

**Title:** Considering Children's Dissent

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**Description:** Although 10-year old Ryan's parents sign a consent form for participation in a clinical trial for a new drug for ADHD, Ryan refuses to assent.

**Headings:** Decision-making Capacity, Assent, and Surrogate Permission; Assent; Minors (children, adolescents)

**Case Type:** Decision making

### Considering Children's Dissent

Ryan is a 10-year old boy who was diagnosed with ADHD at age 7. Put on Ritalin at age 8, it was quickly discovered that he did not respond to this medication (about 20-30% of children do not respond). Ryan's physician also prescribed two other medications, Adderall, and dextroamphetamine, to which he also did not respond.

Ryan has been having many problems in school. Although originally supportive of integrating Ryan into a "normal" 3<sup>rd</sup> grade classroom (Ryan is repeating 3<sup>rd</sup> grade), both Ryan's teacher and school principal have recently expressed concern that not only is Ryan not learning, but he is also disrupting other students as well, and there have been several complaints from parents of other children.

Upon evaluation, Ryan seems to be aware that his inability to pay attention and follow directions creates problems for himself, his family, and his class, but he doesn't want to try another medication. In addition to not helping his hyperactivity and impulsivity, Ritalin made Ryan very nauseous, depressed, tired yet unable to sleep, and blurred his vision. He also doesn't like taking medicine in general because it makes him feel "different" from the other kids in his class and from his older brother and younger sister. He already is very angry at the fact that he has to repeat 3<sup>rd</sup> grade.

You are a researcher conducting a randomized controlled trial on Settler, a potential ADHD drug that shows promising results for those children who have not responded to other drugs used to treat ADHD. When you discuss enrolling Ryan in the study, Ryan's parents immediately sign the consent form and have very few questions or reservations. However, when Ryan is told that he is going to be trying out a new medicine that might work better than the others, he says, "It doesn't matter if it's a new medicine. Medicine makes me sick, and my brother and sister don't have to take it, so I shouldn't have to either." Ryan refuses to sign an assent form. Ryan appears to understand the potential benefits and risks of participation, despite his somewhat aggressive manner.

**Do you enroll Ryan in the study?**