



- [Global Locations](#)
- [Contact Us](#)

- [Search](#)

-->-->-->-->

# Allergan Files Federal Lawsuit to Allow It to Share Relevant Information with the Medical Community on the Safe Use of BOTOX(R) for Common Therapeutic Off-Label Treatments

IRVINE, Calif., Oct 01, 2009 (BUSINESS WIRE) -- Allergan, Inc. (NYSE: AGN) today filed a declaratory relief action in the United States District Court for the District of Columbia seeking a ruling that would allow Allergan to proactively share truthful and relevant information with the medical community to assist physicians in evaluating the risks and benefits of BOTOX<sup>(R)</sup> (onabotulinumtoxinA) for certain "off-label" therapeutic uses. Some of these off-label uses are medically accepted and commonly prescribed but currently unapproved by the United States Food and Drug Administration (FDA). In the lawsuit, Allergan contends that the Government's legal position that it is a crime for a pharmaceutical company to proactively communicate truthful information to physicians about off-label uses of its products violates the First Amendment and is inconsistent with the Federal Food, Drug & Cosmetic Act. The lawsuit does not involve BOTOX<sup>(R)</sup> Cosmetic.

Under current law, drugs are approved by the FDA for specific uses. Once a drug is approved, physicians may exercise their informed medical judgment to prescribe the drug for any use, including off-label uses. It is estimated that approximately 20 percent of all prescriptions in the United States are used by physicians for off-label<sup>i</sup> indications and are often used to treat very serious conditions such as cancer and AIDS. The FDA has acknowledged the legitimacy and importance of the off-label use of many pharmaceutical products. In fact, federal, state and private health plans routinely pay for many off-label drug uses, including off-label therapeutic uses of BOTOX<sup>(R)</sup> for certain types of adult and juvenile spasticity. The FDA and Department of Justice, however, take the position that federal law prohibits pharmaceutical sponsors from proactively providing information to the medical community on off-label uses even when such information is accurate and complete.

This is a particularly significant problem for Allergan today as, effective September 2009, the FDA has required safety updates to the prescribing labels and a Risk Evaluation and Mitigation Strategies (REMS) program for all botulinum toxin products approved in the United States, including BOTOX<sup>(R)</sup>. The safety updates and REMS program require Allergan to speak in general terms about certain off-label uses of BOTOX<sup>(R)</sup>. However, to ensure that physicians are equipped to treat patients as safely and successfully as possible, Allergan believes it important to proactively provide comprehensive information to physicians about these off-label uses, such as dosing guidelines, patient selection criteria and proper injection technique. Without judicial relief, Allergan is unable to engage in a truthful and relevant information exchange with the medical community for fear of prosecution.

"After careful consideration, Allergan filed this lawsuit to enable it to communicate fully with the medical community on off-label, therapeutic uses of BOTOX<sup>(R)</sup> to treat patients suffering from serious, debilitating conditions. To serve the objectives of the FDA-mandated REMS program for BOTOX<sup>(R)</sup> and to assist physicians in evaluating the benefits and risks of the product, Allergan seeks a judgment that would permit it to provide currently available and truthful information to doctors for common off-label uses of BOTOX<sup>(R)</sup>," said Douglas S. Ingram, Allergan's Executive Vice President, Chief Administrative Officer and Secretary. "We believe that the inability to share such important information proactively with the medical community violates the First Amendment and potentially diminishes the quality of patient care."

Allergan's suit does not challenge the Government's ability to prohibit pharmaceutical sponsors from disseminating false or misleading information about their products. Rather, the lawsuit only seeks to permit Allergan to proactively provide the medical community with truthful, important information about common off-label uses of BOTOX<sup>(R)</sup>. Moreover, far from seeking freedom from regulation, Allergan hopes this suit will lead to clear regulatory guidance on how it can lawfully provide accurate and relevant information on the full range of issues physicians should consider in determining the best therapies for their patients.

Allergan is represented in its lawsuit by Paul D. Clement, a partner at King & Spalding LLP in Washington, D.C., and formerly the 43rd Solicitor General of the United States.

### **Investor Information Call**

Allergan will host a 30-minute conference call on Friday, October 2, 2009, commencing at 6:00 a.m. Pacific Time (9:00 a.m. Eastern Time) to discuss the declaratory relief action. You may participate in this call by dialing 1-888-790-3288 or call 1-212-287-1635 from international locations. A passcode, 'Allergan Conference Call,' will be required.

The live Webcast can be accessed through the Allergan Web site, [www.allergan.com](http://www.allergan.com), beginning at 6:00 a.m. Pacific Time. A replay of the discussion will be available soon after the call and can be accessed through [www.allergan.com](http://www.allergan.com), or by dialing 1-800-879-3386 for domestic locations or 1-402-220-4713 for international locations. A passcode will not be required for the replay. The replay will be available for one week following the live call.

### **About BOTOX<sup>(R)</sup> (onabotulinumtoxinA)**

BOTOX<sup>(R)</sup> is a prescription-only medical product that contains tiny amounts of highly purified botulinum toxin protein refined from the bacterium, *Clostridium botulinum*. When injected at approved and labeled doses into a specific muscle or gland, BOTOX<sup>(R)</sup> is expected to diffuse locally and expected to produce a safe and effective result by producing a localized and temporary reduction in the overacting muscle or gland, usually lasting between

3 and 6.7 months depending on the individual patient and indication.

BOTOX<sup>(R)</sup> was first approved by the FDA nearly twenty years ago for the treatment of strabismus and blepharospasm, two eye muscle disorders, making it the first botulinum toxin type A product approved in the world. Since its first approval, BOTOX<sup>(R)</sup> has been recognized by regulatory authorities worldwide as an effective treatment for 21 different indications in approximately 80 countries, benefiting millions of patients worldwide. In the United States, BOTOX<sup>(R)</sup> is also approved for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with the disorder, and for the treatment of severe primary axillary hyperhidrosis (excessive underarm sweating) that is inadequately managed with topical agents. In addition to its therapeutic uses, the same formulation of BOTOX<sup>(R)</sup> with dosing specific to glabellar lines was approved by the FDA in 2002 under the trade name BOTOX<sup>(R)</sup> Cosmetic.

### **FDA-Approved Uses of BOTOX<sup>(R)</sup> and BOTOX<sup>(R)</sup> Cosmetic**

**BOTOX<sup>(R)</sup>** is a prescription medicine that is injected into muscles and used:

- To treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.
- To treat certain types of eye muscle problems (strabismus) or abnormal spasm of the eyelids (blepharospasm) in people 12 years and older.

**BOTOX<sup>(R)</sup>** is also injected into the skin to treat the symptoms of severe underarm sweating (severe primary axillary hyperhidrosis) when medicines used on the skin (topical) do not work well enough.

**BOTOX<sup>(R)</sup> Cosmetic** is a prescription medicine that is injected into muscles and used to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary).

### **Important Safety Information**

**BOTOX<sup>(R)</sup> and BOTOX<sup>(R)</sup> Cosmetic may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with BOTOX<sup>(R)</sup> or BOTOX<sup>(R)</sup> Cosmetic:**

- **Problems swallowing, speaking, or breathing.** These problems can happen hours to weeks after an injection of BOTOX<sup>(R)</sup> or BOTOX<sup>(R)</sup> Cosmetic usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with BOTOX<sup>(R)</sup> or BOTOX<sup>(R)</sup> Cosmetic.
- Swallowing problems may last for several months. People who already have swallowing or breathing problems before receiving BOTOX<sup>(R)</sup> or BOTOX<sup>(R)</sup> Cosmetic have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing.

These symptoms can happen hours to weeks after you receive an injection of **BOTOX<sup>(R)</sup>** or **BOTOX<sup>(R)</sup> Cosmetic**.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving **BOTOX<sup>(R)</sup>** or **BOTOX<sup>(R)</sup> Cosmetic**" in Medication Guide.

There has not been a confirmed serious case of spread of toxin effect away from the injection site when **BOTOX<sup>(R)</sup>** has been used at the recommended dose to treat severe underarm sweating, blepharospasm, or strabismus, or when **BOTOX<sup>(R)</sup> Cosmetic** has been used at the recommended dose to treat frown lines.

**Tell your doctor about all your medical conditions, including if you have:** a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome).

**Tell your doctor about all the medicines you take,** including prescription and nonprescription medicines, vitamins and herbal products.

**BOTOX<sup>(R)</sup> or BOTOX<sup>(R)</sup> Cosmetic can cause serious side effects. Other side effects of BOTOX<sup>(R)</sup> and BOTOX<sup>(R)</sup> Cosmetic include:** dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids, swelling of your eyelids, and dry eyes. Symptoms of an allergic reaction to **BOTOX<sup>(R)</sup>** or **BOTOX<sup>(R)</sup> Cosmetic** may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **BOTOX<sup>(R)</sup>** and **BOTOX<sup>(R)</sup> Cosmetic**. For more information, ask your doctor or pharmacist.

For additional information refer to Medication Guide. This Medication Guide summarizes the most important information about **BOTOX<sup>(R)</sup>** and **BOTOX<sup>(R)</sup> Cosmetic**. If you would like more information, talk with your doctor.

Please see **BOTOX<sup>(R)</sup> full Product Information and Medication Guide**.

Please see **BOTOX<sup>(R)</sup> Cosmetic full Product Information and Medication Guide**.

### **Forward-Looking Statements**

This press release contains "forward-looking statements" including, but not limited to, the statements by Mr. Ingram, statements regarding litigation objectives and outcomes and other statements regarding the safety, effectiveness and adverse events associated with **BOTOX<sup>(R)</sup>** and **BOTOX<sup>(R)</sup> Cosmetic**. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Allergan's expectations and projections. Risks and uncertainties include, among other things, the uncertainties associated with the litigation and appeal process; general industry and pharmaceutical market conditions; technological advances and patents attained by competitors; challenges inherent in the research and development and regulatory processes; challenges related to product marketing; inconsistency of treatment results among patients; potential difficulties in manufacturing a

product; and governmental laws and regulations affecting domestic and foreign operations. Additional information concerning these and other risk factors can be found in press releases issued by Allergan, as well as Allergan's public periodic filings with the Securities and Exchange Commission, including the discussion under the heading "Risk Factors" in Allergan's 2008 Form 10-K and Allergan's Form 10-Q for the quarter ended June 30, 2009. Copies of Allergan's press releases and additional information about Allergan is available on the World Wide Web at [www.allergan.com](http://www.allergan.com) or you can contact the Allergan Investor Relations Department by calling 1-714-246-4636.

### **About Allergan, Inc.**

Founded in 1950, Allergan, Inc., with headquarters in Irvine, California, is a multi-specialty health care company that discovers, develops and commercializes innovative pharmaceuticals, biologics and medical devices that enable people to live life to its greatest potential – to see more clearly, move more freely, express themselves more fully. The Company employs more than 8,000 people worldwide and operates state-of-the-art R&D facilities and world-class manufacturing plants. In addition to its discovery-to-development research organization, Allergan has global marketing and sales capabilities with a presence in more than 100 countries.

© 2009 Allergan, Inc. Irvine, CA 92612. <sup>(R)</sup> marks owned by Allergan, Inc.

<sup>i</sup>*David C. Radley et al., Off-Label Prescribing Among Office-Based Physicians, 166 Archives of Internal Med. 1021, 1021 (2006)*

SOURCE: Allergan, Inc.

#### **Allergan Contacts**

Caroline Van Hove (714) 246-5134 (media)  
Jim Hindman (714) 246-4636 (investors)  
Joann Bradley (714) 246-4766 (investors)  
Emil Schultz (714) 246-4474 (investors)

Copyright Business Wire 2009

© 2007 Allergan, Inc. All Rights Reserved [Home](#) | [Site Map](#) | [Privacy & Terms](#)