

How we became accidental advocates



Dr. Robert Campbell & Dr.
Melvin Smith's
Miracle Transformation of
"Devin Alvarez"
through the
Titanium Rib Implant

2001

Devin is given a terminal diagnosis by his orthopedic surgeon, who also suggested that a fellow in Texas named Robert Campbell may be able to help. After contacting Dr. Campbell and going through the proper steps, Rixys learned of a clinical trial, the Titanium Rib Project, that was studying a device that was not yet FDA approved and was not covered by insurance. Out of desperation, Rixys started an awareness campaign that led her to then Florida Senator, now US House of Representative's Member Debbie Wasserman Schultz



Vertical, Expandible Prosthetic Titanium Rib (VEPTR)

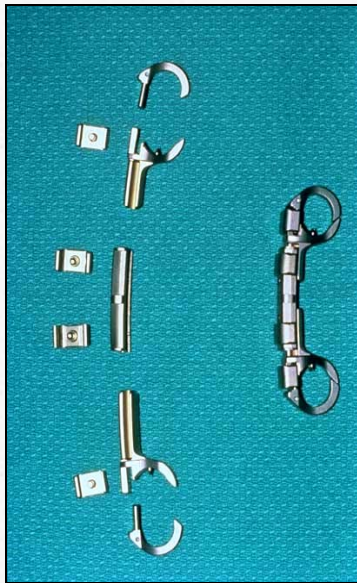
Expansion Thoracoplasty:

- o Prosthetic replacement of chest wall defects
- o Longitudinal Chest Wall distraction for fused ribs
- o Lateral Chest Wall distraction for short rib syndromes
- o Correction of thoracic distortion by infantile scoliosis

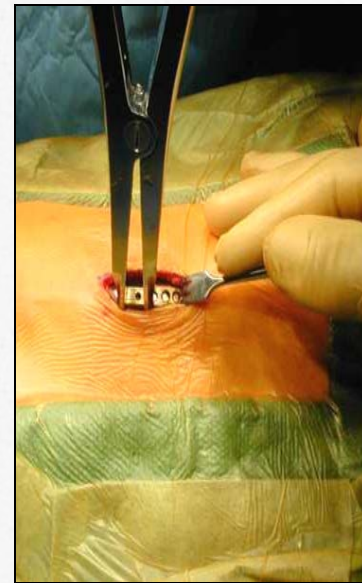
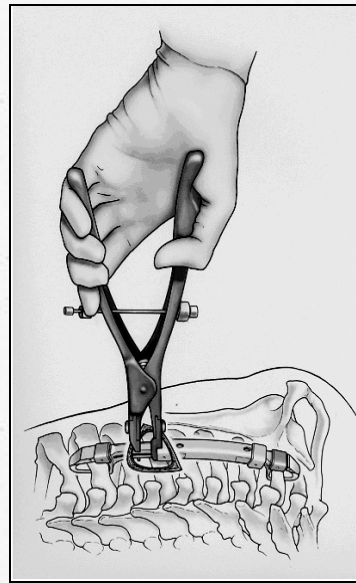


Expansion Thoracoplasty: Dynamic Reconstructive System

Implantation
Surgery



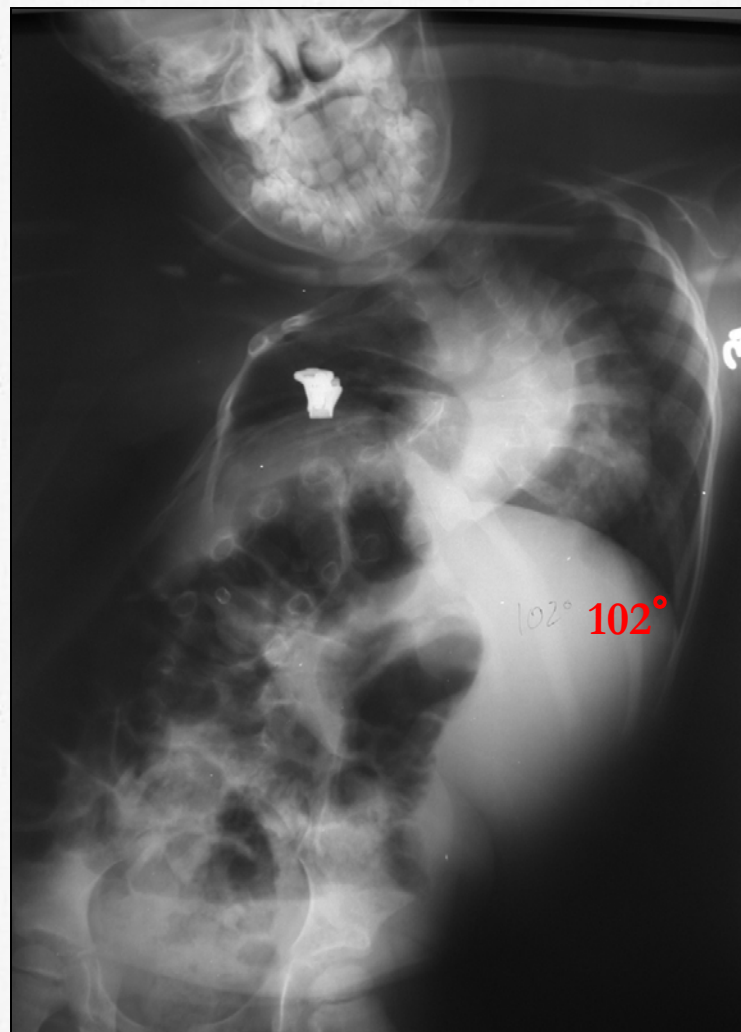
Expansion surgery: every 4 to 6
months in out-patient surgery



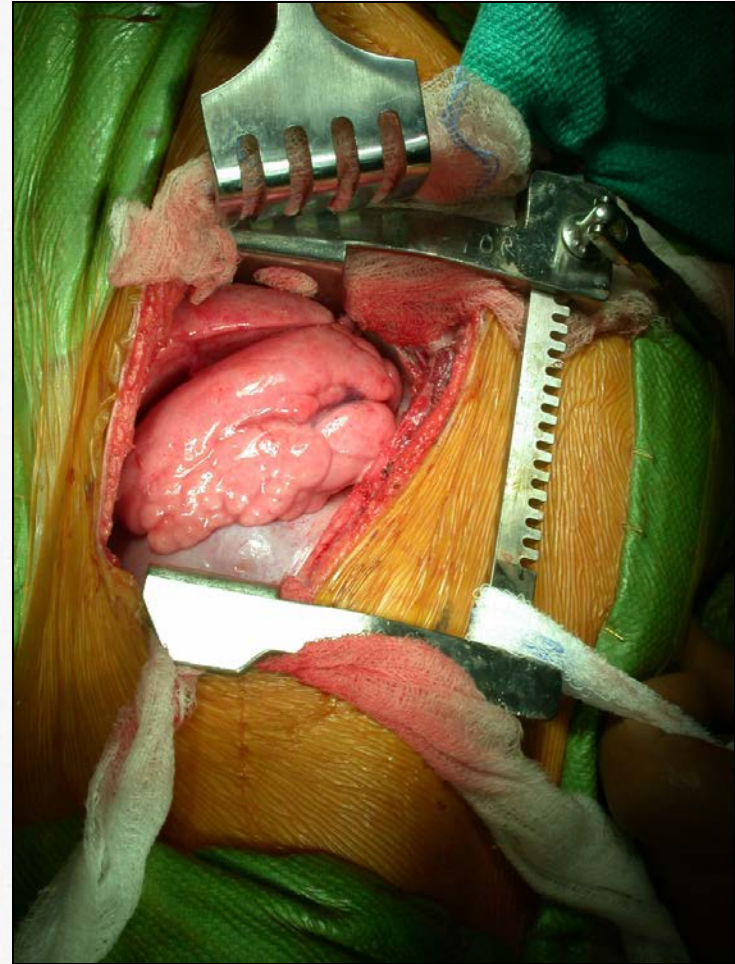
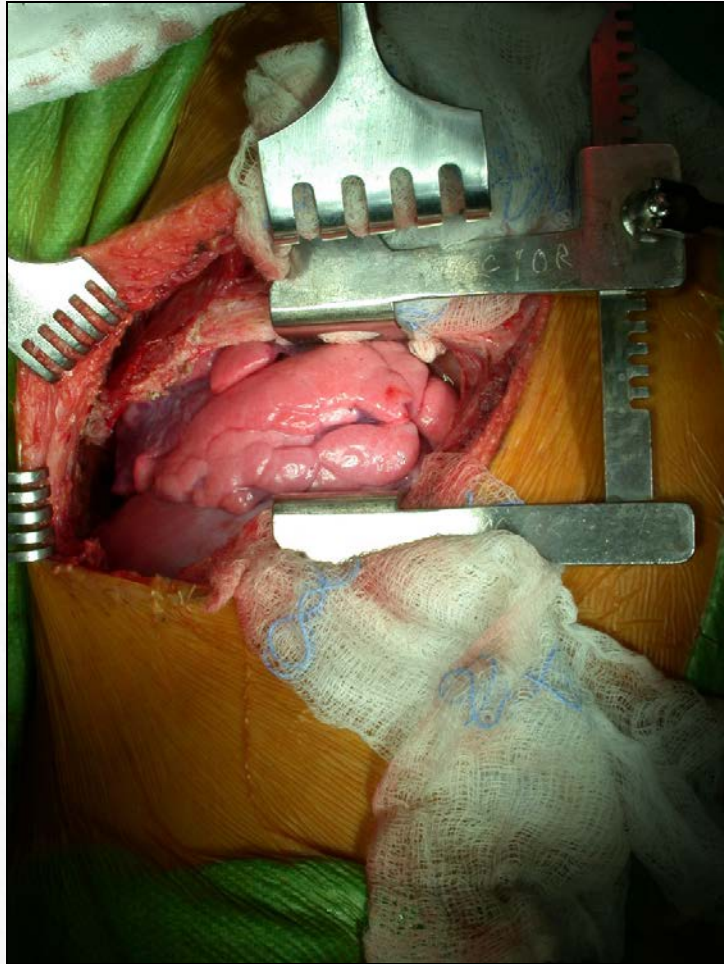
Devin at age 4

42 ° curve at birth,
rapid progression
after age 12 months,
Milwaukee brace for
1 ½ years, unable to
tolerate further use

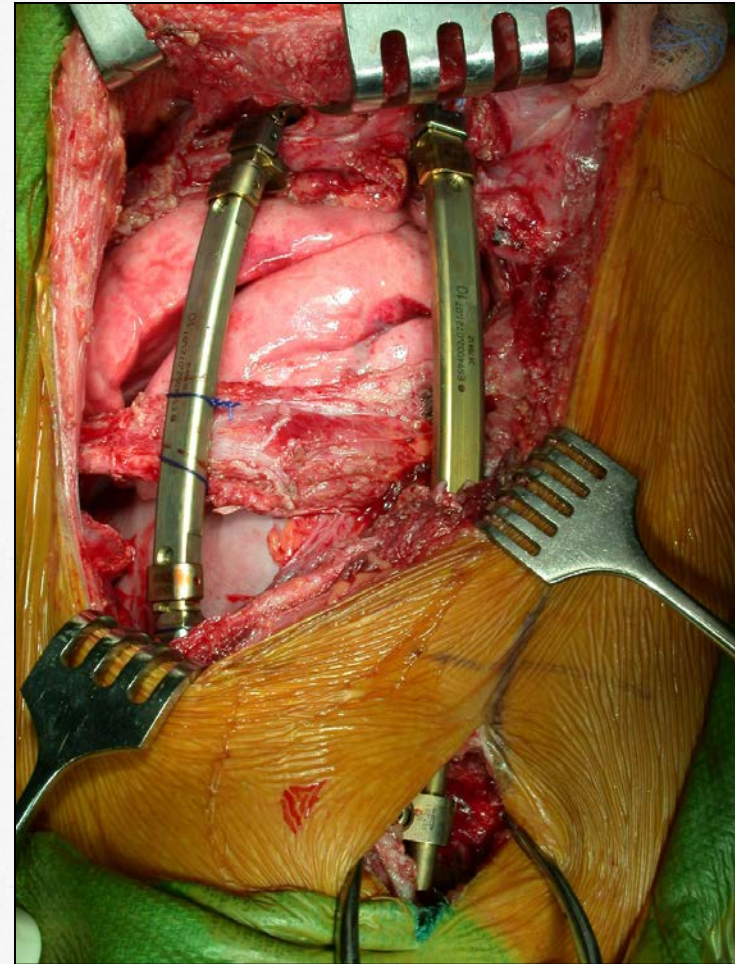
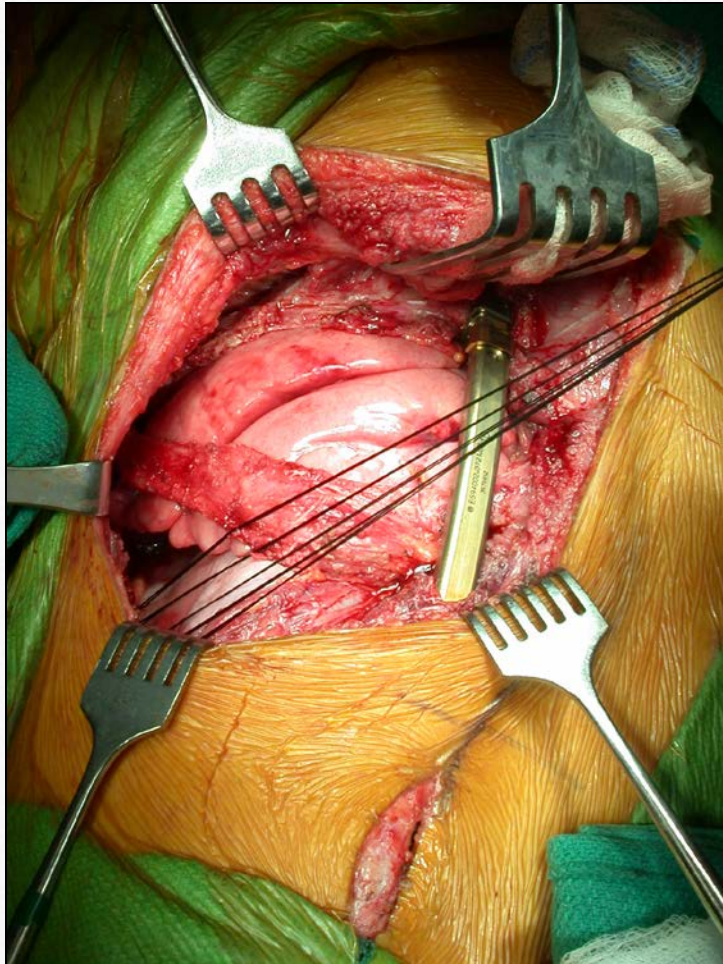


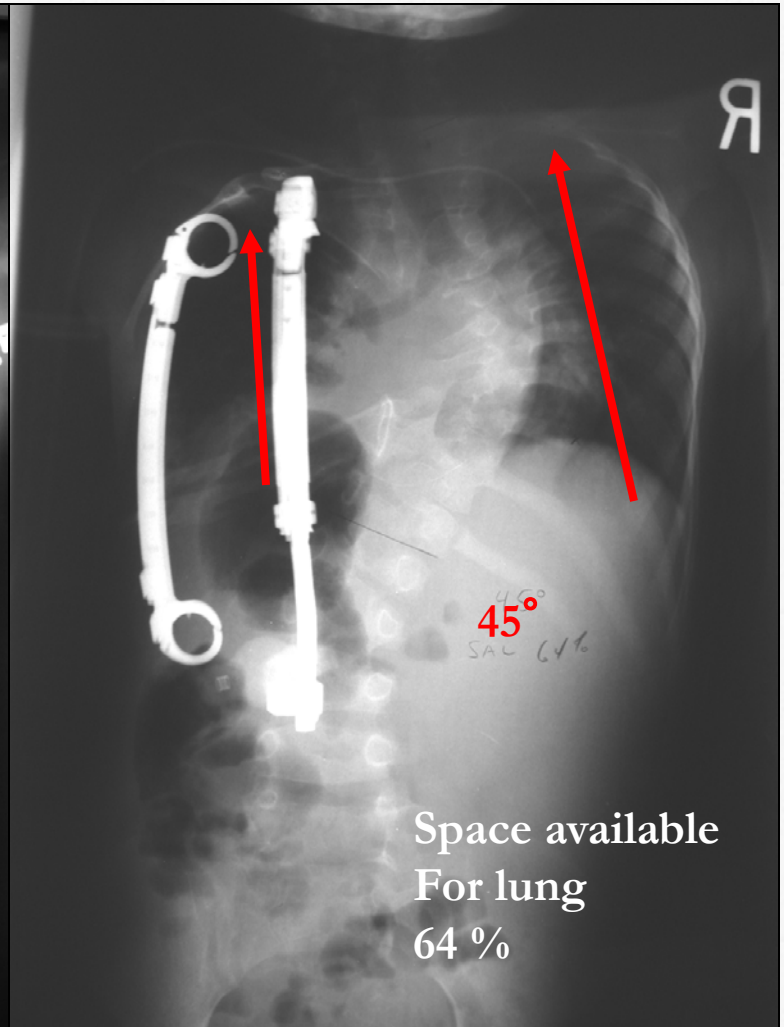
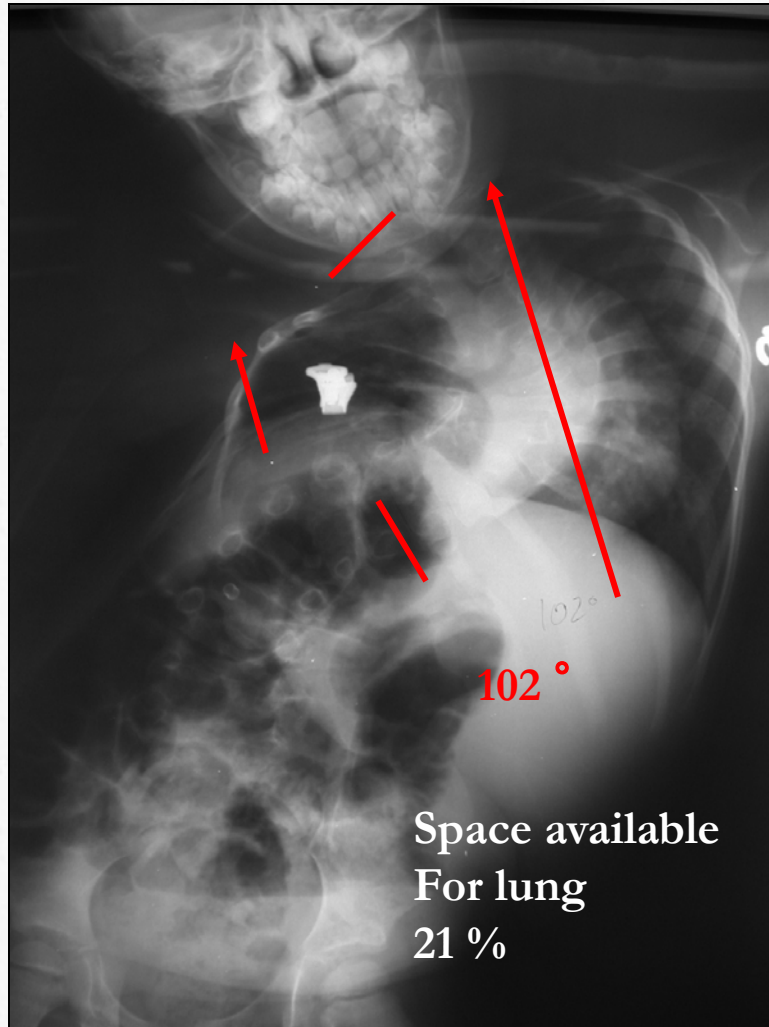


The concave, constricted hemithorax is carefully *lengthened* over 30 minutes by a rib spreader



Correction is stabilized by titanium ribs,
the diaphragm transposed distally to further enlarge the chest









2005

Meeting with the Honorable Governor
John “Ellis” Bush to create advocacy for the
Florida State Med-Waiver Program

2006

Our story received national attention via Good Housekeeping Magazine in a story titled Saving the Smallest Patients



Saving the smallest

What they need most, they often can't get. Why children are being cheated—and what doctors are doing about it

BY LISA COLLIER COOL

It was Labor Day, and Alissa Schmidt was relaxing by a friend's pool in Akron, Ohio. Cradling her week-old baby in her arms, she watched as her three other kids played and her husband, Bill, chatted with a friend. Suddenly, there was a loud splash. Alissa looked up and saw that her four-year-old son, Logan, had jumped into the pool. Seconds later, he was motionless on his back, held aloft by his water wings. "I thought he was doing a back float, but then his head dropped underwater, with his mouth open," says Alissa. "I started screaming, and our friend jumped in and grabbed Logan. Bill tried CPR and pounded on Logan's back, but nothing worked."

As an ambulance waited on the driveway, the boy finally gave a tiny cry and opened his eyes. He seemed fine by the time he got to Akron Children's Hospital. Even so, John Clark, M.D., the pediatric cardiologist treating him, gave Logan an EKG. The results showed that Logan probably had long QT syndrome, a rare and often fatal disorder of the heart's electrical rhythms. Because the condition often runs in families, Dr. Clark then checked the Schmidts' three other kids. He discovered that Logan's three-year-old sister, Lailyn, most likely also had long QT.

"Without treatment, Logan had a 50 percent risk of dying before his 19th birthday," Dr. Clark says. "And Lailyn was also in serious jeopardy." He ordered the blood tests that would show conclusively whether the children had long QT and put the kids on a class of heart drugs called beta-blockers while they waited for the results. When the tests came back, they confirmed the diagnosis. The children stayed on the drugs. But in January 2001, Dr. Clark implanted a defibrillator in Logan's chest to monitor his heart's rhythms and to jolt it back to normal in case of an irregular beat.

Lailyn, however, didn't qualify for this therapy, the most effective for the disorder. Why? The wires needed to connect the device to her heart were too thick to fit through her veins; they could be used only in a child weighing more than 40 pounds. "Defibrillators were made for adults, not four-year-olds," says Dr. Clark.

The Schmidts were worried. "I got like Lailyn was a ticking time bomb, and I prayed every day that nothing would happen," says Alissa. After a year, Logan's defibrillator started kicking in often to correct wildly abnormal heartbeats, suggesting that the drugs were no longer working. This meant that Lailyn herself was in great

problem. "If you push blood through a pump too fast, it could cause damage to red blood cells," says David Wang, Ph.D., a biomedical engineer with CardiacAssist who is working to develop a heart pump for babies. "But if you move it too slowly, there's a risk that a clot could form. And you have to make all this work with a tube that's smaller than a coffee stirrer."

Plus, children grow, so medical equipment must be made in a range of sizes for kids of different ages or be designed to grow along with them. "If a child needs an artificial joint like a knee or a hip, all we can do is order a custom device," says Dr. Campbell. "Then, when the kid gets bigger, we have to have a larger one made. They cost thousands of dollars, and making them can delay treatment for months."

But even in this environment, there have been a number of innovations. When Devin Alvarez of Hillsborough, Florida, was born, he was missing a ribcage and had a very small left lung and a kidney. "Doctors said he might not live through the night," says his mom, Reyes Diaz. Devin did survive, but he grew his spine because horribly twisted. He struggled to stand and to play, and at age three, he still had to crawl up the stairs. "One doctor said nothing could be done," says Reyes. "I started crying. Then he told me about a surgeon who might be able to help."

That surgeon was Dr. Campbell, who had invented an artificial rib that can easily expand as a child grows. In May 2002, Dr. Campbell was able to include Devin in a research study involving rib-implant surgery. The results were amazing.

"Devin was born having a 102-degree curvature of his spine to standing up straight," Reiss says. "When he saw himself in the mirror, his eyes were huge. 'Mommy, I'm not sick anymore,' he said. 'I'd never seen him so happy.'"

To figure out how to generate more success stories like Devin's, an American Academy of Pediatric task force, headed by Dr. Alcamaron, held four brain-



"Mommy, I'm not sick anymore!" Devin said, looking in the mirror.

storming meetings in 2004. Among the suggestions were designating a point person within the National Institutes of Health to help doctors get grants and creating a fast-track FDA approval process for equipment that needs only minor adjustments to work for kids. The task force also hopes to find a way for U.S. doctors to use kid-friendly devices that are available in Europe, where the regulatory process tends to be easier. "The change will make a big difference," says Dr. Alcamaron. "We want to make children's lives better."

Where to find the best care

If your child has a chronic illness or needs surgery, consider having her treated at a children's hospital. Not only do these facilities have pediatric specialists in everything from heart disorders to brain surgery, but they also stock the full range of available kid-size equipment. "Some of these devices, such as laparoscopic instruments for children, are very expensive, so a general hospital may not want to buy them," says Dr. Clark. "And even if surgeons there do have access to this equipment, they're very unlikely to have the same skills as pediatric surgeons who use it every day." Plus, if a baby version of a certain device doesn't exist, the experts at a children's hospital will be more adept at improving other therapies because they've encountered similar problems in the past.

**In 2007 we made a national impact & realized the importance of sharing our story. With our consent to participate Dr. Campbell and US Senator Christopher Dodd shared our story to introduce
Senate Bill 830 Pediatric Medical Device Safety & Improvement Act of 2007**

S. 830—The Pediatric Medical Device Safety and Improvement Act of 2007

On March 8, 2007, Senator Christopher Dodd (D-CT) introduced S. 830, the Pediatric Medical Device Safety and Improvement Act of 2007. A House companion, H.R. 1494, was introduced by Representative Edward Markey (D-MA) on March 13, 2007. The bills are aimed at encouraging the development of medical devices for use by children. Provisions would require NIH, FDA, and AHRQ to develop a plan for expanding medical device research and development. Provisions would also require the Secretary, HHS, to provide grants to a non-profit consortium, which would be tasked with facilitating the development of pediatric devices, by connecting individuals with ideas for pediatric devices with potential manufacturers. The consortium would be required to coordinate with NIH in these efforts and would be responsible for notifying NIH of any unmet needs that the consortium lacks sufficient capacity to address. S. 830 was referred to the Senate Committee on Health, Education, Labor and Pensions (HELP).

2007

Our story received national attention via
The Learning Channel's Amazing Medical Stories & once again we
were able to advocate for rare disorders.



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2007



KEY BISCAWAYNE, Fla. (WSVN) -- The International Kids Fund called on the public to help a toddler with a life threatening heart defect at a Friday morning news conference in Virginia Key.

The organization, making their plea from the Rusty Pelican restaurant, is asking the public to fund corrective surgery for 1-year-old Haitian Johnsley Mainville, whose condition makes it hard for him to get enough oxygen. Medical experts say that the boy will have a maximum of one year to live if not adequately treated. Doctors, whom project the surgery to cost about \$60,000, hope to have all of the necessary funds collected within the next two weeks.

Ten-year-old Devin Alvarez, who himself has undergone more than 20 surgeries to correct a problem with his backbone, believes the public cannot justify withholding a contribution of any size. "If this boy dies, it will be a life lost for no reason," said Alvarez. "This boy must live."

Haitian doctors were unable to diagnose Johnsley's condition until he was about a year old. U.S. doctors say that had Johnsley been born on American soil, his defect would have been detected at birth and subsequently fixed.

The 1-year-old, his mother, Bodeline Deaubiem, and two nuns who run humanitarian missions are in South Florida on humanitarian visas. Deaubiem is well aware of the opportunity those visas have afforded her ailing son. "I have hope for my baby, and I cannot thank the United States of America enough for that," said the toddler's mother.

Read more: <http://www.wsvn.com/news/articles/local/MI68177/#ixzz20517Rj4e>

2008

Rixys, Devin and Dr. Campbell were invited to make an appearance on the national CBS Show, The Doctors. They were able to share their story and once again advocated for rare disorders & pediatric devices.



2010

Rixys reached out to U.S. House of Representatives Member Debbie Wasserman Schultz and the National Organization of Rare Disorders and initiated what later passed as Federal House Resolution 1499 which “Honors Dr. Robert Campbell for his lifelong devotion to children's health care; Recognizes the Vertical Expandable Prosthetic Titanium Rib device which has save the lives of so many infants and children, while giving hope to their families; and “Calls on the Food and Drug Administration to continue to support and incentivize other medical advances to save children's lives threatened by rare disorders.”



2010

**GOVERNOR CHARLIE CRIST APPOINTS
RIXYS ALFONSO TO THE
FLORIDA DEVELOPMENTAL DISABILITIES COUNCIL**

TALLAHASSEE – Governor Charlie Crist today announced the following reappointment and appointments:

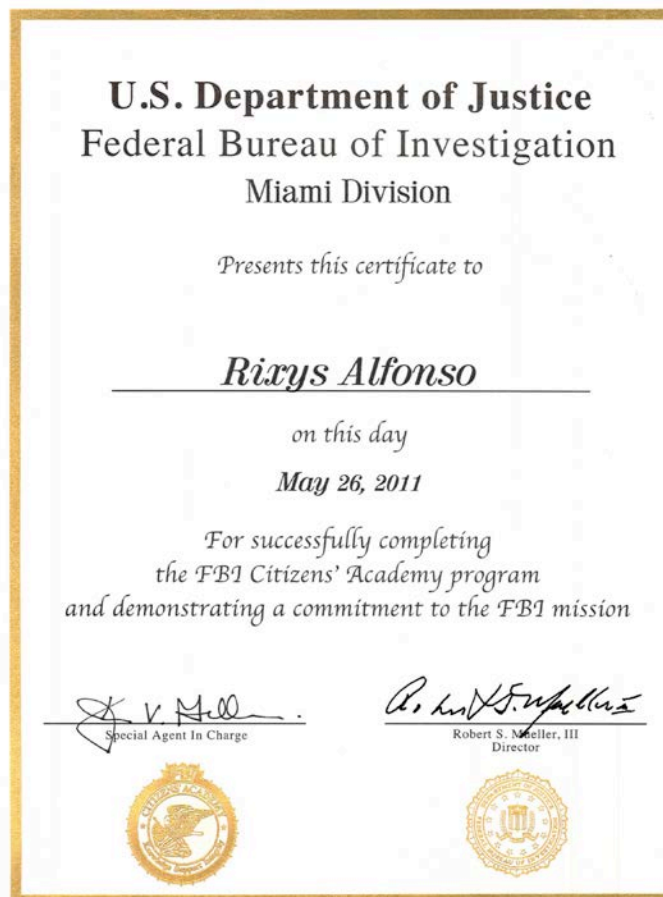
FLORIDA DEVELOPMENTAL DISABILITIES COUNCIL

Rixys Alfonso, 38, of Pembroke Pines, Vice President of Development, Here's Help Inc., succeeding Judith Owen, appointed for a term beginning October 7, 2010, and ending September 30, 2014.

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2011

In honor of her
community work
as a parent
advocate, Rixys
Alfonso was
invited by the
Federal Bureau
of Investigations
to participate and
graduated from
the FBI's
Citizen's
Academy.



2012

Today, Devin is 15 and has enjoyed a life filled with love, happiness and advocacy!

