

## **Botulinum Toxin Safety Issues** (February 13, 2008)

The US Food and Drug Administration (FDA) has issued an “Early Communication” regarding a safety review of botulinum toxins types A and B for both FDA-approved and unapproved (sometimes called “off label”) uses in the United States. This review includes BOTOX® and MYOBLOC®

The FDA is reviewing reports of serious side effects following the use of botulinum toxins, particularly for the management of juvenile cerebral palsy in which large doses of the medication are administered.

**Over more than twenty years of use, there has never been a report of a life threatening adverse reaction to botulinum toxin use in a blepharospasm patient.**

This posting of an “Early Communication” is a routine measure taken by the FDA to provide the public with early information regarding safety or other related reviews, often before any conclusions are or can be made.

The FDA made clear that “the posting of this information does not mean that there is a causal relationship between the botulinum toxins and adverse events. Nor does it mean that the FDA is advising healthcare professionals to discontinue prescribing these products. FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action. FDA intends to update this document when additional information or analyses become available.”

BEBRF joins the Dystonia Medical Research Foundation in supporting the FDA’s efforts to ensure that treatments for all disorders, including dystonia, are safe and effective. We appreciate the manufacturers’ efforts to cooperate with the FDA, putting patient safety above all.

We urge you to consult your own healthcare professional about your individual treatment plan.

Dr. Mark Stacy, Division of Neurology, Duke University, and member of the BEBRF Medical Advisory Board, responds as follows: “...botulinum toxin has been used to treat medical conditions for more than 20 years in Europe and North America, and I would assume many thousands of people have been treated for neurological conditions – perhaps even millions of people. Botulinum toxin works by preventing release of the neurotransmitter, Acetylcholine, from a nerve. If injected into a muscle, the toxin is taken up by the nerve, and transient (1-4 months) local muscle weakness occurs. Interestingly, these nerves also trigger perspiration and salivation, so injections into the salivary glands can treat drooling, and injections into the axilla can

reduce sweating. Injections into the face can reduce wrinkles by weakening the muscles of facial expression. As many people with blepharospasm and other dystonic disorders can tell you, botulinum toxin is a therapy, that in trained and experienced physicians' hands, can do remarkable things – like allow someone to see. When I review the 16 people reported by the watch dog group, there does not appear to be any patient with blepharospasm, Meige syndrome or hemifacial spasm included. While the injection location and dosages are certainly the most important unavailable pieces of information, we also do not know if these complications occurred within the window of efficacy for the toxins. In reviewing the complications associated with these patient deaths, remember that the spread of the toxin from more than 1 inch from the site of the injection, is quite minute, and would be symptomatic only in cases of severe neuromuscular diseases. Spasticity injections are in the arms and legs. These 5 patients and the bladder patient died from aspiration or pneumonia. It seems unlikely that these injections would cause problems with swallowing. The patient injected for drooling, died from aspiration, and it is highly likely this patient was being treated with toxin around the throat area. Please know that I speak for the vast majority of botulinum toxin injectors when I say that we are always respectful of this toxin and the patients who receive this drug. Every effort is made to reduce risk of side effects from our procedures. I urge all patients to discuss any concerns with their physicians at their next scheduled appointments.”

Dr. Alan Scott, Ophthalmologist, Scientist and true medical pioneer spent several years refining the neurotoxin into a clinical product, developing tests for sterility, safety, potency and stability. In 1977 he first tested botulinum toxin A in patients with blepharospasm and strabismus and found the injections to be safe and successful. At the end of thirty years of therapeutic use he says, “There are no known deaths due to BOTOX, botulinum toxin A, injections in blepharospasm patients.”

BEERF, Inc., February 13, 2008