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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92074873
Party	Plaintiff Allergan, Inc.
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It's not magic, it's
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It took forty years to get it.

And ten minutes to do something about it.

Welcome to the age of Botox® Cosmetic. Finally, a simple, non-surgical procedure that can dramatically reduce even your toughest wrinkle within days. One ten-minute treatment - a few tiny injections - relaxes the muscles between your brows that cause lines to form. And keeps them relaxed up to four months. Botox® Cosmetic has been widely tested. And now it's approved by the FDA. So it's really up to you. You can choose to live with wrinkles. Or you can choose to live without them.

Unretouched clinical photos taken while frowning before and after Botox® Cosmetic. In clinical trials, 89% of patients rated improvement in frown lines as moderate or better. Individual results may vary.

Ask your dermatologist, ophthalmologist, or plastic surgeon about Botox® Cosmetic. Or call toll-free or visit our website for a listing of Botox® Cosmetic Network physicians.

The most common side effects are headache, respiratory infection, flu syndrome, temporary eyelid droop, and nausea. Botox® Cosmetic should not be used if there is an infection at injection site.

Please see additional important information on the following page.

It's not magic, it's

BOTOX® Cosmetic
Botulinum Toxin Type A

1-800-BotoxMD
www.BotoxCosmetic.com

BOTOX® COSMETIC (Botulinum Toxin Type A) Purified Neurotoxin Complex

Manufactured by: Allergan Pharmaceuticals (Ireland) Ltd.
A subsidiary of: Allergan, Inc. 2525 Dupont Dr. Irvine, California 92612

Cosmetic Indications and Usage:
BOTOX® COSMETIC is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age.

Contraindications: BOTOX® COSMETIC is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any ingredient in the formulation.

Warnings:
Do not exceed the recommended dosage and frequency of administration of **BOTOX® COSMETIC**. Risks resulting from administration at higher dosages are not known.

Caution should be exercised when administering **BOTOX® COSMETIC** to individuals with peripheral motor neuropathic diseases (e.g., amyotrophic lateral sclerosis, or motor neuropathy) or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome). Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of **BOTOX® COSMETIC**. Published medical literature has reported rare cases of administration of a botulinum toxin to patients with known or unrecognized neuromuscular disorders where the patients have shown extreme sensitivity to the systemic effects of typical clinical doses. In some of these cases, dysphagia has lasted several months and required placement of a gastric feeding tube.

Dysphagia is a commonly reported adverse event following treatment of cervical dystonia patients with all botulinum toxins. In these patients, there are reports of rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube. There is also a case report where a patient developed aspiration pneumonia and died subsequent to the finding of dysphagia.

There have also been rare reports following administration of BOTOX for other indications of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease.

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS:
General:
Epinephrine should be available or other precautionary methods taken as necessary should an anaphylactic reaction occur.

The safe and effective use of **BOTOX® COSMETIC** depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. Physicians administering **BOTOX® COSMETIC** must understand the relevant neuromuscular and/or orbital anatomy of the area involved and any alterations to the anatomy due to prior surgical procedures. Caution should be used when **BOTOX® COSMETIC** treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Reduced blinking from **BOTOX® COSMETIC** injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with VII nerve disorders. In the use of BOTOX for the treatment of blepharospasm, one case of corneal perforation in an aphakic eye requiring corneal grafting has occurred because of this effect. Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means.

Inducing paralysis in one or more extraocular muscles may produce spatial disorientation, double vision or past pointing. Covering the affected eye may alleviate these symptoms.

Caution should be used when **BOTOX® COSMETIC** treatment is used in patients who have an inflammatory skin problem at the injection site, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin or the inability to substantially lessen glabellar lines by physically spreading them apart as these patients were excluded from the Phase 3 safety and efficacy trials.

Injection intervals of **BOTOX® COSMETIC** should be no more frequent than every three months and should be performed using the lowest effective dose (See Adverse Reactions, Immunogenicity).

Information for Patients:
Patients or caregivers should be advised to seek immediate medical attention if swallowing, speech or respiratory disorders arise.

Drug Interactions:
Co-administration of **BOTOX® COSMETIC** and aminoglycosides' or other agents interfering with neuromuscular transmission (e.g., curare-like nondepolarizing blockers, lincosamides, polymyxins, quinidine, magnesium sulfate, anticholinesterases, succinylcholine chloride) should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Pregnancy: **Pregnancy Category C**
Administration of **BOTOX® COSMETIC** is not recommended during pregnancy. There are no adequate and well-controlled studies of **BOTOX® COSMETIC** in pregnant women. When pregnant mice and rats were injected intramuscularly during the period of organogenesis, the developmental NOEL (No Observed Effect Level) of **BOTOX® COSMETIC** was 4 U/kg. Higher doses (8 or 16 U/kg) were associated with reductions in fetal body weights and/or delayed ossification.

In a range finding study in rabbits, daily injection of 0.125 U/kg/day (days 6 to 18 of gestation) and 2 U/kg (days 6 and 13 of gestation) produced severe maternal toxicity, abortions and/or fetal malformations. Higher doses resulted in death of the dams. The rabbit appears to be a very sensitive species to **BOTOX® COSMETIC**.

If the patient becomes pregnant after the administration of this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations that have been observed in rabbits.

Carcinogenesis, Mutagenesis, Impairment of fertility:
Long term studies in animals have not been performed to evaluate carcinogenic potential of **BOTOX® COSMETIC**.

The reproductive NOEL following intramuscular injection of 0, 4, 8, and 16 U/kg was 4 U/kg in male rats and 8 U/kg in female rats. Higher doses were associated with dose-dependent reductions in fertility in male rats (where limb weakness resulted in the inability to mate), and testicular atrophy or an altered estrous cycle in female rats. There were no adverse effects on the viability of the embryos.

Nursing mothers:
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **BOTOX® COSMETIC** is administered to a nursing woman.

Pediatric use:
Use of **BOTOX® COSMETIC** is not recommended in children.

Geriatric use:
Clinical studies of **BOTOX® COSMETIC** did not include sufficient numbers of subjects aged 65 and over to determine statistically whether they respond differently from younger subjects. However, in the two identical phase 3 randomized 3:1, multi-center, double blind, placebo-controlled, parallel-group efficacy studies, the responder rates for both co-primary efficacy variables were higher for subjects ≤ 50 years of age compared to those subjects ≥ 65 years of age. Analysis based on a combined data set showed that, for the investigator's assessment endpoint of subjects aged 65 and over at Day 30, 39% (9/23) of subjects were responders compared to 22% (2/9) in the placebo group. This difference is neither statistically different ($P = 0.228$) nor exceeds the pre-specified 30-percentage-point difference required by the definition of clinically significant. There were no statistically significant between-group differences for the investigator's assessment at maximum frown for this age group. There was a statistically significant difference in favor of **BOTOX® COSMETIC** for the subject's global assessment at all time points ($P = 0.036$) except Day 120 ($P = 0.214$). (See Clinical Trials Section)

There were too few patients over the age of 75 to allow any meaningful comparisons. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased cardiac function and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:
General:
The most serious adverse events reported for other indications studied include rare spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility, after treatment with botulinum toxin. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease (See Warnings). The exact relationship of these events to the botulinum toxin injection has not been established. Additionally, a report of acute angle closure glaucoma one day after receiving an injection of botulinum toxin for blepharospasm was received, with recovery four months later after laser iridotomy and trabeculectomy. Focal facial paralysis, syncope and exacerbation of myasthenia gravis have also been reported after treatment of blepharospasm.

Glabellar Lines:
In clinical trials of **BOTOX® COSMETIC** the most frequently reported adverse events following injection of **BOTOX® COSMETIC** were headache, respiratory infection, flu syndrome, blepharoptosis and nausea.

Less frequently occurring (<3%) adverse reactions included pain in the face, erythema at the injection site and muscle weakness. While local weakness of the injected muscle(s) is representative of the expected pharmacological action of botulinum toxin, weakness of adjacent muscles may occur as a result of the spread of toxin. These events are thought to be associated with the injection and occurred within the first week. The events were generally transient but may last several months.

The data described in Table 1 reflect exposure to **BOTOX® COSMETIC** in 405 subjects aged 18 to 75 who were evaluated in the randomized, placebo-controlled clinical studies to assess the use of **BOTOX® COSMETIC** in the improvement of the appearance of glabellar lines (See clinical studies). Adverse events of any cause were reported for 43.7% of the **BOTOX® COSMETIC** treated subjects and 41.5% of the placebo treated subjects. The incidence of blepharoptosis was higher in the **BOTOX® COSMETIC** treated arm than in placebo (3.2 % vs. 0%, p-value = 0.045). In the open-label, repeat injection study, blepharoptosis was reported for 2.1% (8/373) of subjects in the first treatment cycle and 1.2% (4/343) of subjects in the second treatment cycle. Adverse events of any type were reported for 49.1% (183/373) of subjects overall.

The most frequently reported of these adverse events in the open-label study included respiratory infection, headache, flu syndrome, blepharoptosis, pain and nausea.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not be predictive of rates observed in practice.

TABLE 1.
Randomized Double Blind Studies:
Rates of Adverse Events Reported by >2 or more Subjects in the BOTOX® Cosmetic Group, by Treatment Group.

Adverse Event (in order of decreasing frequency for BOTOX® Cosmetic)	BOTOX® Cosmetic (N=405)	Placebo (N=130)
Overall	177 (43.7%)	54 (41.5%)
Body as a Whole		
Headache	54 (13.3%)	23 (17.7%)
Pain in Face	9 (2.2%)	1 (0.8%)
Flu Syndrome	8 (2.0%)	2 (1.5%)
Pain at Injection Site	7 (1.7%)	1 (0.8%)
Edema at Injection Site	6 (1.5%)	3 (2.3%)
Pain in Back	4 (1.0%)	3 (2.3%)
Injury Accidental	3 (0.7%)	1 (0.8%)
Respiratory System		
Infection	14 (3.5%)	5 (3.8%)
Bronchitis	6 (1.5%)	1 (0.8%)
Sinusitis	6 (1.5%)	1 (0.8%)
Pharyngitis	5 (1.2%)	2 (1.5%)
Dyspnea	3 (0.7%)	0 (0.0%)
Infection Sinus	3 (0.7%)	2 (1.5%)
Laryngitis	3 (0.7%)	0 (0.0%)
Rhinitis	3 (0.7%)	2 (1.5%)
Skin and Appendages		
Erythema	7 (1.7%)	2 (1.5%)
Skin Tightness	4 (1.0%)	0 (0.0%)
Irritation Skin	3 (0.7%)	0 (0.0%)
Digestive System		
Nausea	12 (3.0%)	3 (2.3%)
Dyspepsia	4 (1.0%)	0 (0.0%)
Tooth Disorder	4 (1.0%)	0 (0.0%)
Liver Function Abnormal	3 (0.7%)	2 (1.5%)
Special Senses		
Blepharoptosis	13 (3.2%)	0 (0.0%)
Nervous System		
Dizziness	5 (1.2%)	2 (1.5%)
Paresthesia	4 (1.0%)	1 (0.8%)
Anxiety	3 (0.7%)	0 (0.0%)
Twitch	3 (0.7%)	0 (0.0%)
Musculoskeletal System		
Muscle Weakness	8 (2.0%)	0 (0.0%)
Urogenital System		
Infection Urinary Tract	4 (1.0%)	1 (0.8%)
Hemic and Lymphatic System		
Ecchymosis	7 (1.7%)	3 (2.3%)
Cardiovascular		
Hypertension	4 (1.0%)	0 (0.0%)

In published literature of the use of botulinum toxin type A for facial lines, there has been a single reported incident of diplopia, which resolved completely in three weeks. Transient ptosis, the most frequently reported complication, has been reported in the literature in approximately 5% of patients.

Immunogenicity:
Treatment with **BOTOX® COSMETIC** for cosmetic purposes may result in the formation of antibodies that may reduce the effectiveness of subsequent treatments with **BOTOX® COSMETIC** for glabellar lines or **BOTOX®** for other indications. Formation of neutralizing antibodies to botulinum toxin type A may reduce the effectiveness of **BOTOX® COSMETIC** treatment of the appearance of glabellar lines and the effectiveness of **BOTOX®** in the treatment of other clinical indications such as cervical dystonia, blepharospasm and strabismus by inactivating the biological activity of the toxin. The rate of formation of neutralizing antibodies in patients receiving **BOTOX® COSMETIC** has not been well studied.

The critical factors for neutralizing antibody formation have not been well characterized. The results from some studies of the use of **BOTOX®** in the treatment of other clinical indications suggest that **BOTOX®** injections at more frequent intervals or at higher doses may lead to greater incidence of antibody formation. The potential for antibody formation may be minimized by injecting the lowest effective dose given at the longest feasible intervals between injections.

Passive Adverse Event Surveillance:
The following adverse reactions have been identified since the drug has been marketed: skin rash (including erythema multiforme, urticaria and psoriasiform eruption), pruritus, and allergic reaction. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to botulinum toxin.

Between January 1, 1990 and August 31, 2000, there have been 7 spontaneous reports of serious adverse events documented as being related to the reported cosmetic use of **BOTOX®**, including anaphylactic reaction, myasthenia gravis, decreased hearing, ear noise and localized numbness, blurred vision and retinal vein occlusion, glaucoma, and vertigo with nystagmus.

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Expert answers to your questions about Botox® Cosmetic.

Q: What exactly is a Botox® Cosmetic treatment like?

A: Your doctor will administer a few tiny injections - a procedure that takes about ten minutes. Discomfort is minimal and brief. There is no recovery period or down time.

Q: When will I see results? How long will they last?

A: Within days you'll see a marked improvement. Results last up to four months.

Q: Will Botox® Cosmetic radically change my appearance?

A: You won't look like "you've had work done." It will smooth your frown lines and leave you looking more natural and relaxed.

Q: Is Botox® Cosmetic right for me?

A: If looking your best is important to you, Botox® Cosmetic may be for you. To find a member of the Botox® Cosmetic Physicians Network in your area, call **1-800-BotoxMD** or visit our website at **www.BotoxCosmetic.net.**

(See brief summary of information on adjacent page)

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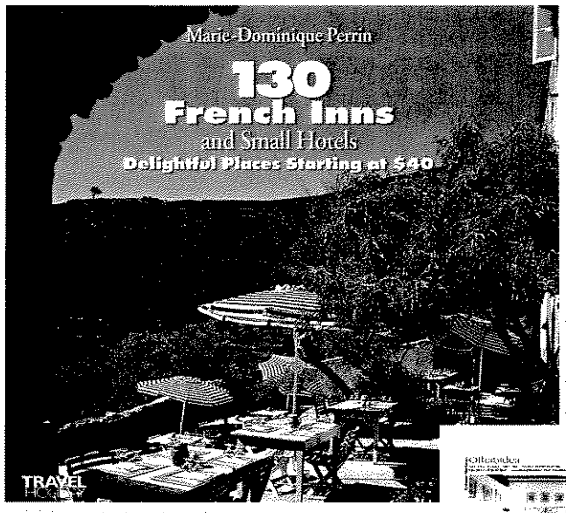
Botulinum Toxin Type A



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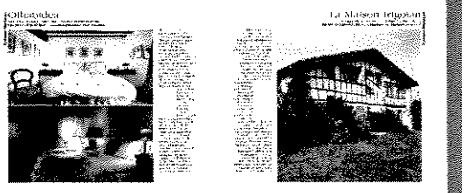

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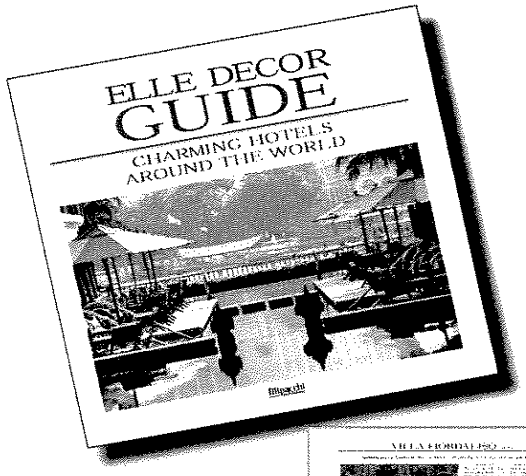

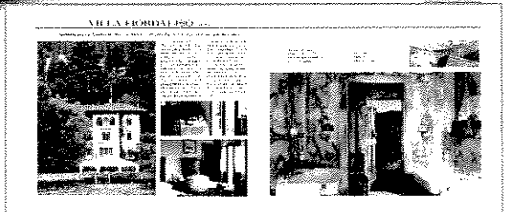

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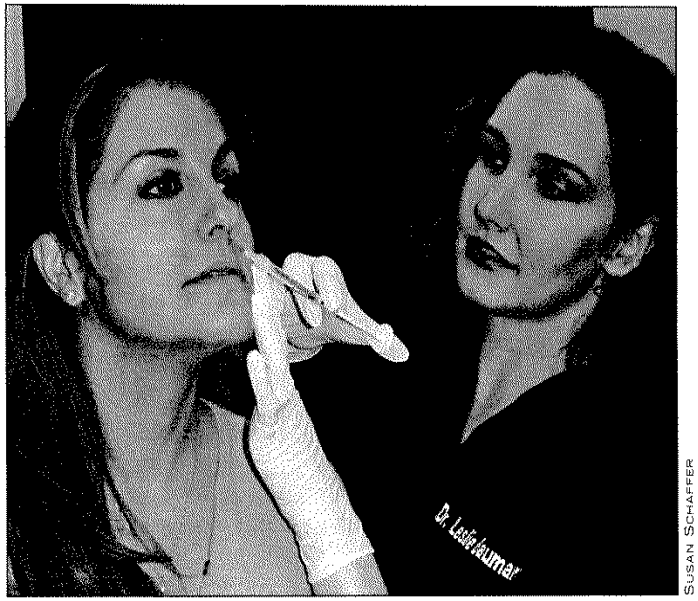
Who Will Pay for 'Procedural Dermatology'? page 5

Skin & Allergy News

VOL. 34, NO. 5 | *The Leading Independent Newspaper for the Dermatologist—Since 1970* | MAY 2003



SUSAN SCHAFFER

Dr. Leslie S. Baumann injects a patient with human-based collagen, which, in her experience, handles as well as bovine collagen.

NO SKIN TESTS REQUIRED

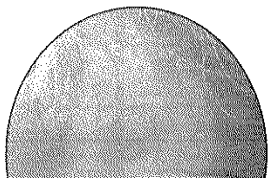
Human Collagen May Spur Switch

BY ELIZABETH MECHCATIE
Senior Writer

Two recently approved dermal for example, wrinkles or scars.

They are essentially the same products as Zyderm and Zyplast—manufactured with similar

INSIDE



AAD INITIATIVE UNVEILED

Campaign Would Protect Surgery In Derm Offices

New legislation may restrict surgery to hospitals or ambulatory surgery centers.

BY BETSY BATES
Los Angeles Bureau

SAN FRANCISCO — Dermatologists managed 82% of nearly 2 million cases of nonmelanoma skin cancer captured in Medicare claims data between 1988 and 1999, performing a wider range of surgical treatments than any other specialty, according to a study presented at the annual meeting of the American Academy of Dermatology.

The data presented by Dr. Tasha O'Connor Manternach and her associates at Wake Forest University, Winston-Salem, N.C., dovetailed with a public initiative based medical and surgical procedures in the face of political challenges.

"Dermatology is an office-based specialty. Our patients deserve the right to be treated in a safe office environment," said Dr. Ron Wheeland, who chairs the academy task force on office-based medicine.

Dr. Fred F. Castrow II, president of the AAD, stressed the need to inform members of the general public that their access to convenient, affordable care may be in jeopardy if legislation restricts surgery to hospitals or ambulatory surgery centers [illegible] providers of office-based surgery

es, the disease extends onto the buttocks and perineum and even into the anal canal, so lesions on the anal verge should prompt physicians to look in the canal as well.

Local excision should be the primary treatment for most cases of VIN III. The carbon dioxide laser works well on mucosal lesions, even on the clitoris, but is associated with scarring and prolonged healing time in hair-bearing areas.

Imiquimod cream has also produced good results in patients with lesions in mucosal areas such as the vestibule and inner labia. Dr. Kaufman recommends that patients use it three times per week, applying it at night and washing it off in the morning, for 2-3 months. ■

rector of the Hormone Center of New York in New York City.

An estimated 10% of American women, including many women with PCOS, remove hair twice a week. Still, hirsutism is frequently detectable if the clinician looks and/or inquires closely enough, he said at a gynecology symposium sponsored by Symposia Medicus.

"Some women will only mask the hair growth with bleaching or will only remove facial and neck hair and not areas

generally useful antiandrogen." Time to efficacy for acne, hirsutism, and alopecia can range from 2 to 12 months.

In patients with PCOS and acne, identifying the patient's syndrome is necessary to effectively treat the acne. "If you only treat the acne and not the underlying androgenic disorder with antiandrogens, you will not have success with the acne in a patient with PCOS," Dr. Redmond said. Acne in this population is not "trivial" and typically leaves permanent scarring. ■

CCURACY

for Group A on the Horizon

be more sensitive than antigen detection," said Dr. Cockerill, who disclosed that he did not have a conflict of interest involving the manufacturer. Results, however, may still take more than 1 day.

A second genetic test, the LightCycler assay, may also approach the accuracy of laboratory culture testing but with same-day results. The test's rapid-cycle real-time polymerase chain reaction (PCR) technology allows quick amplification of *S. pyogenes* DNA and RNA. "We'll see the day when we see point-of-care testing with real-time PCR using battery-operated units in development," Dr. Cockerill predicted.

Speed is "a very real issue. Perception from patients is that the rapid test is the alpha and omega, with results in just 20 minutes," he observed. Perception problems could be overcome if clinicians stress that a test may take longer but will be more accurate, he added.

An accurate diagnosis obviates the need for empirical treatment and the associated risk of resistance. Group A streptococcus infections cause 15%-30% of sore throats.

Improvements in testing may be coming at an opportune time. The overall sensitivity of rapid antigen tests for group A streptococcus has declined over the past few years. There is a [illegible] rapid antigen test detects about 50% of cases of infection. ■

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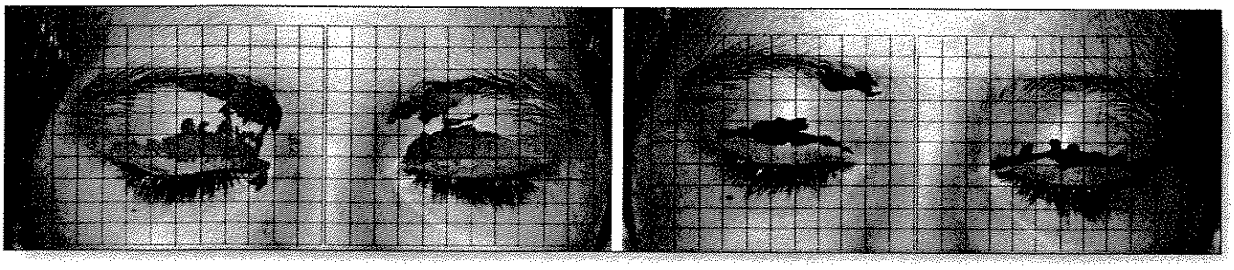

Vitiligo (extent noted in red) at the onset of the study (left) and 2 months later (right). The left eyelid was treated with tacrolimus and the right eyelid with clobetasol. See page 581.

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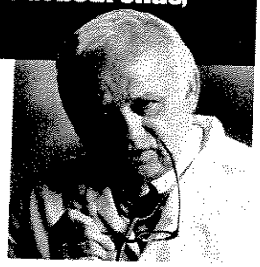
When you burn the candle at both ends, it goes out too soon



Sleep deprived Americans have a 70% higher death rate.
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* 70% higher mortality in a 9 year follow-up period for people getting 6 hours of sleep or less per night. Wingard, D.L., Berkman, L.F., Mortality risk associated with sleeping pattern, Sleep, 1983; 6(2): 102-7.

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BOTOX® —Cosmetic
Botulinum Toxin Type A

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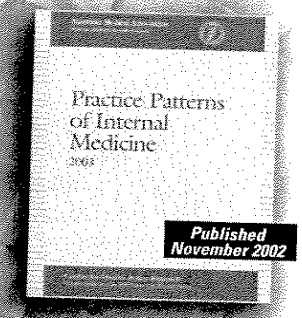
Current Socioeconomic Information

For Internal Medicine



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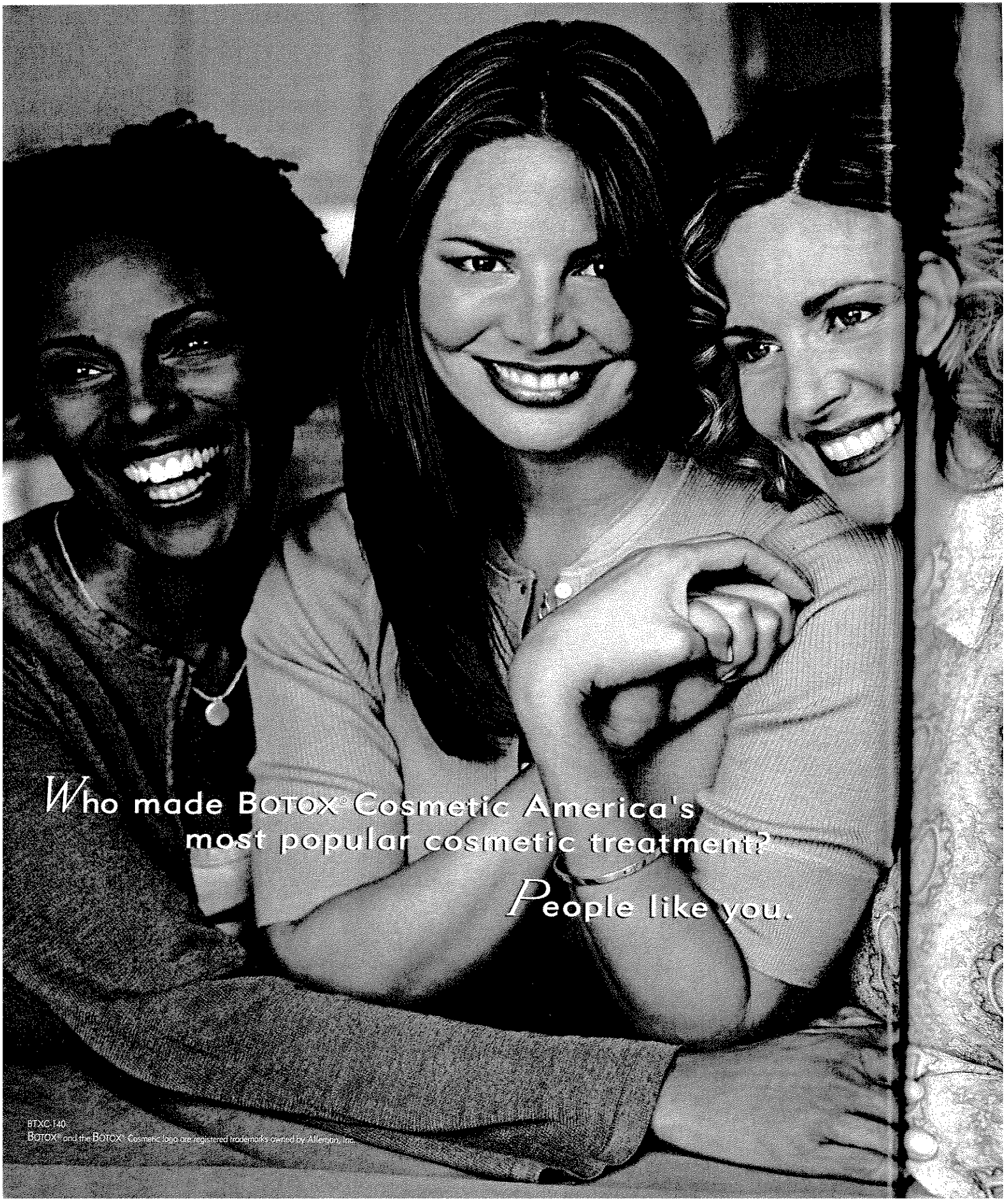

How did BOTOX® Cosmetic become America's most popular cosmetic treatment? Friends told friends. More than half a million people were wowed by BOTOX® Cosmetic in the first year alone. Let's face it, you can't keep something this good quiet for long. One ten-minute treatment – a few tiny injections – and within days, the stubborn, angry-looking frown lines between your brows dramatically relax up to four months. No surgery. No recovery.
And FDA-approved BOTOX® Cosmetic is safe and widely tested.

What exactly is BOTOX® Cosmetic?

It's a natural, purified protein which in very low doses relaxes the overactive muscles that cause frown lines to form.

Is it safe?

BOTOX®, which has been safely used to treat a variety of conditions for more than ten years, is now FDA-approved as BOTOX® Cosmetic for the temporary treatment of frown lines in people aged 18 to 65.

Where does the BOTOX® Cosmetic go?

It generally remains only in the treated muscle and gradually disappears without breaking down or traveling throughout the body.

How long does it last?

About four months, after which lines gradually revert to their pre-treatment appearance.

Will it radically change my appearance?

No. Expect a dramatic improvement in the appearance of your frown lines. Overall, you'll look more relaxed and refreshed but not like "you've had work done."

Will it make me lose expression?

No. The only expression you'll lose is the unintentional frown caused by the overactive muscles between your brows.

The most common side effects, if any occur, may include headache, respiratory infection, flu syndrome, temporary eyelid droop and nausea.

Please see important information on the following page.

It's not magic, it's

BOTOX® Cosmetic
Botulinum Toxin Type A

For a referral to a member of the BOTOX® Cosmetic Physicians Network:
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Log on to hear people talk about BOTOX® Cosmetic in their own words.

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BOTOX® COSMETIC (Botulinum Toxin Type A) Purified Neurotoxin Complex

Manufactured by: Allergan Pharmaceuticals (Ireland) Ltd.
A subsidiary of: Allergan, Inc. 2525 Dupont Dr. Irvine, California 92612

Cosmetic Indications and Usage:
BOTOX® COSMETIC is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age.

Contraindications: BOTOX® COSMETIC is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any ingredient in the formulation.

Warnings:
Do not exceed the recommended dosage and frequency of administration of **BOTOX® COSMETIC**. Risks resulting from administration at higher dosages are not known.

Caution should be exercised when administering **BOTOX® COSMETIC** to individuals with peripheral motor neuropathic diseases (e.g., amyotrophic lateral sclerosis, or motor neuropathy) or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome). Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of **BOTOX® COSMETIC**. Published medical literature has reported rare cases of administration of a botulinum toxin to patients with known or unrecognized neuromuscular disorders where the patients have shown extreme sensitivity to the systemic effects of typical clinical doses. In some of these cases, dysphagia has lasted several months and required placement of a gastric feeding tube.

Dysphagia is a commonly reported adverse event following treatment of cervical dystonia patients with all botulinum toxins. In these patients, there are reports of rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube. There is also a case report where a patient developed aspiration pneumonia and died subsequent to the finding of dysphagia.

There have also been rare reports following administration of BOTOX for other indications of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease.

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS:
General:
Epinephrine should be available or other precautionary methods taken as necessary should an anaphylactic reaction occur.

The safe and effective use of **BOTOX® COSMETIC** depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. Physicians administering **BOTOX® COSMETIC** must understand the relevant neuromuscular and/or orbital anatomy of the area involved and any alterations to the anatomy due to prior surgical procedures. Caution should be used when **BOTOX® COSMETIC** treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Reduced blinking from **BOTOX® COSMETIC** injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with VII nerve disorders. In the use of BOTOX for the treatment of blepharospasm, one case of corneal perforation in an aphakic eye requiring corneal grafting has occurred because of this effect. Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means.

Inducing paralysis in one or more extraocular muscles may produce spatial disorientation, double vision or past pointing. Covering the affected eye may alleviate these symptoms.

Caution should be used when **BOTOX® COSMETIC** treatment is used in patients who have an inflammatory skin problem at the injection site, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin or the inability to substantially lessen glabellar lines by physically spreading them apart as these patients were excluded from the Phase 3 safety and efficacy trials.

Injection intervals of **BOTOX® COSMETIC** should be no more frequent than every three months and should be performed using the lowest effective dose (See Adverse Reactions, Immunogenicity).

Information for Patients:
Patients or caregivers should be advised to seek immediate medical attention if swallowing, speech or respiratory disorders arise.

Drug Interactions:
Co-administration of **BOTOX® COSMETIC** and aminoglycosides[1] or other agents interfering with neuromuscular transmission (e.g., curare-like nondepolarizing blockers, lincosamides, polymyxins, quinidine, magnesium sulfate, anticholinesterases, succinylcholine chloride) should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Pregnancy: **Pregnancy Category C**
Administration of **BOTOX® COSMETIC** is not recommended during pregnancy. There are no adequate and well-controlled studies of **BOTOX® COSMETIC** in pregnant women. When pregnant mice and rats were injected intramuscularly during the period of organogenesis, the developmental NOEL (No Observed Effect Level) of **BOTOX® COSMETIC** was 4 U/kg. Higher doses (8 or 16 U/kg) were associated with reductions in fetal body weights and/or delayed ossification.

In a range finding study in rabbits, daily injection of 0.125 U/kg/day (days 6 to 18 of gestation) and 2 U/kg (days 6 and 13 of gestation) produced severe maternal toxicity, abortions and/or fetal malformations. Higher doses resulted in death of the dams. The rabbit appears to be a very sensitive species to **BOTOX® COSMETIC**.

If the patient becomes pregnant after the administration of this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations that have been observed in rabbits.

Carcinogenesis, Mutagenesis, Impairment of fertility:
Long term studies in animals have not been performed to evaluate carcinogenic potential of **BOTOX® COSMETIC**.

The reproductive NOEL following intramuscular injection of 0, 4, 8, and 16 U/kg was 4 U/kg in male rats and 8 U/kg in female rats. Higher doses were associated with dose-dependent reductions in fertility in male rats (where limb weakness resulted in the inability to mate), and testicular atrophy or an altered estrous cycle in female rats. There were no adverse effects on the viability of the embryos.

Nursing mothers:
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **BOTOX® COSMETIC** is administered to a nursing woman.

Pediatric use:
Use of **BOTOX® COSMETIC** is not recommended in children.

Geriatric use:
Clinical studies of **BOTOX® COSMETIC** did not include sufficient numbers of subjects aged 65 and over to determine statistically whether they respond differently from younger subjects. However, in the two identical phase 3 randomized 3:1, multi-center, double blind, placebo-controlled, parallel-group efficacy studies, the responder rates for both co-primary efficacy variables were higher for subjects ≤50 years of age compared to those subjects ≥ 65 years of age. Analysis based on a combined data set showed that, for the investigator's assessment endpoint of subjects aged 65 and over at Day 30, 39% (9/23) of subjects were responders compared to 22% (2/9) in the placebo group. This difference is neither statistically different ($P = 0.228$) nor exceeds the pre-specified 30-percentage-point difference required by the definition of clinically significant. There were no statistically significant between-group differences for the investigator's assessment at maximum frown for this age group. There was a statistically significant difference in favor of **BOTOX® COSMETIC** for the subject's global assessment at all time points ($P = 0.036$) except Day 120 ($P = 0.214$). (See Clinical Trials Section)

There were too few patients over the age of 75 to allow any meaningful comparisons. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased cardiac function and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:
General:
The most serious adverse events reported for other indications studied include rare spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility, after treatment with botulinum toxin. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease (See Warnings). The exact relationship of these events to the botulinum toxin injection has not been established. Additionally, a report of acute angle closure glaucoma one day after receiving an injection of botulinum toxin for blepharospasm was received, with recovery four months later after laser iridotomy and trabeculectomy. Focal facial paralysis, syncope and exacerbation of myasthenia gravis have also been reported after treatment of blepharospasm.

Glabellar Lines:
In clinical trials of **BOTOX® COSMETIC** the most frequently reported adverse events following injection of **BOTOX® COSMETIC** were headache, respiratory infection, flu syndrome, blepharoptosis and nausea.

Less frequently occurring (<3%) adverse reactions included pain in the face, erythema at the injection site and muscle weakness. While local weakness of the injected muscle(s) is representative of the expected pharmacological action of botulinum toxin, weakness of adjacent muscles may occur as a result of the spread of toxin. These events are thought to be associated with the injection and occurred within the first week. The events were generally transient but may last several months.

The data described in Table 1 reflect exposure to **BOTOX® COSMETIC** in 405 subjects aged 18 to 75 who were evaluated in the randomized placebo-controlled clinical studies to assess the use of **BOTOX® COSMETIC** in the improvement of the appearance of glabellar lines (See clinical studies). Adverse events of any cause were reported for 43.7% of the **BOTOX® COSMETIC** treated subjects and 41.5% of the placebo treated subjects. The incidence of blepharoptosis was higher in the **BOTOX® COSMETIC** treated arm than in placebo (3.2 % vs. 0% p-value = 0.045). In the open-label, repeat injection study, blepharoptosis was reported for 2.1% (8/373) of subjects in the first treatment cycle and 1.2% (4/343) of subjects in the second treatment cycle. Adverse events of any type were reported for 49.1% (183/373) of subjects overall.

The most frequently reported of these adverse events in the open-label study included respiratory infection, headache, flu syndrome, blepharoptosis, pain and nausea.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not be predictive of rates observed in practice.

TABLE 1.
Randomized Double Blind Studies:
Rates of Adverse Events Reported by >2 or more Subjects in the BOTOX® Cosmetic Group, by Treatment Group.

Adverse Event (in order of decreasing frequency for BOTOX® Cosmetic)	BOTOX® Cosmetic (N=405)	Placebo (N=130)
Overall	177 (43.7%)	54 (41.5%)
Body as a Whole		
Headache	54 (13.3%)	23 (17.7%)
Pain in Face	9 (2.2%)	1 (0.8%)
Flu Syndrome	8 (2.0%)	2 (1.5%)
Pain at Injection Site	7 (1.7%)	1 (0.8%)
Edema at Injection Site	6 (1.5%)	3 (2.3%)
Pain in Back	4 (1.0%)	3 (2.3%)
Injury Accidental	3 (0.7%)	1 (0.8%)
Respiratory System		
Infection	14 (3.5%)	5 (3.8%)
Bronchitis	6 (1.5%)	1 (0.8%)
Sinusitis	6 (1.5%)	1 (0.8%)
Pharyngitis	5 (1.2%)	2 (1.5%)
Dyspnea	3 (0.7%)	0 (0.0%)
Infection Sinus	3 (0.7%)	2 (1.5%)
Laryngitis	3 (0.7%)	0 (0.0%)
Rhinitis	3 (0.7%)	2 (1.5%)
Skin and Appendages		
Erythema	7 (1.7%)	2 (1.5%)
Skin Tightness	4 (1.0%)	0 (0.0%)
Irritation Skin	3 (0.7%)	0 (0.0%)
Digestive System		
Nausea	12 (3.0%)	3 (2.3%)
Dyspepsia	4 (1.0%)	0 (0.0%)
Tooth Disorder	4 (1.0%)	0 (0.0%)
Liver Function Abnormal	3 (0.7%)	2 (1.5%)
Special Senses		
Blepharoptosis	13 (3.2%)	0 (0.0%)
Nervous System		
Dizziness	5 (1.2%)	2 (1.5%)
Paresthesia	4 (1.0%)	1 (0.8%)
Anxiety	3 (0.7%)	0 (0.0%)
Twitch	3 (0.7%)	0 (0.0%)
Musculoskeletal System		
Muscle Weakness	8 (2.0%)	0 (0.0%)
Urogenital System		
Infection Urinary Tract	4 (1.0%)	1 (0.8%)
Hemic and Lymphatic System		
Ecchymosis	7 (1.7%)	3 (2.3%)
Cardiovascular		
Hypertension	4 (1.0%)	0 (0.0%)

In published literature of the use of botulinum toxin type A for facial lines, there has been a single reported incident of diplopia, which resolved completely in three weeks. Transient ptosis, the most frequently reported complication, has been reported in the literature in approximately 5% of patients.

Immunogenicity:
Treatment with **BOTOX® COSMETIC** for cosmetic purposes may result in the formation of antibodies that may reduce the effectiveness of subsequent treatments with **BOTOX® COSMETIC** for glabellar lines or **BOTOX®** for other indications. Formation of neutralizing antibodies to botulinum toxin type A may reduce the effectiveness of **BOTOX® COSMETIC** treatment of the appearance of glabellar lines and the effectiveness of **BOTOX®** in the treatment of other clinical indications such as cervical dystonia, blepharospasm and strabismus by inactivating the biological activity of the toxin. The rate of formation of neutralizing antibodies in patients receiving **BOTOX® COSMETIC** has not been well studied.

The critical factors for neutralizing antibody formation have not been well characterized. The results from some studies of the use of **BOTOX®** in the treatment of other clinical indications suggest that **BOTOX®** injections at more frequent intervals or at higher doses may lead to greater incidence of antibody formation. The potential for antibody formation may be minimized by injecting the lowest effective dose given at the longest feasible intervals between injections.

Passive Adverse Event Surveillance:
The following adverse reactions have been identified since the drug has been marketed: skin rash (including erythema multiforme, urticaria and psoriasiform eruption), pruritus, and allergic reaction. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to botulinum toxin.

Between January 1, 1990 and August 31, 2000, there have been 7 spontaneous reports of serious adverse events documented as being related to the reported cosmetic use of **BOTOX®**, including anaphylactic reaction, myasthenia gravis, decreased hearing, ear noise and localized numbness, blurred vision and retinal vein occlusion, glaucoma, and vertigo with nystagmus.

ALLERGAN

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JOURNAL OF THE AMERICAN ACADEMY OF
DERMATOLOGY

JUNE 2003 · VOLUME 48 · NUMBER 6 · INDEX ISSUE

Connections between psoriasis and Crohn's disease

David James Najarian, BS, and Alice B. Gottlieb, MD, PhD
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Botulinum toxin

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CARMOL® (10% Sulfacetamide Sodium, USP) Scalp Treatment Lotion

See package insert for full prescribing information.

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INDICATIONS AND USAGE: **CARMOL® Scalp Treatment Lotion** is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

CONTRAINDICATIONS: **CARMOL® Scalp Treatment Lotion** is contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the preparation.

WARNINGS: Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sulfacetamide sodium topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported. In one of these cases, there was a fatal outcome.

PRECAUTIONS: *General:* Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. Hypersensitivity reactions may recur when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If **CARMOL® Scalp Treatment Lotion** produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded, or severely burned areas. Under these circumstances, potentially any of the adverse effects produced by the systemic administration of these agents could occur and appropriate observations and laboratory determinations should be performed. *Information For Patients:* Patients should discontinue **CARMOL® Scalp Treatment Lotion** if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. **CARMOL® Scalp Treatment Lotion** also should be discontinued promptly and the physician notified if any arthritis, fever, or sores in the mouth develop. *Drug Interactions:* **CARMOL® Scalp Treatment Lotion** is incompatible with silver preparations. *Carcinogenesis, Mutagenesis, and Impairment of Fertility:* Long-term animal studies for carcinogenic potential have not been performed on **CARMOL® Scalp Treatment Lotion** to date. Studies on reproduction and fertility also have not been performed. One author detected chromosomal nondisjunction in the yeast, *Saccharomyces cerevisiae*, following application of sulfacetamide sodium. The significance of this finding to the topical use of sulfacetamide sodium in the human is unknown. *Pregnancy Category C:* Animal reproduction studies have not been conducted with **CARMOL® Scalp Treatment Lotion.** It also is not known whether **CARMOL® Scalp Treatment Lotion** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **CARMOL® Scalp Treatment Lotion** should be used by a pregnant woman only if clearly needed. *Nursing Mothers:* It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **CARMOL® Scalp Treatment Lotion** is administered to a nursing woman. *Pediatric Use:* Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS: Reports of irritation and hypersensitivity to sulfacetamide sodium are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sulfacetamide sodium, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome has been reported. (See **WARNINGS.**)

OVERDOSAGE: The oral LD_{50} of sulfacetamide in mice is 16.5 g/kg. In the event of overdosage, emergency treatment should be started immediately. *Manifestations:* Overdosage may cause nausea and vomiting. Large doses may cause hematuria, crystalluria, and renal shutdown due to precipitation of sulfa crystals in the renal tubules and urinary tract. *Treatment:* The patient should be induced to vomit, even if emesis has occurred spontaneously. Pharmacologic vomiting by the administration of ipecac syrup is a preferred method. However, vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of eight to twelve fluid ounces of water. If emesis does not occur within 15 minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in infants and children. Following emesis, any drug remaining in the stomach may be absorbed by activated charcoal administered as a slurry with water. If vomiting is unsuccessful or contraindicated, gastric lavage should be performed. Isotonic and one-half isotonic saline are the lavage solutions of choice. Saline cathartics, such as milk of magnesia, draw water into the bowel by osmosis and, therefore, may be valuable for their action in rapid dilution of bowel content. After emergency treatment, the patient should continue to be medically monitored.

Observe kidney function for up to 1 week and have the patient ingest copious amounts of fluid during this period. Mannitol infusions may be helpful at the first sign of oliguria. Alkalinization of the urine by ingestion of bicarbonate is very helpful in preventing crystallization of sulfa drug in the kidney.

DOSAGE AND ADMINISTRATION: *Seborrheic dermatitis including seborrhea sicca*— In mild cases involving the scalp and adjacent skin areas, including noninflammatory types with scaling (dandruff), the lotion should be applied as directed by a physician with best results occurring when applied at bedtime and allowed to remain overnight. Its application should be preceded by a shampoo if the hair and scalp are oily or greasy or if there is considerable debris. In severe cases with crusting, heavy scaling, and inflammation involving the scalp or the scalp and other skin, the lotion should be applied twice daily. Initially, the hair and scalp should be cleansed with a nonirritating shampoo, such as, **CARMOL® Deep Cleansing Antibacterial Shampoo** (10% Urea base). To ensure intimate contact of the medication with the affected skin, cleansing should be repeated as frequently as necessary thereafter.

The plastic tube is convenient for applying **CARMOL® Scalp Treatment Lotion** especially for patients with thick hair. The hair should be parted a section at a time and a small quantity of lotion squeezed on the scalp from the inverted tube. The scalp should be completely moistened and the lotion gently rubbed in with the fingertips. The hair should then be brushed thoroughly for 2 to 3 minutes. Shampooing following **CARMOL® Scalp Treatment Lotion** is not necessary, but the hair should be washed at least once a week. (Rinsing with plain water or thorough brushing will remove any excess medication.) The application of the lotion, as described, should be repeated 8 to 10 times. As the eruption subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the eruption recur after stopping therapy, the application of **CARMOL® Scalp Treatment Lotion** should be reinitiated as at the beginning of treatment.

Secondary Cutaneous Bacterial Infections — The lotion should be applied to affected areas 2 to 4 times daily until the infection has cleared.

HOW SUPPLIED: **CARMOL® Scalp Treatment Lotion** 85 g (3 oz.) NDC 10337-653-19 plastic squeeze tube, box of one or as part of a **CARMOL® Scalp Treatment Kit** NDC 10337-655-01 also containing **CARMOL® Deep Cleansing Antibacterial Shampoo** (10% Urea base) and a **CARMOL® Scalp Treatment Brush.**

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PATENT PENDING

ANNOUNCEMENT
Neoral® Pregnancy Registry for Psoriasis and Rheumatoid Arthritis

The Neoral® pregnancy registry is an ongoing, national research study to evaluate the outcomes of pregnancy in women who have psoriasis (PSO) or rheumatoid arthritis (RA) and have been treated with Neoral® (cyclosporine, USP) MODIFIED.

This registry was established with grant support from Novartis in conjunction with experts in teratology, obstetrics and gynecology, rheumatology, dermatology, and transplant surgery at Thomas Jefferson University.

The purpose of the Neoral® registry is to enroll all women with either PSO or RA who are pregnant and are taking Neoral®. With the information gathered, we hope to gain valuable knowledge so that we can better advise patients with these conditions who must take immunosuppressants during pregnancy. Patient confidentiality is strictly maintained.

If you have patients with PSO or RA who have taken Neoral® at any time during their pregnancy, you are encouraged to notify the registry, as early in the pregnancy as possible. To obtain more information and/or to register patients, please contact the registry at: 1-888-522-5581 or email: neoral.registry@mail.tju.edu website: http://www.jeffersonhealth.org/tjuh/neoralregistry.

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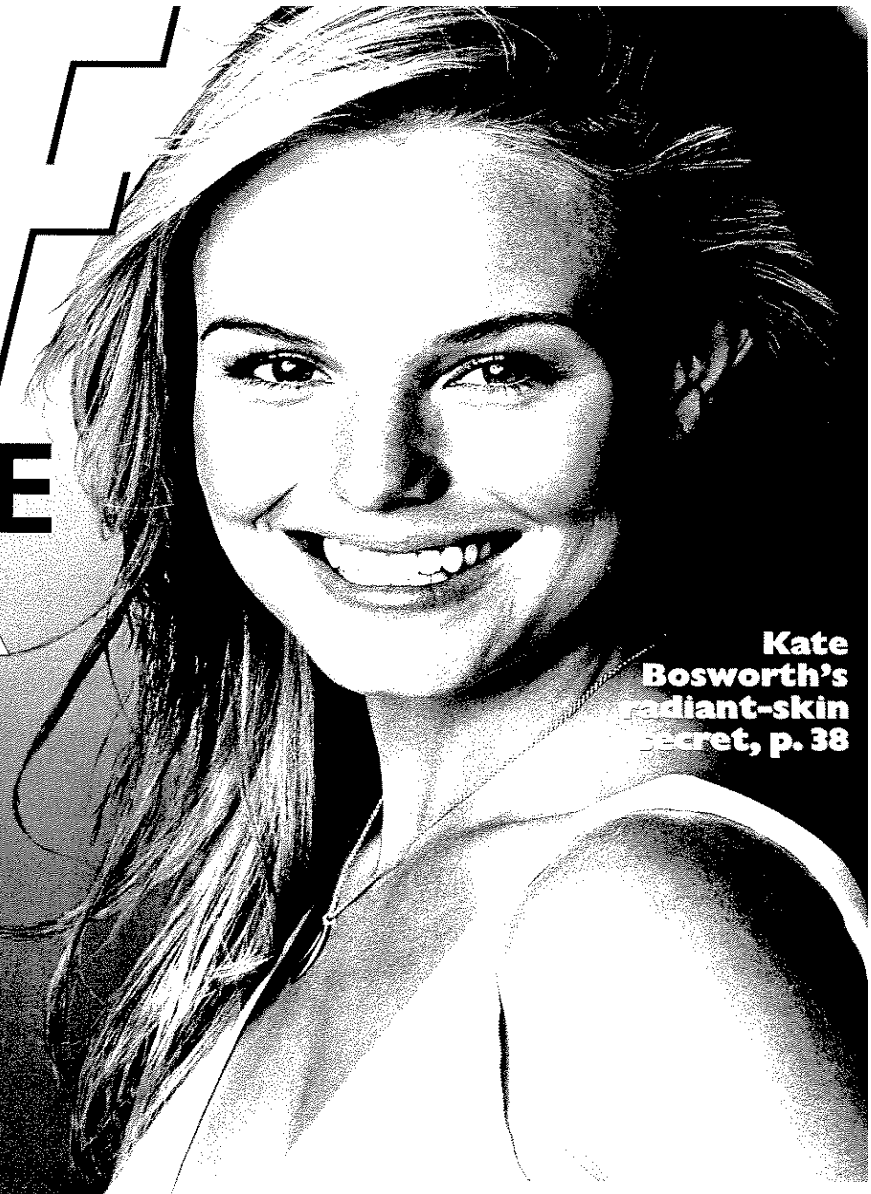

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How did BOTOX® Cosmetic become America's most popular cosmetic treatment? Friends told friends. Wives told husbands. More than half a million people were wowed by BOTOX® Cosmetic in the last year alone. One ten-minute treatment – a few tiny injections – and within days, the stubborn, angry-looking frown lines between your brows dramatically relax up to four months. No surgery. No recovery. And FDA-approved BOTOX® Cosmetic is safe and widely tested.

What exactly is BOTOX® Cosmetic?

It's a natural, purified protein which in very low doses relaxes the overactive muscles that cause frown lines to form.

Is it safe?

BOTOX®, which has been safely used to treat a variety of conditions for more than ten years, is now FDA-approved as BOTOX® Cosmetic for the temporary treatment of frown lines in people aged 18 to 65.

Where does the BOTOX® Cosmetic go?

It generally remains only in the treated muscle and gradually disappears without breaking down or traveling throughout the body.

How long does it last?

About four months, after which lines gradually revert to their pre-treatment appearance.

Will it radically change my appearance?

No. Expect a dramatic improvement in the appearance of your frown lines. Overall, you'll look more relaxed and refreshed but not like "you've had work done."

Will it make me lose expression?

No. The only expression you'll lose is the unintentional frown caused by the overactive muscles between your brows.

The most common side effects, if any occur, may include headache, respiratory infection, flu syndrome, temporary eyelid droop and nausea.

Please see important information on the following page.

It's not magic, it's

BOTOX® Cosmetic
Botulinum Toxin Type A

For a referral to a member of the BOTOX® Cosmetic Physicians Network:
1-800-BOTOXMD • www.BOTOXCosmetic.com
Log on to hear people talk about BOTOX® Cosmetic in their own words.

AGN002733

BOTOX® COSMETIC (Botulinum Toxin Type A) Purified Neurotoxin Complex

Manufactured by: Allergan Pharmaceuticals (Ireland) Ltd.
A subsidiary of: Allergan, Inc. 2525 Dupont Dr. Irvine, California 92612

Cosmetic Indications and Usage:
BOTOX® COSMETIC is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age.

Contraindications: BOTOX® COSMETIC is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any ingredient in the formulation.

Warnings:
Do not exceed the recommended dosage and frequency of administration of **BOTOX® COSMETIC**. Risks resulting from administration at higher dosages are not known.

Caution should be exercised when administering **BOTOX® COSMETIC** to individuals with peripheral motor neuropathic diseases (e.g., amyotrophic lateral sclerosis, or motor neuropathy) or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome). Patients with neuromuscular disorders may be at increased risk of clinically significant systemic effects including severe dysphagia and respiratory compromise from typical doses of **BOTOX® COSMETIC**. Published medical literature has reported rare cases of administration of a botulinum toxin to patients with known or unrecognized neuromuscular disorders where the patients have shown extreme sensitivity to the systemic effects of typical clinical doses. In some of these cases, dysphagia has lasted several months and required placement of a gastric feeding tube.

Dysphagia is a commonly reported adverse event following treatment of cervical dystonia patients with all botulinum toxins. In these patients, there are reports of rare cases of dysphagia severe enough to warrant the insertion of a gastric feeding tube. There is also a case report where a patient developed aspiration pneumonia and died subsequent to the finding of dysphagia.

There have also been rare reports following administration of BOTOX for other indications of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease.

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS:
General:
Epinephrine should be available or other precautionary methods taken as necessary should an anaphylactic reaction occur.

The safe and effective use of **BOTOX® COSMETIC** depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. Physicians administering **BOTOX® COSMETIC** must understand the relevant neuromuscular and/or orbital anatomy of the area involved and any alterations to the anatomy due to prior surgical procedures. Caution should be used when **BOTOX® COSMETIC** treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Reduced blinking from **BOTOX® COSMETIC** injection of the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with VII nerve disorders. In the use of BOTOX for the treatment of blepharospasm, one case of corneal perforation in an aphakic eye requiring corneal grafting has occurred because of this effect. Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means.

Inducing paralysis in one or more extraocular muscles may produce spatial disorientation, double vision or past pointing. Covering the affected eye may alleviate these symptoms.

Caution should be used when **BOTOX® COSMETIC** treatment is used in patients who have an inflammatory skin problem at the injection site, marked facial asymmetry, ptosis, excessive dermatochalasis, deep dermal scarring, thick sebaceous skin or the inability to substantially lessen glabellar lines by physically spreading them apart as these patients were excluded from the Phase 3 safety and efficacy trials.

Injection intervals of **BOTOX® COSMETIC** should be no more frequent than every three months and should be performed using the lowest effective dose (See Adverse Reactions, Immunogenicity).

Information for Patients:
Patients or caregivers should be advised to seek immediate medical attention if swallowing, speech or respiratory disorders arise.

Drug Interactions:
Co-administration of **BOTOX® COSMETIC** and aminoglycosides† or other agents interfering with neuromuscular transmission (e.g., curare-like nondepolarizing blockers, lincosamides, polymyxins, quinidine, magnesium sulfate, anticholinesterases, succinylcholine chloride ‡ should only be performed with caution as the effect of the toxin may be potentiated.

The effect of administering different botulinum neurotoxin serotypes at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Pregnancy: **Pregnancy Category C**
Administration of **BOTOX® COSMETIC** is not recommended during pregnancy. There are no adequate and well-controlled studies of **BOTOX® COSMETIC** in pregnant women. When pregnant mice and rats were injected intramuscularly during the period of organogenesis, the developmental NOEL (No Observed Effect Level) of **BOTOX® COSMETIC** was 4 U/kg. Higher doses (8 or 16 U/kg) were associated with reductions in fetal body weights and/or delayed ossification.

In a range finding study in rabbits, daily injection of 0.125 U/kg/day (days 6 to 18 of gestation) and 2 U/kg (days 6 and 13 of gestation) produced severe maternal toxicity, abortions and/or fetal malformations. Higher doses resulted in death of the dams. The rabbit appears to be a very sensitive species to **BOTOX® COSMETIC**.

If the patient becomes pregnant after the administration of this drug, the patient should be apprised of the potential risks, including abortion or fetal malformations that have been observed in rabbits.

Carcinogenesis, Mutagenesis, Impairment of fertility:
Long term studies in animals have not been performed to evaluate carcinogenic potential of **BOTOX® COSMETIC**.

The reproductive NOEL following intramuscular injection of 0, 4, 8, and 16 U/kg was 4 U/kg in male rats and 8 U/kg in female rats. Higher doses were associated with dose-dependent reductions in fertility in male rats (where limb weakness resulted in the inability to mate), and testicular atrophy or an altered estrous cycle in female rats. There were no adverse effects on the viability of the embryos.

Nursing mothers:
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **BOTOX® COSMETIC** is administered to a nursing woman.

Pediatric use:
Use of **BOTOX® COSMETIC** is not recommended in children.

Geriatric use:
Clinical studies of **BOTOX® COSMETIC** did not include sufficient numbers of subjects aged 65 and over to determine statistically whether they respond differently from younger subjects. However, in the two identical phase 3 randomized 3:1, multi-center, double blind, placebo-controlled, parallel-group efficacy studies, the responder rates for both co-primary efficacy variables were higher for subjects ≤ 50 years of age compared to those subjects ≥ 65 years of age. Analysis based on a combined data set showed that, for the investigator's assessment endpoint of subjects aged 65 and over at Day 30, 39% (9/23) of subjects were responders compared to 22% (2/9) in the placebo group. This difference is neither statistically different ($P = 0.226$) nor exceeds the pre-specified 30-percentage-point difference required by the definition of clinically significant. There were no statistically significant between-group differences for the investigator's assessment at maximum frown for this age group. There was a statistically significant difference in favor of **BOTOX® COSMETIC** for the subject's global assessment at all time points ($P = 0.036$) except Day 120 ($P = 0.214$). (See Clinical Trials Section)

There were too few patients over the age of 75 to allow any meaningful comparisons. in general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased cardiac function and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:
General:
The most serious adverse events reported for other indications studied include rare spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility, after treatment with botulinum toxin. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease (See Warnings). The exact relationship of these events to the botulinum toxin injection has not been established. Additionally, a report of acute angle closure glaucoma one day after receiving an injection of botulinum toxin for blepharospasm was received, with recovery four months later after laser iridotomy and trabeculectomy. Focal facial paralysis, syncope and exacerbation of myasthenia gravis have also been reported after treatment of blepharospasm.

Glabellar Lines:
In clinical trials of **BOTOX® COSMETIC** the most frequently reported adverse events following injection of **BOTOX® COSMETIC** were headache, respiratory infection, flu syndrome, blepharoptosis and nausea.

Less frequently occurring (<3%) adverse reactions included pain in the face, erythema at the injection site and muscle weakness. While local weakness of the injected muscle(s) is representative of the expected pharmacological action of botulinum toxin, weakness of adjacent muscles may occur as a result of the spread of toxin. These events are thought to be associated with the injection and occurred within the first week. The events were generally transient but may last several months.

The data described in Table 1 reflect exposure to **BOTOX® COSMETIC** in 405 subjects aged 18 to 75 who were evaluated in the randomized, placebo-controlled clinical studies to assess the use of **BOTOX® COSMETIC** in the improvement of the appearance of glabellar lines (See clinical studies). Adverse events of any cause were reported for 43.7% of the **BOTOX® COSMETIC** treated subjects and 41.5% of the placebo treated subjects. The incidence of blepharoptosis was higher in the **BOTOX® COSMETIC** treated arm than in placebo (3.2 % vs. 0%, p-value = 0.045). In the open-label, repeat injection study, blepharoptosis was reported for 2.1% (8/373) of subjects in the first treatment cycle and 1.2% (4/343) of subjects in the second treatment cycle. Adverse events of any type were reported for 49.1% (183/373) of subjects overall.

The most frequently reported of these adverse events in the open-label study included respiratory infection, headache, flu syndrome, blepharoptosis, pain and nausea.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not be predictive of rates observed in practice.

TABLE 1.
Randomized Double Blind Studies:
Rates of Adverse Events Reported by >2 or more Subjects in the BOTOX® Cosmetic Group, by Treatment Group.

Adverse Event (in order of decreasing frequency for BOTOX® Cosmetic)	BOTOX® Cosmetic (N=405)	Placebo (N=130)
Overall	177 (43.7%)	54 (41.5%)
Body as a Whole		
Headache	54 (13.3%)	23 (17.7%)
Pain in Face	9 (2.2%)	1 (0.8%)
Flu Syndrome	8 (2.0%)	2 (1.5%)
Pain at Injection Site	7 (1.7%)	1 (0.8%)
Edema at Injection Site	6 (1.5%)	3 (2.3%)
Pain in Back	4 (1.0%)	3 (2.3%)
Injury Accidental	3 (0.7%)	1 (0.8%)
Respiratory System		
Infection	14 (3.5%)	5 (3.8%)
Bronchitis	6 (1.5%)	1 (0.8%)
Sinusitis	6 (1.5%)	1 (0.8%)
Pharyngitis	5 (1.2%)	2 (1.5%)
Dyspnea	3 (0.7%)	0 (0.0%)
Infection Sinus	3 (0.7%)	2 (1.5%)
Laryngitis	3 (0.7%)	0 (0.0%)
Rhinitis	3 (0.7%)	2 (1.5%)
Skin and Appendages		
Erythema	7 (1.7%)	2 (1.5%)
Skin Tightness	4 (1.0%)	0 (0.0%)
Irritation Skin	3 (0.7%)	0 (0.0%)
Digestive System		
Nausea	12 (3.0%)	3 (2.3%)
Dyspepsia	4 (1.0%)	0 (0.0%)
Tooth Disorder	4 (1.0%)	0 (0.0%)
Liver Function Abnormal	3 (0.7%)	2 (1.5%)
Special Senses		
Blepharoptosis	13 (3.2%)	0 (0.0%)
Nervous System		
Dizziness	5 (1.2%)	2 (1.5%)
Paresthesia	4 (1.0%)	1 (0.8%)
Anxiety	3 (0.7%)	0 (0.0%)
Twitch	3 (0.7%)	0 (0.0%)
Musculoskeletal System		
Muscle Weakness	8 (2.0%)	0 (0.0%)
Urogenital System		
Infection Urinary Tract	4 (1.0%)	1 (0.8%)
Hemic and Lymphatic System		
Ecchymosis	7 (1.7%)	3 (2.3%)
Cardiovascular		
Hypertension	4 (1.0%)	0 (0.0%)

In published literature of the use of botulinum toxin type A for facial lines, there has been a single reported incident of diplopia, which resolved completely in three weeks. Transient ptosis, the most frequently reported complication, has been reported in the literature in approximately 5% of patients.

Immunogenicity:
Treatment with **BOTOX® COSMETIC** for cosmetic purposes may result in the formation of antibodies that may reduce the effectiveness of subsequent treatments with **BOTOX® COSMETIC** for glabellar lines or **BOTOX®** for other indications. Formation of neutralizing antibodies to botulinum toxin type A may reduce the effectiveness of **BOTOX® COSMETIC** treatment of the appearance of glabellar lines and the effectiveness of **BOTOX®** in the treatment of other clinical indications such as cervical dystonia, blepharospasm and strabismus by inactivating the biological activity of the toxin. The rate of formation of neutralizing antibodies in patients receiving **BOTOX® COSMETIC** has not been well studied.

The critical factors for neutralizing antibody formation have not been well characterized. The results from some studies of the use of **BOTOX®** in the treatment of other clinical indications suggest that **BOTOX®** injections at more frequent intervals or at higher doses may lead to greater incidence of antibody formation. The potential for antibody formation may be minimized by injecting the lowest effective dose given at the longest feasible intervals between injections.

Passive Adverse Event Surveillance:
The following adverse reactions have been identified since the drug has been marketed: skin rash (including erythema multiforme, urticaria and psoriasiform eruption), pruritus, and allergic reaction. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to botulinum toxin.

Between January 1, 1990 and August 31, 2000, there have been 7 spontaneous reports of serious adverse events documented as being related to the reported cosmetic use of **BOTOX®**, including anaphylactic reaction, myasthenia gravis, decreased hearing, ear noise and localized numbness, blurred vision and retinal vein occlusion, glaucoma, and vertigo with nystagmus.

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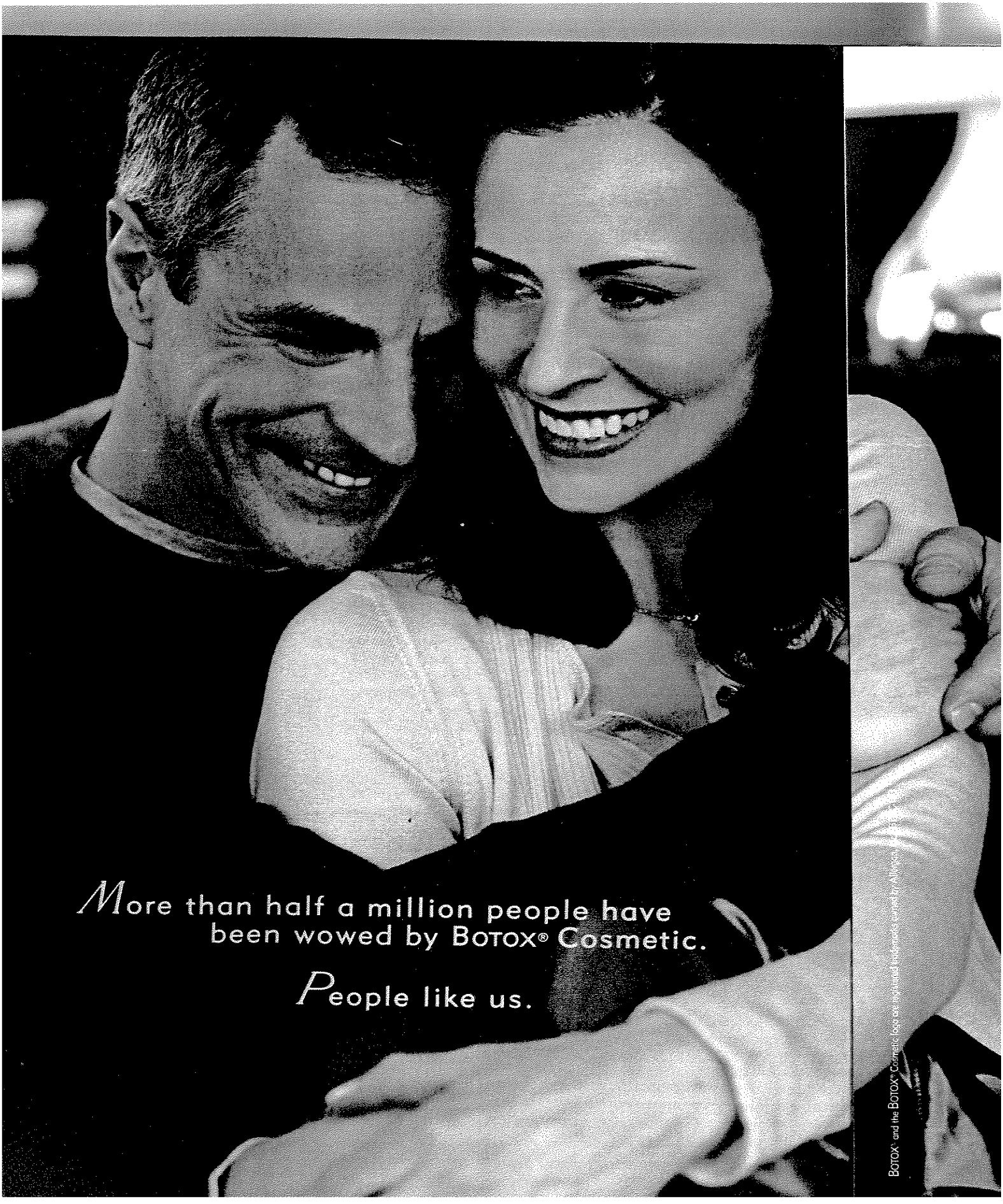
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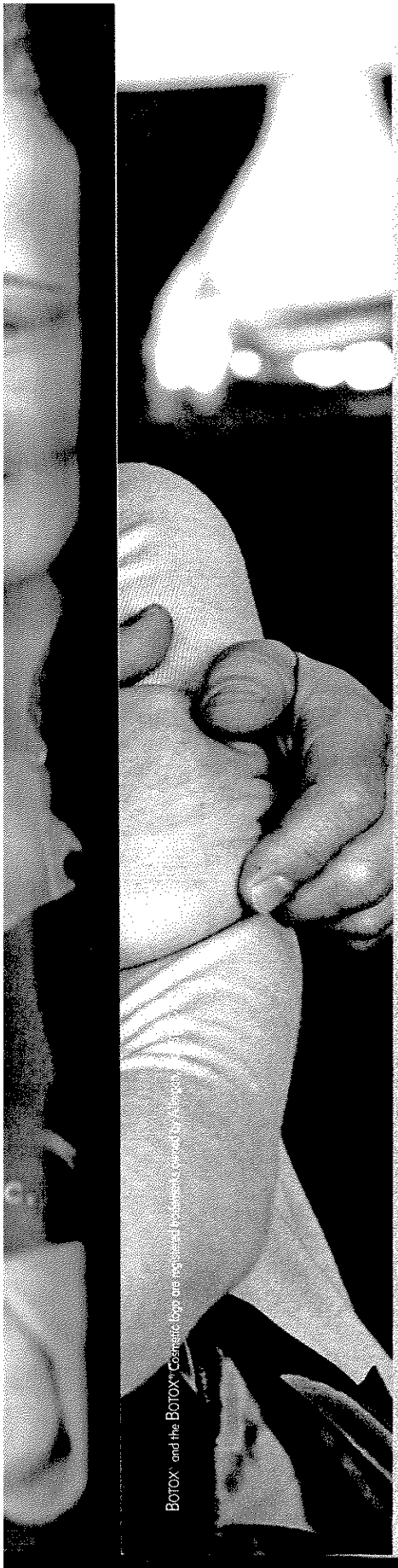

You've probably heard about BOTOX® Cosmetic.

You may even be considering it.

To help you decide if it's for you, talk to your doctor.

Visit BOTOXCosmetic.com for the
answers to the questions you've been wondering about.

We'll even help you find an experienced doctor in your area.
Haven't you waited long enough?

It's not magic, it's BOTOX® Cosmetic.

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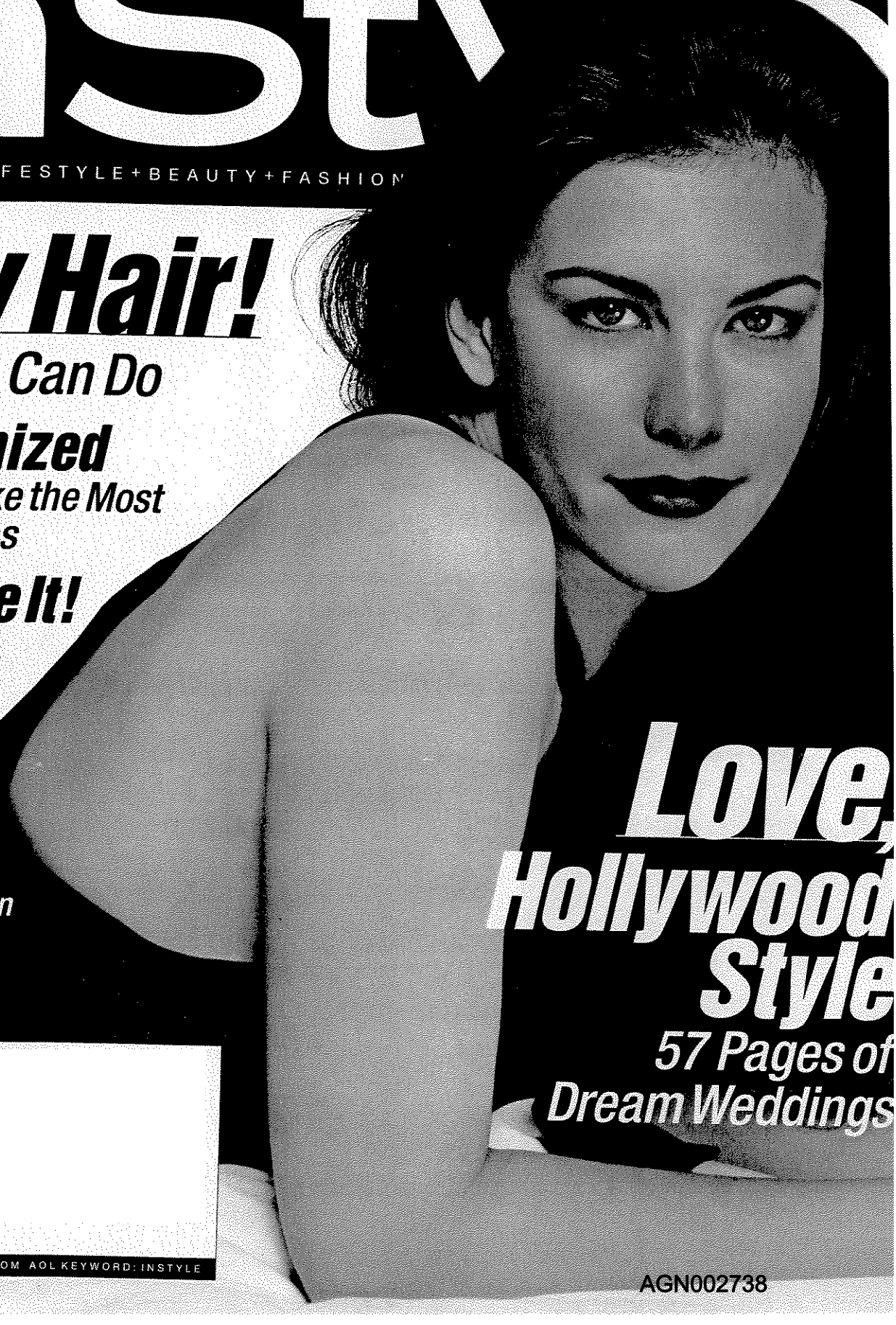

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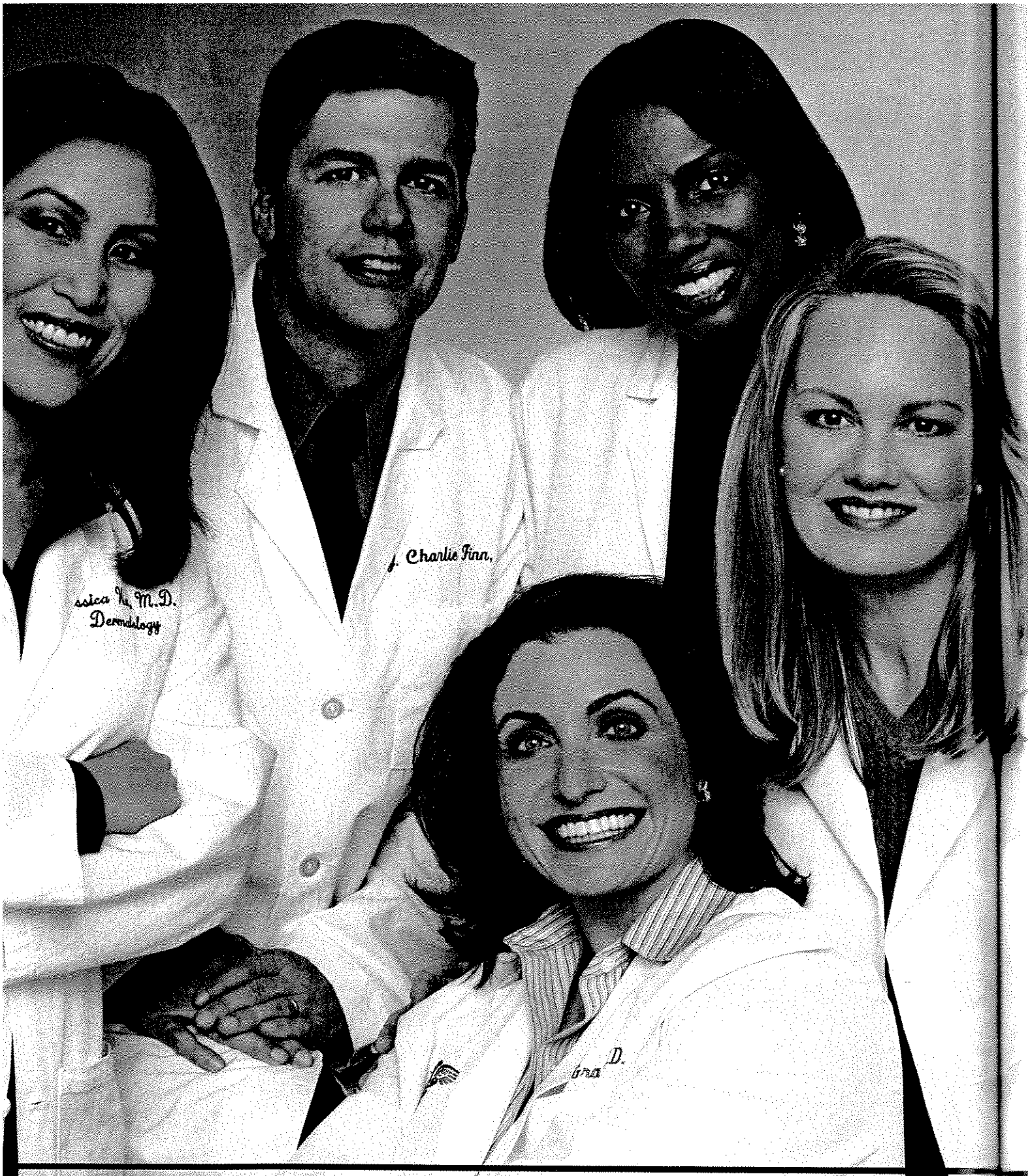

L to R:
Dr. Jessica Wu, Dermatologist; Dr. Charlie Finn, Plastic Surgeon; Dr. Jeannette Graf, Dermatologist; Dr. Cheryl Burgess, Dermatologist; Dr. Joan Kaestner, Ophthalmologist

We don't just recommend BOTOX® Cosmetic. *We use it ourselves.*

In fact, more women dermatologists now use BOTOX® Cosmetic themselves than any other physician-administered cosmetic treatment.

They've read the research and treated thousands of patients. More than half have actually used it themselves. So they know firsthand how effective BOTOX® Cosmetic is. It's the only treatment approved by the FDA for the temporary reduction of moderate to severe frown lines between the brows in patients 18 to 65 years of age.

Proven. Simple. Effective.

So far, more than a million people have been treated since FDA approval in 2002. Ten minutes – a few tiny injections – and within days there's a noticeable improvement. There's no recovery or downtime. You can even do it on your lunch break. And results last up to four months.

Get the inside story.

Call 800-BOTOXMD or visit BOTOXCosmetic.com to find an experienced doctor in your area. Tour the website to watch the procedure being administered, see before and after pictures, and hear directly from people just like you.

The most common side effects include headache, respiratory infection, flu syndrome, temporary eyelid droop, and nausea. Patients who suffer from neurological disorders may be at increased risk of significant side effects. Prescription only. Please see important information on the following page.

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BOTOX® Cosmetic
Botulinum Toxin Type A

The more you know, the better it looks.

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BOTOX® COSMETIC (Botulinum Toxin Type A) Purified Neurotoxin Complex

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A subsidiary of: Allergan, Inc. 2525 Dupont Dr. Irvine, California 92612

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Clinical studies of **BOTOX® COSMETIC** did not include sufficient numbers of subjects aged 65 and over to determine statistically whether they respond differently from younger subjects. However, in the two identical phase 3 randomized 3:1, multi-center, double blind, placebo-controlled, parallel-group efficacy studies, the responder rates for both co-primary efficacy variables were higher for subjects ≤50 years of age compared to those subjects ≥ 65 years of age. Analysis based on a combined data set showed that, for the investigator's assessment endpoint of subjects aged 65 and over at Day 30, 39% (9/23) of subjects were responders compared to 22% (2/9) in the placebo group. This difference is neither statistically different ($P = 0.226$) nor exceeds the pre-specified 30-percentage-point difference required by the definition of clinically significant. There were no statistically significant between-group differences for the investigator's assessment at maximum frown for this age group. There was a statistically significant difference in favor of **BOTOX® COSMETIC** for the subject's global assessment at all time points ($P = 0.036$) except Day 120 ($P = 0.214$).
(See Clinical Trials Section)

There were too few patients over the age of 75 to allow any meaningful comparisons. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased cardiac function and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:
General:
The most serious adverse events reported for other indications studied include rare spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility, after treatment with botulinum toxin. There have also been rare reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease (See Warnings). The exact relationship of these events to the botulinum toxin injection has not been established. Additionally, a report of acute angle closure glaucoma one day after receiving an injection of botulinum toxin for blepharospasm was received, with recovery four months later after laser iridotomy and trabeculectomy. Focal facial paralysis, syncope and exacerbation of myasthenia gravis have also been reported after treatment of blepharospasm.

Glabellar Lines:
In clinical trials of **BOTOX® COSMETIC** the most frequently reported adverse events following injection of **BOTOX® COSMETIC** were headache, respiratory infection, flu syndrome, blepharoptosis and nausea.

Less frequently occurring (<3%) adverse reactions included pain in the face, erythema at the injection site and muscle weakness. While local weakness of the injected muscle(s) is representative of the expected pharmacological action of botulinum toxin, weakness of adjacent muscles may occur as a result of the spread of toxin. These events are thought to be associated with the injection and occurred within the first week. The events were generally transient but may last several months.

The data described in Table 1 reflect exposure to **BOTOX® COSMETIC** in 405 subjects aged 18 to 75 who were evaluated in the randomized, placebo-controlled clinical studies to assess the use of **BOTOX® COSMETIC** in the improvement of the appearance of glabellar lines (See clinical studies). Adverse events of any cause were reported for 43.7% of the **BOTOX® COSMETIC** treated subjects and 41.5% of the placebo treated subjects. The incidence of blepharoptosis was higher in the **BOTOX® COSMETIC** treated arm than in placebo (3.2 % vs. 0%, p-value = 0.045). In the open-label, repeat injection study, blepharoptosis was reported for 2.1% (8/373) of subjects in the first treatment cycle and 1.2% (4/343) of subjects in the second treatment cycle. Adverse events of any type were reported for 49.1% (183/373) of subjects overall.

The most frequently reported of these adverse events in the open-label study included respiratory infection, headache, flu syndrome, blepharoptosis, pain and nausea.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not be predictive of rates observed in practice.

TABLE 1.
Randomized Double Blind Studies:
Rates of Adverse Events Reported by >2 or more Subjects in the BOTOX® Cosmetic Group, by Treatment Group.

Adverse Event (in order of decreasing frequency for BOTOX® Cosmetic)	BOTOX® Cosmetic (N=405)	Placebo (N=130)
Overall	177 (43.7%)	54 (41.5%)
Body as a Whole		
Headache	54 (13.3%)	23 (17.7%)
Pain in Face	9 (2.2%)	1 (0.8%)
Flu Syndrome	8 (2.0%)	2 (1.5%)
Pain at Injection Site	7 (1.7%)	1 (0.8%)
Edema at Injection Site	6 (1.5%)	3 (2.3%)
Pain in Back	4 (1.0%)	3 (2.3%)
Injury Accidental	3 (0.7%)	1 (0.8%)
Respiratory System		
Infection	14 (3.5%)	5 (3.8%)
Bronchitis	6 (1.5%)	1 (0.8%)
Sinusitis	6 (1.5%)	1 (0.8%)
Pharyngitis	5 (1.2%)	2 (1.5%)
Dyspnea	3 (0.7%)	0 (0.0%)
Infection Sinus	3 (0.7%)	2 (1.5%)
Laryngitis	3 (0.7%)	0 (0.0%)
Rhinitis	3 (0.7%)	2 (1.5%)
Skin and Appendages		
Erythema	7 (1.7%)	2 (1.5%)
Skin Tightness	4 (1.0%)	0 (0.0%)
Irritation Skin	3 (0.7%)	0 (0.0%)
Digestive System		
Nausea	12 (3.0%)	3 (2.3%)
Dyspepsia	4 (1.0%)	0 (0.0%)
Tooth Disorder	4 (1.0%)	0 (0.0%)
Liver Function Abnormal	3 (0.7%)	2 (1.5%)
Special Senses		
Blepharoptosis	13 (3.2%)	0 (0.0%)
Nervous System		
Dizziness	5 (1.2%)	2 (1.5%)
Paresthesia	4 (1.0%)	1 (0.8%)
Anxiety	3 (0.7%)	0 (0.0%)
Twitch	3 (0.7%)	0 (0.0%)
Musculoskeletal System		
Muscle Weakness	8 (2.0%)	0 (0.0%)
Urogenital System		
Infection Urinary Tract	4 (1.0%)	1 (0.8%)
Hemic and Lymphatic System		
Ecchymosis	7 (1.7%)	3 (2.3%)
Cardiovascular		
Hypertension	4 (1.0%)	0 (0.0%)

In published literature of the use of botulinum toxin type A for facial lines, there has been a single reported incident of diplopia, which resolved completely in three weeks. Transient ptosis, the most frequently reported complication, has been reported in the literature in approximately 5% of patients.

Immunogenicity:
Treatment with **BOTOX® COSMETIC** for cosmetic purposes may result in the formation of antibodies that may reduce the effectiveness of subsequent treatments with **BOTOX® COSMETIC** for glabellar lines or **BOTOX®** for other indications. Formation of neutralizing antibodies to botulinum toxin type A may reduce the effectiveness of **BOTOX® COSMETIC** treatment of the appearance of glabellar lines and the effectiveness of **BOTOX®** in the treatment of other clinical indications such as cervical dystonia, blepharospasm and strabismus by inactivating the biological activity of the toxin. The rate of formation of neutralizing antibodies in patients receiving **BOTOX® COSMETIC** has not been well studied.

The critical factors for neutralizing antibody formation have not been well characterized. The results from some studies of the use of **BOTOX®** in the treatment of other clinical indications suggest that **BOTOX®** injections at more frequent intervals or at higher doses may lead to greater incidence of antibody formation. The potential for antibody formation may be minimized by injecting the lowest effective dose given at the longest feasible intervals between injections.

Passive Adverse Event Surveillance:
The following adverse reactions have been identified since the drug has been marketed: skin rash (including erythema multiforme, urticaria and psoriasiform eruption), pruritus, and allergic reaction. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to botulinum toxin.

Between January 1, 1990 and August 31, 2000, there have been 7 spontaneous reports of serious adverse events documented as being related to the reported cosmetic use of **BOTOX®**, including anaphylactic reaction, myasthenia gravis, decreased hearing, ear noise and localized numbness, blurred vision and retinal vein occlusion, glaucoma, and vertigo with nystagmus.

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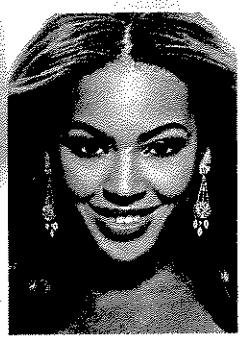
SPECIAL DOUBLE ISSUE

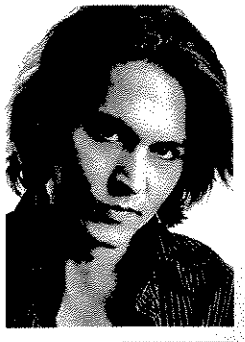
People

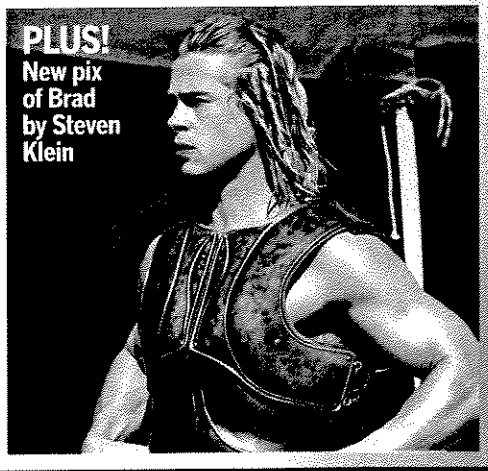
PAT TILLMAN
Honoring a Hero

50 MOST BEAUTIFUL PEOPLE

JENNIFER ANISTON







PLUS!
New pix of Brad by Steven Klein

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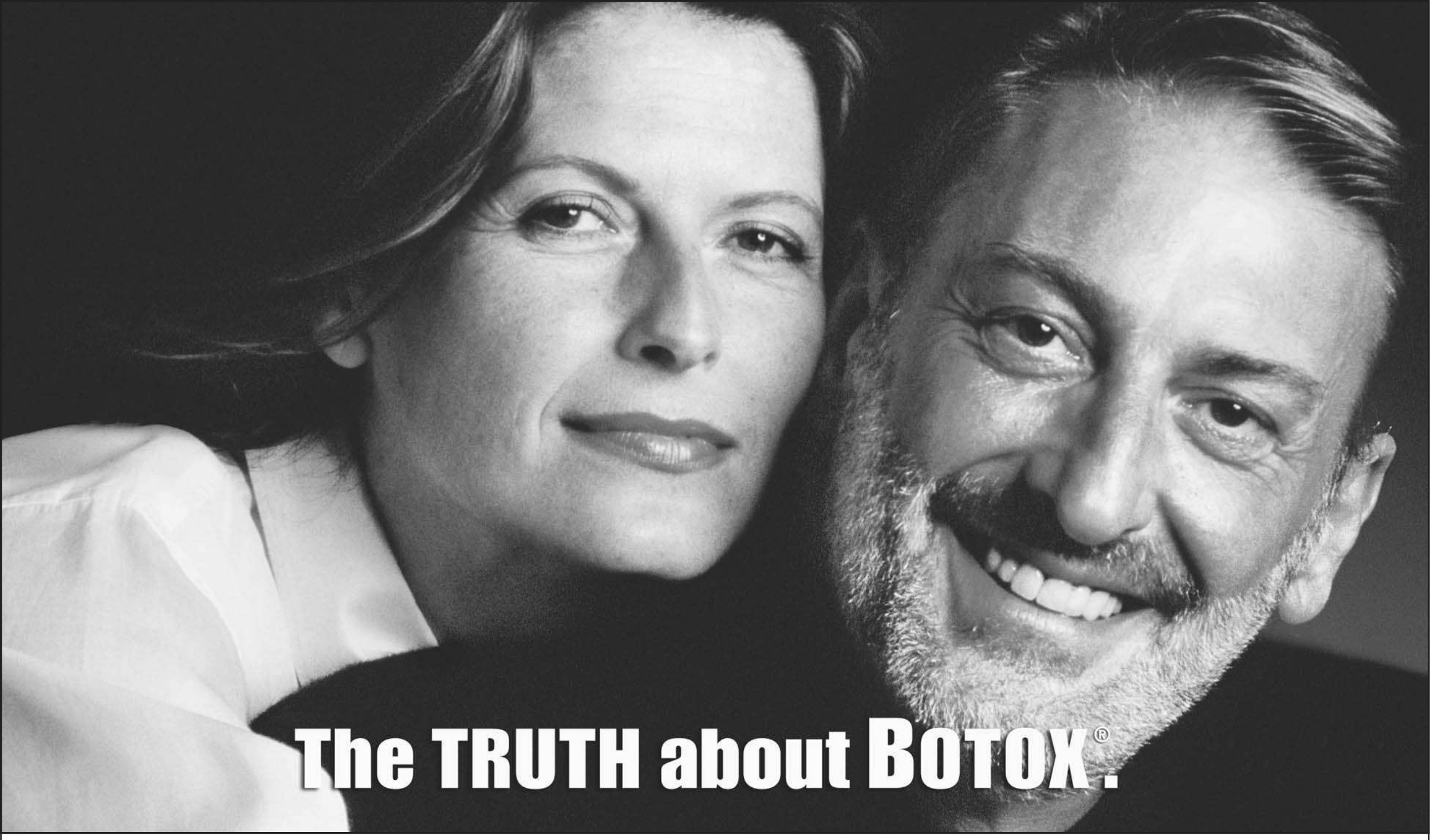
HAIR: LAWRENCE DEPALMA @ STOCKLAND MARTEL. MAKEUP: BILLY B FOR STREETERS. STYLIST: NIMA CHANDLER FOR JAM ARTS. TOP BY DIESEL; SHIRT BY CHANEL; NECKLACE BY M2. LOCATION: JERRY'S RESTAURANT, SOHO. BOTTOM: TIME LIFE PICTURES/GETTY IMAGES

AGN002743



BOTOX® has been safely used millions of times to treat millions of people.

And not just for cosmetic purposes. Since its FDA-approval in 1989, the therapeutic use of BOTOX® has quietly brought welcome relief to patients suffering from certain life-altering conditions. Without fanfare or headlines.

That's why Allergan, the maker of BOTOX®, wants you to know the whole story.

BOTOX® is safe and we can prove it

Widely tested over two decades, BOTOX® has one of the most proven safety profiles in the pharmaceutical industry. Side effects are typically temporary, localized to the treatment site and depend upon the condition being treated.

BOTOX® is a natural purified protein

BOTOX® is derived from bacteria, in much the same way penicillin is derived from mold. It is manufactured under strict quality control standards by Allergan and is administered in extremely dilute dosages by a licensed medical professional.

BOTOX® is temporary

BOTOX® is administered locally, via tiny injections. It generally remains only in the treated muscle, gradually disappearing without breaking down or traveling throughout the body, which may explain why serious side effects are uncommon.

BOTOX® is the future

The potential of BOTOX® is so promising, Allergan has invested more than $175 million in research and development over the past three years alone. We're currently working with medical experts the world over to develop innovative new treatments for a broad range of undertreated disorders.

Truth may not be as provocative as myth. But to the millions of patients who have safely benefited from BOTOX®, the truth is a lot more comforting.

Please see additional important information.

BOTOX®
Botulinum Toxin Type A

ALLERGAN®

To find out more, visit www.BotoxCosmetic.com or www.Botox.com

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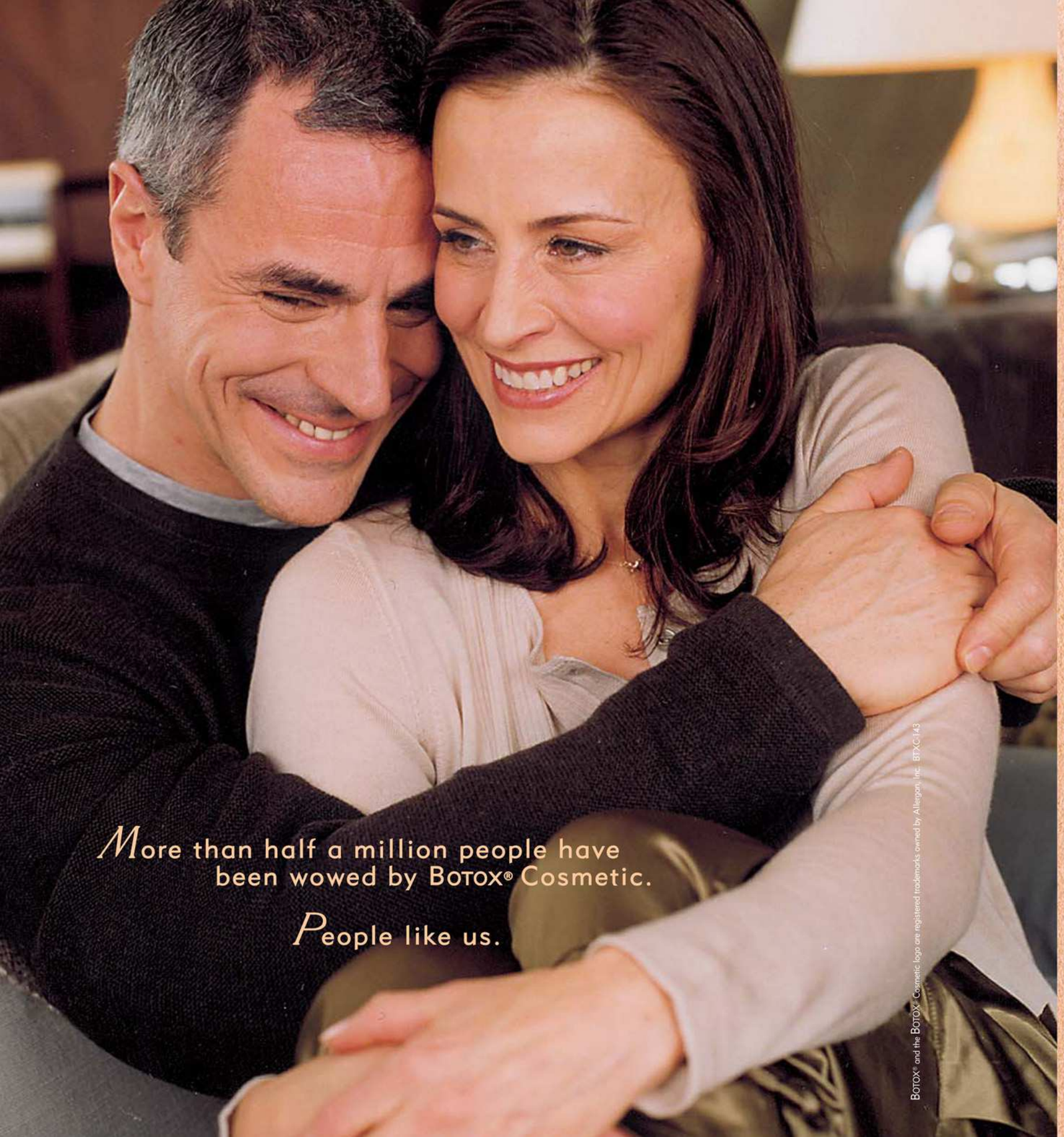

You've probably heard about BOTOX® Cosmetic.

You may even be considering it.

To help you decide if it's for you, talk to your doctor.

Visit BOTOXCosmetic.com for the
answers to the questions you've been wondering about.

We'll even help you find an experienced doctor in your area.
Haven't you waited long enough?

It's not magic, it's BOTOX® Cosmetic.

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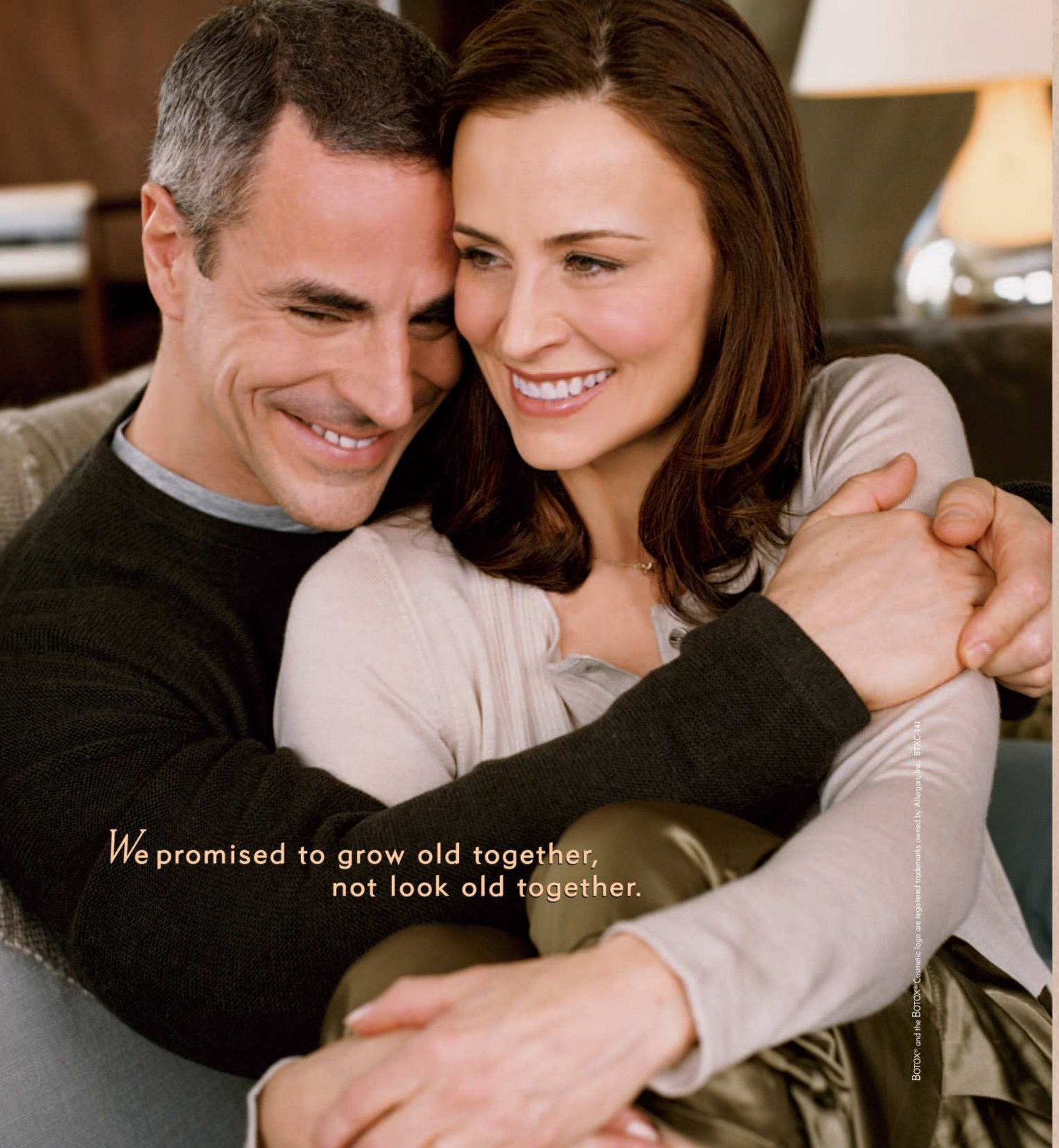

How did BOTOX® Cosmetic become America's most popular cosmetic treatment? Friends told friends. Wives told husbands. More than half a million people were wowed by BOTOX® Cosmetic in the last year alone. One ten-minute treatment – a few tiny injections – and within days, the stubborn, angry-looking frown lines between your brows dramatically relax up to four months. No surgery. No recovery. And FDA-approved BOTOX® Cosmetic is safe and widely tested.

What exactly is BOTOX® Cosmetic?

It's a natural, purified protein which in very low doses relaxes the overactive muscles that cause frown lines to form.

Is it safe?

BOTOX®, which has been safely used to treat a variety of conditions for more than ten years, is now FDA-approved as BOTOX® Cosmetic for the temporary treatment of frown lines in people aged 18 to 65.

Where does the BOTOX® Cosmetic go?

It generally remains only in the treated muscle and gradually disappears without breaking down or traveling throughout the body.

How long does it last?

About four months, after which lines gradually revert to their pre-treatment appearance.

Will it radically change my appearance?

No. Expect a dramatic improvement in the appearance of your frown lines. Overall, you'll look more relaxed and refreshed but not like "you've had work done."

Will it make me lose expression?

No. The only expression you'll lose is the unintentional frown caused by the overactive muscles between your brows.

The most common side effects, if any occur, may include headache, respiratory infection, flu syndrome, temporary eyelid droop and nausea.

Please see important information on the following page.

It's not magic, it's

BOTOX® Cosmetic
Botulinum Toxin Type A

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More than half a million people have already been wowed by BOTOX® Cosmetic, America's most popular cosmetic treatment. One ten-minute treatment – a few tiny injections – and within days, stubborn frown lines relax up to four months. No surgery. No recovery. And BOTOX® Cosmetic is safe, widely tested and FDA-approved for the temporary treatment of frown lines in people aged 18 to 65.

What exactly is BOTOX® Cosmetic? It's a natural purified protein which in low doses relaxes the overactive muscles that cause frown lines to form. By dramatically improving the appearance of frown lines, you'll look more relaxed and refreshed but not like "you've had work done." The only expression you'll lose is the unintentional frown caused by the overactive muscles between your brows.

The most common side effects, if any occur, may include headache, respiratory infection, flu syndrome, temporary eyelid droop and nausea.

Please see important information on the following page.

It's not magic, it's

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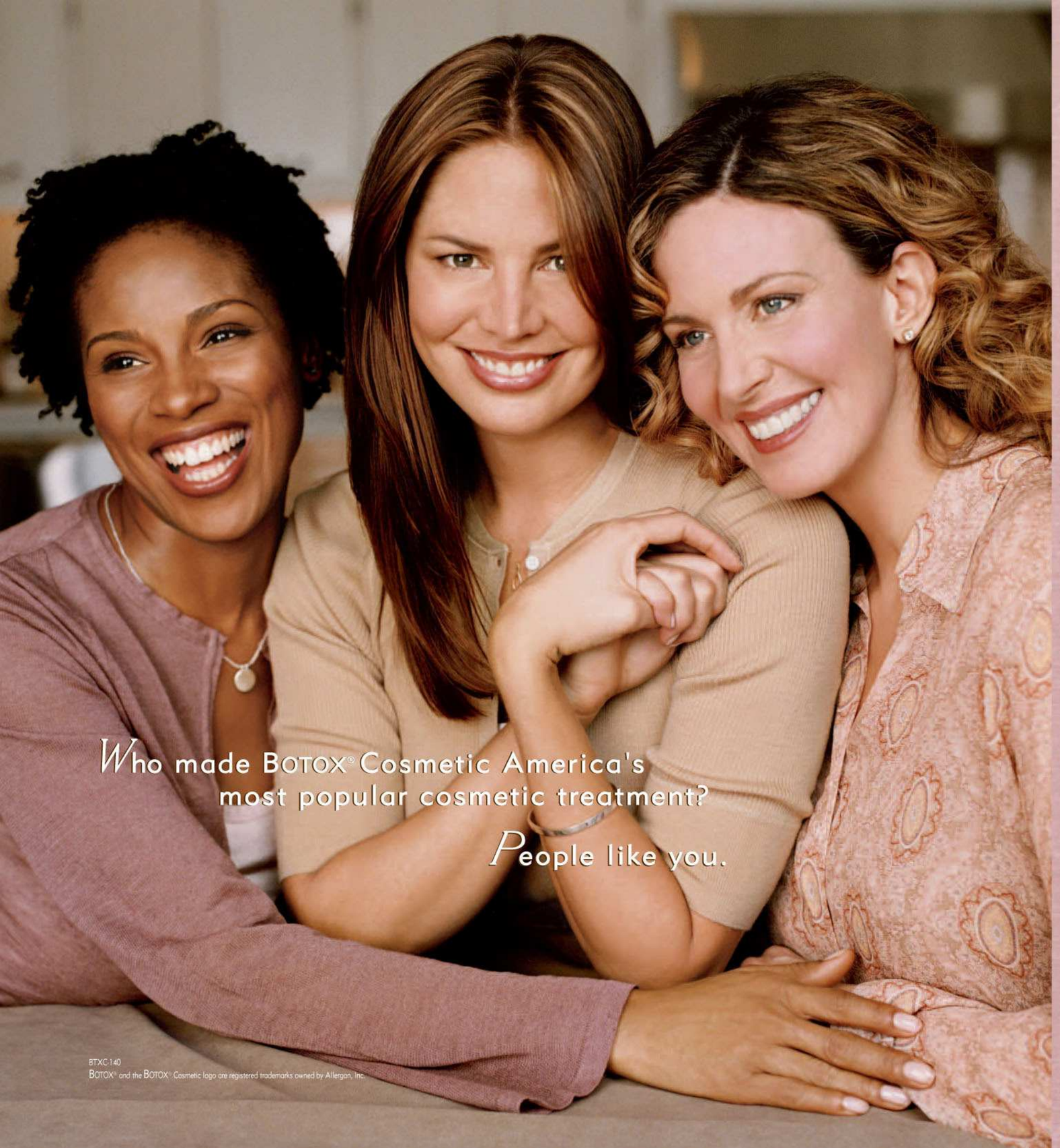

BTXC-140

How did BOTOX® Cosmetic become America's most popular cosmetic treatment? Friends told friends. More than half a million people were wowed by BOTOX® Cosmetic in the first year alone. Let's face it, you can't keep something this good quiet for long. One ten-minute treatment – a few tiny injections – and within days, the stubborn, angry-looking frown lines between your brows dramatically relax up to four months. No surgery. No recovery. And FDA-approved BOTOX® Cosmetic is safe and widely tested.

What exactly is BOTOX® Cosmetic?

It's a natural, purified protein which in very low doses relaxes the overactive muscles that cause frown lines to form.

Is it safe?

BOTOX®, which has been safely used to treat a variety of conditions for more than ten years, is now FDA-approved as BOTOX® Cosmetic for the temporary treatment of frown lines in people aged 18 to 65.

Where does the BOTOX® Cosmetic go?

It generally remains only in the treated muscle and gradually disappears without breaking down or traveling throughout the body.

How long does it last?

About four months, after which lines gradually revert to their pre-treatment appearance.

Will it radically change my appearance?

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Please see important information on the following page.

It's not magic, it's

BOTOX® Cosmetic

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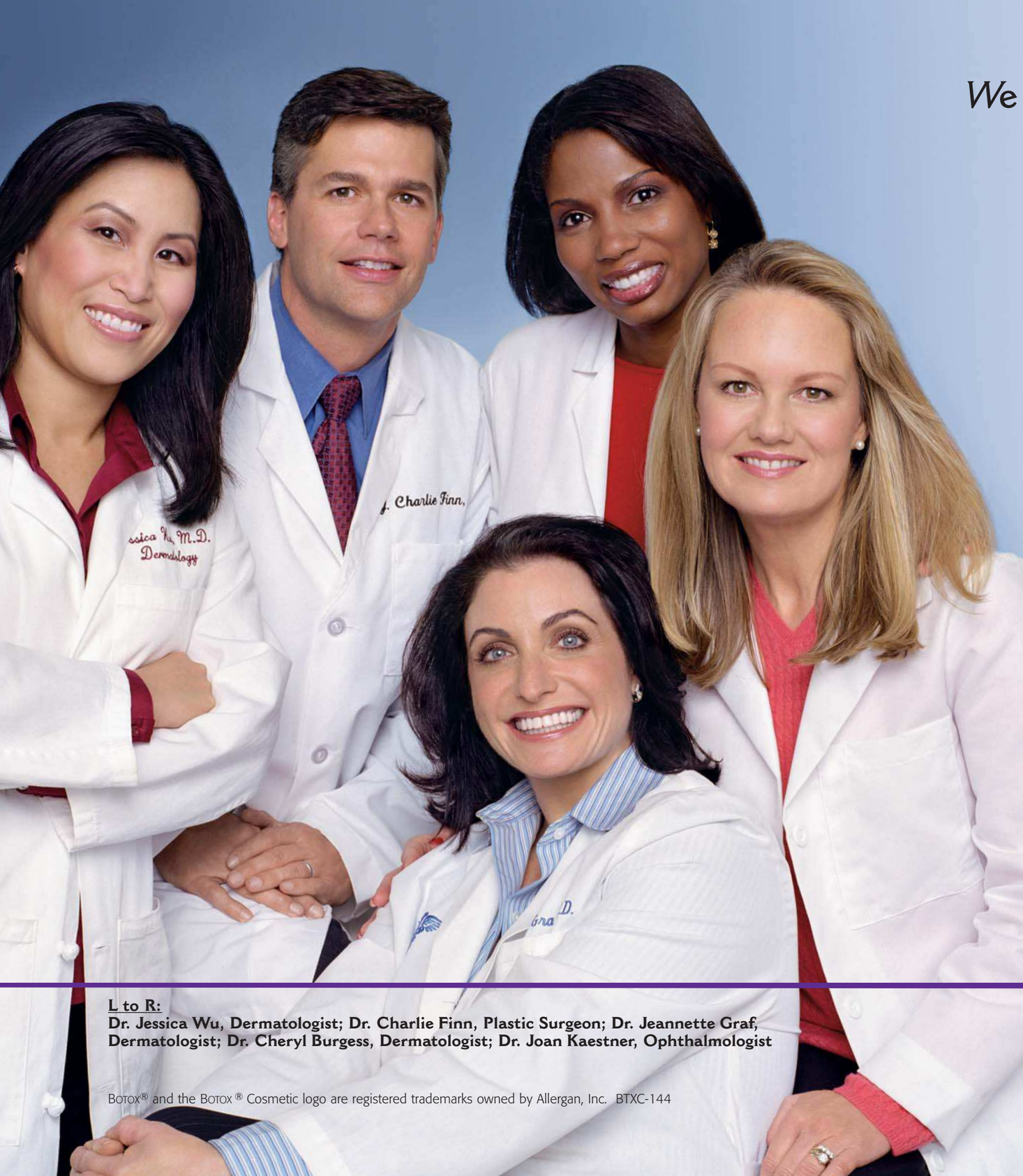

We don't just recommend Botox® Cosmetic. *We use it ourselves.*

In fact, more women dermatologists now use Botox® Cosmetic themselves than any other physician-administered cosmetic treatment.

They've read the research and treated thousands of patients. More than half have actually used it themselves. So they know firsthand how effective Botox® Cosmetic is. It's the only treatment approved by the FDA for the temporary reduction of moderate to severe frown lines between the brows in patients 18 to 65 years of age.

Proven. Simple. Effective.

So far, more than a million people have been treated since FDA approval in 2002. Ten minutes – a few tiny injections – and within days there's a noticeable improvement. There's no recovery or downtime. You can even do it on your lunch break. And results last up to four months.

Get the inside story.

Call 800-BotoxMD or visit BotoxCosmetic.com to find an experienced doctor in your area. Tour the website to watch the procedure being administered, see before and after pictures, and hear directly from people just like you.

The most common side effects include headache, respiratory infection, flu syndrome, temporary eyelid droop, and nausea. Patients who suffer from neurological disorders may be at increased risk of significant side effects. Prescription only. Please see important information on the following page.

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L to R:
Dr. Jessica Wu, Dermatologist; Dr. Charlie Finn, Plastic Surgeon; Dr. Jeannette Graf, Dermatologist; Dr. Cheryl Burgess, Dermatologist; Dr. Joan Kaestner, Ophthalmologist

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The more you know, the better it looks.

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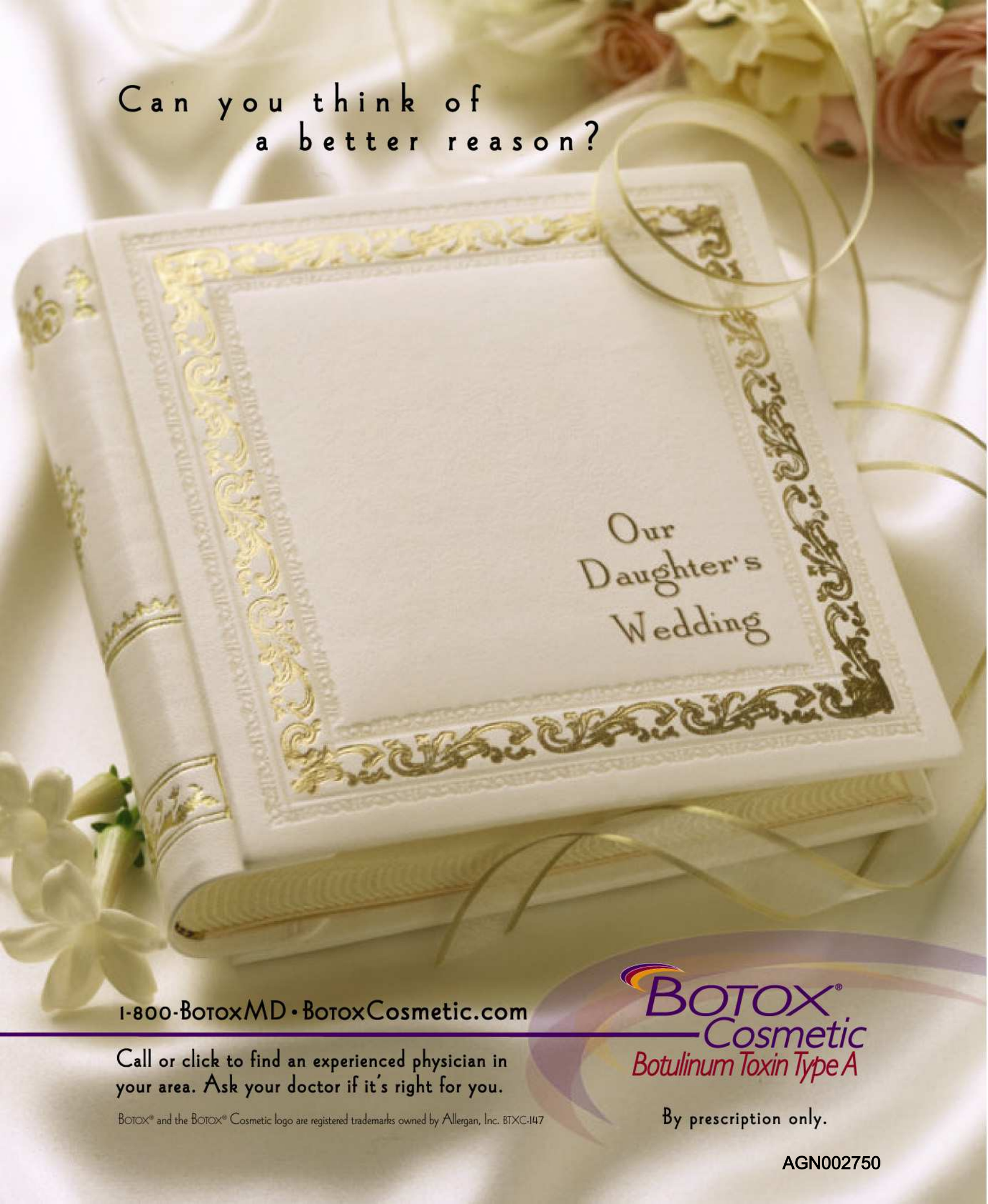
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More women dermatologists now use BOTOX® *Cosmetic themselves than any other physician-administered cosmetic treatment.*

Why? They've read the research and treated thousands of patients. More than half have actually used it themselves. They know firsthand how effective and dependable BOTOX® Cosmetic is. And it's the only treatment approved by the FDA for the temporary reduction of moderate to severe frown lines between the brows in patients 18-65 years of age.

Proven. Simple. Effective.

Ten minutes – a few tiny injections – and within days there's a noticeable improvement. There's no recovery or downtime. You can even do it on your lunch break. And results last up to four months.

Get the inside story.

Call 800-BOTOXMD or visit BOTOXCosmetic.com for more information and to find an experienced doctor in your area.

The most common side effects include headache, respiratory infection, flu syndrome, temporary eyelid droop, and nausea. Patients who suffer from neurological disorders may be at increased risk of significant side effects. Prescription only. Please see important information on the following page.

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The more you know, the better it looks.

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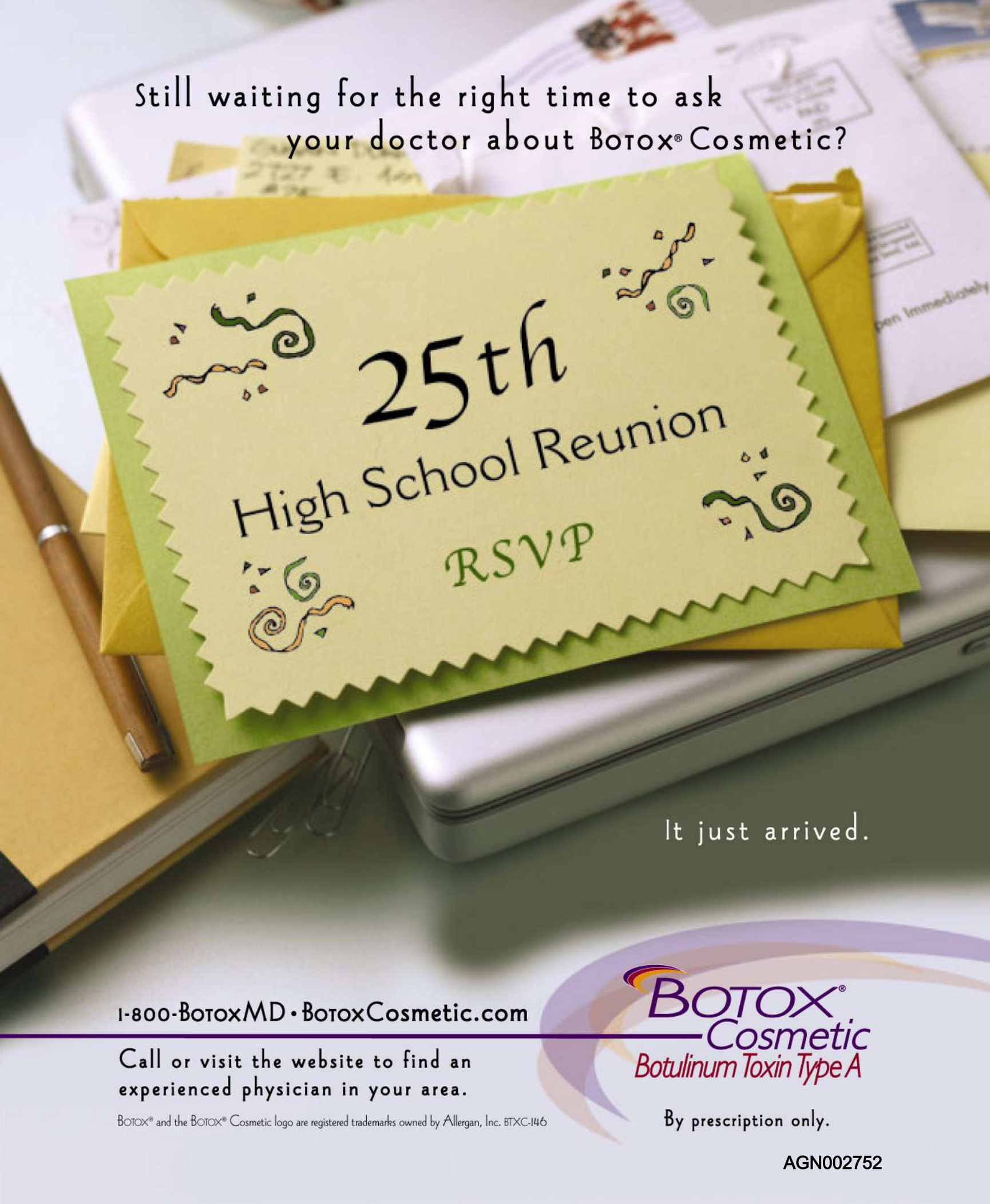
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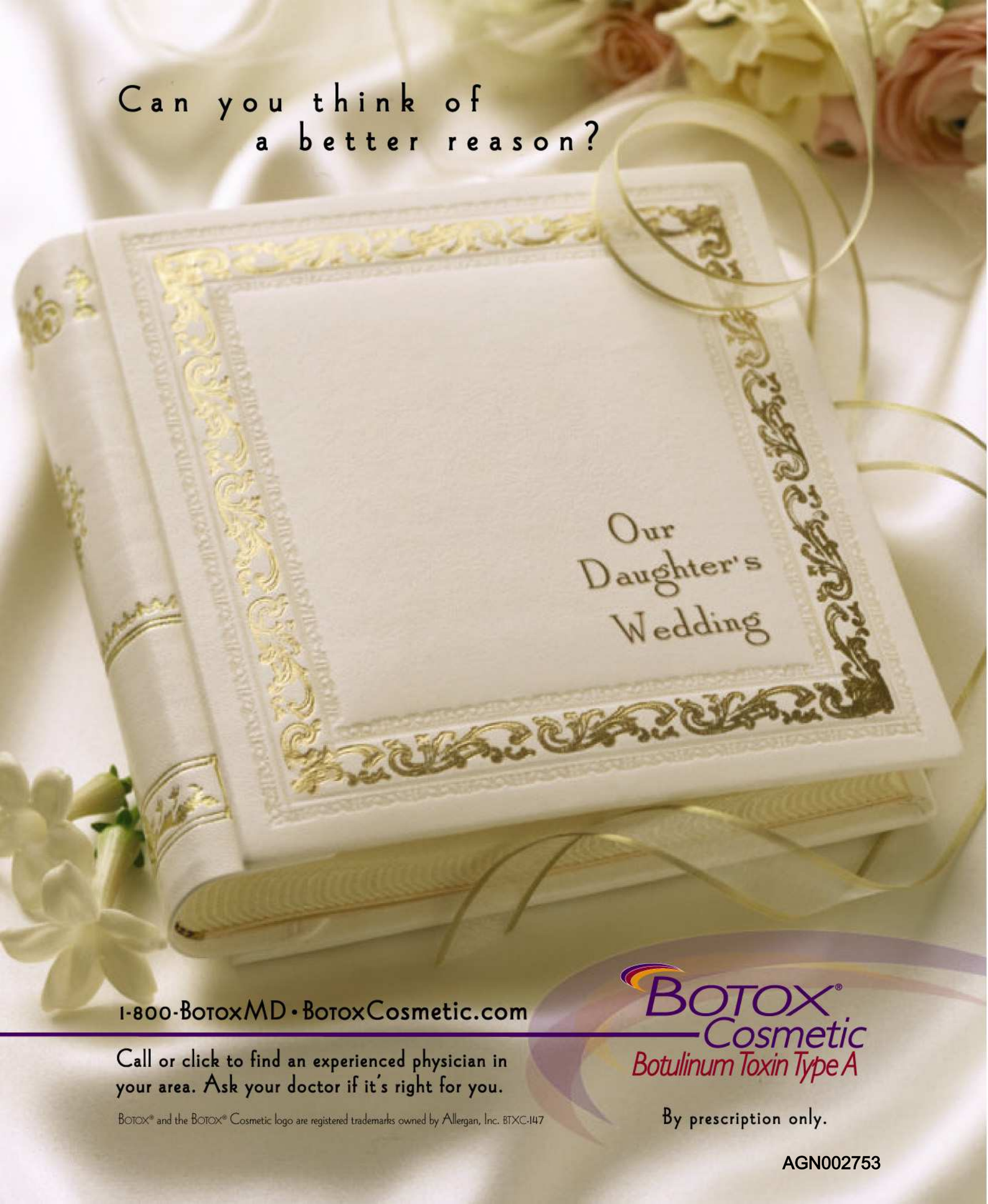

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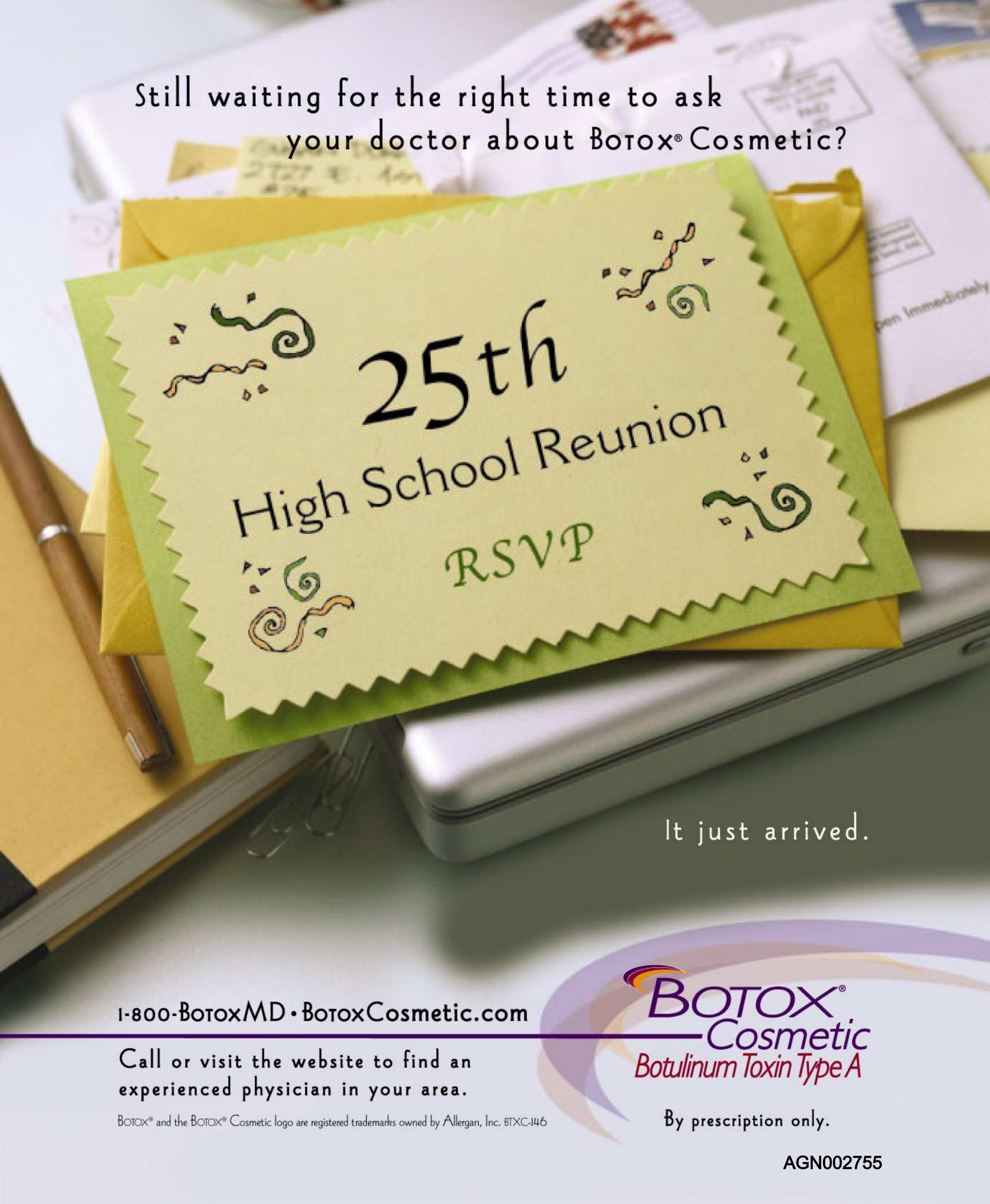
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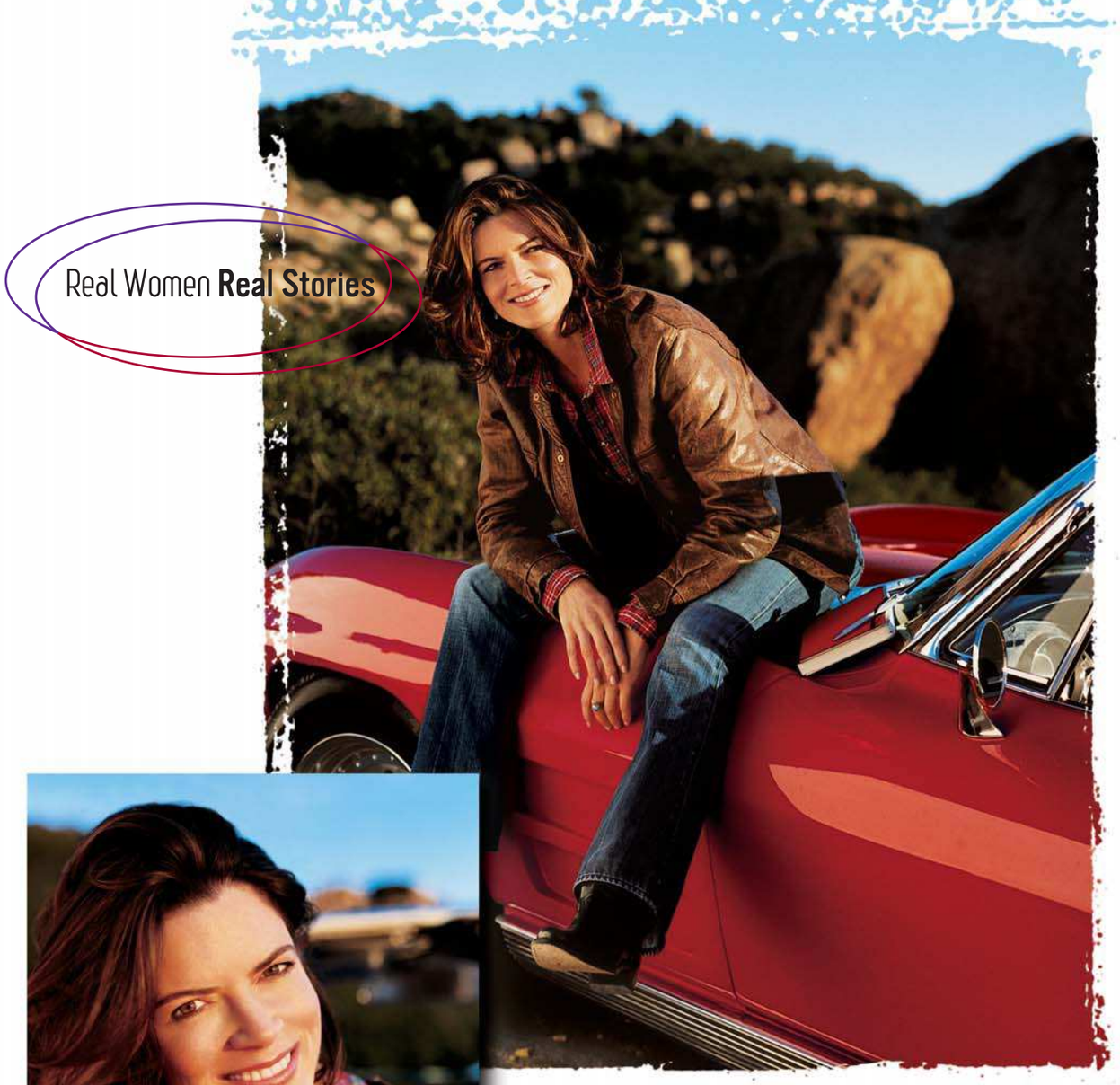
Real Women **Real Stories**



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"I was really curious about Botox® Cosmetic.

But something kept holding me back. So I did my homework. I talked to my friends. **Then I talked to my doctor.** She told me Botox® Cosmetic is the only prescription treatment approved by the FDA for the frown lines between your brows. Ten minutes – a few tiny injections administered by your doctor – lasts up to four months!

My friend Suzy's deep frown line practically disappeared within days. That's when I decided to make the appointment. I never thought Botox® Cosmetic was for someone like me. **But now I think, why not me?"** Colette, Wilton, CT

Don't know where to find a doctor? Visit BotoxCosmetic.com for the name of an experienced physician in your area.

The one, the only™
Botox® Cosmetic.

Individual results may vary. Botox® Cosmetic is approved for the temporary treatment of moderate to severe frown lines between the brows in people ages 18-65. In clinical studies, 89% of patients and 80% of doctors rated improvement as moderate or better. Ask your doctor if Botox® Cosmetic is right for you.

Important Safety Information: Patients with certain neurological disorders such as ALS, myasthenia gravis or Lambert-Eaton syndrome may be at increased risk of serious side effects. Serious allergic reactions have been rarely reported. If you think you're having an allergic reaction or other unusual symptoms such as difficulty swallowing, speaking or breathing, call your doctor immediately. The most common side effects following injection include headache, respiratory infection, flu syndrome, temporary eyelid droop and nausea.

Please see additional information on the following page.

BOTOX® Cosmetic
Botulinum Toxin Type A

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Real Women **Real Stories**

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"I told my doctor I need a change. But nothing drastic.

And not like I've had work done. **She had two words for me: Botox® Cosmetic,** the only prescription treatment approved by the FDA for the frown lines between your brows. Ten minutes – a few tiny injections administered by your doctor – lasts up to four months! My doctor explained how the change would be subtle but noticeable. **And let's be honest, if it's so subtle nobody notices, what's the point?** I didn't just wake up one morning and say today's the day I ask my doctor about Botox® Cosmetic. It took me a while to decide. **The only thing I regret is not talking to her sooner."** Kathrin, Traverse City, MI

Don't know where to find a doctor? Visit BotoxCosmetic.com for the name of an experienced physician in your area.

The one, the only™
Botox® Cosmetic.

Individual results may vary. Botox® Cosmetic is approved for the temporary treatment of moderate to severe frown lines between the brows in people ages 18-65. In clinical studies, 89% of patients and 80% of doctors rated improvement as moderate or better. Ask your doctor if Botox® Cosmetic is right for you.

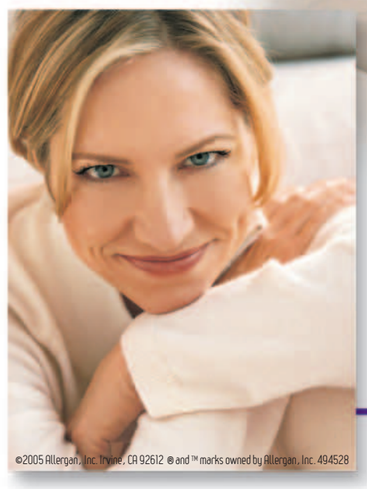
Important Safety Information: Patients with certain neurological disorders such as ALS, myasthenia gravis or Lambert-Eaton syndrome may be at increased risk of serious side effects. Serious allergic reactions have been rarely reported. If you think you're having an allergic reaction or other unusual symptoms such as difficulty swallowing, speaking or breathing, call your doctor immediately. The most common side effects following injection include headache, respiratory infection, flu syndrome, temporary eyelid droop and nausea.

Please see additional information on the following page.

BOTOX® Cosmetic
Botulinum Toxin Type A

AGN002757

Real Women **Real Stories**



Visit BotoxCosmetic.com
or call 1-800-BotoxMD

By prescription only

"There are over-the-counter creams and lotions. And then there's Botox® Cosmetic.

My doctor said they're just not the same. **She said only prescription Botox® Cosmetic is approved by the FDA to treat the frown lines between your brows.** Ten minutes – a few tiny injections administered by your doctor – lasts up to four months! **That was good to know.** With all the claims some over-the-counter creams and lotions make, I was pretty confused. They pop an "X" in their name and claim they're better than Botox®. That's why I asked my doctor. You can read about Botox® Cosmetic. You can discuss it with friends. **But if you really want the facts, talk to your doctor."** Laura, Los Angeles, CA

Don't know where to find a doctor? Visit BotoxCosmetic.com for the name of an experienced physician in your area.

The one, the only™
Botox® Cosmetic.

Individual results may vary. Botox® Cosmetic is approved for the temporary treatment of moderate to severe frown lines between the brows in people ages 18-65. In clinical studies, 89% of patients and 80% of doctors rated improvement as moderate or better. Ask your doctor if Botox® Cosmetic is right for you.

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Please see additional information on the following page.

BOTOX® Cosmetic
Botulinum Toxin Type A

AGN002758

Why ask your doctor about BOTOX® Cosmetic?

Everybody has their own reason
for looking into BOTOX® Cosmetic.
If you haven't called your doctor yet,
isn't it about time?

The ONE. The ONLY.™

BOTOX® Cosmetic
Botulinum Toxin Type A

1·800·BOTOX·MD

By Prescription Only

To Find a Doctor In Your Area, Visit www.BotoxCosmetic.com

AGN002759

Why ask your doctor about BOTOX® Cosmetic?

Everybody has their own reason for looking into BOTOX® Cosmetic. If you haven't called your doctor yet, isn't it about time?

The ONE. The ONLY.™

BOTOX® Cosmetic
Botulinum Toxin Type A

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By Prescription Only

To Find a Doctor In Your Area, Visit www.BotoxCosmetic.com

AGN002760


Why ask your doctor about BOTOX® Cosmetic
I did it for ME
Everybody has their own reason for looking into BOTOX® Cosmetic. If you haven't called your doctor yet, isn't it about time?
The ONE. The ONLY.™
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AGN002761


Why ask your doctor about BOTOX® Cosmetic?
This is my time
I've waited long enough
Everybody has their own reason for looking into BOTOX® Cosmetic. If you haven't called your doctor yet, isn't it about time?
The ONE. The ONLY.™
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AGN002762

IMPORTANT SAFETY INFORMATION (CONTINUED)

Serious and/or immediate allergic reactions have been reported. They include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Get medical help right away if you are wheezing or have asthma symptoms, or if you become dizzy or faint.

Do not receive BOTOX® Cosmetic if you: are allergic to any of the ingredients in BOTOX® Cosmetic (see Medication Guide for ingredients); had an allergic reaction to any other botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA); have a skin infection at the planned injection site.

Tell your doctor about all your muscle or nerve conditions, such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX® Cosmetic.

Tell your doctor about all your medical conditions, including: plans to have surgery; had surgery on your face; have trouble raising your eyebrows; drooping eyelids; any other abnormal facial change; are pregnant or plan to become pregnant (it is not known if BOTOX® Cosmetic can harm your unborn baby); are breast-feeding or plan to (it is not known if BOTOX® Cosmetic passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® Cosmetic with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX® Cosmetic in the past.**

Tell your doctor if you have received any other botulinum toxin product in the last 4 months; have received injections of botulinum toxin such as Myobloc®, Dysport®, or Xeomin® in the past (tell your doctor exactly which product you received); have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take aspirin-like products or blood thinners.

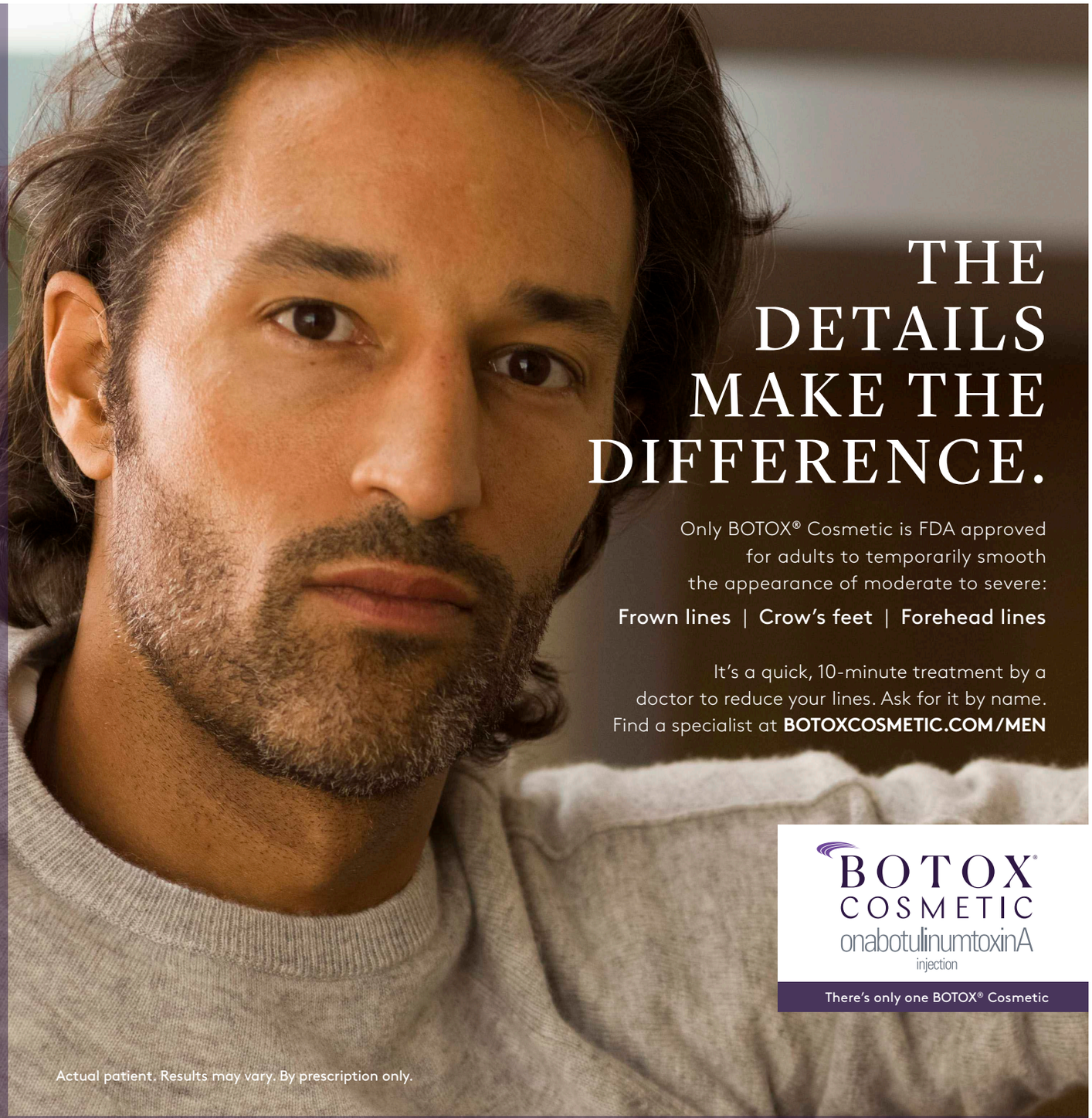
Other side effects of BOTOX® Cosmetic include: dry mouth; discomfort or pain at the injection site; tiredness; headache; neck pain; and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids and eyebrows, swelling of your eyelids and dry eyes.

For more information refer to the Medication Guide or talk with your doctor.

To report a side effect, please call Allergan at 1-800-678-1605.

Please see Summary of Important Information about BOTOX® Cosmetic on next page.

BCT110820 03/18



THE DETAILS MAKE THE DIFFERENCE.

Only BOTOX® Cosmetic is FDA approved for adults to temporarily smooth the appearance of moderate to severe:

Frown lines | Crow's feet | Forehead lines

It's a quick, 10-minute treatment by a doctor to reduce your lines. Ask for it by name. Find a specialist at **BOTOXCOSMETIC.COM/MEN**

BOTOX® COSMETIC onabotulinumtoxinA injection

There's only one BOTOX® Cosmetic

Actual patient. Results may vary. By prescription only.

IMPORTANT SAFETY INFORMATION

BOTOX® Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX® Cosmetic:

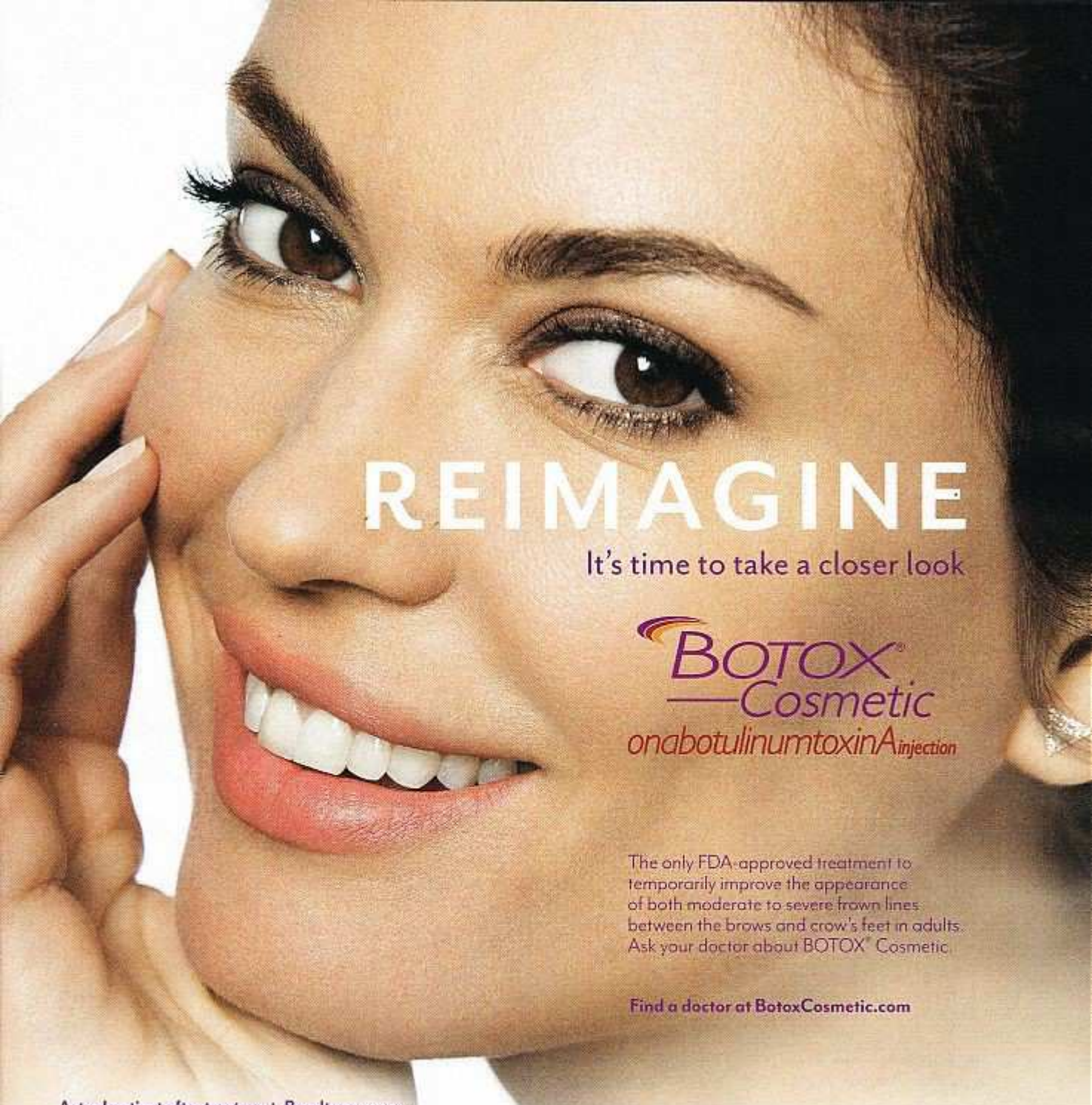
- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing.

BOTOX® Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.
There has not been a confirmed serious case of spread of toxin effect when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, and/or forehead lines.

BOTOX® Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX® Cosmetic. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

See adjacent page for additional Important Safety Information for BOTOX® Cosmetic.

AGN002884



Actual patient after treatment. Results may vary.

IMPORTANT SAFETY INFORMATION

BOTOX® 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 any time (hours to weeks) after injection of BOTOX® Cosmetic:

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing. **If this happens, do not drive a car, operate machinery, or do other dangerous activities**

The dose of BOTOX® Cosmetic is not the same as, or comparable to, any other botulinum toxin product.

There has not been a confirmed serious case of spread of toxin effect when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines or both at the same time.

Serious and/or immediate allergic reactions have been reported. They 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.

BY PRESCRIPTION ONLY

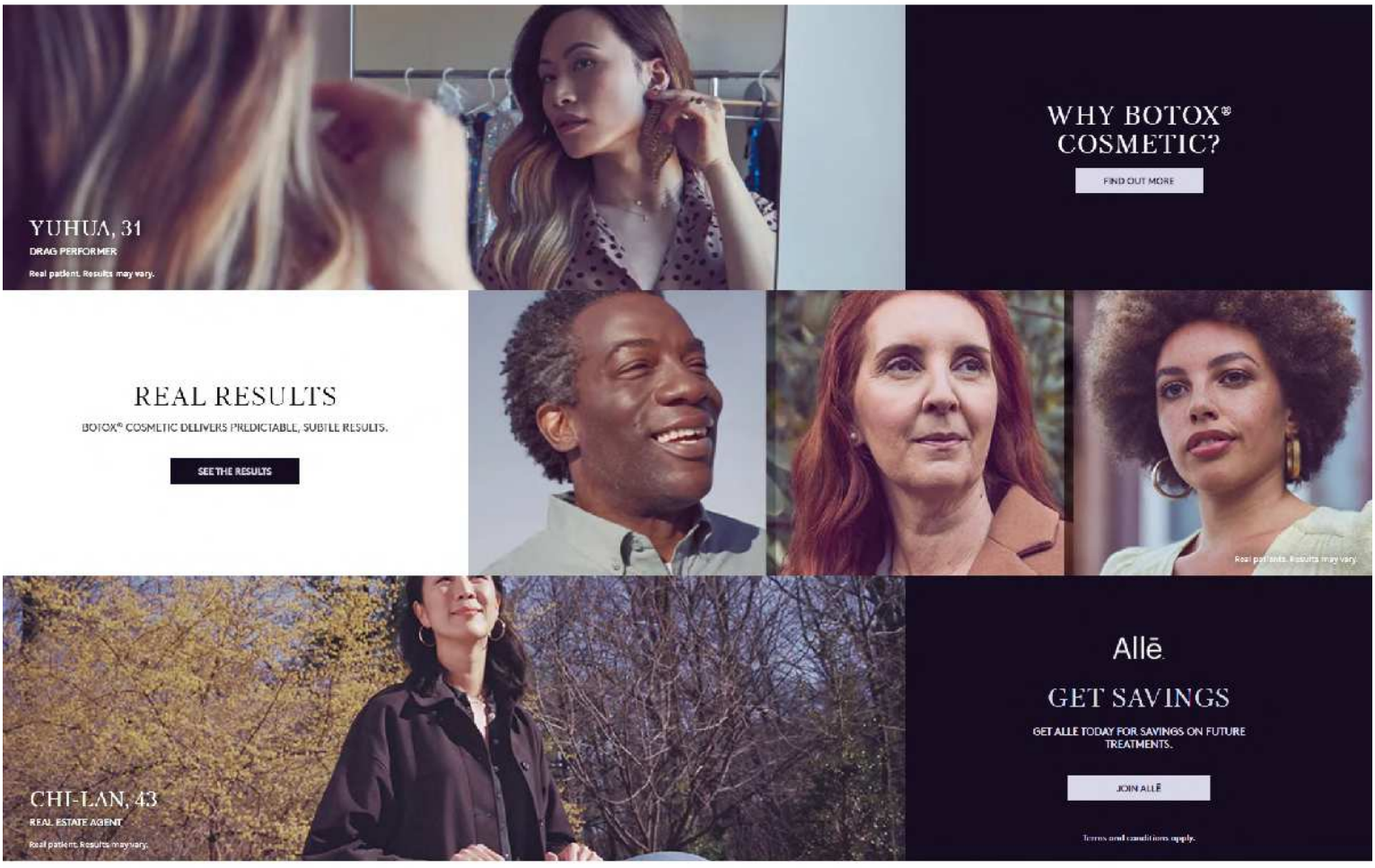
See adjacent page for additional safety information associated with BOTOX® Cosmetic

EXHIBIT G

STILL YOU. WITH FEWER LINES.

Only BOTOX® Cosmetic is FDA-approved to temporarily make moderate to severe frown lines, crow's feet, and forehead lines look better in adults.

SEE FOR YOURSELF



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IMPORTANT SAFETY INFORMATION & APPROVED USES

BOTOX® Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX® Cosmetic.

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BOTOX® Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.

There has not been a confirmed serious case of spread of toxin effect when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, and/or forehead lines.

BOTOX® Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX® Cosmetic. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Serious and/or immediate allergic reactions have been reported. These may include itching, hives, red itchy welts, wheezing, asthma symptoms, dizziness or fainting. Call your doctor right away if you get wheezing or have asthma symptoms, or if you become dizzy or faint.

Do not receive BOTOX® Cosmetic if you: are allergic to any of the ingredients in BOTOX® Cosmetic (see Medication Guide for ingredients), had an allergic reaction to any other botulinum toxin product such as Myobloc® (rimabotulinumtoxinB), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA), have a skin infection at the proposed injection site.

Tell your doctor about all your muscle or nerve conditions, such as ALS or Lou Gehrig's disease, myasthenia gravis, or Lambert-Eaton syndrome, as you may be at increased risk of serious side effects including difficulty swallowing and difficulty breathing from typical doses of BOTOX® Cosmetic.

Tell your doctor about all your medical conditions, including: plans to have surgery; had surgery on your face; have trouble raising your eyebrows; drooping eyelids; any other abnormal facial changes; are pregnant or plan to become pregnant. It is not known if BOTOX® Cosmetic can harm your unborn baby; are breast-feeding or plan to. It is not known if BOTOX® Cosmetic passes into breast milk.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using BOTOX® Cosmetic with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received BOTOX® Cosmetic in the past.**

Tell your doctor if you have received any other botulinum toxin product in the last 4 months. Have received injections of botulinum toxin such as Myobloc®, Dysport®, or Xeomin® in the past. Tell your doctor exactly which product you received. Have recently received an antibiotic by injection. Take muscle relaxants, take an allergy or cold medicine, take a sleep medicine, take aspirin-like products or blood thinners.

Other side effects of BOTOX® Cosmetic include: dry mouth, discomfort or pain at the injection site, dizziness, headache, neck pain, and eye problems: double vision, blurred vision, decreased eyesight, drooping eyelids and eyebrows, swelling of your eyelids and dry eyes.

APPROVED USES

BOTOX® Cosmetic is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines, crow's feet lines, and frown lines between the eyebrows in adults.

For more information, refer to the Medication Guide or talk with your doctor.

To report a side effect, please call Allergan at 1-800-678-1605.

Please see **BOTOX® Cosmetic** full Product Information including Boxed Warning and Medication Guide.

BOTOX COSMETIC onabotulinumtoxinA

CONTACT US FIND A SPECIALIST ALLÉ™ APP

Healthcare Professionals: I have questions about products, new accounts, payments, or orders?
Call Customer Service at 1-800-377-7790

Product Information including Medication Guide
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Allergan Aesthetics an AbbVie company

EXHIBIT H

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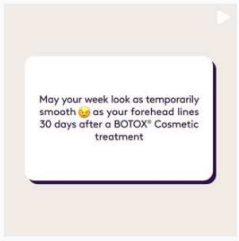
BOTOX® Cosmetic

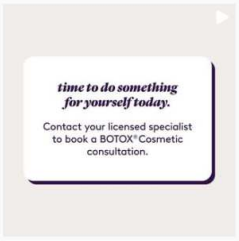
Please see highlights for full Product Information including Boxed Warning and Medication Guide.

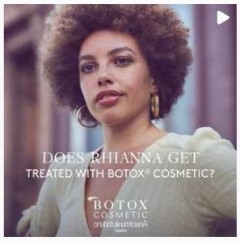
btxc.co/botoxcosmetic

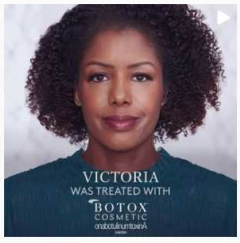
Full PI | Safety Info | What is it? | How it wor... | The Research | The History | Treatment ...

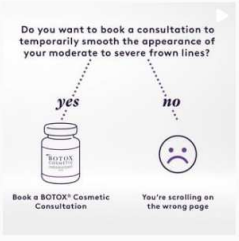
POSTS REELS IGTV TAGGED












ENJOY THOSE
DOUBLE POINTS
BOOK A CONSULTATION TODAY!
BOTOX COSMETIC


THE #1 SELLING TREATMENT
OF ITS KIND
BOTOX® COSMETIC


NEWBEAUTY
WINNER
WINNER IN THE "IN-OFFICE TREATMENTS" CATEGORY
BOTOX COSMETIC


Severe forehead lines are just not my thing. Hbu?


GRINELL WAS TREATED WITH
BOTOX® COSMETIC
BOTOX COSMETIC


DOUBLE POINTS
ENDS SEPTEMBER 30
EARN ON JUVÉDERM® WHEN ADDED TO A BOTOX® COSMETIC APPOINTMENT
BOTOX COSMETIC


MARIA, 26


celebrating
Hispanic Heritage
month


TAP FOR
IMPORTANT
SAFETY
INFORMATION

EXHIBIT I

BOTOX® Cosmetic onabotulinumtoxinA

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BOTOX® Cosmetic is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines... **See More**

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https://www.botoxcosmetic.com/

Pharmaceuticals

Safety Information

Approved Uses
BOTOX® Cosmetic is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines, crow's feet lines, and frown lines between the eyebrows in adults.

IMPORTANT SAFETY INFORMATION
BOTOX® Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX® Cosmetic:... **See More**

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BOTOX® Cosmetic onabotulinumtoxinA
September 1 at 1:26 PM

Approved Uses

BOTOX® Cosmetic is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines, crow's feet lines, and frown lines between the eyebrows in adults.

IMPORTANT SAFETY INFORMATION

BOTOX® Cosmetic may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of BOTOX® Cosmetic:

- **Problems swallowing, speaking, or breathing,** due to weakening of associated muscles, can be severe and result in loss of life. You are at the highest risk if these problems are pre-existing before injection. Swallowing problems may last for several months.
- **Spread of toxin effects.** The effect of botulinum toxin may affect areas away from the injection site and cause serious symptoms including: loss of strength and all-over muscle weakness, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, and trouble swallowing.

BOTOX® Cosmetic dosing units are not the same as, or comparable to, any other botulinum toxin product.

There has not been a confirmed serious case of spread of toxin effect when BOTOX® Cosmetic has been used at the recommended dose to treat frown lines, crow's feet lines, and/or forehead lines.

BOTOX® Cosmetic may cause loss of strength or general muscle weakness, vision problems, or dizziness within hours to weeks of taking BOTOX® Cosmetic. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

Serious and/or immediate allergic reactions have been report·d. They include: itching, rash, red itchy welts, wheezing, asthma symptoms, or

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OTHER POSTS

BOTOX® Cosmetic onabotulinumtoxinA
September 10 at 10:45 AM

For Boxed Warning and Medication Guide, see bit.ly/BTXCpi
-
Ask to #SeeTheVial before getting treated to ensure it's BOTOX® Cosmetic. ✨Visit http://btxc.co/btxchome to find a licensed specialist near you. #BotoxCosmetic
-
BOTOX® Cosmetic (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe forehead lines, crow's feet, and

For Boxed Warning and Medication Guide, see bit.ly/BTX...

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Allergan USA, Inc. is responsible for this Page.

Page manager locations include: United States, Romania, Belgium

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Create Page

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BOTOX® Cosmetic onabotulinumtoxinA

September 8 at 10:31 AM ·

For Boxed Warning and Medication Guide, see bit.ly/BTXCpi

-

Look what's here! 👀 It's Double Points in Allē, back for a limited time! Earn up to $180 in points after adding a @juvederm treatment to your next BOTOX® Cosmetic appointment. Visit https://www.alle.com/article/member_points_event to learn more. #BotoxCosmetic #Juvederm #AlleDoublePoints

-

BOTOX® Cosmetic (onobotulinumtoxinA) is a prescription medicine that is injected into muscles and used to temporarily improve th... **See More**

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BOTOX® Cosmetic onabotulinumtoxinA
September 6 at 9:45 AM ·

For Boxed Warning and Medication Guide, see bit.ly/BTXCpi
-
Saying goodbye to summer and to temporarily moderate to severe crow's feet (after booking a consultation with a licensed specialist). 😉✌ Visit http://btxc.co/btxchome to find a licensed specialist near you, and see whether BOTOX® Cosmetic is right for you.
-
BOTOX® Cosmetic (onabotulinumtoxinA) is a prescription medicine that is injected into muscles and used to temporarily improve the look of moderate to severe fo... **See More**

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EXHIBIT J

Instant Bright Eye Mask

These cooling gel patches soothe and hydrate the under-eye area for an instant refresh. Unique hydrogel technology reduces the appearance of puffiness to help eyes look youthful and rested.

A perfect companion to Instant Bright Eye Cream or any SkinMedica® eye product.

Appropriate for all skin types.

Price	Net Weight	Contents
$48.00MSRP	0.08 Oz. / 2.34 g per set	6 sets of 2 patches

Buy Now | Find a Provider

Store at room temperature 15° - 30°C (59° - 86°F).
Made in Korea.

What's Inside

Key Ingredients

***Rhodiola rosea* root (golden root) extract:**
Antioxidants

***Scutellaria baicalensis* (golden herb) extract:**
Supports skin rejuvenation

***Saccharomyces cerevisiae* (Baker's Yeast) extract:**
Supports skin moisture

Ingredients
Water/Aqua, Glycerin, Gelatin, Sodium Polyacrylate, Polyvinyl Alcohol, Cellulose Gum, Caprylyl/Capryl Glucoside, Sorbitol, 1,2-Hexanediol, Butylene Glycol, Illicium Verum (Anise) Fruit Extract, Scutellaria Baicalensis Root Extract, Saccharomyces Cerevisiae Extract, Rhodiola Rosea Root Extract, Betaine, Cyclopentasiloxane, Aluminum Glycinate, Phenoxyethanol, Pentylene Glycol, Sodium Dehydroacetate, Potassium Sorbate, Disodium EDTA, Tartaric Acid

When to Apply
Weekly or as needed.

Where to Apply
Apply to the under-eye area.

How to Apply
Remove patch from backing. Apply gel side down to under-eye area and press firmly, smoothing out the edges. Ensure mask lies firmly onto the skin. Leave on for 15 to 20 minutes and gently peel from face. No need to rinse.

Your Perfect Skin Care Regimen

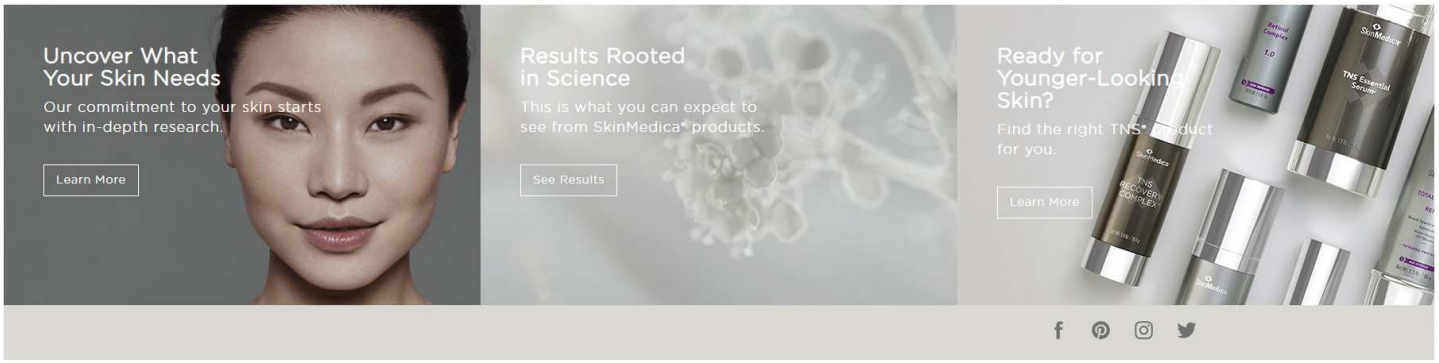
If you are new to SkinMedica® or just want to learn more about our award-winning products, this is the perfect place to start.

TNS Essential Serum®
$281MSRP

HA5® Rejuvenating Hydrator 2 Oz.
$178MSRP

HA5® Rejuvenating Hydrator 1 Oz.
$120MSRP

Total Defense and Repair SPF 50+
$68MSRP



CAUTION: Do not use Retinol Complex if you are pregnant, lactating, or planning to become pregnant. Mild redness, peeling, and irritation are expected when using this product. Use a sunscreen and limit sun exposure while using this product and for a week following discontinuation.

CAUTION: GlyPro products used together may cause irritation.

Sunburn alert: AHA/BHA Exfoliating Cleanser, AHA/BHA Cream, Rejuvenative Toner, and all GlyPro products contain an alpha-hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using these products and for a week following discontinuation.

IMPORTANT! SUNSCREEN IS REQUIRED TO OPTIMIZE AND MAINTAIN THE RESULTS OF USING LYTERA® 2.0 PIGMENT CORRECTING SERUM.

Most SkinMedica® products are intended to meet the FDA's definition of a cosmetic product, an article applied to the human body to cleanse, beautify, promote attractiveness, and alter appearances. These SkinMedica® products are not intended to be drug products that diagnose, treat, cure, or prevent any disease or condition. These products have not been approved by the FDA, and the statements here have not been evaluated by the FDA.

SkinMedica® TOTAL DEFENSE + REPAIR Broad Spectrum Sunscreens (SPF 34, SPF 34 Tinted, and SPF 50+) and Essential Defense Broad Spectrum Sunscreens (Everyday Clear SPF 47, Mineral Shield Tinted SPF 32, and Mineral Shield SPF 35) are over-the-counter drug products that are formulated and marketed pursuant to the FDA's governing regulations set forth at 21 CFR Part 352.

The PA rating system is used in Japan to classify UVA protection and is not an FDA requirement on sunscreens sold in the U.S.

SkinMedica® Purifying Foaming Wash is an over-the-counter drug product that is formulated and marketed pursuant to the FDA's governing regulations set forth at 21 CFR Part 333 Subpart D.

Not all products are available in Canada. Subject to change at any time without prior notice.

EXHIBIT K

ALLERGAN

2002
annual report

A Growing Focus

AGN000159

AGN Financial Highlights

In millions, except per share data	Year Ended December 31, 2002	2001	2000	1999	1998
STATEMENT OF OPERATIONS HIGHLIGHTS					
Product net sales	$1,385.0	$1,142.1	$992.1	$828.6	$716.0
Product gross margin	1,163.3	944.0	794.4	658.2	545.5
Research and development	233.1	227.5	165.7	140.6	97.7
Earnings (loss) from continuing operations	64.0	171.2	165.9	143.7	(86.6)
Earnings (loss) from discontinued operations	11.2	54.9	49.2	44.5	(3.6)
Net earnings (loss)	75.2	224.9	215.1	188.2	(90.2)
Basic earnings (loss) per share:					
Continuing operations	0.49	1.30	1.27	1.09	(0.66)
Discontinued operations	0.09	0.42	0.38	0.33	(0.03)
Diluted earnings (loss) per share					
Continuing operations	0.49	1.29	1.24	1.06	(0.66)
Discontinued operations	0.08	0.40	0.37	0.33	(0.03)
Dividends per share	0.36	0.36	0.32	0.28	0.26
ADJUSTED AMOUNTS [a]					
Adjusted earnings from continuing operations	252.3	207.7	166.6	133.9	102.4
Adjusted basic earnings per share from continuing operations	1.95	1.58	1.27	1.01	0.78
Adjusted diluted earnings per share from continuing operations	1.92	1.55	1.25	0.99	0.76
Pro Forma diluted earnings per share adjusted for dissynergies related to spin-off of Advanced Medical Optics, Inc.[b]	1.88	1.48	–	–	–

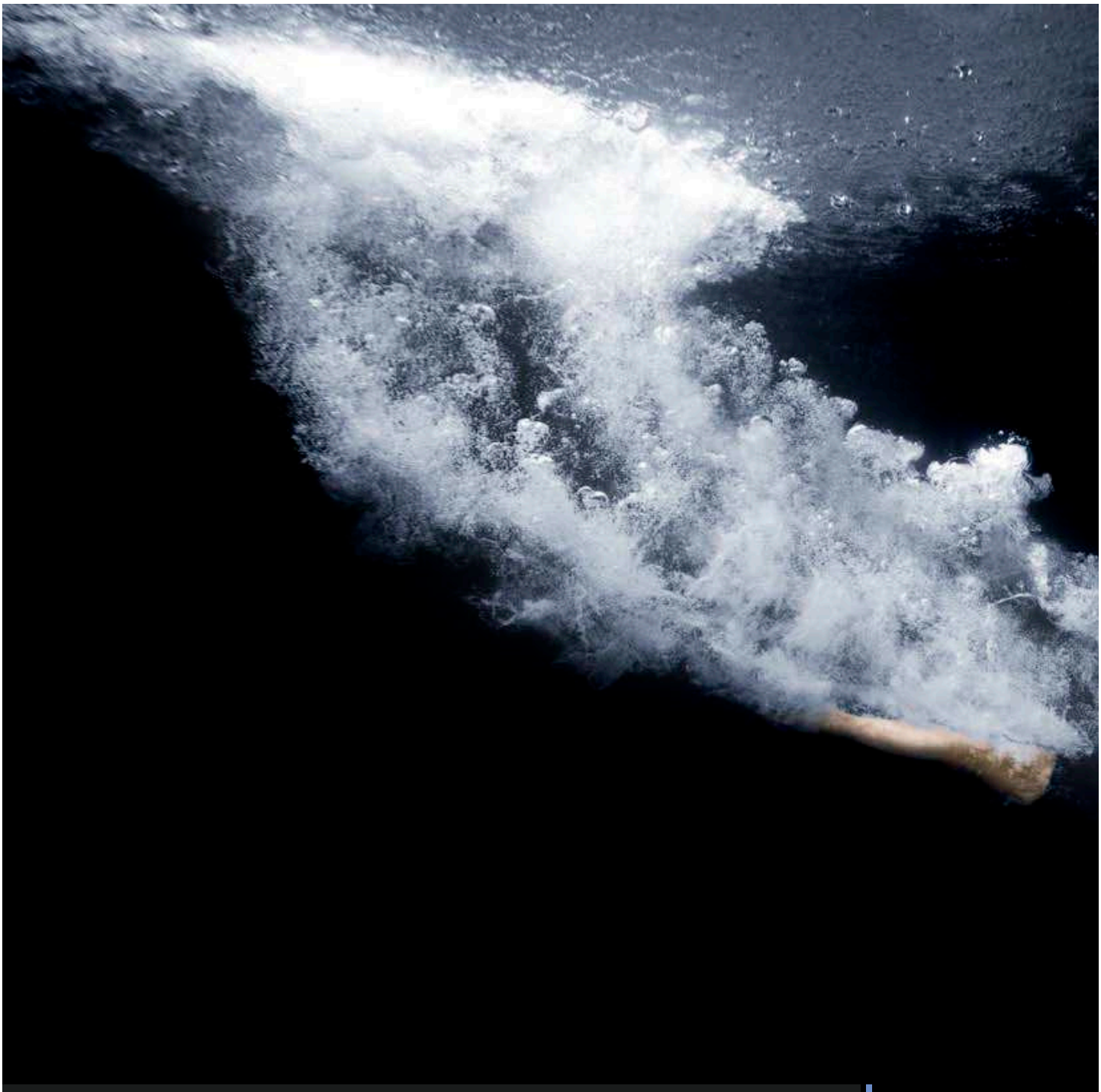
In millions	Year Ended December 31, 2002	2001	2000	1999	1998
NET SALES BY PRODUCT LINE					
Specialty Pharmaceuticals:					
Eye Care Pharmaceuticals	$ 827.3	$ 753.7	$683.9	$576.2	$510.1
Skin Care	90.2	78.9	68.7	76.6	80.6
BOTOX/Neuromodulators	439.7	309.5	239.5	175.8	125.3
Total Pharmaceutical Sales	1,357.2	1,142.1	992.1	828.6	716.0
Other	27.8	–	–	–	–
Total Net Sales	$1,385.0	$1,142.1	$992.1	$828.6	$716.0
PRODUCTS SOLD BY LOCATION					
Domestic	70.6%	67.0%	63.4%	60.7%	58.5%
International	29.4%	33.0%	36.6%	39.3%	41.5%

(a) The adjusted amounts in 2002 exclude the after-tax effect of the following: 1) $118.7 million in litigation settlement costs, 2) net cost of $100.3 million associated with the spin-off of the Company's ophthalmic surgical and contact lens care businesses which consist of a restructuring charge and asset write-offs of $63.5 million, duplicate operating expenses of $42.5 million and gain of $5.7 million on sale of a facility, 3) $30.2 million loss on the permanent impairment of investments, 4) $1.7 million unrealized loss on derivative instruments, 5) net gain of $1.0 million from partnering agreements, and 6) a $11.7 million charge for the early extinguishment of convertible debt.

The adjusted amounts in 2001 exclude the $40.0 million one-time charge for in-process research and development related to the purchase of Allergan Specialty Therapeutics, Inc. (ASTI) and the after-tax effect of the following: 1) $6.2 million restructuring charge and asset write-off reversals consisting of $1.7 million restructuring charge reversal and a $4.5 million gain on sale of a facility reducing the write-offs recorded in 1998, 2) income of $1.5 million from a partnering agreement, 3) $4.5 million loss on the permanent impairment of equity investments, 4) gain on the sale of divested pharmaceutical products in Brazil of $2.0 million, 5) $4.2 million unrealized gain on derivative instruments, and 6) $4.4 million associated with the spin-off of the Company's ophthalmic surgical and contact lens care businesses.

The adjusted amounts in 2000 exclude the after-tax effect of the following: 1) a $0.2 million restructuring charge, 2) gain on the sale of investments of $1.3 million, and 3) expenses of $2.0 million from partnering agreements.

The adjusted amounts in 1999 exclude the after-tax effect of the following: 1) $3.6 million in restructuring charge reversals, 2) $0.8 million in asset gains, reducing write-offs recorded in 1998, 3) gain on sales of investments of $14.0 million, 4) the contribution to The Allergan Foundation of $6.9 million, 5) income of $9.5 million, net of expenses of $5.7 million, from partnering agreements, and 6) other one-time costs totaling $1.1 million.



Unwavering Commitment

ANNUAL REPORT 2005

Diving deeper. Reaching further.

ALLERGAN

AGN000279

In millions, except per share data	2005	2004	Year Ended December 31, 2003
STATEMENT OF OPERATIONS HIGHLIGHTS (As reported under U.S. GAAP)			
Product net sales	**$2,319.2**	$2,045.6	$1,755.4
Gross profit	**1,919.6**	1,658.9	1,435.1
Research and development	**391.0**	345.6	763.5
Earnings (loss) from continuing operations	**403.9**	377.1	(52.5)
Earnings from discontinued operations	**—**	—	—
Net earnings (loss)	**403.9**	377.1	(52.5)
Basic earnings (loss) per share:			
Continuing operations	**3.08**	2.87	(0.40)
Discontinued operations	**—**	—	—
Diluted earnings (loss) per share:			
Continuing operations	**3.01**	2.82	(0.40)
Discontinued operations	**—**	—	—
Dividends per share	**0.40**	0.36	0.36
ADJUSTED AMOUNTS (a)			
Adjusted earnings from continuing operations	**453.3**	368.8	305.2
Adjusted basic earnings per share:			
Continuing operations	**3.46**	2.81	2.34
Adjusted diluted earnings per share:			
Continuing operations	**3.38**	2.75	2.30
NET SALES BY PRODUCT LINE			
Specialty Pharmaceuticals:			
Eye Care Pharmaceuticals	**$1,321.7**	$1,137.1	$ 999.5
BOTOX®/Neuromodulators	**830.9**	705.1	563.9
Skin Care	**120.2**	103.4	109.3
Total Pharmaceutical Sales	**2,272.8**	1,945.6	1,672.7
Other	**46.4**	100.0	82.7
Total Net Sales	**$2,319.2**	$2,045.6	$1,755.4
PRODUCT SOLD BY LOCATION			
Domestic	**67.5%**	69.1%	70.4%
International	**32.5%**	30.9%	29.6%

(a) The adjusted amounts in 2005 exclude income taxes of $49.6 million related to the repatriation of foreign earnings that had been previously permanently reinvested outside the United States, and income tax benefits of $24.1 million related to the resolution of uncertain tax positions and an additional benefit for state income taxes of $1.4 million, and the after-tax effects of the following: 1) $28.8 million restructuring charge and $5.6 million of transition/duplicate operating costs related to the streamlining of the Company's European operations, 2) $12.9 million restructuring charge related to the scheduled termination of the Company's manufacturing and supply agreement with Advanced Medical Optics, 3) $7.9 million gain on the sale of a distribution business in India, 4) $7.3 million reduction in interest expense related to the resolution of uncertain income tax positions and $2.1 million of interest income related to previously paid state income taxes, 5) $5.7 million gain on the sale of assets previously used in contract manufacturing activities, 6) $2.3 million restructuring charge related to the streamlining of the Company's operations in Japan, 7) $0.6 million gain on the sale of a former manufacturing plant in Argentina, 8) $0.8 million gain on the sale of a third party equity investment, 9) $3.6 million gain on the termination of the Vitrase collaboration agreement with ISTA Pharmaceuticals, 10) $3.0 million buy-out of a license agreement with Johns Hopkins University, 11) $0.4 million in costs related to the acquisition of Inamed Corporation, and 12) $1.1 million unrealized gain on derivative instruments.

The adjusted amounts in 2004 exclude the favorable recovery of $6.1 million of previously paid state income taxes and the after-tax effects of the following: 1) income of $2.4 million from a patent infringement settlement, 2) $7.0 million restructuring charge related to the scheduled termination of the Company's manufacturing and supply agreement with Advanced Medical Optics, 3) $0.4 million unrealized loss on derivative instruments, and 4) income of $11.5 million from a technology transfer fee and a revised Vitrase collaboration agreement with ISTA Pharmaceuticals.

The adjusted amounts in 2003 exclude the after-tax effects of the following: 1) $179.2 million charge for in-process research and development related to the purchase of Oculex Pharmaceuticals, Inc., 2) $278.8 million charge for in-pro the purchase of Bardeen Sciences Company, LLC, 3) $0.4 asset write-offs, net related to the 2002 spin-off of the lens care businesses, 4) $0.3 million unrealized loss on de charge for the early extinguishment of convertible debt.

The adjusted amounts in 2002 exclude the after-tax effe litigation settlement costs, 2) net costs of $100.3 million Company's ophthalmic surgical and contact lens care bus consist of restructuring charge and asset write-offs of $ of $42.5 million and gain of $5.7 million on sale of a fac temporary impairment of equity investments, 4) $1.7 milli 5) net gain of $1.0 million from partnering agreements, a extinguishment of convertible debt.

The adjusted amounts in 2001 exclude the $40.0 million ment related to the purchase of Allergan Specialty Thera following: 1) $6.2 million restructuring charge and asset restructuring charge reversal and a $4.5 million gain on recorded in 1998, 2) income of $1.5 million from a part on the permanent impairment of equity investments, 4) pharmaceutical products in Brazil, 5) $4.2 million unreal 6) $4.4 million associated with the 2002 spin-off of the lens care businesses.

The foregoing language contains certain non-GAAP fi adjustments. For a reconciliation of these non-GAAP measures, please refer to pages 2 and 3 of this Annua

Creating Opportunities Through Specialization

A BREAKTHROUGH YEAR IN R&D

2010
ANNUAL REPORT

ALLERGAN

AGN000383

Financial Summary

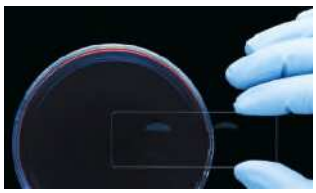
In millions, except per share data	Year Ended December 31, 2010	2009	2008	2007	2006
STATEMENT OF OPERATIONS HIGHLIGHTS					
(As reported under U.S. GAAP)					
Product net sales	**$ 4,819.6**	$ 4,447.6	$ 4,339.7	$ 3,879.0	$ 3,010.1
Total revenues	**4,919.4**	4,503.6	4,403.4	3,938.9	3,063.3
Research and development	**804.6**	706.0	797.9	718.1	1,055.5
Earnings (loss) from continuing operations	**4.9**	623.8	564.7	487.0	(127.0)
Loss from discontinued operations	**—**	—	—	(1.7)	—
Net earnings attributable to noncontrolling interest	**4.3**	2.5	1.6	0.5	0.4
Net earnings (loss) attributable to Allergan, Inc.	**$ 0.6**	$ 621.3	$ 563.1	$ 484.8	$ (127.4)
Net basic earnings (loss) per share attributable to Allergan, Inc. stockholders	**$ 0.00**	$ 2.05	$ 1.85	$ 1.59	$ (0.43)
Net diluted earnings (loss) per share attributable to Allergan, Inc. stockholders	**$ 0.00**	$ 2.03	$ 1.84	$ 1.57	$ (0.43)
Dividends per share	**$ 0.20**	$ 0.20	$ 0.20	$ 0.20	$ 0.20
ADJUSTED AMOUNTS[a]					
Adjusted net earnings attributable to Allergan, Inc.	**$ 973.9**	$ 849.8	$ 786.5	$ 672.9	$ 547.2
Adjusted net basic earnings per share attributable to Allergan, Inc. stockholders	**$ 3.21**	$ 2.80	$ 2.59	$ 2.21	$ 1.86
Adjusted net diluted earnings per share attributable to Allergan, Inc. stockholders	**$ 3.16**	$ 2.78	$ 2.57	$ 2.18	$ 1.83
NET SALES BY PRODUCT LINE					
Specialty Pharmaceuticals:					
Eye Care Pharmaceuticals	**$ 2,262.0**	$ 2,100.6	$ 2,009.1	$ 1,776.5	$ 1,530.6
BOTOX®/Neuromodulator	**1,419.4**	1,309.6	1,310.9	1,211.8	982.2
Skin Care	**229.5**	208.0	113.7	110.7	125.7
Urologics	**62.5**	65.6	68.6	6.0	—
Total specialty pharmaceuticals	**3,973.4**	3,683.8	3,502.3	3,105.0	2,638.5
Medical Devices:					
Breast Aesthetics	**319.1**	287.5	310.0	298.4	177.2
Obesity Intervention	**243.3**	258.2	296.0	270.1	142.3
Facial Aesthetics	**283.8**	218.1	231.4	202.8	52.1
Core medical devices	**846.2**	763.8	837.4	771.3	371.6
Other	**—**	—	—	2.7	—
Total medical devices	**846.2**	763.8	837.4	774.0	371.6
Total product net sales	**$ 4,819.6**	$ 4,447.6	$ 4,339.7	$ 3,879.0	$ 3,010.1
PRODUCT SOLD BY LOCATION					
Domestic	**62.6%**	65.4%	64.6%	65.7%	67.4%
International	**37.4%**	34.6%	35.4%	34.3%	32.6%

The information for 2008 and 2007 in this Annual Report has been retrospectively adjusted to reflect the impact of the adoption in the first quarter of 2009 of updates to Financial Accounting Standards Board guidance related to the accounting for convertible debt instruments that may be settled fully or partially in cash upon conversion. The information for 2006 was not retrospectively adjusted.

(a) The adjusted amounts in 2010 exclude an income tax benefit of $0.7 million for a change in estimated income taxes related to uncertain tax positions included in prior year filings, and the after-tax effects of the following: 1) $14.4 million of external costs associated with responding to the U.S. Department of Justice (DOJ) subpoena and related stockholder derivative litigation costs associated with the DOJ settlement; 2) $609.2 million of legal settlement costs associated with an announced resolution with the DOJ regarding Allergan's past U.S. sales and marketing practices relating to certain therapeutic uses of BOTOX®; 3) $369.1 million of aggregate charges related to the impairment of SANCTURA® assets; 4) $36.0 million of licensing fee income for a development and commercialization agreement with Bristol-Myers Squibb Company; 5) $114.5 million amortization of certain acquired intangible assets related to business combinations, asset acquisitions and product licenses; 6) $7.9 million of expense from changes in fair value of contingent consideration, $33.0 million for a distributor termination fee and $1.1 million of integration and transaction costs associated with the purchase of a distributor's business in Turkey related to Allergan's products; 7) $43.0 million for an upfront payment for technology that has not achieved regulatory approval and related transaction costs of $0.4 million; 8) $10.6 million write-off of manufacturing assets related to the abandonment of an eye care product; 9) $25.1 million non-cash interest expense associated with amortization of convertible debt discount; 10) $0.8 million restructuring charges and $0.5 million of integration and transaction costs related to the acquisition of Serica Technologies, Inc.; 11) a $0.3 million restructuring charge reversal related to the phased closure of the Arklow, Ireland breast implant manufacturing plant and a $0.2 million restructuring charge reversal related to the streamlining of the Company's European operations; and 12) $7.6 million unrealized loss on derivative instruments.

The adjusted amounts in 2009 exclude a net expense of $4.1 million for a change in estimated income taxes related to pre-acquisition periods associated with business combinations and uncertain tax positions included in prior year filings and an income tax benefit of $6.7 million related to foreign research and development tax credits received for tax years prior to 2008, and the after-tax effects of the following: 1) $124.4 million amortization of certain acquired intangible assets related to business combinations, asset acquisitions and product licenses; 2) $78.6 million compensation expense from stock option modifications, $42.2 million restructuring charges and $2.3 million asset impairments and accelerated depreciation costs related to the restructuring plan announced in February 2009; 3) $24.5 million non-cash interest expense associated with amortization of convertible debt discount; 4) $24.6 million net gain on the sale of investments; 5) $10.0 million for an upfront payment for the in-licensing of technology that has not achieved regulatory approval; 6) $8.4 million restructuring charges and $14.5 million for the rollout of capitalized employee retention termination benefits and accelerated depreciation costs and one-time termination benefits related to the phased closure of the Arklow, Ireland breast implant manufacturing plant; 7) $32.2 million of external costs associated with responding to the DOJ subpoena; 8) $14.0 million gain on settlement of a manufacturing and distribution agreement related to an eye care pharmaceuticals product; 9) $18.0 million contribution to The Allergan Foundation; 10) $5.3 million of loss on the extinguishment of convertible debt; 11) a $0.3 million restructuring charge reversal related to the phased closure of the Fremont, California collagen manufacturing plant and $0.6 million of restructuring charges related to the streamlining of the Company's European operations; 12) $0.4 million of integration and transition costs related to the acquisition of Groupe Cornéal Laboratoires (Cornéal); 13) $0.8 million for the fair market value inventory adjustment rollout and $0.4 million of transaction costs associated with the creation of Samil Allergan Ophthalmic Joint Venture Company; and 14) $13.6 million unrealized loss on derivative instruments.

Innovation for the future



ALLERGAN

2012 ANNUAL REPORT

AGN000763

Financial Summary

In millions, except per share data	2012	2011	2010	2009	2008
	Year Ended December 31,				
STATEMENT OF OPERATIONS HIGHLIGHTS (As reported under U.S. GAAP)					
Product net sales	**$ 5,708.8**	$ 5,347.1	$ 4,819.6	$ 4,447.6	$ 4,339.7
Total revenues	**5,806.1**	5,419.1	4,919.4	4,503.6	4,403.4
Research and development	**989.6**	902.8	804.6	706.0	797.9
Net earnings	**1,102.5**	938.1	4.9	623.8	564.7
Net earnings attributable to noncontrolling interest	**3.7**	3.6	4.3	2.5	1.6
Net earnings attributable to Allergan, Inc.	**$ 1,098.8**	$ 934.5	$ 0.6	$ 621.3	$ 563.1
Net basic earnings per share attributable to Allergan, Inc. stockholders	**$ 3.64**	$ 3.07	$ 0.00	$ 2.05	$ 1.85
Net diluted earnings per share attributable to Allergan, Inc. stockholders	**$ 3.58**	$ 3.01	$ 0.00	$ 2.03	$ 1.84
Dividends per share	**$ 0.20**	$ 0.20	$ 0.20	$ 0.20	$ 0.20
ADJUSTED AMOUNTS[a]					
Adjusted net earnings attributable to Allergan, Inc.	**$ 1,272.3**	$ 1,131.8	$ 973.9	$ 849.8	$ 786.5
Adjusted net basic earnings per share attributable to Allergan, Inc. stockholders	**$ 4.22**	$ 3.72	$ 3.21	$ 2.80	$ 2.59
Adjusted net diluted earnings per share attributable to Allergan, Inc. stockholders	**$ 4.14**	$ 3.65	$ 3.16	$ 2.78	$ 2.57
NET SALES BY PRODUCT LINE					
Specialty Pharmaceuticals:					
Eye Care Pharmaceuticals	**$ 2,692.2**	$ 2,520.2	$ 2,262.0	$ 2,100.6	$ 2,009.1
BOTOX®/Neuromodulator	**1,766.3**	1,594.9	1,419.4	1,309.6	1,310.9
Skin Care	**298.4**	260.1	229.5	208.0	113.7
Urologics	**27.7**	56.8	62.5	65.6	68.6
Total specialty pharmaceuticals	**4,784.6**	4,432.0	3,973.4	3,683.8	3,502.3
Medical Devices:					
Breast Aesthetics	**377.1**	349.3	319.1	287.5	310.0
Obesity Intervention	**159.5**	203.1	243.3	258.2	296.0
Facial Aesthetics	**387.6**	362.7	283.8	218.1	231.4
Total medical devices	**924.2**	915.1	846.2	763.8	837.4
Total product net sales	**$ 5,708.8**	$ 5,347.1	$ 4,819.6	$ 4,447.6	$ 4,339.7
PRODUCT SOLD BY LOCATION					
Domestic	**60.9%**	60.2%	62.6%	65.4%	64.6%
International	**39.1%**	39.8%	37.4%	34.6%	35.4%

(a) The adjusted amounts represent certain non-GAAP financial measures. For a reconciliation of these non-GAAP financial measures to GAAP financial measures, please refer to pages 8 and 9 of this Annual Report.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2014

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 1-10269

Allergan, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**95-1622442**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
2525 Dupont Drive Irvine, California	**92612**
(Address of Principal Executive Offices)	(Zip Code)

(714) 246-4500
(Registrant's Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.01 Par Value	New York Stock Exchange

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☑	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of June 30, 2014, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $50,168 million based on the closing sale price as reported on the New York Stock Exchange.

Common stock outstanding as of February 12, 2015 — 307,605,860 shares (including 7,368,166 shares held in treasury).

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The following table compares net sales by product line within each reportable segment and certain selected pharmaceutical products for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		Change in Product Net Sales			Percent Change in Product Net Sales		
	2014	2013	Total	Performance	Currency	Total	Performance	Currency
			(in millions)					
Net Sales by Product Line:								
Specialty Pharmaceuticals:								
Eye Care Pharmaceuticals	$3,257.9	$2,890.3	$367.6	$ 407.1	$ (39.5)	12.7 %	14.1 %	(1.4)%
Botox®/Neuromodulator	2,230.6	1,982.2	248.4	280.6	(32.2)	12.5 %	14.2 %	(1.7)%
Skin Care and Other	523.6	466.5	57.1	58.3	(1.2)	12.2 %	12.5 %	(0.3)%
Total Specialty Pharmaceuticals	6,012.1	5,339.0	673.1	746.0	(72.9)	12.6 %	14.0 %	(1.4)%
Medical Devices:								
Breast Aesthetics	406.7	377.9	28.8	33.8	(5.0)	7.6 %	8.9 %	(1.3)%
Facial Aesthetics	661.8	477.5	184.3	199.4	(15.1)	38.6 %	41.8 %	(3.2)%
Core Medical Devices	1,068.5	855.4	213.1	233.2	(20.1)	24.9 %	27.3 %	(2.4)%
Other	45.5	3.1	42.4	42.4	—	N/A	N/A	N/A
Total Medical Devices	1,114.0	858.5	255.5	275.6	(20.1)	29.8 %	32.1 %	(2.3)%
Total product net sales	$7,126.1	$6,197.5	$928.6	$ 1,021.6	$ (93.0)	15.0 %	16.5 %	(1.5)%
Domestic product net sales	63.4%	62.0%						
International product net sales	36.6%	38.0%						
Selected Product Net Sales (a):								
Alphagan® *P*, *Alphagan*® and *Combigan*®	$ 515.4	$ 474.1	$ 41.3	$ 48.8	$ (7.5)	8.7 %	10.3 %	(1.6)%
Lumigan® Franchise	662.6	625.3	37.3	42.4	(5.1)	6.0 %	6.8 %	(0.8)%
Total Glaucoma Products	1,186.3	1,108.5	77.8	90.5	(12.7)	7.0 %	8.2 %	(1.2)%
Restasis®	1,083.7	940.0	143.7	149.4	(5.7)	15.3 %	15.9 %	(0.6)%
Latisse®	98.6	100.0	(1.4)	(0.4)	(1.0)	(1.4)%	(0.4)%	(1.0)%
Total Specialty Pharmaceuticals and Core Medical Devices	7,080.6	6,194.4	886.2	979.2	(93.0)	14.3 %	15.8 %	(1.5)%

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number	Exact name of registrant as specified in its charter, principal office and address and telephone number	State of incorporation or organization	I.R.S. Employer Identification No.
001-36867	**Allergan plc** Clonshaugh Business and Technology Park Coolock, Dublin, D17 E400, Ireland (862) 261-7000	Ireland	98-1114402
001-36887	**Warner Chilcott Limited** Cannon's Court 22 Victoria Street Hamilton HM 12 Bermuda (441) 295-2244	Bermuda	98-0496358

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Allergan plc Ordinary Shares, $0.0001 par value	New York Stock Exchange
Allergan plc 5.500% Mandatory Convertible Preferred Shares, Series A, par value of $0.0001	New York Stock Exchange
Actavis Funding SCS $500,000,000 Floating Rate Notes due 2016*	New York Stock Exchange

*Notes issued by Actavis Funding SCS and guaranteed by Warner Chilcott Limited

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Allergan plc	☐
Warner Chilcott Limited	☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Allergan plc	Large accelerated filer	☒ Accelerated filer	☐
	Non-accelerated filer (Do not check if a smaller reporting company)	☐ Smaller reporting company	☐
Warner Chilcott Limited	Large accelerated filer	☐ Accelerated filer	☐
	Non-accelerated filer (Do not check if a smaller reporting company)	☒ Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of Allergan plc as of June 30, 2015, based upon the last sale price reported for such date on the New York Stock Exchange, was $119.0 billion. The calculation of the aggregate market value of voting and non-voting stock excludes Class A ordinary shares of Allergan plc held by executive officers, directors, and stockholders that the registrant concluded were affiliates of Allergan plc on that date.

Number of shares of Allergan plc's Ordinary Shares outstanding on February 15, 2016: 394,687,384

This Annual Report on Form 10-K is a combined report being filed separately by two different registrants: Allergan plc and Warner Chilcott Limited. Warner Chilcott Limited is an indirect wholly owned subsidiary of Allergan plc. The information in this Annual Report on Form 10-K is equally applicable to Allergan plc and Warner Chilcott Limited, except where otherwise indicated. Warner Chilcott Limited meets the conditions set forth in General Instruction H(1)(a) and (b) of Form 10-K and, to the extent applicable, is therefore filing this form with a reduced disclosure format.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K ("Annual Report") is incorporated by reference from the Allergan plc proxy statement to be filed pursuant to Regulation 14A with respect to the Registrant's Annual Meeting of Shareholders to be held on or about May 5, 2016.

ALLERGAN PLC

WARNER CHILCOTT LIMITED

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FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2015

The following is a reconciliation of net revenues for the operating segments to the Company's net revenues for the years ended December 31, 2015 and 2014 ($ in millions):

	Years Ended December 31,		Change	
	2015	2014	Dollars	%
Segment net revenues	$ 15,060.9	$ 6,738.9	$ 8,322.0	123.5%
Corporate revenues	10.1	-	10.1	n.a.
Net revenues	**$ 15,071.0**	**$ 6,738.9**	**$ 8,332.1**	**123.6%**

No country represents ten percent or more of net revenues outside of the United States. The US Brands, US Medical Aesthetics, and Anda Distribution segments are comprised solely of sales within the United States.

The following table presents global net revenues for the top products of the Company for the years ended December 31, 2015 and 2014 ($ in millions):

	Years Ended December 31,											
	Global				U.S.				International			
	2015	2014	$ Change	% Change	2015	2014	$ Change	% Change	2015	2014	$ Change	% Change
Botox®	$ 1,975.7	$ -	$ 1,975.7	n.a.	$ 1,386.6	$ -	$ 1,386.6	n.a.	$ 589.1	$ -	$ 589.1	n.a.
Restasis®	1,047.8	-	1,047.8	n.a.	999.6	-	999.6	n.a.	48.2	-	48.2	n.a.
Namenda XR®	759.3	269.5	489.8	181.7%	759.3	269.5	489.8	181.7%	-	-	-	n.a.
Bystolic®	646.1	292.6	353.5	120.8%	644.8	291.6	353.2	121.1%	1.3	1.0	0.3	30.0%
Asacol®/Delzicol®	618.5	614.1	4.4	0.7%	552.9	541.0	11.9	2.2%	65.6	73.1	(7.5)	(10.3)%
Fillers	573.9	-	573.9	n.a.	304.3	-	304.3	n.a.	269.6	-	269.6	n.a.
Namenda® IR	556.3	629.7	(73.4)	(11.7)%	556.3	629.7	(73.4)	(11.7)%	-	-	-	n.a.
Lumigan®/Ganfort®	547.3	-	547.3	n.a.	260.7	-	260.7	n.a.	286.6	-	286.6	n.a.
Linzess®/Constella®	459.3	174.4	284.9	163.4%	454.8	173.2	281.6	162.6%	4.5	1.2	3.3	275.0%
Alphagan®/Combigan®	411.1	-	411.1	n.a.	285.0	-	285.0	n.a.	126.1	-	126.1	n.a.
Lo Loestrin®	349.6	277.1	72.5	26.2%	346.5	275.7	70.8	25.7%	3.1	1.4	1.7	121.4%
Viibryd®/Fetzima®	327.6	140.3	187.3	133.5%	327.6	140.3	187.3	133.5%	-	-	-	n.a.
Estrace® Cream	326.2	258.2	68.0	26.3%	326.2	258.2	68.0	26.3%	-	-	-	n.a.
Minastrin® 24	273.0	217.9	55.1	25.3%	272.4	217.9	54.5	25.0%	0.6	-	0.6	n.a.
Silicone Implants	229.7	-	229.7	n.a.	113.3	-	113.3	n.a.	116.4	-	116.4	n.a.
Carafate ® / Sulcrate ®	213.1	90.9	122.2	134.4%	213.1	90.9	122.2	134.4%	-	-	-	n.a.
Aczone®	170.8	-	170.8	n.a.	170.8	-	170.8	n.a.	-	-	-	n.a.
Other Products Revenues	3,360.3	1,750.0	1,610.3	92.0%	2,684.1	1,623.2	1,060.9	65.4%	676.2	126.8	549.4	433.3%
Total Products Revenues	**12,845.6**	**4,714.7**	**8,130.9**	**172.5%**	**10,658.3**	**4,511.2**	**6,147.1**	**136.3%**	**2,187.3**	**203.5**	**1,983.8**	**974.8%**
ANDA Revenues	2,225.4	2,024.2	201.2	9.9%	2,225.4	2,024.2	201.2	9.9%	-	-	-	n.a.
Total Net Revenues	**$15,071.0**	**$6,738.9**	**$ 8,332.1**	**123.6%**	**$12,883.7**	**$6,535.4**	**$ 6,348.3**	**97.1%**	**$2,187.3**	**$203.5**	**$ 1,983.8**	**974.8%**

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2016

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number	Exact name of registrant as specified in its charter, principal office and address and telephone number	State of incorporation or organization	I.R.S. Employer Identification No.
001-36867	**Allergan plc** Clonshaugh Business and Technology Park Coolock, Dublin, D17 E400, Ireland (862) 261-7000	Ireland	98-1114402
001-36887	**Warner Chilcott Limited** Cannon's Court 22 Victoria Street Hamilton HM 12 Bermuda (441) 295-2244	Bermuda	98-0496358

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Allergan plc Ordinary Shares, $0.0001 par value	New York Stock Exchange
Allergan plc 5.500% Mandatory Convertible Preferred Shares, Series A, par value of $0.0001	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Allergan plc	☐
Warner Chilcott Limited	☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Allergan plc	Large accelerated filer	☒	Accelerated filer	☐
	Non-accelerated filer (Do not check if a smaller reporting company)	☐	Smaller reporting company	☐
Warner Chilcott Limited	Large accelerated filer	☐	Accelerated filer	☐
	Non-accelerated filer (Do not check if a smaller reporting company)	☒	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of Allergan plc as of June 30, 2016, based upon the last sale price reported for such date on the New York Stock Exchange, was $91.3 billion. The calculation of the aggregate market value of voting and non-voting stock excludes Class A ordinary shares of Allergan plc held by executive officers, directors, and stockholders that the registrant concluded were affiliates of Allergan plc on that date.

Number of shares of Allergan plc's Ordinary Shares outstanding on February 17, 2017: 335,224,713

This Annual Report on Form 10-K is a combined report being filed separately by two different registrants: Allergan plc and Warner Chilcott Limited. Warner Chilcott Limited is an indirect wholly owned subsidiary of Allergan plc. The information in this Annual Report on Form 10-K is equally applicable to Allergan plc and Warner Chilcott Limited, except where otherwise indicated. Warner Chilcott Limited meets the conditions set forth in General Instruction H(1)(a) and (b) of Form 10-K and, to the extent applicable, is therefore filing this form with a reduced disclosure format.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K ("Annual Report") is incorporated by reference from the Allergan plc proxy statement to be filed pursuant to Regulation 14A with respect to the Registrant's Annual General Meeting of Shareholders to be held on or about May 4, 2017.

ALLERGAN PLC

WARNER CHILCOTT LIMITED

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FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2016

The following is a reconciliation of net revenues for the operating segments to the Company's net revenues for the years ended December 31, 2016 and 2015 ($ in millions):

	Years Ended December 31,		Change	
	2016	2015	Dollars	%
Segment net revenues	$ 14,616.9	$ 12,835.5	$ 1,781.4	13.9%
Corporate revenues	(46.3)	(147.4)	101.1	(68.6)%
Net revenues	**$ 14,570.6**	**$ 12,688.1**	**$ 1,882.5**	**14.8%**

No country represents ten percent or more of net revenues outside of the United States. The US Specialized Therapeutics and US General Medicine segments are comprised solely of sales within the United States.

The following table presents global net revenues for the top products of the Company for the years ended December 31, 2016 and 2015 ($ in millions):

	Year Ended December 31, 2016					Year Ended December 31, 2015					Change	
	US Specialized Therapeutics	US General Medicine	International	Corporate	Total	US Specialized Therapeutics	US General Medicine	International	Corporate	Total	Dollars	Percentage
Botox®	$ 1,983.2	$ -	$ 803.0	$ -	$ 2,786.2	$ 1,386.4	$ -	$ 584.4	$ -	$ 1,970.8	$ 815.4	41.4%
Restasis®	1,419.3	-	68.0	-	1,487.3	999.6	-	48.2	-	1,047.8	439.7	42.0%
Fillers	446.9	-	420.4	-	867.3	304.4	-	269.5	-	573.9	293.4	51.1%
Lumigan®/Ganfort®	326.4	-	361.7	-	688.1	260.7	-	283.4	-	544.1	144.0	26.5%
Linzess®/Constella®	-	625.6	17.3	-	642.9	-	454.8	4.5	-	459.3	183.6	40.0%
Bystolic® / Byvalson®	-	638.8	1.7	-	640.5	-	644.8	1.3	-	646.1	(5.6)	(0.9)%
Namenda XR®	-	627.6	-	-	627.6	-	759.3	-	-	759.3	(131.7)	(17.3)%
Alphagan®/Combigan®	376.6	-	169.3	-	545.9	285.0	-	126.1	-	411.1	134.8	32.8%
Asacol®/Delzicol®	-	360.8	53.7	-	414.5	-	552.9	65.5	-	618.4	(203.9)	(33.0)%
Lo Loestrin®	-	403.5	-	-	403.5	-	346.5	3.1	-	349.6	53.9	15.4%
Estrace® Cream	-	379.4	-	-	379.4	-	326.2	-	-	326.2	53.2	16.3%
Eye Drops	186.5	-	276.2	-	462.7	177.0	-	220.6	-	397.6	65.1	16.4%
Breast Implants	206.0	-	149.9	-	355.9	175.0	-	125.5	-	300.5	55.4	18.4%
Viibryd®/Fetzima®	-	342.3	-	-	342.3	-	327.6	-	-	327.6	14.7	4.5%
Minastrin® 24	-	325.9	1.4	-	327.3	-	272.4	0.6	-	273.0	54.3	19.9%
Ozurdex ®	84.4	-	179.0	-	263.4	56.1	-	112.3	-	168.4	95.0	56.4%
Carafate ® / Sulcrate ®	-	229.0	2.4	-	231.4	-	213.1	-	-	213.1	18.3	8.6%
Aczone®	217.3	-	-	-	217.3	170.8	-	-	-	170.8	46.5	27.2%
Zenpep®	-	200.7	-	-	200.7	-	167.4	-	-	167.4	33.3	19.9%
Canasa®/Salofalk®	-	178.7	17.7	-	196.4	-	137.1	18.5	-	155.6	40.8	26.2%
Saphris®	-	166.8	-	-	166.8	-	186.7	-	-	186.7	(19.9)	(10.7)%
Armour Thyroid	-	166.5	-	-	166.5	-	130.8	-	-	130.8	35.7	27.3%
Teflaro®	-	133.6	-	-	133.6	-	137.6	-	-	137.6	(4.0)	(2.9)%
Rapaflo®	116.6	-	5.8	-	122.4	115.2	-	10.9	-	126.1	(3.7)	(2.9)%
SkinMedica®	108.3	-	-	-	108.3	76.6	-	-	-	76.6	31.7	41.4%
Savella®	-	103.2	-	-	103.2	-	106.4	-	-	106.4	(3.2)	(3.0)%
Tazorac®	95.5	-	0.8	-	96.3	92.3	-	1.4	-	93.7	2.6	2.8%
Vraylar™	-	94.3	-	-	94.3	-	-	-	-	-	94.3	n.a.
Viberzi®	-	93.3	-	-	93.3	-	12.3	-	-	12.3	81.0	n.m.
Latisse®	77.9	-	8.5	-	86.4	63.2	-	10.0	-	73.2	13.2	18.0%
Lexapro®	-	66.6	-	-	66.6	-	71.6	-	-	71.6	(5.0)	(7.0)%
Namzaric®	-	57.5	-	-	57.5	-	11.2	-	-	11.2	46.3	n.m.
Kybella® / Belkyra®	50.2	-	2.3	-	52.5	3.2	-	-	-	3.2	49.3	n.m.
Dalvance®	-	39.3	-	-	39.3	-	16.8	-	-	16.8	22.5	133.9%
Avycaz®	-	36.1	-	-	36.1	-	22.6	-	-	22.6	13.5	59.7%
Liletta®	-	23.3	-	-	23.3	-	14.8	-	-	14.8	8.5	57.4%
Enablex®	-	17.1	-	-	17.1	-	69.2	-	-	69.2	(52.1)	(75.3)%
Namenda® IR	-	15.1	-	-	15.1	-	556.3	-	-	556.3	(541.2)	(97.3)%
Other Products Revenues	116.4	598.9	342.2	33.7	1,091.2	144.3	800.0	301.5	10.0	1,255.8	(164.6)	(13.1)%
Less product sold through our Anda Distribution business	n.a.	n.a.	n.a.	(80.0)	(80.0)	n.a.	n.a.	n.a.	(157.4)	(157.4)	77.4	(49.2)%
Total Net Revenues	**$ 5,811.7**	**$ 5,923.9**	**$ 2,881.3**	**$ (46.3)**	**$ 14,570.6**	**$ 4,309.8**	**$ 6,338.4**	**$ 2,187.3**	**$ (147.4)**	**$ 12,688.1**	**$ 1,882.5**	**14.8%**

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number	Exact name of registrant as specified in its charter, principal office and address and telephone number	State of incorporation or organization	I.R.S. Employer Identification No.
001-36867	**Allergan plc** Clonshaugh Business and Technology Park Coolock, Dublin, D17 E400, Ireland (862) 261-7000	Ireland	98-1114402
001-36887	**Warner Chilcott Limited** Canon's Court 22 Victoria Street Hamilton HM 12 Bermuda (441) 295-2244	Bermuda	98-0496358

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Allergan plc Ordinary Shares, $0.0001 par value	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Allergan plc	☐
Warner Chilcott Limited	☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Allergan plc	Large accelerated filer	☒	Accelerated filer	☐
	Non-accelerated filer	☐	Smaller reporting company	☐
	Emerging growth company	☐		
Warner Chilcott Limited	Large accelerated filer	☐	Accelerated filer	☐
	Non-accelerated filer	☒	Smaller reporting company	☐
	Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of Allergan plc as of June 30, 2018, based upon the last sale price reported for such date on the New York Stock Exchange, was $56.5 billion. The calculation of the aggregate market value of voting and non-voting stock excludes Class A ordinary shares of Allergan plc held by executive officers, directors, and stockholders that the registrant concluded were affiliates of Allergan plc on that date.

Number of shares of Allergan plc's Ordinary Shares outstanding on February 8, 2019: 332,614,474

This Annual Report on Form 10-K is a combined report being filed separately by two different registrants: Allergan plc and Warner Chilcott Limited. Warner Chilcott Limited is an indirect wholly owned subsidiary of Allergan plc. The information in this Annual Report on Form 10-K is equally applicable to Allergan plc and Warner Chilcott Limited, except where otherwise indicated. Warner Chilcott Limited meets the conditions set forth in General Instruction H(1)(a) and (b) of Form 10-K and, to the extent applicable, is therefore filing this form with a reduced disclosure format.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K ("Annual Report") is incorporated by reference from the Allergan plc proxy statement to be filed pursuant to Regulation 14A with respect to the Registrant's Annual General Meeting of Shareholders to be held on May 1, 2019.

ALLERGAN PLC

WARNER CHILCOTT LIMITED

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FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2018

US Specialized Therapeutics Segment

The following table presents top product sales and net contribution for the US Specialized Therapeutics segment for the years ended December 31, 2018, 2017 and 2016 ($ in millions):

	Years Ended December 31,			2018 vs 2017		2017 vs 2016	
	2018	2017	2016 (1)	$ Change	% Change	$ Change	% Change
Total Eye Care	**$ 2,235.7**	**$ 2,460.2**	**$ 2,437.7**	**$ (224.5)**	**(9.1)%**	**$ 22.5**	**0.9%**
Restasis®	1,197.0	1,412.3	1,419.5	(215.3)	(15.2)%	(7.2)	(0.5)%
Alphagan®/Combigan®	375.4	377.3	376.6	(1.9)	(0.5)%	0.7	0.2%
Lumigan®/Ganfort®	291.8	317.5	326.4	(25.7)	(8.1)%	(8.9)	(2.7)%
Eye Drops	202.7	199.5	186.5	3.2	1.6%	13.0	7.0%
Ozurdex®	111.0	98.4	84.4	12.6	12.8%	14.0	16.6%
Other Eye Care	57.8	55.2	44.3	2.6	4.7%	10.9	24.6%
Total Medical Aesthetics	**2,774.6**	**2,449.2**	**1,622.9**	**325.4**	**13.3%**	**826.3**	**50.9%**
Facial Aesthetics	**1,487.3**	**1,362.8**	**1,226.3**	**124.5**	**9.1%**	**136.5**	**11.1%**
Botox® Cosmetics	907.3	812.2	729.2	95.1	11.7%	83.0	11.4%
Juvederm® Collection	548.2	501.1	446.9	47.1	9.4%	54.2	12.1%
Kybella®	31.8	49.5	50.2	(17.7)	(35.8)%	(0.7)	(1.4)%
Plastic Surgery	**263.0**	**242.6**	**210.4**	**20.4**	**8.4%**	**32.2**	**15.3%**
Breast Implants	263.0	242.6	206.0	20.4	8.4%	36.6	17.8%
Other Plastic Surgery	-	-	4.4	-	n.a.	(4.4)	(100.0)%
Regenerative Medicine	**523.9**	**433.9**	**-**	**90.0**	**20.7%**	**433.9**	**n.a.**
Alloderm®	407.3	321.2	-	86.1	26.8%	321.2	n.a.
Other Regenerative Medicine	116.6	112.7	-	3.9	3.5%	112.7	n.a.
Body Contouring	**361.6**	**256.7**	**-**	**104.9**	**40.9%**	**256.7**	**n.a.**
Coolsculpting ® Consumables	235.3	150.1	-	85.2	56.8%	150.1	n.a.
Coolsculpting ® Systems & Add On Applicators	126.3	106.6	-	19.7	18.5%	106.6	n.a.
Skin Care(5)	**138.8**	**153.2**	**186.2**	**(14.4)**	**(9.4)%**	**(33.0)**	**(17.7)%**
Total Medical Dermatology	**115.5**	**273.6**	**331.3**	**(158.1)**	**(57.8)%**	**(57.7)**	**(17.4)%**
Aczone®	55.1	166.3	217.3	(111.2)	(66.9)%	(51.0)	(23.5)%
Tazorac®	25.4	65.4	95.5	(40.0)	(61.2)%	(30.1)	(31.5)%
Other Medical Dermatology	35.0	41.9	18.5	(6.9)	(16.5)%	23.4	n.m.
Total Neuroscience and Urology	**1,720.4**	**1,550.3**	**1,371.5**	**170.1**	**11.0%**	**178.8**	**13.0%**
Botox® Therapeutics(4)	1,638.5	1,442.2	1,254.0	196.3	13.6%	188.2	15.0%
Rapaflo®	81.9	108.1	116.6	(26.2)	(24.2)%	(8.5)	(7.3)%
Other Neuroscience and Urology	-	-	0.9	-	n.a.	(0.9)	(100.0)%
Other revenues	**74.1**	**70.3**	**48.3**	**3.8**	**5.4%**	**22.0**	**45.5%**
Net revenues	**$ 6,920.3**	**$ 6,803.6**	**$ 5,811.7**	**$ 116.7**	**1.7%**	**$ 991.9**	**17.1%**
Operating expenses:							
Cost of sales(2)	565.2	495.4	290.9	69.8	14.1%	204.5	70.3%
Selling and marketing	1,348.3	1,369.5	1,137.0	(21.2)	(1.5)%	232.5	20.4%
General and administrative	205.3	208.2	174.2	(2.9)	(1.4)%	34.0	19.5%
Segment contribution	**$ 4,801.5**	**$ 4,730.5**	**$ 4,209.6**	**$ 71.0**	**1.5%**	**$ 520.9**	**12.4%**
Segment margin	69.4%	69.5%	72.4%		(0.1)%		(2.9)%
Segment gross margin(3)	91.8%	92.7%	95.0%		(0.9)%		(2.3)%

(1) Includes revenues earned that were distributed through our former Anda Distribution business to third party customers.

(2) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(3) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(4) Includes Botox® Hyperhidrosis of $67.2 million and $65.2 million which was previously disclosed under Medical Dermatology in the years ended December 31, 2017 and 2016, respectively.

(5) Includes SkinMedica® and Latisse®.

International Segment

The following tables present top product sales and net contribution for the International segment for the years ended December 31, 2018, 2017 and 2016 ($ in millions):

	Years Ended December 31,		Change					
	2018	2017	$ Overall Change	$ Operational Change (3)	$ Currency Change	% Overall Change	% Operational Change (3)	% Currency Change
Total Eye Care	**$ 1,294.6**	**$ 1,282.1**	**$ 12.5**	**$ 19.4**	**$ (6.9)**	**1.0%**	**1.5%**	**(0.5)%**
Lumigan®/Ganfort®	392.6	371.5	21.1	15.2	5.9	5.7%	4.1%	1.6%
Eye Drops(4)	279.7	281.0	(1.3)	3.7	(5.0)	(0.5)%	1.3%	(1.8)%
Ozurdex®	187.7	213.4	(25.7)	(32.2)	6.5	(12.0)%	(15.0)%	3.0%
Alphagan®/Combigan®	176.0	175.1	0.9	5.8	(4.9)	0.5%	3.3%	(2.8)%
Restasis®	64.5	61.3	3.2	5.9	(2.7)	5.2%	9.6%	(4.4)%
Other Eye Care	194.1	179.8	14.3	21.0	(6.7)	8.0%	11.7%	(3.7)%
Total Medical Aesthetics	**1,533.3**	**1,366.6**	**166.7**	**185.6**	**(18.9)**	**12.2%**	**13.6%**	**(1.4)%**
Facial Aesthetics	**1,262.3**	**1,104.5**	**157.8**	**178.0**	**(20.2)**	**14.3%**	**16.1%**	**(1.8)%**
Botox® Cosmetics	641.2	557.0	84.2	96.6	(12.4)	15.1%	17.3%	(2.2)%
Juvederm® Collection	614.8	540.7	74.1	81.9	(7.8)	13.7%	15.1%	(1.4)%
Belkyra® (Kybella®)	6.3	6.8	(0.5)	(0.5)	(0.0)	(7.4)%	(7.4)%	0.0%
Plastic Surgery	**131.5**	**158.6**	**(27.1)**	**(28.7)**	**1.6**	**(17.1)%**	**(18.1)%**	**1.0%**
Breast Implants	130.1	156.9	(26.8)	(28.5)	1.7	(17.1)%	(18.2)%	1.1%
Other Plastic Surgery	1.4	1.7	(0.3)	(0.2)	(0.1)	(17.6)%	(11.7)%	(5.9)%
Regenerative Medicine	**16.8**	**16.5**	**0.3**	**(0.1)**	**0.4**	**1.8%**	**(0.6)%**	**2.4%**
Alloderm®	8.0	7.5	0.5	0.4	0.1	6.7%	5.4%	1.3%
Other Regenerative Medicine	8.8	9.0	(0.2)	(0.5)	0.3	(2.2)%	(5.5)%	3.3%
Body Contouring	**107.5**	**73.7**	**33.8**	**35.0**	**(1.2)**	**45.9%**	**47.5%**	**(1.6)%**
Coolsculpting ® Consumables	64.2	41.6	22.6	23.1	(0.5)	54.3%	55.5%	(1.2)%
Coolsculpting ® Systems & Add On Applicators	43.3	32.1	11.2	11.9	(0.7)	34.9%	37.1%	(2.2)%
Skin Care	**15.2**	**13.3**	**1.9**	**1.4**	**0.5**	**14.3%**	**10.5%**	**3.8%**
Botox® Therapeutics and Other	**611.5**	**587.4**	**24.1**	**22.7**	**1.4**	**4.1%**	**3.9%**	**0.2%**
Botox® Therapeutics	390.4	357.5	32.9	34.9	(2.0)	9.2%	9.8%	(0.6)%
Asacol®/Delzicol®	45.7	50.2	(4.5)	(5.9)	1.4	(9.0)%	(11.8)%	2.8%
Constella®	24.1	21.9	2.2	1.8	0.4	10.0%	8.2%	1.8%
Other Products	151.3	157.8	(6.5)	(8.1)	1.6	(4.1)%	(5.1)%	1.0%
Other revenues	**65.3**	**83.4**	**(18.1)**	**(18.5)**	**0.4**	**(21.7)%**	**(22.2)%**	**0.5%**
Net revenues	**$ 3,504.7**	**$ 3,319.5**	**$ 185.2**	**$ 209.2**	**$ (24.0)**	**5.6%**	**6.3%**	**(0.7)%**
Operating expenses:								
Cost of sales(1)	537.1	478.7	58.4	66.2	(7.8)	12.2%	13.8%	(1.6)%
Selling and marketing	928.7	913.8	14.9	14.9	0.0	1.6%	1.6%	0.0%
General and administrative	141.7	120.6	21.1	25.6	(4.5)	17.5%	21.2%	(3.7)%
Segment contribution	**$ 1,897.2**	**$ 1,806.4**	**$ 90.8**	**$ 102.5**	**$ (11.7)**	**5.0%**	**5.6%**	**(0.6)%**
Segment margin	54.1%	54.4%				(0.3)%		
Segment gross margin(2)	84.7%	85.6%				(0.9)%		

(1) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(2) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(3) Defined as overall change excluding foreign exchange impact.

(4) Includes Optive® sales of $114.1 million which were previously disclosed separately in the year ended December 31, 2017.

	Years Ended December 31,		Change					
	2017	2016	$ Overall Change	$ Operational Change (3)	$ Currency Change	% Overall Change	% Operational Change (3)	% Currency Change
Total Eye Care	**$ 1,282.1**	**$ 1,219.4**	**$ 62.7**	**$ 48.0**	**$ 14.7**	**5.1%**	**3.9%**	**1.2%**
Lumigan®/Ganfort®	371.5	361.7	9.8	4.9	4.9	2.7%	1.3%	1.4%
Eye Drops(4)	281.0	276.2	4.8	1.1	3.7	1.7%	0.4%	1.3%
Ozurdex®	213.4	179.0	34.4	32.4	2.0	19.2%	18.1%	1.1%
Alphagan®/Combigan®	175.1	169.3	5.8	4.0	1.8	3.4%	2.3%	1.1%
Restasis®	61.3	68.0	(6.7)	(5.9)	(0.8)	(9.9)%	(8.7)%	(1.2)%
Other Eye Care	179.8	165.2	14.6	11.5	3.1	8.8%	6.9%	1.9%
Total Medical Aesthetics	**1,366.6**	**1,064.6**	**302.0**	**301.3**	**0.7**	**28.4%**	**28.3%**	**0.1%**
Facial Aesthetics	**1,104.5**	**902.7**	**201.80**	**202.1**	**(0.3)**	**22.4%**	**22.4%**	**(0.0)%**
Botox® Cosmetics	557.0	480.0	77.0	83.5	(6.5)	16.0%	17.4%	(1.4)%
Juvederm® Collection	540.7	420.4	120.3	114.2	6.1	28.6%	27.1%	1.5%
Belkyra® (Kybella®)	6.8	2.3	4.5	4.4	0.1	n.m.	n.m.	4.3%
Plastic Surgery	**158.6**	**150.7**	**7.90**	**7.3**	**0.6**	**5.2%**	**4.8%**	**0.4%**
Breast Implants	156.9	149.9	7.0	6.4	0.6	4.7%	4.3%	0.4%
Other Plastic Surgery	1.7	0.8	0.9	0.9	-	n.m.	n.m.	0.0%
Regenerative Medicine	**16.5**	**-**	**16.5**	**16.5**	**-**	**n.a.**	**n.a.**	**n.a.**
Alloderm®	7.5	-	7.5	7.5	-	n.a.	n.a.	n.a.
Other Regenerative Medicine	9.0	-	9.0	9.0	-	n.a.	n.a.	n.a.
Body Contouring	**73.7**	**-**	**73.7**	**73.7**	**-**	**n.a.**	**n.a.**	**n.a.**
Coolsculpting ® Consumables	41.6	-	41.6	41.6	-	n.a.	n.a.	n.a.
Coolsculpting ® Systems & Add On Applicators	32.1	-	32.1	32.1	-	n.a.	n.a.	n.a.
Skin Care	**13.3**	**11.2**	**2.1**	**1.7**	**0.4**	**18.8%**	**15.2%**	**3.6%**
Botox® Therapeutics and Other	**587.4**	**537.3**	**50.1**	**43.6**	**6.5**	**9.3%**	**8.1%**	**1.2%**
Botox® Therapeutics	357.5	323.0	34.5	30.1	4.4	10.7%	9.3%	1.4%
Asacol®/Delzicol®	50.2	53.7	(3.5)	(2.3)	(1.2)	(6.5)%	(4.3)%	(2.2)%
Constella®	21.9	17.3	4.6	4.5	0.1	26.6%	26.0%	0.6%
Other Products	157.8	143.3	14.5	11.3	3.2	10.1%	7.9%	2.2%
Other revenues	**83.4**	**60.0**	**23.4**	**22.4**	**1.0**	**39.0%**	**37.3%**	1.7%
Net revenues	**$ 3,319.5**	**$ 2,881.3**	**$ 438.2**	**$ 415.3**	**$ 22.9**	**15.2%**	**14.4%**	**0.8%**
Operating expenses:								
Cost of sales(1)	478.7	418.2	60.5	55.4	5.1	14.5%	13.3%	1.2%
Selling and marketing	913.8	788.2	125.6	114.7	10.9	15.9%	14.5%	1.4%
General and administrative	120.6	117.2	3.4	2.3	1.1	2.9%	2.0%	0.9%
Segment contribution	**$ 1,806.4**	**$ 1,557.7**	**$ 248.7**	**$ 242.9**	**$ 5.8**	**16.0%**	**15.6%**	**0.4%**
Segment margin	54.4%	54.1%				0.3%		
Segment gross margin(2)	85.6%	85.5%				0.1%		

(1) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(2) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(3) Defined as overall change excluding foreign exchange impact.

(4) Includes Optive® sales of $114.1 million and $101.9 million which were previously disclosed separately in the years ended December 31, 2017 and December 31, 2016, respectively.

The following tables present our revenue disaggregated by geography for our International segment ($ in millions):

	Years Ended December 31,					
	2018	2017	$ Overall Change	$ Operational Change	% Overall Change	% Operational Change
Europe	$ 1,482.6	$ 1,439.2	$ 43.4	$ 22.1	3.0%	1.5%
Asia Pacific, Middle East and Africa	1,089.9	929.9	160.0	156.0	17.2%	16.8%
Latin America and Canada	862.4	863.3	(0.9)	48.9	(0.1)%	5.7%
Other*	69.8	87.1	(17.3)	(17.8)	(19.9)%	(20.4)%
Total International	$ 3,504.7	$ 3,319.5	$ 185.2	$ 209.2	5.6%	6.3%

*Includes royalty and other revenue

	Years Ended December 31,					
	2017	2016	$ Overall Change	$ Operational Change	% Overall Change	% Operational Change
Europe	$ 1,439.2	$ 1,322.8	$ 116.4	$ 115.5	8.8%	8.7%
Asia Pacific, Middle East and Africa	929.9	776.1	153.8	153.0	19.8%	19.7%
Latin America and Canada	863.3	722.3	141.0	119.8	19.5%	16.6%
Other*	87.1	60.1	27.0	27.0	44.9%	44.9%
Total International	$ 3,319.5	$ 2,881.3	$ 438.2	$ 415.3	15.2%	14.4%

*Includes royalty and other revenue

The Zeltiq Acquisition contributed the following to the segment in the years ended December 31, 2018 and 2017 ($ in millions):

	For the Years Ended December 31,	
	2018	2017
Net revenues	$ 107.5	$ 73.7
Operating expenses:		
Cost of sales	39.2	25.6
Selling and marketing	54.0	39.0
General and administrative	3.5	-

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Net Revenues

Years Ended December 31, 2018 and 2017

The increase in net revenues in the year ended December 31, 2018 was primarily due to the operational growth of total Facial Aesthetics and Botox® Therapeutics, as well as the Zeltiq Acquisition. Within Facial Aesthetics, the increase in sales of Botox® Cosmetics was driven primarily by demand growth and higher average prices. The increase in sales of Botox® Therapeutics was driven primarily by demand growth. Juvederm® Collection revenues increased versus the prior year period, primarily resulting from demand growth. Within total Eye Care, Ozurdex® decreased versus the prior year period, primarily driven by the third quarter product recall and the temporary period of not shipping product. Plastic Surgery decreased versus the prior year period, primarily driven by a fourth quarter suspension of sales and withdrawal of the remaining textured breast implants from the market in Europe. This suspension and withdrawal followed the non-renewal of our textured breast implant CE Mark licenses in Europe pending a request for additional information by LNE-GMED, the notified body responsible for certification of our breast implants. Sales returns reserves recorded for the recalls totaled $56.7 million in the year ended December 31, 2018.

Years Ended December 31, 2017 and 2016

The increase in net revenues in the year ended December 31, 2017 was primarily due to the operational growth of total Facial Aesthetics, Eye Care and Botox® Therapeutics, as well as the acquisition of Zeltiq, which contributed $73.7 million of net revenues during the year ended December 31, 2017. Within Total Eye Care, Ozurdex® increased primarily due to demand growth. Within Facial Aesthetics, Juvederm® Collection revenues increased primarily resulting from demand growth. Botox® Cosmetics sales grew due to demand growth. Botox® Therapeutics sales also grew due to demand growth. International operational growth came from all regions primarily driven by Facial Aesthetics.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2019
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number	Exact name of registrant as specified in its charter, principal office and address and telephone number	State of incorporation or organization	I.R.S. Employer Identification No.
001-36867	**Allergan plc** Clonshaugh Business and Technology Park Coolock, Dublin, D17 E400, Ireland (862) 261-7000	Ireland	98-1114402
001-36887	**Warner Chilcott Limited** Victoria Place, 5th Floor Hamilton HM 10 Bermuda (441) 295-2244	Bermuda	98-0496358

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Allergan plc Ordinary Shares, $0.0001 par value	AGN	New York Stock Exchange
Floating rate notes due 2020	AGN20A	New York Stock Exchange
0.500% notes due 2021	AGN21	New York Stock Exchange
1.500% notes due 2023	AGN 23A	New York Stock Exchange
1.250% notes due 2024	AGN 24A	New York Stock Exchange
2.625% notes due 2028	AGN28	New York Stock Exchange
2.125% notes due 2029	AGN29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Allergan plc	Yes ☒	No ☐
Warner Chilcott Limited	Yes ☒	No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Allergan plc	☐
Warner Chilcott Limited	☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Allergan plc	Large accelerated filer	☒	Accelerated filer	☐
	Non-accelerated filer	☐	Smaller reporting company	☐
	Emerging growth company	☐		
Warner Chilcott Limited	Large accelerated filer	☐	Accelerated filer	☐
	Non-accelerated filer	☒	Smaller reporting company	☐
	Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Allergan plc	Yes ☐	No ☒
Warner Chilcott Limited	Yes ☐	No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of Allergan plc as of June 30, 2019, based upon the last sale price reported for such date on the New York Stock Exchange, was $54.8 billion. The calculation of the aggregate market value of voting and non-voting stock excludes Class A ordinary shares of Allergan plc held by executive officers, directors, and stockholders that the registrant concluded were affiliates of Allergan plc on that date.

Number of shares of Allergan plc's Ordinary Shares outstanding on February 12, 2020: 329,002,015

This Annual Report on Form 10-K is a combined report being filed separately by two different registrants: Allergan plc and Warner Chilcott Limited. Warner Chilcott Limited is an indirect wholly owned subsidiary of Allergan plc. The information in this Annual Report on Form 10-K is equally applicable to Allergan plc and Warner Chilcott Limited, except where otherwise indicated. Warner Chilcott Limited meets the conditions set forth in General Instruction H(1)(a) and (b) of Form 10-K and, to the extent applicable, is therefore filing this form with a reduced disclosure format.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K ("Annual Report") is incorporated by reference from the Allergan plc proxy statement to be filed pursuant to Regulation 14A with respect to the Registrant's 2020 Annual General Meeting of Shareholders or, alternatively included in amendment to this Form 10-K which will be filed within 120 days of the Regisrant's fiscal year ended December 31, 2019.

US Specialized Therapeutics Segment

The following table presents top product sales and net contribution for the US Specialized Therapeutics segment for the years ended December 31, 2019, 2018 and 2017 ($ in millions):

	Years Ended December 31,			2019 vs 2018		2018 vs 2017	
	2019	2018	2017	$ Change	% Change	$ Change	% Change
Total Eye Care	**$ 2,182.4**	**$ 2,235.7**	**$ 2,460.2**	**$ (53.3)**	**(2.4)%**	**$ (224.5)**	**(9.1)%**
Restasis®	1,138.4	1,197.0	1,412.3	(58.6)	(4.9)%	(215.3)	(15.2)%
Alphagan®/Combigan®	360.0	375.4	377.3	(15.4)	(4.1)%	(1.9)	(0.5)%
Lumigan®/Ganfort®	269.2	291.8	317.5	(22.6)	(7.7)%	(25.7)	(8.1)%
Eye Drops	230.4	202.7	199.5	27.7	13.7%	3.2	1.6%
Ozurdex®	125.5	111.0	98.4	14.5	13.1%	12.6	12.8%
Other Eye Care	58.9	57.8	55.2	1.1	1.9%	2.6	4.7%
Total Medical Aesthetics	**2,772.0**	**2,774.6**	**2,449.2**	**(2.6)**	**(0.1)%**	**325.4**	**13.3%**
Facial Aesthetics	**1,606.2**	**1,487.3**	**1,362.8**	**118.9**	**8.0%**	**124.5**	**9.1%**
Botox® Cosmetics	991.3	907.3	812.2	84.0	9.3%	95.1	11.7%
Juvederm® Collection	587.5	548.2	501.1	39.3	7.2%	47.1	9.4%
Kybella®	27.4	31.8	49.5	(4.4)	(13.8)%	(17.7)	(35.8)%
Plastic Surgery	**254.4**	**263.0**	**242.6**	**(8.6)**	**(3.3)%**	**20.4**	**8.4%**
Breast Implants	254.4	263.0	242.6	(8.6)	(3.3)%	20.4	8.4%
Regenerative Medicine	**505.3**	**523.9**	**433.9**	**(18.6)**	**(3.6)%**	**90.0**	**20.7%**
Alloderm®	395.9	407.3	321.2	(11.4)	(2.8)%	86.1	26.8%
Other Regenerative Medicine	109.4	116.6	112.7	(7.2)	(6.2)%	3.9	3.5%
Body Contouring	**248.1**	**361.6**	**256.7**	**(113.5)**	**(31.4)%**	**104.9**	**40.9%**
Coolsculpting ® Consumables	185.3	235.3	150.1	(50.0)	(21.2)%	85.2	56.8%
Coolsculpting ® Systems & Add On Applicators	62.8	126.3	106.6	(63.5)	(50.3)%	19.7	18.5%
Skin Care (3)	**158.0**	**138.8**	**153.2**	**19.2**	**13.8%**	**(14.4)**	**(9.4)%**
Total Medical Dermatology	**44.0**	**115.5**	**273.6**	**(71.5)**	**(61.9)%**	**(158.1)**	**(57.8)%**
Aczone®	9.3	55.1	166.3	(45.8)	(83.1)%	(111.2)	(66.9)%
Other Medical Dermatology(4)	34.7	60.4	107.3	(25.7)	(42.5)%	(46.9)	(43.7)%
Total Neuroscience and Urology	**1,762.7**	**1,720.4**	**1,550.3**	**42.3**	**2.5%**	**170.1**	**11.0%**
Botox® Therapeutics	1,739.2	1,638.5	1,442.2	100.7	6.1%	196.3	13.6%
Rapaflo®	23.5	81.9	108.1	(58.4)	(71.3)%	(26.2)	(24.2)%
Other revenues	**58.9**	**74.1**	**70.3**	**(15.2)**	**(20.5)%**	**3.8**	**5.4%**
Net revenues	**$ 6,820.0**	**$ 6,920.3**	**$ 6,803.6**	**$ (100.3)**	**(1.4)%**	**$ 116.7**	**1.7%**
Operating expenses:							
Cost of sales(1)	578.2	565.2	495.4	13.0	2.3%	69.8	14.1%
Selling and marketing	1,490.4	1,348.3	1,369.5	142.1	10.5%	(21.2)	(1.5)%
General and administrative	190.1	205.3	208.2	(15.2)	(7.4)%	(2.9)	(1.4)%
Segment contribution	**$ 4,561.3**	**$ 4,801.5**	**$ 4,730.5**	**$ (240.2)**	**(5.0)%**	**$ 71.0**	**1.5%**
Segment margin	66.9%	69.4%	69.5%		(2.5)%		(0.1)%
Segment gross margin(2)	91.5%	91.8%	92.7%		(0.3)%		(0.9)%

(1) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(2) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(3) Includes SkinMedica® and Latisse®.

(4) Includes Tazorac® sales of $25.4 million and $65.4 million which were previously disclosed separately in the year ended December 31, 2018 and 2017, respectively.

International Segment

The following tables present top product sales and net contribution for the International segment for the years ended December 31, 2019, 2018 and 2017 ($ in millions):

	Years Ended December 31,		Change					
	2019	2018	$ Overall Change	$ Operational Change [3]	$ Currency Change	% Overall Change	% Operational Change [3]	% Currency Change
Total Eye Care	**$ 1,251.1**	**$ 1,294.6**	**$ (43.5)**	**$ 31.4**	**$ (74.9)**	**(3.4)%**	**2.4%**	**(5.8)%**
Lumigan®/Ganfort®	360.8	392.6	(31.8)	(12.0)	(19.8)	(8.1)%	(3.1)%	(5.0)%
Eye Drops	235.8	279.7	(43.9)	(30.2)	(13.7)	(15.7)%	(10.8)%	(4.9)%
Ozurdex®	274.6	187.7	86.9	103.8	(16.9)	46.3%	55.3%	(9.0)%
Alphagan®/Combigan®	162.0	176.0	(14.0)	(4.6)	(9.4)	(8.0)%	(2.6)%	(5.4)%
Restasis®	50.2	64.5	(14.3)	(10.7)	(3.6)	(22.2)%	(16.6)%	(5.6)%
Other Eye Care	167.7	194.1	(26.4)	(14.9)	(11.5)	(13.6)%	(7.7)%	(5.9)%
Total Medical Aesthetics	**1,480.8**	**1,533.3**	**(52.5)**	**25.9**	**(78.4)**	**(3.4)%**	**1.7%**	**(5.1)%**
Facial Aesthetics	**1,331.1**	**1,262.3**	**68.8**	**143.2**	**(74.4)**	**5.5%**	**11.3%**	**(5.8)%**
Botox® Cosmetics	671.7	641.2	30.5	71.5	(41.0)	4.8%	11.2%	(6.4)%
Juvederm® Collection	656.1	614.8	41.3	74.5	(33.2)	6.7%	12.1%	(5.4)%
Belkyra® (Kybella®)	3.3	6.3	(3.0)	(2.8)	(0.2)	(47.6)%	(44.4)%	(3.2)%
Plastic Surgery	**1.8**	**131.5**	**(129.7)**	**(129.2)**	**(0.5)**	**(98.6)%**	**(98.3)%**	**(0.3)%**
Breast Implants	0.6	130.1	(129.5)	(129.0)	(0.5)	(99.5)%	(99.2)%	(0.3)%
Other Plastic Surgery	1.2	1.4	(0.2)	(0.2)	-	(14.3)%	(14.3)%	0.0%
Regenerative Medicine	**14.6**	**16.8**	**(2.2)**	**(1.7)**	**(0.5)**	**(13.1)%**	**(10.1)%**	**(3.0)%**
Alloderm®	7.9	8.0	(0.1)	(0.0)	(0.1)	(1.3)%	0.0%	(1.3)%
Other Regenerative Medicine	6.7	8.8	(2.1)	(1.7)	(0.4)	(23.9)%	(19.3)%	(4.6)%
Body Contouring	**118.7**	**107.5**	**11.2**	**13.9**	**(2.7)**	**10.4%**	**12.9%**	**(2.5)%**
Coolsculpting ® Consumables	76.3	64.2	12.1	13.5	(1.4)	18.8%	21.0%	(2.2)%
Coolsculpting ® Systems & Add On Applicators	42.4	43.3	(0.9)	0.4	(1.3)	(2.1)%	0.9%	(3.0)%
Skin Care	**14.6**	**15.2**	**(0.6)**	**(0.3)**	**(0.3)**	**(3.9)%**	**(2.0)%**	**(1.9)%**
Botox® Therapeutics and Other	**603.0**	**611.5**	**(8.5)**	**21.5**	**(30.0)**	**(1.4)%**	**3.5%**	**(4.9)%**
Botox® Therapeutics	389.1	390.4	(1.3)	21.2	(22.5)	(0.3)%	5.4%	(5.7)%
Asacol®/Delzicol®	36.1	45.7	(9.6)	(8.2)	(1.4)	(21.0)%	(17.9)%	(3.1)%
Constella®	23.8	24.1	(0.3)	0.5	(0.8)	(1.2)%	2.1%	(3.3)%
Other Products	154.0	151.3	2.7	8.0	(5.3)	1.8%	5.3%	(3.5)%
Other revenues	**67.1**	**65.3**	**1.8**	**2.4**	**(0.6)**	**2.8%**	**3.7%**	**(0.9)%**
Net revenues	**$ 3,402.0**	**$ 3,504.7**	**$ (102.7)**	**$ 81.2**	**$ (183.9)**	**(2.9)%**	**2.3%**	**(5.2)%**
Operating expenses:								
Cost of sales[1]	548.3	537.1	11.2	34.7	(23.5)	2.1%	6.5%	(4.4)%
Selling and marketing	934.7	928.7	6.0	55.1	(49.1)	0.6%	5.9%	(5.3)%
General and administrative	117.0	141.7	(24.7)	(21.2)	(3.5)	(17.4)%	(15.0)%	(2.4)%
Segment contribution	**$ 1,802.0**	**$ 1,897.2**	**$ (95.2)**	**$ 12.6**	**$ (107.8)**	**(5.0)%**	**0.7%**	**(5.7)%**
Segment margin	53.0%	54.1%				(1.1)%		
Segment gross margin[2]	83.9%	84.7%				(0.8)%		

(1) Excludes amortization and impairment of acquired intangibles including product rights, as well as indirect cost of sales not attributable to segment results.

(2) Defined as net revenues less segment related cost of sales as a percentage of net revenues.

(3) Defined as overall change excluding foreign exchange impact.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-35565

AbbVie Inc.

(Exact name of registrant as specified in its charter)

Delaware	**32-0375147**
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification number)

1 North Waukegan Road
North Chicago, Illinois 60064-6400
(847) 932-7900
(Address, including zip code, and telephone number of principal executive offices)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	ABBV	New York Stock Exchange
		Chicago Stock Exchange
0.500% Senior Notes due 2021	ABBV21C	New York Stock Exchange
1.500% Senior Notes due 2023	ABBV23B	New York Stock Exchange
1.375% Senior Notes due 2024	ABBV24	New York Stock Exchange
1.250% Senior Notes due 2024	ABBV24B	New York Stock Exchange
0.750% Senior Notes due 2027	ABBV27	New York Stock Exchange
2.125% Senior Notes due 2028	ABBV28	New York Stock Exchange
2.625% Senior Notes due 2028	ABBV28B	New York Stock Exchange
2.125% Senior Notes due 2029	ABBV29	New York Stock Exchange
1.250% Senior Notes due 2031	ABBV31	New York Stock Exchange

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☒	Accelerated Filer ☐
Non-Accelerated Filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the 1,747,782,344 shares of voting stock held by non-affiliates of the registrant, computed by reference to the closing price as reported on the New York Stock Exchange, as of the last business day of AbbVie Inc.'s most recently completed second fiscal quarter (June 30, 2020), was $171,597,270,533. AbbVie has no non-voting common equity.

Number of common shares outstanding as of January 31, 2021: 1,765,881,690

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the 2021 AbbVie Inc. Proxy Statement are incorporated by reference into Part III. The Definitive Proxy Statement will be filed on or about March 22, 2021.

ABBVIE INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2020
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Note 16 Segment and Geographic Area Information

AbbVie operates as a single global business segment dedicated to the research and development, manufacturing, commercialization and sale of innovative medicines and therapies. This operating structure enables the Chief Executive Officer, as chief operating decision maker (CODM), to allocate resources and assess business performance on a global basis in order to achieve established long-term strategic goals. Consistent with this structure, a global research and development and supply chain organization is responsible for the discovery, manufacturing and supply of products. Commercial efforts that coordinate the marketing, sales and distribution of these products are organized by geographic region or therapeutic area. All of these activities are supported by a global corporate administrative staff. The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the CODM for purposes of assessing performance, allocating resources and planning and forecasting future periods.

Substantially all of AbbVie's net revenues in the United States are to three wholesalers. Outside the United States, products are sold primarily to health care providers or through distributors, depending on the market served. The following tables detail AbbVie's worldwide net revenues:

years ended December 31 (in millions)		2020	2019	2018
Immunology				
Humira	United States	$ 16,112	$ 14,864	$ 13,685
	International	3,720	4,305	6,251
	Total	$ 19,832	$ 19,169	$ 19,936
Skyrizi	United States	$ 1,385	$ 311	$ —
	International	205	44	—
	Total	$ 1,590	$ 355	$ —
Rinvoq	United States	$ 653	$ 47	$ —
	International	78	—	—
	Total	$ 731	$ 47	$ —
Hematologic Oncology				
Imbruvica	United States	$ 4,305	$ 3,830	$ 2,968
	Collaboration revenues	1,009	844	622
	Total	$ 5,314	$ 4,674	$ 3,590
Venclexta	United States	$ 804	$ 521	$ 247
	International	533	271	97
	Total	$ 1,337	$ 792	$ 344
Aesthetics				
Botox Cosmetic [a]	United States	$ 687	$ —	$ —
	International	425	—	—
	Total	$ 1,112	$ —	$ —
Juvederm Collection [a]	United States	$ 318	$ —	$ —
	International	400	—	—
	Total	$ 718	$ —	$ —
Other Aesthetics [a]	United States	$ 666	$ —	$ —
	International	94	—	—
	Total	$ 760	$ —	$ —
Neuroscience				
Botox Therapeutic [a]	United States	$ 1,155	$ —	$ —
	International	232	—	—
	Total	$ 1,387	$ —	$ —
Vraylar [a]	United States	$ 951	$ —	$ —
Duodopa	United States	$ 103	$ 97	$ 80
	International	391	364	350
	Total	$ 494	$ 461	$ 430
Ubrelvy [a]	United States	$ 125	$ —	$ —
Other Neuroscience [a]	United States	$ 528	$ —	$ —
	International	11	—	—
	Total	$ 539	$ —	$ —