

Idaho group illustrates how to elevate issues affecting children

by Noreen Womack, M.D., FAAP

Idaho recently lost millions of federal dollars for child care when a bill to change state licensing requirements to meet federal standards failed to get a hearing. Many pediatricians and voters were unaware of the bill until after it failed.

Afterwards, Idaho Children Are Primary (ICAP) was created to bring issues affecting children and families to the forefront of legislative and policy discussions. The 501(c)(4) nonprofit organization rates every state bill pertaining to children and families by asking: “Is this good for Idaho kids?” At the end of the legislative session, ICAP publishes the Kids

Matter Index (KMI), which indicates how often each legislator voted for kids and families.

“The general public is often unaware of their legislators’ votes on issues relating to kids and families,” said ICAP President Diane Schwarz. “The KMI is a tool that parents can use throughout the session and in election season to hold their representatives accountable for their votes that directly impact Idaho’s kids.”

ICAP has partnered with other organizations involved in children’s advocacy, including the AAP Idaho Chapter.

“ICAP has helped the Idaho Chapter look at legislators’ actions and voting as it relates to the most important issues facing children in the state of Idaho,” said Chapter Executive Director Sherry Iverson. “The well-respected board critically looks at key issues that the majority of Idahoans feel are important, which helps our chapter develop the most effective ways to advocate for children and providers. As a small chapter with limited resources, this work has been invaluable.”

One of the keys to ICAP’s success is the makeup of its eight-member advisory board. It includes a bipartisan mix of pediatricians, educators, former lawmakers and businesspeople, as well as former Idaho first lady Patricia Kempthorne. All decisions regarding bills must be unanimous.

In addition, the group’s expenses are low. The founders, legal and nonprofit consultants, and advisory board members all volunteer their time. Expenses include maintaining a website (www.idahochildrenareprimary.org), social media presence and mailing award certificates and letters to lawmakers.

“ICAP has provided a desperately needed accountability metric for voters, who generally deeply value the interests of children but often don’t know how to determine whether elected leaders are actually promoting those interests,” said Idaho State House Minority Leader Ilana Rubel (D), who played an advisory role in ICAP’s conception. “ICAP empowers the public to make informed voting choices that help children, and informs politicians how they can use their power to improve kids’ lives.”



Dr. Womack is an early childhood champion for the AAP Idaho Chapter.

John’s Wort, **CYP2D6 Inhibitors:** The concomitant use of Dyanavel XR and CYP2D6 inhibitors may increase the exposure of Dyanavel XR compared to the use of the drug alone and increase the risk of serotonin syndrome. Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome particularly during Dyanavel XR initiation and after a dosage increase. If serotonin syndrome occurs, discontinue Dyanavel XR and the CYP2D6 inhibitor. Examples: Paroxetine and fluoxetine (also serotonergic drugs), quinidine, ritonavir. **Alkalinizing Agents:** Increase blood levels and potentiate the action of amphetamine. Co-administration of Dyanavel XR and gastrointestinal alkalinizing agents should be avoided. Examples: Gastrointestinal alkalinizing agents (e.g., sodium bicarbonate); urinary alkalinizing agents (e.g., acetazolamide, some thiazides). **Acidifying Agents:** Lower blood levels and efficacy of amphetamines. Increase dose based on clinical response. Examples: Gastrointestinal acidifying agents (e.g., guanethidine, reserpine, glutamic acid HCl, ascorbic acid); urinary acidifying agents (e.g., ammonium chloride, sodium acid phosphate, methenamine salts). **Tricyclic Antidepressants:** May enhance the activity of tricyclic or sympathomimetic agents causing striking and sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated. Monitor frequently and adjust or use alternative therapy based on clinical response. Examples: Desipramine, protriptyline. **Drug/Laboratory Test Interactions** Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amphetamine may interfere with urinary steroid determinations.

USE IN SPECIFIC POPULATIONS

Pregnancy *Pregnancy Exposure Registry* There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Dyanavel XR during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychostimulants at 1-866-961-2388 or visiting online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>. **Risk Summary** There are limited published data on the use of amphetamines in pregnant women. These data are insufficient to determine a drug-associated risk of major congenital malformations or miscarriage. Adverse pregnancy outcomes, including premature delivery and low birth weight, have been seen in infants born to mothers dependent on amphetamines. There are limited published studies and small case series that report on the use of methylphenidate in pregnant women; however, the data are insufficient to inform any drug-associated risks. **Clinical Considerations** Fetal/Neonatal adverse reactions: Amphetamines, such as Dyanavel XR, may cause vasoconstriction, including vasoconstriction of placental blood vessels, and may increase the risk for intrauterine growth restriction. In addition, amphetamines can stimulate uterine contractions increasing the risk of premature delivery. Premature delivery and low birth weight infants have been reported in amphetamine-dependent mothers. Monitor infants born to mothers taking amphetamines for symptoms of withdrawal, such as feeding difficulties, irritability, agitation, and excessive drowsiness. CNS stimulant medications, such as Quillivant XR and QuilliChew ER, can cause vasoconstriction and thereby decrease placental perfusion. No fetal and/or neonatal adverse reactions have been reported with the use of therapeutic doses of methylphenidate during pregnancy. **Lactation: Risk Summary** Based on limited case reports in published literature, amphetamine (d- or d, l-) is present in human milk, at relative infant doses of 2% to 13.8% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.9 and 7.5. There are no reports of adverse effects on the breastfed infant and no effects on milk production. However, long term neurodevelopmental effects on infants from stimulant exposure are unknown. Because of the potential for serious adverse reactions in a breastfed infant, advise patients that breastfeeding is not recommended during treatment with Dyanavel XR. Limited published literature reports that methylphenidate is present in human milk, which resulted in infant doses of 0.16% to 0.7% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.1 and 2.7. There are no reports of adverse effects on the breastfed infant and no effects on milk production. Long-term neurodevelopmental effects on infants from CNS stimulant exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Quillivant XR and QuilliChew ER, and any potential adverse effects on the breastfed infant from Quillivant XR and QuilliChew ER, or from the underlying maternal condition. **Clinical Considerations** Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia,

anorexia, and reduced weight gain. **Pediatric Use:** Safety and effectiveness for Dyanavel XR, Quillivant XR, and QuilliChew ER have been established in pediatric patients with ADHD ages 6 to 17 years. Safety and efficacy of these products in pediatric patients younger than 6 years with ADHD have not been established. **Long-Term Growth Suppression** Growth should be monitored during treatment with stimulants, including Dyanavel XR, Quillivant XR, and QuilliChew ER. Children who are not growing or gaining weight as expected may need to have their treatment interrupted. The long-term efficacy of methylphenidate in pediatric patients has not been established. **Geriatric Use:** Dyanavel XR, Quillivant XR, and QuilliChew ER have not been studied in patients over the age of 65 years.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: Dyanavel XR contains amphetamine, and Quillivant XR and QuilliChew ER contain methylphenidate; amphetamine and methylphenidate are Schedule II controlled substances in the U.S. Controlled Substance Act (CSA). **Abuse:** CNS stimulants including Dyanavel XR, Quillivant XR, QuilliChew ER, other amphetamines and methylphenidates have a high potential for abuse. Abuse is characterized by impaired control over drug use, compulsive use, continued use despite harm, and craving. Signs and symptoms of CNS stimulant abuse include increased heart rate, respiratory rate, blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, suicidal or homicidal ideation have also been observed. Abusers of CNS stimulants may use other unapproved routes of administration which can result in overdose and death. To reduce the abuse of CNS stimulants, including Dyanavel XR, Quillivant XR, and QuilliChew ER, assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants, monitor for signs of abuse while on therapy, and re-evaluate the need for Dyanavel XR, Quillivant XR, and QuilliChew ER use. **Dependence: Tolerance** Tolerance (a state of adaptation in which exposure to a drug results in a reduction of the drug’s desired and/or undesired effects over time) may occur during the chronic therapy of CNS stimulants including Dyanavel XR, Quillivant XR, and QuilliChew ER. **Dependence** Physical dependence (which is manifested by a withdrawal syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) can occur in patients treated with CNS stimulants including Dyanavel XR, Quillivant XR, and QuilliChew ER. Withdrawal symptoms after abrupt cessation following prolonged high-dosage administration of CNS stimulants include dysphoric mood; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

OVERDOSAGE

Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice for treatment of overdose with amphetamine or methylphenidate. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses. Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperreflexia, and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Other reactions include arrhythmias, hypertension or hypotension, circulatory collapse, nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma. Signs and symptoms of acute methylphenidate overdose, resulting principally from overstimulation of the CNS and from excessive sympathomimetic effects, may include the following: nausea, vomiting, diarrhea, restlessness, anxiety, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperreflexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, hypotension, tachypnea, mydriasis, dryness of mucous membranes, and rhabdomyolysis.

Manufactured by: Tris Pharma, Inc., Monmouth Junction, NJ 08852
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Based on DXR LB8417, Rev 06; QXR LB8529 Rev. 00, and QCH LB8533 Rev. 00 DYANAVEL is a trademark of Tris Pharma, Inc. Quillivant XR and QuilliChew ER are trademarks of NextWave Pharmaceuticals, Inc.

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