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FDA ADVISES ABOUT BOTOX DANGERS

The name Botox is most widely known for its cosmetic uses in reducing facial wrinkles. Beyond that, it has also found its way into use for the treatment of a variety of conditions including spasticity (muscle spasms) in the limbs of children with cerebral palsy. Now, based on reports of safety problems and several deaths associated with the product, the U.S. Food and Drug Administration has issued an advisory concerning its possible dangers.

The botulism toxin from which Botox, Botox cosmetics and a similar product known as Myobloc are made has been linked to adverse reactions. These include respiratory failure and death following treatment for a variety of conditions using a wide range of doses, said the FDA. The adverse effects are found in both FDA-approved and non-approved usages. The most severe cases reported involved children with cerebral palsy.

According to the advisory, the reactions appear to be related to the spread of the injected Botox toxin to areas in the body that are distant from the site of the injection. The person then begins to develop symptoms that mimic the symptoms of botulism poisoning, which include difficulty swallowing, physical weakness and breathing problems. Several deaths have been reported, mainly among children. The FDA makes it clear in the advisory that using Botox to treat cerebral palsy in children is not an FDA approved use.

Botox (botulinum toxin Type A) is approved for treatment of conditions such as spasm of the eyelids, severe neck muscle spasms, and excessive sweating. Botox cosmetic (also botulinum toxin Type A) is approved for temporary improvement in the appearance of moderate to severe facial frown lines. Reported cases of botulinum type A in children under 16 years of age include difficulty in swallowing and breathing, some involving hospitalization or death. Adult issues include similar symptoms plus muscular weakness, but with no deaths reported.

Myobloc (botulinum toxin Type B) is approved for the treatment of adults with cervical dystonia (neurological disorder that causes involuntary muscle spasms and twisting of the limbs). The safety and effectiveness of Myobloc for cervical dystonia in children have not been established.

The FDA considers this to be an early warning that a Botox investigation is underway. At this point, the FDA is not advising healthcare professionals to discontinue prescribing these products.

Source The U.S. Food and Drug Administration. "FDA Notifies Public of Adverse Reactions Linked to Botox Use." February 2008. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01796.html and FDA. "Ongoing Safety Review." February 2008. http://www.fda.gov/cder/drug/early_comm/botulinium_toxins.htm