The Use of Botulinum Toxin Products in Cosmetic Applications – What’s the Litigation Risk?

By Donna Marie Baloy, Esq.

Botulinum toxin products such as Botox® and Dysport® are used cosmetically for temporary improvement in the appearance of glabellar lines (“frown lines”) and lateral canthal lines (“crow’s feet”) in adults. Essentially, these products employ a neurotoxin, botulinum toxin type A, which works by weakening or paralyzing muscles and/or blocking nerves. In addition to its cosmetic uses, botulinum toxin is also approved by the FDA for use in a variety of therapeutic applications: overactive bladder, urinary incontinence, migraine headaches, upper limb spasticity, cervical dystonia (painful contraction of neck muscles), hyperhidrosis (severe underarm sweating), blepharospasm and strabismus.

Botulinum toxin was first approved by the FDA in 1989 for treating strabismus (a disorder in which the two eyes do not line up in the same direction) and blepharospasm (abnormal spasm of the eyelids). In 2002, it was approved for its first cosmetic indication -- the temporary treatment of moderate to severe glabellar lines (“frown lines”) between the eyebrows. It was marketed as Botox® cosmetic by Allergan Corporation. Since that time, the term “botox” has been widely used by the public to refer to any brand of botulinum toxin, much as the brand name “Kleenex” has become a generic equivalent for “facial tissue” in common parlance. In September 2013, Botox® cosmetic was approved by the FDA for its second cosmetic indication -- the temporary treatment of lateral canthal lines (“crow’s feet”). Continued

The warnings that accompany botulinum toxin products http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103000s5260lbl.pdf include an FDA-required black box warning (The FDA’s strongest form of warning) of the risk of the distant spread of toxin effects from the injection site. These effects can include swallowing and breathing difficulties that could lead to death. Pre-existing neuromuscular disorders or cardiovascular disease can also put patients at risk for serious side effects, as can use in patients with compromised respiratory function or dysphagia (difficulty swallowing.). However, the most common adverse reactions from the approved, cosmetic uses of botulinum toxin are eyelid ptosis (drooping) and eyelid edema.

One surprising risk from the use of botulinum toxin is the existence of counterfeit product. In April 2013, the FDA warned of counterfeit Botox cosmetic being offered for sale by unlicensed suppliers. http://www.fda.gov/drugs/drugsafety/ucm349503.htm. The outer box is counterfeit and the vial inside contains a foreign version of the drug not approved for sale or use in the United States. As these drugs were produced without FDA oversight, there is reason to question whether the manufacture, quality, storage and handling of these products meet U.S. standards, and the FDA advised users to consider these drugs unsafe.

With the widespread use of botulinum toxin for cosmetic and therapeutic uses, what is the risk from lawsuits alleging injury from the use or misuse of botulinum toxin? One Massachusetts General Hospital dermatologist recently set out to research precisely that issue and the results were published in a scholarly medical journal. Dermatol. Surg. 2013 Nov; 39(11):1587-91. doi: 10.1111/dsu.12188. Analysis of botulinum toxin products and litigation in the United States, Korman JB, Jalian HR, Avram MM.

Dr. John B. Korman used the Lexis/Nexis Academic database to conduct a nationwide search for federal and state cases involving allegations of adverse effects from the administration of botulinum toxin type A between the years 1985 and 2012. A secondary nationwide search for lawsuits was made of newspapers and wire services. He located 24 lawsuits, mostly in state courts. All named the manufacturer of the drug, Allergan Corp., as a defendant. In three of the cases, physicians were named as co-defendants, including one dermatologist. None of the suits named a dermatologist as a defendant when the use of the drug was for on-label indications and cosmetic use. Most of the cases were settled, but five went to trial. Two of the trials resulted in multi-million dollar verdicts for the plaintiff.

In one, an Oklahoma jury awarded $15 million in 2010 to a female patient who received five injections of Botox for wrinkles and alleged it caused her double vision, breathing difficulty and severe pain in her extremities, finding that Allergan did not adequately warn of the possible side-effects. The Oklahoma Court of Appeals upheld the verdict last year. Continued
In the other, a Virginia man was awarded $212 million by a jury in 2011, $12 million in compensatory damages and $200 million in punitive damages, although the punitive damages were later reduced to $350,000 due to a statutory cap on punitive damages. (Later, the verdict was thrown out on appeal and a new trial was ordered.) He was injected with Botox to address a movement disorder in his hand – an off-label use. He alleged that he suffered a disabling auto-immune disorder and brain damage as a result.

In the final analysis, given the great number of cosmetic procedures involving the injection of botulinum toxin, the number of lawsuits alleging adverse effects is relatively small. This should be of some comfort to clinicians, particularly those using the product for on-label indications in approved dosages. As Dr. Korman concludes, “The troves of clinical data gathered following millions of treatments suggest that botulinum toxin products are exceptionally safe, especially for cosmetic applications. Nevertheless, botulinum toxin lawsuits alleging complications from its clinical use arise periodically, and practicing dermatologists should at least be mindful of this possibility.”

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