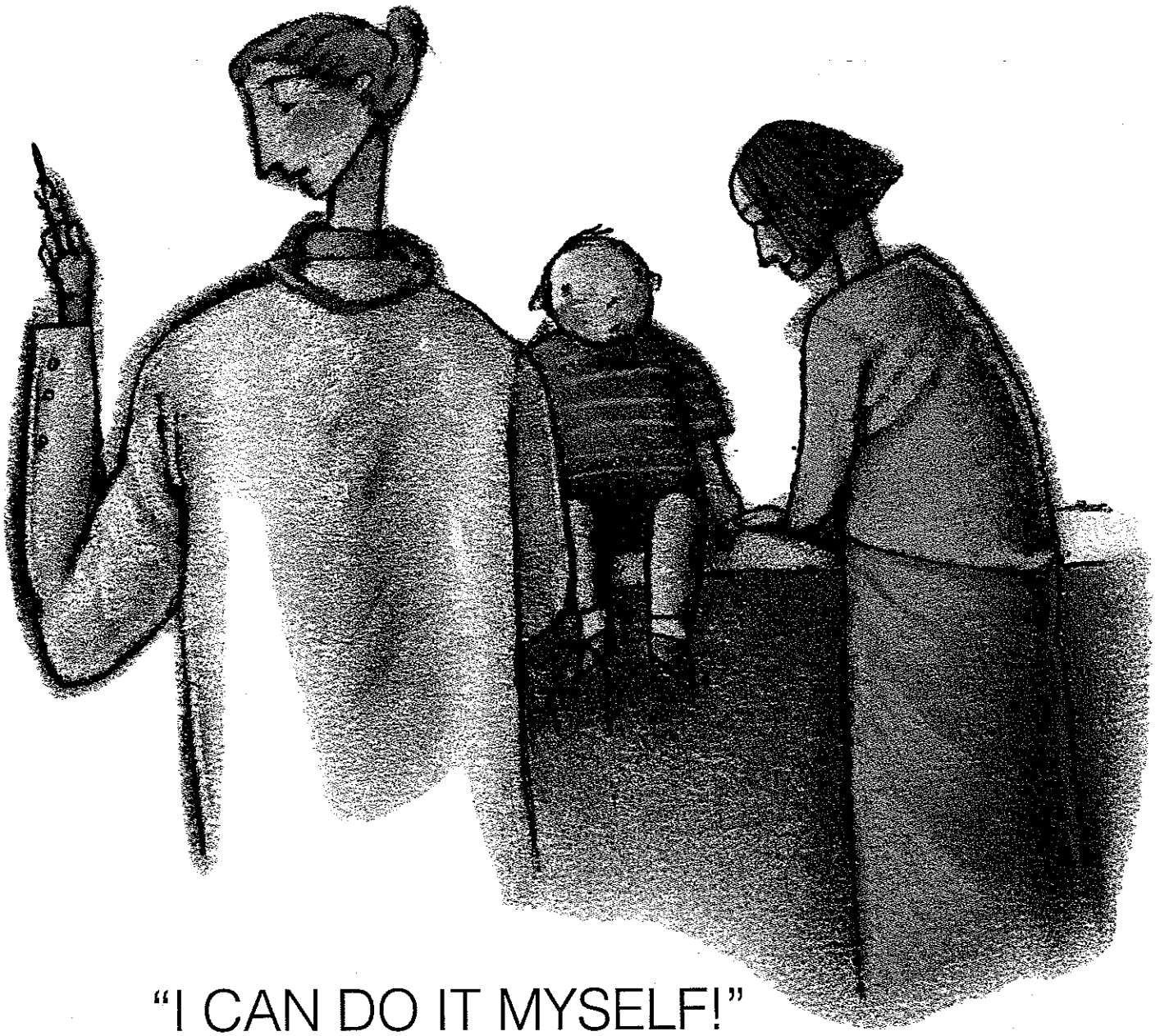

"I CAN DO IT MYSELF!"

Children's participation in nonbeneficial research: should they decide?

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# Why a Teenager over Age 14 Should Be Able to Consent, Rather than Merely Assent, to Participation as a Human Subject of Research

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U.S. federal regulations require the consent of both a parent (sometimes two parents) and the child who is contemplating participating as a human subject in research. The requirement that the child consent, which the regulations call "assent," gives to two different sources of authority—parents and child—the power to veto the child's participation in the research. This requirement might be based on the presumption that it is better to err on the side of not participating as a research subject, at least where the research is nontherapeutic, or it might be based on the presumption that without this requirement children would be insufficiently involved in the decision-making process leading to their participation in research. The first of these is fully discussed by David Wendler and Seema Shah (2003) and the thoughtful commentators who have responded to their article. The second presumption—that children should be more involved in the decision to become research subjects—is also well addressed with regard to children under age 14, where Wendler and Shah would replace the "assent" requirement with a "dissent" requirement.

While we are concerned with the bifurcated research consent/assent process for all children, our primary concern is with the formal legal consent requirement that allows parents to veto the decisions made by children over age 14 who decide to participate in research as human subjects. In fact, at age 14 children generally ought to be recognized as independent agents who are capable of making all of their healthcare decisions, including the decision to participate as a research subject, without the threat of any parental veto. The real reason for the regulatory "assent" requirement for these children is that the legal rule in every state that gives the authority to consent to parents of teenagers under 18 does not reflect the real decision-making capabilities of those young adults. The proper way to address this issue is to recognize the legal authority of those over 14 to make all of their own healthcare decisions, including the decision to participate as a human subject in any kind of research.

As Wendler and Shah and their commentators point out, maturity and the ability to make sound decisions do not suddenly appear on a child's eighteenth birthday. Moral and emotional development are gradual processes. Studies have shown that most children are as mature and emotionally developed at age 14 as they are at age 18. In a 1982 study the decision making of different age groups—9-year-olds, 14-year-olds, and 21-year-olds—were tested with regard to a hypothetical illness and proposed medical treatment. The subjects' understanding of facts, treatment outcomes, choices to be made, and decision-making processes were studied. While the nine-year-olds were a bit more conservative and chose inpatient care more often, the 14-year-olds and the 21-year-olds generally made the same decisions (Schlam and Wood 2000). In another study, one in which children were asked to give health advice to their peers, 12-year-olds were found to be as competent as 19-year-olds (Cauffman and Steinberg 1995).

In order to be capable of giving informed consent to medical treatment, children (or adults, for that matter) must be able to understand the nature, extent, and probable outcome of treatment. They must be able to understand the information provided and rationally make and voluntarily reach a decision (Schlam and Wood 2000; Furrow 2000). The American Academy of Pediatrics (AAP Committee on Bioethics 1995) has not only supported the finding that children achieve decisional capacity much ear-

lier than is recognized by state laws, but it recommends that adolescents should be more involved than they now are in their own healthcare decision making. Several other studies found that by age 13 or 14 minors can reason abstractly about hypothetical situations, reason about multiple alternatives and consequences, consider multiple variables, combine variables in more complex ways, and use information systematically (Mlyniec 1996). These studies suggest that there is no difference in legal competency between older minors and adults. It would appear from theories of development and empirical evidence that 14-year-olds are capable of giving informed consent to treatment.

Moreover, Kolhberg's and Piaget's theories of development indicate that children as young as 14 are as developed as adults. Piaget theorized that knowledge develops continually from a state of lesser knowledge to one that is more complete and effective (Thomas 1992). He recognized four specific stages of development. The final stage is the formal operations period, which develops between the ages of 11 and 15. During this time children can imagine the past, present, and future conditions of a problem and create hypotheses about what might logically occur under different conditions. Children at this level can engage in pure thought independent of actions they see or perform, and they can hypothesize and draw deductions, understand theories, and combine ideas to solve problems (Mlyniec 1996). According to Piaget, by the age of 15 a child's thinking has evolved into a mature state, and adult thought is within the child's capabilities.

Kohlberg also studied child development, but his theories are focused on moral development. Kohlberg's six stages of moral development are nearly parallel to Piaget's four levels of intellectual development. Although there are no real age boundaries to Kohlberg's theory, he determined that by age 16, Piaget's stage four is dominant (Silverthorn 1999). Kohlberg also concluded that the ability to think morally, which enables the child to place a moral problem within the context of the bigger picture, usually occurs around age 13 or 14 (Crain 1985). By the age of 14 a child is likely to achieve the level of moral development that would allow him or her to make appropriate decisions, considering altruistic reasons for alternative actions. Thus, by that age a young adult is not only able to understand enough to make therapeutic healthcare decisions but is sufficiently morally mature to be able to decide to volunteer for service as a subject in nontherapeutic research.

Finally, some courts have recognized the rule of sevens, derived from old English law. Under this rule, children under seven have no capacity to consent, children age 7 to 14 are presumed not to have the capacity to consent, and children age 14 and above are presumed to have capacity to consent (Schlam and Wood 2000). Courts have used this rule to support a presumption that a teenager older than age 14 has the capacity to give informed consent to medical treatment. While the mature-minor doctrine is a starting point in which some children are deemed capable of making medical decisions, it is invoked only when the child's maturity is proven by clear and convincing evidence. We believe that this presumption of incompetence for young adults between ages 14 and 18 should be reversed. The rule of sevens should be applied, and children age 14 or older should be presumed competent unless there is clear and convincing evidence that they are not capable of making mature decisions.

Of course, those engaged in doing research should be aware of the fact that their younger subjects (along with many others) might be particularly susceptible to outside influences, and they should take steps to assure that these subjects, like all others, make truly informed, competent, and voluntary decisions. In addition, some teenagers over age 14, like some adults, will not be capable of making healthcare decisions, and researchers, like all healthcare providers, should be prepared to recognize that disability when the usual levels of maturity, understanding, and communication ability are not present. Finally, our discussion does not suggest that children under age 14 should be afforded the authority to consent to any medical procedure, whether as a patient or a research subject. Researchers should devise methods of encouraging the participation of these younger children in the decision to become research subjects—through the application of the notion of "assent" or otherwise—while respecting the moral and legal rights of the parents to consent to their child's participation. For young adults above the age of 14, though, theories of intellectual development and moral development, and the traditions of the common law, suggest that there be a presumption of capacity that should not be trumped by the parent's authority to give (or withhold) consent. ■

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