

Botox and Myobloc Side Effects Prompt Warning

By Lauran Neergaard AP February 8, 2008

WASHINGTON - The popular anti-wrinkle drug Botox and a competitor Myobloc have been linked to some deaths and other severe side effects suggestive of botulism, the government warned doctors Friday.

Botox and Myobloc use botulinum toxin, which blocks nerve impulses to muscles, causing them to relax.

But in rare cases, the toxin may have spread beyond the injection site to other parts of the body, resulting in such problems as paralysis of respiratory muscles and difficulty swallowing, the Food and Drug Administration said.

The FDA said the deaths were all among child patients, mostly those with cerebral palsy treated for limb spasms, a condition the FDA has never formally approved for the drugs' use in this country although other countries have.

The problems may be caused by overdoses of the drugs, the FDA said.

Caroline Van Hove, a spokeswoman for Botox maker Allergan Inc., said children with cerebral palsy have far larger doses injected into their leg muscles than the doses given adults seeking wrinkle care.

But the FDA warned that it also has reports of side effects in people of all ages given the drugs for a variety of conditions.

Friday's warning came two weeks after the consumer advocacy group Public Citizen petitioned the FDA to strengthen warnings to users of Botox and Myobloc - citing 180 reports of U.S. patients suffering fluid in the lungs, difficulty swallowing or pneumonia, including 16 deaths.

It is not the first warning about the potential for botulinum toxin to spread after the drugs' injection; the products' labels say it can happen.

Still, the FDA said Friday that its investigation into the side effects is still in its early stages.

For now, the agency said doctors should warn all patients receiving a botulinum toxin injection, whether for cosmetic purposes or as a medical treatment, to seek immediate care if they experience difficulty swallowing or breathing, slurred speech or muscle weakness.

That falls short of Public Citizen's request that the agency put a black-box warning, the FDA's sternest, on the drugs' labels and require that every patient receive a pamphlet outlining the risk before every injection.

“Every doctor needs to be notified about this, every patient needs to be notified,” said Public Citizen's Dr. Sidney Wolfe. “Children are showing the way, unfortunately some are dead children.” He said drug regulators in Britain and Germany last year required sterner warnings be sent to every doctor in those countries.