

# Battling Autism

An Interview with Dr. Joan Fallon,  
Chief Executive Officer and Founder, Curemark

**EDITORS' NOTE** *Having filed her first patent application in 1999, Dr. Joan Fallon has worked to research autism and related disorders as well as to bring her findings to a platform for commercialization. As a seasoned clinician, she worked as a pediatric chiropractor for 25 years specializing in pediatric development. She taught anatomy, physiology, and developmental biology as an assistant professor of natural science and mathematics at Yeshiva University, in addition to lecturing about pediatric development around the world. Dr. Fallon served on the advisory board for Oxford health plans, as well as on the boards of numerous not for profits. Dr. Fallon's discovery of the biomarker for autism and ADHD, and her vast array of the intellectual property in the area of gastrointestinal secretory deficiencies, form the basis of Curemark. As a pediatric specialist, she was one of the first physicians of any type to enter Romania and to help determine the state of the Romanian orphanages. She served as an advisor to the New York Yankees for disability services for the new Yankee Stadium. She has a B.A. degree from Franklin and Marshall College, a D.C. degree from Palmer University, and she has completed her work for the M.Sc. in clinical investigation from Harvard University's joint program with Massachusetts General Hospital.*



Joan Fallon

**COMPANY BRIEF** *Curemark ([www.curemark.com](http://www.curemark.com)) is a drug research and development company focused on the treatment of neurological and other diseases, especially those with dysautonomic components, by addressing certain key gastrointestinal/pancreatic secretory deficiencies.*

**What was the vision that led to the creation of Curemark?**  
I was in clinical practice and saw some interesting things the kids were going through during the early days of identifying and battling autism.

It was clear that it was a heterogeneous group, and that autism has a lot of core and noncore symptoms. In some cases, the noncore symptoms predominate.

What was curious to me was that no one was looking at the whole spectrum. They

made certain assumptions early on that it was caused by different things, none of which I bought into. So the question for me was, what is going on with these kids?

Through testing, I discovered early on that they had something in common, which was a low level of a specific enzyme that had only been seen before in cystic fibrosis.

I tested a lot of children in my own practice and in other practices, and found there was a large subset of children who had this low

enzyme.

I was at a family dinner one night with my brother who is an inventor, and he said, I think you should patent that finding. I asked why. He asked if it could benefit the kids. I said, if it holds true, then absolutely. He said, it needs a commercial value.

At the end of 1999, I sent the patent in. The first patent was granted in 2003 covering this biomarker that we have and certain types of treatments for autism.

I went back to school to expand my base of knowledge. Following that, I had friends who watched this process evolve who said, here is a check; quit your practice and figure out what to do.

So I did that, never thinking it would be where it is today in terms of what we have accomplished and what we're going to do.

My idea was to see if there is indeed a low level of this enzyme in these children and if we can replace that enzyme and benefit these children.

**How has the company evolved since its inception?**

I assembled a very focused team, starting with my Chief Scientific Officer, Matt Heil, who has 30 years' experience in the field of pharma, biotech, and finance around biotech.

We had some challenges: We had to figure out how to deliver this enzyme because the delivery system had to have special qualities that didn't exist at the time. Children are sensitive, so it needed to be taste-masked and granular-masked. We found a technology for which we have exclusive license to use for these enzyme products that meets these goals. It's used in food every day.

It had to be a product that didn't have a lot of garbage in it – things that are in many pharmaceuticals: flow agents, colorants, extenders, binders, etc.

We developed it as a sprinkle product that goes on the children's food and then we went about doing an FDA clinical trial.

We hired FDA regulatory specialists – people who are well-known in the field and went to the FDA to discuss what we wanted to do. They gave us guidance, and then we did a large Phase III clinical trial at 18 sites across the U.S. and had good results.

We met with the FDA in April and we're now going to start to submit our new drug application. They want us to look at some biomarker issues with the kids.

**Where does the battle to overcome autism stand today? How far have the efforts progressed?**

The understanding is far from where it needs to be. Very early on, in the more organized scientific way, everyone determined there was a gene to be found. Carrying the genome card is all fine and good but we need treatment today.

The understanding that it's not a one-drug, one-disease model is a good thing in general for the industry. Previously, people were looking at diseases as silos and at conditions falling into one system or another.

We're just now beginning to look at autism as a spectrum and there is a great deal of room for many different treatments, both behavioral and pharmaceutical.

**How do you define success?**

I brought Curemark up as if it were a child that needed attention in all areas of its development.

We are now poised to do any number of things: we have been in talks with companies that are interested in buying us; we can do an IPO; or we can do a vertical integration and go it alone.

But success for me is getting this drug to the children.

**Do you miss the days of practicing?**

All the time. I miss the kids. I miss their spontaneity; the pureness of their ability to express what goes on for them.

I think empowerment of children through any aspect of their lives is really one of the most important things. Without empowerment, their lives won't be as good as they could be. ●