



Joan Fallon

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. Her discovery of a potential 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. 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. from Franklin and Marshall College, a D.C. from Palmer University, and completed coursework for the M.Sc. in clinical investigation from Harvard University's joint program with Massachusetts General Hospital.*

COMPANY BRIEF *Curemark (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.*

How is Curemark positioned in this market?

The focus from the beginning has been about getting new drugs to children to help them.

The autism numbers have gone up significantly over time. It's affecting 1 in 68 children now, and 1 in 42 boys. It wasn't long ago that we thought it was 1 in 250. So it's a big difference in terms of the prevalence of the autism spectrum disorder.

I would have also thought that by now there would be other drugs further along in development, but there aren't. This saddens me because it's important that the children have options for

The Power of Disruption

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

treatment, both in behavioral therapies and cognitive therapies, and in terms of drug therapy.

We have a Fast-Track designation from the FDA. Fast-Track is a program that facilitates the development and expedites the review of new drugs that are intended to treat serious conditions and demonstrate the potential to address unmet medical needs. We have begun pre-registration of our drug with the FDA, too. We're well down the road to bringing the first drug to market for core symptoms for autism.

Do you get the support you need when you're working towards disruptive technologies?

The pharma industry has not embraced disruption to the degree that other technology sectors have. However, we have been disruptive with the drug discovery model, financing model, and the medical paradigm that we are challenging. Disruption, as you know, is never easy.

Most biotech companies take venture capital and follow a path to an IPO. There has been no venture capital for autism drugs, period. So we've had to raise money in another fashion.

This is a very different model of drug development than the one that has been used in the past. Most drug development involved looking at novel compounds created in the laboratory that you can patent, then retrofitting them into disease states. I believe this model has shown a decreasing probability of success over time.

When it comes to disrupting how drugs are discovered, we took the patient-centered model where we looked at the needs of patients, and formulated a drug to treat them. We tested it with those patients and, hopefully, once it's approved, we can get it to all of the patients who need it.

We also disrupted the medical paradigm by thinking that giving a drug to aid in a digestive process could actually change neurology. Much has happened since we first put this concept out there. We now know, for example, that specific amino acids actually turn on and off certain genes. We now know they play a role in epigenetics, which means we may be able to replace an enzyme that was missing in the digestive process, an enzyme that cleaves these amino acids. The byproduct of now having an amino acid pool that is complete, is that the individual's neurology is actually affected. This is all new and disruptive.

Where is the voice to tell the story for funding and can more be done to get support?

Autism Speaks does an awesome job acting as a voice for the patients with autism. President

Obama recently signed the new Autism Cares Act and this will bring funding to research.

But we tend to fund scientists who think a certain way and then get locked into paradigms that aren't disruptive. Those old paradigms may not be able to reach the threshold of developing a treatment for a disease we know very little about.

Until we start funding research outside of the box, it will be a long time before we can find treatment for not just autism, but for many other diseases. It took a water bucket challenge to bring awareness to ALS, even though ALS bears the name of the very famous baseball player, Lou Gehrig.

You're also addressing other neurological diseases. How broad has your focus become?

Autism was first described in 1943 when it was called childhood schizophrenia. For a long time, we looked at schizophrenia as a disease that happens in young adults.

But in recent years, we have looked at schizophrenia more as a childhood developmental disorder. We know now there are certain signs, observable early in childhood, that show whether someone is at risk for developing schizophrenia. These observations have led to uncovering a thread that runs through certain diseases.

When I was first working on autism, ADHD was considered part of that same spectrum. Now, these are two distinct entities though, we often find a common thread through them. Research shows that 30 to 40 percent of children with autism have co-morbid ADHD.

The threads that go through these conditions are more physiological than we have looked at previously, so there are other applications for our enzyme or preparations like our enzyme. We hope to explore these down the road.

In leading this effort, is it sometimes hard to stay upbeat?

Entrepreneurs tend to be happy people because they are dreaming of something that has an end result. If they can meet milestones along the way, it makes them happier and gives them more incentive.

This is how I have looked at it. I have a goal that I have never taken my eye off of, but I know there have been and will be bumps along the way.

The entrepreneurial culture is extremely important to how you treat the people that work with you and how you bring everything along. You also can't let one aspect of your business lag behind the others. Having all aspects of your business mature together translates into a very good prognosis for the company and for the patients you hope to treat. ●