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Management of Hirsutism

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ABSTRACT

Hirsutism is a relatively common condition affecting about 5%-10% of women of childbearing age. Herein, we present an overview of hirsutism with emphasis on its etiology and therapeutic options.

Key Words: antiandrogens, hirsutism, insulin-sensitizing agents, oral contraceptives, PCOS, polycystic ovary syndrome

Hirsutism is defined as excessive terminal hair growth in women, which has a typical male pattern distribution. It should be differentiated from hypertrichosis, a generalized excessive hair growth that may be hereditary or result from some drugs, such as cyclosporine. Hirsutism is a relatively common disorder that affects about 5%-10% of women of reproductive age.[1] Unwanted hair growth can be associated with significant psychosocial consequences that negatively affect patients' quality of life.

Causes

More than 70% of hirsutism is caused by polycystic ovary syndrome (PCOS).[2] PCOS is the most common endocrinopathy in females, affecting 5%-10% of women of childbearing age.[2] According to the Rotterdam criteria for diagnosis of PCOS,[3] the diagnosis could be achieved if 2 of the following 3 criteria are present:

- Oligo- or anovulation (menstrual cycles longer than 35 days or fewer than 10 menses a year).
- Clinical (hirsutism, acne, androgenetic alopecia) or biochemical evidence of hyperandrogenism.
- Polycystic ovaries (≥12 follicles in each ovary measuring 2-9mm in diameter and/or increased ovarian volume to >10ml) on ultrasound examination.

Other less common causes include idiopathic hirsutism (i.e., with no other clinical or biochemical abnormalities) (23%), nonclassic adrenal hyperplasia (4.3%), ovarian or adrenal androgen secreting tumors (0.2%), Cushing's syndrome, acromegaly, hyperprolactinemia, and drugs.

Diagnostic Approach

Clinical history, thorough physical examination and laboratory investigations can be crucial in the correct evaluation of hirsutism. The history should include the onset and progression of hirsutism, the pattern of menstruation, weight gain, and the use of androgenic drugs, such as anabolic and androgenic steroids, and valproic acid.

A rapid progression of hirsutism and evidence of virilization (e.g., clitoromegaly, an increase in muscle mass, and a deepening of the voice) can be noted with rare androgen secreting tumors.

The severity of hirsutism can be measured objectively using the Ferriman-Gallwey hirsutism scoring system.[4] A score of 8 or more has been used to define the presence of hirsutism. As the response of a pilosebaceous follicle to androgen varies considerably, the hirsutism score does not correlate well with the androgen level.

A thorough abdominal and pelvic examination may rarely show a palpable ovarian mass.

According to the Endocrine Society Clinical Practice Guidelines,[5] testing for androgen is recommended in women with moderate-to-severe hirsutism or hirsutism of any degree when it is associated with any of the following: sudden onset, rapid progression menstrual irregularity, infertility, central obesity, clitoromegaly, or acanthosis nigricans. The initial tests for hirsutism should include early morning plasma total testosterone and free testosterone. If testosterone levels are more than 1.5-2 times the upper normal limit, or if a history of rapid virilization is found, dehydroepiandrosterone sulphate (DHEA-S) and androstenedione should be measured to identify an adrenal or ovarian source of hyperandrogenemia.

In patients with a positive family history of congenital adrenal hyperplasia or in members of high risk ethnic groups such as Ashkenazi Jews, Hispanics, and Slavics, measurement of an early morning follicular phase level of 17-hydroxyprogesterone is recommended.

If there are features of Cushing's syndrome, thyroid dysfunction, acromegaly or hyperprolactinemia, an endocrine workup should be carried out accordingly. Transvaginal ultrasonographic imaging of the ovaries is recommended for patients with either menstrual disturbances or clinical or biochemical hyperandrogenism.

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Treatment

The therapeutic options of hirsutism can be divided into systemic, topical, and dermato-cosmetic therapies. Patients should be informed that the response to systemic agents is slow; occurring over 3-6 months after therapy has begun.

Systemic Treatment

Oral Contraceptives

Oral contraceptive (OC) agents are considered to be the first-line therapy for hirsutism in premenopausal women.[5] This treatment option has the advantage of regulating the menstrual cycle and providing contraception. Oral contraceptive pills commonly contain ethinyl estradiol (EE), in combination with a progestin. The most androgenic progestins are norgestrel and levonorgestrel, whereas the least androgenic progestins are norgestimate and desogestrel. Other progestins, such as cyproterone acetate and drospirenone, work as androgen receptor antagonists. The recommended OC includes a combination of EE with either 2mg of cyproterone acetate (Diane-35®, Schering) or 3mg drospirenone (Yasmin®, Bayer Healthcare).

The mechanisms by which OCs improve hirsutism include the suppression of luteinizing hormone secretion, resulting in the inhibition of ovarian androgen biosynthesis, stimulation of sex hormone binding globulin production (effectively decreasing serum free androgen concentrations), and a mild reduction in adrenal androgen synthesis. OCs should not be prescribed to women with a history of venous thrombosis.

Antiandrogens

Spironolactone (Aldactone®, Pfizer), an aldosterone antagonist, has several actions including inhibition of the androgen receptor, suppression of adrenal androgen biosynthesis, and inhibition of the 5α-reductase enzyme. A recent Cochrane review of trials comparing spironolactone 100mg/d with placebo showed a significant subjective improvement in hair growth (odds ratio 7.18, 95% confidence interval [CI] 1.96 to 26.28). The Ferriman-Gallwey score, however, did not validate these findings (weighted mean difference 7.20, 95% CI -10.98 to -3.42).[6] Spironolactone is generally well tolerated with few side-effects, such as menorrhagia, lethargy and stomach upset. A clinically significant hypotension and increased serum potassium levels are rare if spironolactone has been used at doses of 100mg/day. In the first months of treatment, measurements of blood pressure and serum potassium levels every 4 weeks are recommended. Spironolactone should not be prescribed to patients with renal insufficiency or hyperkalemia. As spironolactone usually causes feminization of the male fetus as well as menstrual alterations, it is best to add oral contraceptive pills.

Cyproterone acetate (CA) is a progestin with antiandrogenic activity that interferes with the binding of dihydrotestosterone to the androgen receptor and inhibits the secretion of gonadotropin, thereby reducing ovarian and adrenal androgen production. CA (2mg) combined with EE has been shown to be more effective than placebo, but not better than other antiandrogens.[7] A small randomized controlled study[8] showed that CA when combined with EE at a dosage of 0.01mg/d for the first week, 0.02mg/d for the second week, 0.01mg/d for the third week, followed by a pause of 7 days, and 12.5mg CA/d added during the first 10 days of every month for 12 months seems to be the most effective treatment to reduce the hirsutism score when compared with flutamide 250mg/d, finasteride 5mg/d, and ketoconazole 300mg/d. The recommended dose is 12.5-100mg/d added to the first 10 days of each calendar pack of oral contraceptives. Side-effects of CA include weigh gain, loss of libido, depression, headache, mastodynia, and feminization of the male fetus.

Flutamide is a pure nonsteroidal antiandrogen that acts as an androgen receptor blocker. Studies have shown that flutamide 250-500mg/d is more effective than finasteride[9] and triptorelin,[10] a long acting gonadotropin-releasing hormone antognist. A systematic review and meta-analysis of randomized controlled trials (RCTs) assessing the efficacy of different antiandrogens for the treatment of hirsutism reported that when compared with metformin, flutamide reduced the hirsutism score by 5 (95% CI 3.0-7.0; I^2=0%). Spironolactone reduced the score by 1.3 (95% CI 0.03-2.6).[11] Due to its propensity for severe hepatotoxicity, which is occasionally fatal, flutamide should not be used as first-line therapy for hirsutism.

Finasteride is a potent inhibitor of the type 2 isoenzyme of 5-α-reductase, which blocks the conversion of testosterone to 5-α-dihydrotestosterone. Finasteride has been shown to lower hirsutism scores by 30%-60% in addition to reducing the average hair diameter.[12] In comparative studies, finasteride demonstrated efficacy similar to that of other antiandrogens with fewer adverse effects.[13] Other trials suggested that spironolactone and flutamide were more effective than finasteride.[14,15] In women with hirsutism, finasteride is used in doses of 2.5-7.5mg/d. Doses of 2.5mg and 5mg seem to be equally effective.[16] As with the other antiandrogens, the use of finasteride requires a reliable method of contraception in order to avoid a pregnancy given the potential risk of feminization of the male fetus.

Insulin-Sensitizing Drugs

Metformin lowers hepatic glucose production and decreases insulin levels. Thiazolidinediones (rosiglitazone and pioglitazone) sensitize end organs to insulin through their action on the peroxisome-proliferator-activated receptor-γ. Meta-analyses of RCTs of insulin sensitizers for the treatment of hirsutism concluded that insulin sensitizers provide limited or no improvement for women with hirsutism.[17]

Gonadotropin-Releasing Hormone (GnRH) Agonists

GnRH agonists suppress luteinizing hormone, and to a lesser degree follicle stimulating hormone secretion, leading to a decline in ovarian androgen production. GnRH

agonist therapy seems to have no therapeutic advantage over OC and antiandrogens.[18,19] As GnRH agonist therapy is expensive, requires injections, and estrogen needs to be added to the therapy, its use should be reserved for severe forms of hyperandrogenemia, such as patients with ovarian hyperthecosis who have a suboptimal response to OCs and antiandrogens.

Glucocorticoids

Glucocorticoids can be prescribed to women who:

- have hirsutism that is due to nonclassic congenital adrenal hyperplasia
- have a suboptimal response to OCs and/or antiandrogens
- exhibit poor tolerance to OCs
- are seeking ovulation induction.

Topical Treatment

Eflornithine hydrochloride cream 13.9% (Vaniqa®, Skin Mediea) has been approved by the US FDA for the reduction of unwanted facial hair in women. Noticeable results take about 6-8 weeks. Adverse effects include itching and skin dryness.

Direct Hair Removal Methods

A wide range of hair removal methods have been advocated over the years with varying degrees of success. These modalities can be divided into temporary methods of hair removal and permanent methods of hair reduction. Temporary methods of hair removal include plucking, waxing, shaving and chemical depilatory agents. Although not a method of hair removal, bleaching serves to lighten the color of the external hair shafts so that they are less noticeable. Permanent methods of hair reduction include photoepilation (using laser and intense pulse light [IPL]) and electrolysis. Photoepilation seems to be superior to the conventional methods, such as shaving, waxing and electrolysis. A Cochrane review of photoepilation of unwanted hair growth showed that alexandrite and diode lasers are more effective, whereas little evidence was obtained for the effect from IPL, Nd:YAG, or ruby lasers.[20] However, some longer wavelength lasers (Nd:YAG), or IPL, appear to provide benefits in patients who have darker skin types and therefore have less risk of burning and dyspigmentation. Paradoxical hypertrichosis is a possible, but rare, adverse effect of photoepilation, particularly in dark-skinned individuals.[21,22]

Conclusion

Hirsutism is usually a benign, but extremely distressing condition. Although several treatment options exist, we recommend the use of OCs with antiandrogenic activity as first-line therapy for the majority of premenopausal women. An antiandrogen can be added if the response to OCs is suboptimal after 6 months of use. Laser/photoepilation are the preferred direct hair removal methods. Logical combinations tailored to the individual clinical profile can accomplish the best results in most patients.

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Body Piercing: More Than Skin Deep

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ABSTRACT

Young adult populations (18-25 years of age) throughout the world have latched onto the mainstream trend of body piercing. Best health care practices for these individuals involves the knowledge of proper procedural techniques, postsite care, common complications, and treatment modalities.

Key words: blood transfusions, body art, body piercings, infective endocarditis, piercing infections, scarring, skin trauma

Creativity and ubiquity are the only constants of body piercing.[1,2] Yet, no matter what one's opinion is about body piercings, don't become distracted by them and delay important medical care.[3] Body piercing has been around for centuries in various societies as part of ritualistic or cultural practices, and now it is rapidly becoming a worldwide mainstream fashion trend, especially among young adults aged 18-25 years. According to Armstrong et al., body piercing is defined as the insertion of a needle to create a fistula-like opening (into either cartilage or skin) for the introduction of decorative ornaments, which can include insertion of jewelry, plastic or wood plugs, beads, or pearls.[1] Current US body piercing rates are approximately 36%,[5] and those figures are similar for smaller studies[2,6] that also excluded ear lobe piercings. Women tend to report obtaining body piercings more so than men do.

Body Piercing Regulated Environment

An actual body piercing procedure only takes a few moments, but given the invasive technique of the procedure, an earlier study[6] cited frequent infections (45%) and skin irritations (39%) as prevalent piercing site problems, often because no aftercare instructions for proper skin treatment were provided. Now, considering the overall amount of body piercing worldwide and the presence of a better (but certainly not perfect) regulated body art environment,[7] the number of self-reported complications remain around 17%-35%.[8] While most body piercings are not problematic, the potential for localized infections, as well as associated systemic diseases, is present so long as the piercing site remains open.[1,9,10] These infections may become an even more invasive problem with the emergence of community acquired methicillin resistant *Stapthylococcus aureus* (CA-MRSA).[3]

Blood transfusions have also been affected by the increase in body piercing.[11] For many years, individuals with new piercings could not donate blood for at least 1 year following the piercing. In 2005, the Canadian Blood Services reduced their deferral period from 12 to 6 months, and the US has reduced their deferral period (which varies from state to state) if body art was obtained in regulated areas. Current evidence indicates disease transmission has not increased with these new regulations, and Spain is currently examining a deferral period reduction to 4 months.

Pierced Seeking Prompt Treatment

Many individuals with body piercings do not perceive their body art as "permanent"; frequently they say, "If I don't like it, I can remove it." They are often aware of the procedural risks; however, when initial site irritation, pain, or oozing occurs, most skin problems may be dismissed or self-treated.[12] Other times, individuals are "embarrassed," thinking the infection could be their fault, and/or "fear" that the jewelry needs to be removed. Additionally, findings from recent studies[13-15] suggest that these individuals look to the internet or return to the piercer for assistance, instead of seeing their health care provider, due to the clinicians' lack of adequate knowledge, judgmental perspectives about body art, and limited educational resources about piercings.

Piercing History Helps Determine Your Diagnosis

Where was the piercing obtained?

Stores/kiosks in shopping malls provide ear lobe and high rim ear piercings using piercing guns, and sell benzalkonium chloride solution as their after-care product of choice. This solution does not have adequate microbicidal activity against *Pseudomonas aeruginosa* infections and has been frequently mentioned in outbreaks of auricular chondritis.[16-19] Additionally, limited employee training and supervision, along with inadequate quality control measures have also been reported.

What type of after-care was done?

Diminished skin integrity is greater with newly acquired body piercings, especially from procedures obtained during warm weather months.[12] In a regulated body art environment, piercing artists emphasize conscientious care of the piercing site following the procedure with careful monitoring of the site until it is completely healed.[7,10,20-21] While healing times are dependent on site location, facial piercings usually heal within 2 months, and covered areas can take up to 6 months. Yet, a completely healed site requires judicious care of the piercing site for at least 1 year until the skin epithelializes, "toughening up" the area for the adjustment of wearing various piercing inserts.[1]

What kind of jewelry was placed in the site?
Due to the overall increase in jewelry containing nickel, there has been a marked increase in contact dermatitis related to nickel allergy,[22] especially if it is purchased in shopping malls. Carefully selecting piercing jewelry (comprised of niobium, titanium, 300 grade surgical steel, or gold) that is found in piercing studios helps avoid allergen exposure, scarring, and risks of delayed infection.[9,21]

Should jewelry be removed or not?
Retaining the jewelry at the site when an infection initially occurs, allows for better drainage and epidermal healing, whereas removal can potentiate abscess formation in deeper skin structures. However, if there is not resolution within 5-7 days, the jewelry should be removed, followed by surgical incision and drainage, and possible hospitalization with intravenous antibiotic therapy, especially for high ear-rim piercing infections.[16-19]

Local Complications

Secondary trauma from body piercings (Table 1)[12] can occur frequently at the naval (40%), ear (35%), nose (12%), tongue, chin, eyebrows, genitals (8%), and nipple (5%). Common complications include bleeding, bacterial or viral infections, mechanical tissue tearing, keloid scarring, nerve impairment, and allergies. These complications can arise from the body piercing procurement and/or limited procedural after-care. Embedded earrings are also frequently seen.[23] Exposed wounds from piercing inserts can also occur from physical assaults, motor vehicle accidents, or aggressive contact sports.[12] Additionally, as more people retain their body art for longer periods of time, other effects can evolve, which may involve further invasive, corrective procedures from a specialist.

Management of Infections

Bacterial skin infections at or near the site are considered the most commonly reported complication of body piercings, with causative organisms primarily consisting of 2 gram-positive bacteria: *Staphylococcus*, and group A Beta-hemolytic *Streptococcus*, and 1 gram-negative bacteria: *Pseudomonas*.[24] Ideally, pharmacological interventions would be pathogen-specific, based on cultures of the affected site. However, due to the length of time cultures take to be processed, it is not always reasonable to delay treatment, as a more severe infection can ensue if left untreated.

Current infectious disease guidelines[24] recommend that the majority of minor skin and soft-tissue infections may be treated with penicillins, first-generation or second-generation oral cephalosporins, macrolides, or clindamycin. Of note, though, is that there is growing resistance of MRSA strains to clindamycin, in the range of approximately 50%. CA-MRSA strains showed continued responsiveness to trimethoprim-sulfamethoxazole and tetracycline. Ideally, after initiation of antibiotic therapy, patient follow-up at 24-48 hours is important. If the patient is not demonstrating a positive response to therapy, the clinician should strongly consider that the progression of infection may be a result of resistance or a sign of a more severe infection.[24] In the event that the infection causes the formation of skin abscesses, the clinician should consider a more aggressive combination approach to therapy, including antibiotics and possible incision and drainage of related skin abscesses.[11]

Systemic Infections from Piercing
Although rare, systemic infections, such as infective endocarditis (IE) or sepsis, can also occur.[25] These are thought to be "triggered either by normal flora at the puncture site, microorganism colonization around the jewelry, or by a localized site infection that stimulates episodes of transient bacteremia, that can seed various areas of the heart."[25] More than 25 IE cases in the past decade have come from tongue, navel, earlobe, lower lip, and nipple piercings. If an individual with a new piercing (i.e., up to 4 months), with or without a history of congenital heart disease, presents with unexplained fever, night chills, weakness, myalgia, arthralgia, lethargy, or malaise, IE should be considered, especially as body piercing continues to increase. Prophylactic antibiotic regimens have been suggested since 1999, but the treatment is still being debated.[24]

Conclusion

While piercers are knowledgeable regarding the techniques and procedures of body piercing, treatment for health concerns and complications related to piercings should be provided by knowledgeable clinicians. Non-judgmental, informative care is crucial when complications arise.[1,20] Yet, as you work with those who have piercing complications, remember that removing a piercing does not remove the individual's motive or rationale for obtaining the piercing. Often, within about 6 months they will obtain another,[1,2,20] so applicable education about piercing care remains vital for preventing further or repeated sequelae.

Recommendations for care of a new piercing as defined by the Association of Professional Piercers include:[22]

- Instruct patients to wash the piercing site with soap and water or a diluted saline solution (1/8 tsp of salt to 8 oz of water) twice per day, because piercing tracts can become portals or reservoirs for viruses and bacteria.
- Recommend the use of antiseptic mouthwash (alcohol-free) for oral piercings.
- Instruct individuals with oral piercings to use ice chips or other cool fluids to reduce swelling and ease discomfort during the initial healing phase.
- Advise against the use of alcohol, Hibiclens® (Mölnlyke Healthcare), hydrogen peroxide, Bactine® (Bayer Healthcare), and Betadine® (Purdue Products LP) in piercing care.
- Encourage patients to search the Association of Professional Piercers website[21] for further educational material regarding each type of piercing.

Body Piercing Site	Documented Complications
Cheek, tongue, uvula, lips	• Post-piercing edema may cause airway obstruction. • Other problems include altered eating habits, salivary gland injuries, increased salivary flow, speech impediments (lisp), pain, loss of taste, permanent numbness, and uncontrolled drooling. • Dental trauma of the teeth includes dental abrasions, cusp fractures, chips, and cracks, called "wrecking ball" fractures, and the "cracked-tooth syndrome." • Swallowing or aspirating loosened jewelry can compromise the airway and cause gastrointestinal damage. • Lingual blood vessel perforation (during piercing) can cause severe bleeding, hematomas, or hypovolemic shock. • Pierced athletes have the greater risk for infection because of contact trauma, dirty activity settings, increased blood flow, increased perspiration, and increased breathing rates. • Labret piercing jewelry (cleft of chin) can become embedded in the lower lip soft tissue.
Ear	• Ear lobe (not considered a true body piercing) • Tears or splits from pulling on the earrings or stretching the skin of the ear lobe, perhaps never returning to it original form if wearing heavy jewelry or flesh tunnels. • Mid- to high-rim cartilage • Auricular perichondritis, perichondrial abscess, or auricular necrosis can occur with or without symptoms. • A subperiosteal abscess with perichondritis causes loss of cartilage. • Severe ear deformities can be seen with transcartilagenous piercings, sometimes called "cauliflower ear." • Additional complications include keloid formation, allergic metal contact dermatitis, and embedded jewelry.
Eyebrows	• Local inflammation can result, producing eyelid redness, pressure, pain, swelling of the face and cheek, and a solid, tender, movable, cherry-size swelling of the eyebrow.
Genitals [12-15] *Women: labia minora, labia majora, and the clitoral prepuce or body* *Men: foreskin, scrotum, urethra, perineum, and penile glans. Creativity abounds with this site.**	Women: • Many unsubstantiated complications such as scarring, allergic metal reactions, bleeding, keloids, and infections of genital piercings have been reported, yet current medical literature and research is limited. The major self-reported complications are site sensitivity and skin irritation.[15] Questions remain if piercings should be removed for delivery. Men: • Prince Albert (most common male genital piercing that perforates the urinary meatus and corona) frequently alters urinary flow. • Other single case reports discuss: urethral rupture and tissue destruction, large-vessel or nerve injury and infection causing infertility from an ascending infection, such as prostatitis or testis infection due to scrotal piercing, and penile rings causing engorgement and priapism.
Navel	• Infection rates increase because of increased skin moisture from friction and tight-fitting clothes. • Superficially placed piercings cause scarring by migrating to the skin surface, especially with obesity and during the third trimester of pregnancy.
Nipple *(done to enlarge the nipple, for esthetics, and to enhance sensitivity)* [14,16]	• It has been reported that breastfeeding with nipple piercing can cause breast discomfort for the mother or, if the jewelry is dislodged, could cause the infant to aspirate the jewelry, yet the international breastfeeding organization, La Leche League, supports breastfeeding with healed nipple piercings; individual patient assessment is emphasized to provide the best care and to decide whether or not the jewelry should be removed. For further information, see: http://www.lalecheleague.org/llleaderweb/LV/LVJunJul99p64.html.) • One report of mastitis due to *Mycobacterium abscessus* and another of hyperprolactinemia and galactorrhea have been cited. • Dislodgement from physical assaults and aggressive contact sports can occur.
Nose	• Cartilage piercings may cause septal hematomas. • Nasal piercings can cause edema and extra mucous formation. • Later, the nasal stud can become embedded in the edematous nasal tissue. • Granulomatous perichondritis may occur due to alar cartilage that is destroyed by granulomatous inflammation. • Nasal studs may be aspirated or swallowed; a nasal ring may be pulled out due to the jewelry migrating forward. • Piercing across the bridge of the nose is risky because of the many fascicles present.

Table 1. Secondary trauma occurring at specific body piercing sites[12]

*Usually heavy-gauge jewelry is worn, but beads, pearls, or other inert material can be inserted under penile tissue and is called penis marbles, nodules, or bulleetus.

Table and Listing of Early Piercing Care are reprinted with permission. Kuchinski A, Pereira P, Armstrong ML. Caring for Pierced Patients: Attitudes, Secondary Trauma, and Forensic Evidence. Mosby's Nursing Consult at: http://www.nursingconsult.com/das/stat/view/138582404-2/cup. Published September 16, 2008. Accessed May 20, 2009.

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Update on Drugs

Name/Company	Approval Dates/Comments
Collagen-based dermal filler *Evolence*® Ortho Dermatologics	The US FDA approved a labeling supplement in June 2009 that includes efficacy and safety data through 12 months, for this collagen-based dermal filler for the correction of moderate to deep facial wrinkles and folds, e.g., nasolabial folds.
Injectable Poly-L-lactic acid *Sculptra Aesthetic*® sanofi-aventis US	The US FDA approved this facial injectable in July 2009 for the correction of shallow to deep nasolabial fold (smile lines) countour deficiencies and other facial wrinkles that are treated with the appropriate injection technique in healthy patients.
Ibritumomab tiuxetan *Zevalin*® Spectrum Pharmaceuticals	The US FDA approved an expanded label for this product in August 2009 for the treatment of patients with previously untreated follicular non-Hodgkin's lymphoma who achieve a partial or complete response to first-line chemotherapy.

Drug News

In August 2009, the US FDA reported that it is requiring stronger warnings in the prescribing information for a class of drugs known as TNF blockers. The warnings, which included an updated boxed warning, highlight the increased risk of cancer in children and adolescents who receive these drugs to treat juvenile rheumatoid arthritis, the inflammatory bowel disorder, Crohn's disease, and other inflammatory diseases. The FDA is working with the manufacturers to explore new ways to further define the risk of cancer in children and adolescents who use these drugs.

Based on a safety evaluation of botulinum toxin (Btx) products, the US FDA concluded that the prescribing information for OnabotulinumtoxinA (marketed as Botox®/Botox Cosmetic®) and RimabotulinumtoxinB (marketed as Myobloc®) must be updated to ensure their continued safe use. On July 31, 2009, the FDA approved the following revisions to the prescribing information of Botox®/Botox Cosmetic® and Myobloc®:

- A Boxed Warning highlighting the possibility of potentially life-threatening distant spread of toxin effect from the injection site after local injection.
- A Risk Evaluation and Mitigation Strategy (REMS) that includes a medication to help patients understand the risks and benefits of Btx products.
- Changes to the established drug names to reinforce individual potencies and prevent medication errors. The potency units are specific to each botulinum toxin product, and the doses or units of biological activity cannot be compared or converted from one product to any other Btx product. The new established names reinforce these differences and the lack of interchangeability among products.

The other Btx product in this class, abobotulinumtoxinA (marketed as Dysport®), was approved in April 2009 and included the Boxed Warning, REMS, and new established name at the time of approval. The FDA urges healthcare professionals and patients to report side-effects from the use of these products to the FDA's MedWatch Adverse Event Reporting program. For more information see http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm174949.htm.