EDITOR'S NOTEBOOK/Bernard Rimland, Ph.D.

Secretin Update: March 1999

Six months have passed since the secretin story was first made public at our Defeat Autism Now! conference in New Jersey. The media coverage, in the U.S. and overseas, has been extensive. Just a few weeks ago the autism/secretin connection was a front page story in the *Wall Street Journal* (March 10, 1999). Media interest shows no sign of abating, judging from the phone calls and faxes which arrive daily.

Where are we now? The news still looks good, which is news in itself. Our best estimate is that somewhere around 2,500 to 3,000 autistic children (mostly children—a few adults) have been given secretin by perhaps 200 to 250 physicians around the U.S. The vast majority have received the secretin by infusion, by means of a "push" IV injection, taking just a minute or two. A few have received the secretin transdermally, and a few others have been treated by sublingual drops. The usual IV dose is 2 clinical units (CUs) per kg of body weight. A few physicians have given as many as 300 infusions, and quite a number of physicians have given in excess of 100 infusions. I am aware of several patients having been given nine or more infusions. So far, initial fears that repeated infusions may sensitize the patient, and thus cause problems, have not proven justified.

Supply: The biggest problem is the serious shortage of secretin, which has been made from pig tissue. Synthetic human secretin is believed to have several advantages over the natural pig source secretin. Several laboratories have begun manufacturing it. Clinical trials comparing the synthetic human secretin with the porcine and a placebo are scheduled to begin soon at a number of university medical centers. Once the clinical trials have been completed to the satisfaction of the Food and Drug Administration, synthetic human secretin will be placed on the market and that should considerably decrease the present problems with supply and cost. I have, regrettably, not been able to get any firm estimates of when the supply situation will improve, but I'm hoping it will be better in a few months.

Efficacy: We continue to receive very positive reports from both the families of autistic children, and the physicians who are using the secretin. It is difficult to get a clear estimate of what percentage of autistic children and adults show benefit, but our best estimate is still in the neighborhood of about 70 percent. Parents continue to report greatly improved eye contact and interest in the child's surroundings, fewer tantrums, better sleeping, greatly accelerated language development and toilet training, and a number of other benefits.

The *Wall Street Journal* article was generally very positive, although it mentioned an unpublished study by neurologist Michael Chez, M.D., of Chicago, who reported seeing no benefit from the secretin he had given to some of his patients. We have heard from dozens of physicians that they are seeing very good results, so Dr. Chez's negative report is puzzling. Dr. Chez is well known for his work with seizure disorders in children, so it is at least possible that his failure to find good results was a result of the subjects' being seizure-prone and/or on anticonvulsant medication.

> It is difficult to estimate how many autistic individuals benefit from secretin, but it appears to be in the neighborhood of 70 percent.

Adverse effects: About 5 to 10 percent of the children seem to grow worse immediately after the secretin is given, for a few days, or in a few instances, up to a few weeks. The adverse reactions are hyperactivity, and in a few cases, aggressiveness.

Although the reports of hyperactivity and sometimes aggression are infrequent, they are a bit worrisome. However, one must remember that such problems are quite common in autistic children, and may have occurred whether or not the child was given secretin.

I am reminded of the first study that Dr. Stephen M. Edelson and I conducted on Auditory Integration Training (AIT). One half of the sample of autistic children were treated with music that had been specially modulated electronically. The other half of the sample listened to the same music, but unmodulated. A few days after the study had begun, one of the teenage boys became quite violent and aggressive, to the point where he had to be taken out of the home for a time. Dr. Edelson was very concerned. He immediately broke the code for that subject, to find if the boy had been listening to ordinary music or the specially modulated music. As it turned out, he was in the placebo group and was just listening to ordinary, everyday music. What a disaster it would have been if he had been in the experimental group, listening to modulated music! No one would have been sure that it was not the modulated music that had caused the problem, and the incident might have destroyed the then-new nationwide interest in AIT. Subsequently, a number of controlled studies have been conducted which show AIT to be very helpful to many autistic children.

A few untoward incidents, such as the above, even though coincidental rather than causative, could easily derail an emerging form of treatment. Thus far that has not happened with secretin, and as time goes on it becomes even less likely that any significant harmful effects will be attributable to secretin.

Some physicians are reluctant to give secretin to children who have a history of seizures, or are on anticonvulsant medication, for fear, which may or may not be justified, that the secretin may have adverse effects on such children. One youngster had a seizure while the secretin was administered but, after investigation, it was concluded that the secretin was probably not the cause of the seizure. The child's family has a history of seizures, the child had an abnormal EEG to begin with, and the child had struggled against the infusion, so the stress of the situation might have led to the seizure.

Secretin patent. When Victoria Beck learned that the university medical school doctors who had initially scoffed at her discovery of the autism/secretin connection had later applied for a patent on the use of secretin in autism, she protested. After an investigation, the university acknowledged that she was the rightful owner of the patent.

A patent is very important to the parents of autistic children. With a patent, drug companies will have an incentive to invest in research, because they will have the exclusive right to market the patented product. If there is no patent (as is true for vitamin B6 and DMG), no drug company will invest in research, because their competitors, with no financial investment, will also be able to sell the product.

Among the parents who are extremely interested in secretin are Walter Herlihy and his wife, Nancy LeGendre, of Massachusetts, who have two autistic daughters. Both Walter and Nancy have PhDs in biochemistry, and Walter is the Chief Executive Officer of the Repligen Corporation, a biotechnology firm in Needham, Massachusetts. Several weeks ago, Repligen purchased the patent rights for secretin as a treatment for autism from Victoria and Gary Beck, who have generously assigned the bulk of the proceeds from the sale, and the subsequent royalties, to the Autism Research Institute. The Institute will use these much needed funds to continue the progress that is being made toward finding causes and better treatments for autism. Dr. Herlihy pledges to move full speed ahead on bringing high quality synthetic human secretin to the families seeking it, as quickly as possible. That is welcome news indeed.

For more information on developments regarding secretin, see www.repligen.com.