

# Health Letter

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## Ethical Implications of Cosmetic Surgery for Aging

Combine the aging of our population, our obsession with youth, and our faith in technology with excesses of disposable income for many people, and it is no surprise that we are awash in technological advances in the battle against visible signs of aging. Setting aside, for the moment, the heavily advertised, poorly-researched, and often downright fraudulent vitamin E, B, C, alpha-hydroxy-retinol-herbal-antioxidant-collagen-aminoacid-mineral antiaging concoctions, real technological advances have occurred over the last decade that have made it possible to erase external signs of aging previously considered indelible. But while physicians have made the technology of "skin rejuvenation" increasingly accessible, its intrinsic value and ethical implications have been largely unquestioned by the medical community. Why do we perform these procedures? What goals are we trying to achieve? Are these goals worthwhile? What is their impact on patients? On medicine? On society? A situation has developed in which there has been ample investigation into what physicians can do, but far less examination of what they *should* do. Cosmetic procedures are invasive, potentially hazardous techniques that have implications far beyond their value as "practice builders." As physicians enter the realm of cosmetic surgery, they have a responsibility to explore the moral and psychosocial as well as the scientific and technical implications of

the procedures they perform.

Let us start by examining the central question, "Why perform cosmetic surgery for aging?" If the goal of medical treatment is to promote health and healing, what is the purpose of medical procedures where no disease exists, i.e. in performing surgery for aging?

The professional literature on the ethics of cosmetic surgery, though disturbingly sparse, takes one of three tacks, each of which is highly questionable. The first is that aging is a physical disease and that external signs of aging are *de facto* evidence of illness. The second avoids the issue of aging as a physical disease by ascribing illness to the patient's mind rather than body. The third skirts the question of healing alto-

gether, changing the goal of medicine from promotion of health to promotion of happiness. Each of these will be examined in turn.

### Aging as a Physical Illness

If aging of the skin is a pathological rather than a normal, physiological process, eventual dissatisfaction with our appearance is unavoidable and youth-promoting, cosmetic procedures are required for good health. Although the concept of aging as a disease seems peculiar to most of us, it is standard for cosmetic surgeons, who discuss the *treatment* of brown spots, *repair* of wrinkles, and *correction* of sagging skin as if aging were a disease which needs to be treated, repaired, or corrected. Topics such

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as the "treatment of the aging face," are discussed with the same weight as treatment of diabetes or treatment of tuberculosis. After all, the object of treatment is necessarily disease; normal, physiologic processes, such as breathing or eating, cannot be treated. By making the aging face the object of treatment, aging is defined as a disease that requires intervention.

There are both practical and theoretical problems with defining aging as an illness. Perhaps the most problematic is that, in defining aging as an illness, we implicitly define life as an illness. Aging may end with death, but it begins at birth. How do we know at what point aging changes from physiology to pathology? Who is to say that puberty is acceptable, but menopause is not? Growth continues throughout our lives on many different levels. To demean aging by labeling it a disease limits our potential and undermines our humanity.

Unlike plastic surgery, which corrects deformities that deviate from the anatomical norm, surgery for the aging face removes anatomically normal features because they trigger a negative stereotype. Every time surgeons agree to perform a facelift, they legitimize the need for that facelift. They confirm that looking old is objectionable, that aging is an aberration, and that society is *justified* in discriminating against it. At medical conferences in this country, the mere presence of aging skin is tantamount to an indication for cosmetic surgery. Of course, such attitudes are not unique to medicine. The cosmetic industry has made a multimillion dollar business of blurring the lines between health, beauty, and aging, portraying health and beauty as attributes of youth while assigning ugliness and disease to the elderly. But physicians are charged with protecting the health and well-being of their patients, and it is difficult to believe that fostering the attitude that aging skin is inherently offensive is in the best interest of their patients.

Is aging really a disease? When

examined objectively, the proper determinant of healthy skin is its function, not its appearance. Despite its spots and wrinkles, elderly skin functions remarkably well in the vast majority of individuals far into old age. Some functional problems, such as a decline in the skin's protective barrier function, occasionally become clinical problems, but the correction of these conditions is hardly the objective of cosmetic surgery. In fact, the injury to the skin surface incurred by laser resurfacing, chemical peeling, and other popular cosmetic techniques exacerbates rather than ameliorates the defect in barrier function.

#### **Aging as a Mental Illness**

As much as cosmetic surgery may invoke a model of disease to legitimize its place in medicine, the concept of a "cosmetic disease" is a hard sell to the public, which tends to view cosmetic procedures as frivolous, and to insurance carriers, which

### *What is the meaning of self-esteem in the context of cosmetic surgery for aging?*

classify them as unnecessary. In response, cosmetic surgery has increasingly taken to promoting itself as a cure, not for the body, but for the mind—a sort of instant alternative to psychotherapy for aging individuals who suffer from lack of self-esteem. Perhaps then, as a therapy for psychological disease, cosmetic surgery for aging could be a legitimate form of medical treatment.

Before tackling the issue of whether cosmetic surgery enhances self-esteem, a more basic question needs to be addressed: what is the meaning of self-esteem in the con-

text of cosmetic surgery for aging? (Though this question may seem unnecessarily pedantic, anyone in the business of physically altering another human being in the name of self-esteem had better have a pretty good idea of just what self-esteem is and what enhances it.) Although pride in one's appearance is certainly part of the definition, equating self-esteem with pride somehow misses the mark. We all know vain, self-absorbed, proud individuals who are preoccupied with their appearance because of insecurity rather than self-esteem. If pride is to result in self-esteem rather than vanity, it must include an additional element, namely, authenticity. Any self-image worthy of enhancement, through cosmetic surgery or other means, must be a true reflection of who that person is. Enhancement of a false self-image can result in narcissism or even self-contempt, but it does not result in true self-esteem.

The self that benefits from cosmetic surgery is an impostor. It is built on the premise that pretending to be something we are not builds character. Cosmetic surgeons are in the business, not of enhancing who we are, but of replacing who we are with who we or they think we should be. Only a false self created by the myth of agelessness can profit from surgery for aging. Only an idealized self in pursuit of perpetual youth can benefit from procedures to erase the effects of time. There is no question that a false self can be bolstered by any of a number of cosmetic disguises. But how do people whose worth is defined by a vision of eternal youth maintain self-esteem with time gnawing at their heels? How do we maintain our equanimity knowing that the image we have created is a fraud? As much as we may cover, smooth, or conceal the external evidence, each day we are 24 hours older and, in the end, we are who we are. In this context, a request for cosmetic surgery seems more like self-abnegation than self-esteem.

The truly insidious part of nurturing an illusion is that the true self,



# Product Recalls

May 7—July 10, 2002

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

## DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is [www.fda.gov](http://www.fda.gov).

### Name of Drug or Supplement; Class of Recall; Problem

**Dalyvite Liquid**, a multi-vitamin liquid packed in brown, plastic bottles, One Pint (473 mL). Product was distributed under the Hi-Tech label; Goldline label; Class III; Product is contaminated with yeast, & complaints of swollen containers were received

**Doxycycline Hyclate Capsules**, 100mg, 500-count bottles, Rx; Class III; Active ingredient fails to meet test specification for related compounds

**Levoxyl Tablets**, 50 mcg, and 100 mcg, Rx; Class II; Product from manufacturer lacks stability prior to expiration date (subpotency and super potency)

**Lomotil Tablets** (diphenoxylate hydrochloride, 2.5 mg and atropine sulfate, .025 mg), 100 tablets, Rx only; Class II; Tablets supplied by the manufacturer may contain metal particles

**Lomotil Tablets**, (diphenoxylate hydrochloride), Rx, bottles of 100, 1,000, 2,500, and unit dose cartons of 100; Class II; Tablets may contain metal particles

**Premarin Tablets** (conjugated estrogens tablets) 0.625 mg, Rx; Class III; Failure to meet dissolution specifications

**Tamiflu Capsules** (oseltamivir phosphate), 75mg, 10 capsule cartons and 15 x1 capsule Professional Samples, Rx only; Class III; Potential cross contamination with active ingredients which could include mefloquine, levodopa/benserazide, and/or sulfamethoxazole

### Lot #: Quantity and Distribution; Manufacturer

Lot 101624 EXP 2/03; 15,413—pint bottles distributed nationwide; Hi-Tech Pharmacal Co., Inc., Amityville, New York

Lot 2985-103511 EXP 12/04; 3,601, 500-count bottles distributed nationwide; Ivax Pharmaceuticals, Inc., Miami, Florida

Product codes 5297-0, 5297-1, 5300-0; 13,820–100 mcg tablets, 18,600 — 50 mcg tablets distributed nationwide; Allscripts Healthcare Solutions, Libertyville, Illinois

Lot Number: 021245, EXP 4/17/04; 1,288 bottles of 100 tablets distributed nationwide; G.D. Searle & Company, Chicago, Illinois. Recalled by AmeriSource Health Services Corp., Columbus, Ohio

Lot Numbers C200511 and C200682 in 100 tablet bottles; Lot Numbers C200195 and C200577 in 1,000 tablet bottles; Lot Number C200363 in 2,500 tablet bottles; Lot Number C200360 in 100 tablet unit dose carton; 9,720 bottles and cartons distributed nationwide; Pharmacia Corp., Kalamazoo, Michigan

Lot Numbers: 9001566, 9010254, 9010255, EXP 07/03, 9010509, 9010510, EXP 10/03; 47,024 bottles of 100; 9,255 bottles of 1000; and 1,408 bottles of 5000 distributed nationwide; Wyeth-Ayerst Laboratories, Richmond, Virginia

Cartons of 10 capsules B1022-01, B1023-01, B1024-01, B1025-01, B1025-02 EXP 6/02. B1029, B1029-01 EXP 9/02. Physician Samples (15s) B1025-03 EXP 6/02; 1,021,141 trade lots; 1,800 free goods; 153,264 physician samples distributed nationwide; Roche Laboratories, Nutley, New Jersey

## DRUGS AND DIETARY SUPPLEMENTS *cont.*

### *Name of Drug or Supplement; Class of Recall; Problem*

**Tri-Nasal Nasal Spray** (triamcinolone acetonide), 50 mcg (0.05%), 120 metered sprays, 15mL bottles and professional samples, Rx; Class III; Subpotent, potency of the active ingredient triamcinolone acetonide cannot be assured through labeled expiration date

### *Lot #: Quantity and Distribution; Manufacturer*

Product code: 5050-15 and 5050-00; 377,742 distributed nationwide; Muro Pharmaceutical, Inc., Tewksbury, Massachusetts

## MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call 1-800-FDA-1088. The FDA web site is <http://www.fda.gov>.

### *Name of Device; Class of Recall; Problem*

**Interplak Power Plaque Remover Toothbrush**; Class II; Batteries leaking hydrogen gas during charging popping off the end cap

### *Lot #: Quantity and Distribution; Manufacturer*

Model number 12209W; 15,758 units distributed nationwide; Conair Corp., East Windsor, New Jersey

## CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at 1-800-638-2772. The CPSC web site is [www.cpsc.gov](http://www.cpsc.gov).

### *Name of Product; Problem*

**Adapter Plugs** (International); Plug can separate when the plug is removed, exposing live electrical conductors, posing an electric shock or electrocution hazard

### *Lot #: Quantity and Distribution; Manufacturer*

2-prong slip-on; 22,000 sold nationwide from November 2000 through March 2002; PM International Ltd., Edison, New Jersey (800) 377-6332

**Cigarette Lighters**; May have child-resistant mechanisms that do not meet federal safety standards

Disposable, metal, with top that resembles a pencil across a protractor and triangle; 1,800 sold nationwide from December 2000 through May 2001; L.A. Lighter Inc., Azusa, California (800) 499-4708

**Cigarette Lighters**; Lighters do not have child-resistant mechanisms

Refillable liquid or gas fueled with various decals; 6,000 sold in northern California from March 1999 through April 2002; Specialty Sales Co. Inc., Castro Valley, California (510) 581-3869

**Drip Pans**; Hot burners can ignite the pans and pose a fire hazard

Various sizes SKU 845289; 294,000 sold at Dollar Tree Stores nationwide from April through May 2002; Dollar Tree Stores, Inc., Chesapeake, Virginia (800) 876-8077

**Electrical Paintings**; Paintings can short circuit, posing a shock or fire hazard

Motion Picture Series painted on glass, illuminated by a light bulb; 150 sold at flea markets in Texas and Arkansas from December 2001 through April 2002; UL United Inc., Houston, Texas (866) 332-6643

**Emergency Escape Smoke Hoods**; Consumers may have purchased the hoods for protection from tear gas or chemical warfare agents, but should be used only to provide protection from smoke caused by fires

EVAC-U8 bright green plastic with clear red top; 27,400 sold by web-based distributors, catalogues and travel stores from May 1997 through April 2002; Brookdale International Systems, Inc., Vancouver, British Columbia, Canada (800) 459-3822

**C O N S U M E R   P R O D U C T S   *cont.***

<i>Name of Product; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
<b>Ice Shavers;</b> Stainless steel blade can cut consumers and cause injury	Orange and blue with palm tree design; 1,000 sold nationwide throughout May 2002; Bath & Body Works Inc., Columbus, Ohio (800) 395-1001
<b>Instant Hot Water Dispensers;</b> Water can leak from the metal holding tank, wet insulating material and cause electrical arcing and heat build-up, posing a fire hazard	Various brand names with serial numbers 999-10 or between 1000 and 3084000; 252,000 half-gallon units sold nationwide from January 1972 through December 1996; In-Sink-Erator, Racine, Wisconsin (800) 295-8727
<b>Little Wooden Push Cars,</b> Recall to Repair; A child can pull the horn off the car's steering wheel, and a small part inside poses a choking hazard	Natural wood, 24 inches long with "Radio Flyer" written on sides; 15,000 sold nationwide from February 1999 through June 2002; Radio Flyer Inc., Chicago, Illinois (800) 621-7613 <a href="http://www.radioflyer.com">www.radioflyer.com</a>
<b>Mountain Bicycles</b> with "Ballistic 105" front suspension forks; Can break apart, causing riders to lose control	Next Ultra Shock with Ballistic 105 front suspension forks, blue; 132,000 sold at Wal-Mart stores nationwide from May 1999 through December 2000; Dynacraft Industries Inc., San Rafael, California (800) 288-1560 <a href="http://www.dynacraftbike.com">www.dynacraftbike.com</a>
<b>Pop 'n Scoot Ride-on Toys;</b> Young children who lean forward can fall forward over the handlebars, causing injury	Molded plastic with clear dome filled with beads, model 1568-01; 21,400 sold nationwide from March 2001 through May 2002; The Little Tikes Company, Hudson, Ohio (866) 765-6729 <a href="http://www.littletikes.com">www.littletikes.com</a>
<b>Potpourri Simmering Pots;</b> Flames from candles inside these potpourri pots can flare out of the side ventilation holes, possibly causing burns to consumers	Six-sided white ceramic, sold under the Martha Stewart Everyday Brand; 80,000 sold nationwide from September 2001 through March 2002; Candle-lite, Cincinnati, Ohio (800) 718-7151
<b>Propane Heaters;</b> Heaters can emit high levels of carbon monoxide (CO), which poses a risk of CO poisoning to consumers	Model 883-1000-0 outdoor tabletop; 45,000 sold nationwide from September 2001 through May 2002; The Brinkmann Corporation, Dallas, Texas (800) 675-5301
<b>Stove Fuel;</b> Corrosion can cause the can to leak fuel, posing a fire or injury hazard	Packaged in red metal cans, batch number 2003-2; 9,700 cans sold nationwide from March through June 2002; Mountain Safety Research, Seattle, Washington (800) 531-9531 <a href="http://www.msrcorp.com">www.msrcorp.com</a>
<b>Toy Tracks</b> attached to children's activity centers; Toy track can break, presenting a cut or pinch hazard and exposed small parts pose a choking hazard to young children	Tot Wheels V models 4511 and 4521 and Convertible Entertainer models 4562 and 35225; 152,000 sold nationwide from November 2001 through May 2002; Graco Children's Products, Inc., Elverson, Pennsylvania (800) 673-0392 <a href="http://www.gracobaby.com">www.gracobaby.com</a>
<b>Washer and Gas Dryers;</b> Dryer can overheat, posing a fire hazard	Whirlpool, Kenmore and General Electric brands, numerous models; 17,000 sold nationwide from January 2000 through May 2002; Whirlpool Corp., Benton Harbor, Michigan (866) 251-1607 <a href="http://www.repair.whirlpool.com">www.repair.whirlpool.com</a>

# Is Your Doctor Selling You to the Highest Bidder?

Until relatively recently, human experiments to determine whether or not drugs work as intended were deemed too complex to entrust to non-academic physicians. But things progress slowly in the groves of Academe, and pharmaceutical company executives of late have come under increasing pressure from stockholders for ever-larger dividends. As a result, the focus of experimental medicine is moving away from the bureaucratic, stodgy campus environment to venues where studies can be completed more rapidly. Increasingly, industrial sponsors of new products are turning to private practice physicians' offices for research subjects.

But how to recruit research subjects from private practices when doctors are already swimming in a sea of clinical work and insurance company forms and procedures? In a society where everything (and, apparently, everyone) is a potential commodity, can it be any surprise that the solution favored by the pharmaceutical industry is—you guessed it—the almighty buck. Physicians are frequently offered thousands of dollars in “finder’s fees” merely for plumbing their patient lists for eligible patients and then referring them to the industry as potential subjects.

An article in the *British Medical Journal* raises serious questions about these practices. As Drs. Jammi Rao and Sant Cassia point out, “cash payments can influence doctors’ motives for joining a clinical trial.” Worthy research (and clinical care) can be displaced by more remunerative drug company funded research, often dedicated more to the creation of the blockbuster drugs sought by

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*Physicians are frequently offered thousands of dollars in “finder’s fees”*

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the industry than to true scientific progress. (Many of these drugs aren’t blockbusters at all, offering little or no advantage over existing, cheaper, generic drugs—but that is another story.) “A system that allows commercially driven and clinically dubious research to crowd out good and much needed clinical trials, and that denies patients their opportunity to put their altruism to the best possible use,” say the doctors, “is unethical and unacceptable.”

Even if the research is legitimate, finder’s fees are improper. As questionable a guardian of medical ethics as the American Medical Association declared in 1996 that “[o]ffering or

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*Approximately 90 percent of patients thought they should be told who paid for the study*

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accepting payment for referring patients to research studies (finder’s fees) is also unethical.” A companion organization in Britain, the Royal College of Physicians, requires that recruitment fees be disclosed to research ethics committees.

But as Drs. Rao and Cassia point out, patients also have a right to know about these sometimes shady fiscal arrangements. “Not to require a similar disclosure to patients is as cynical as it is demanding of blind and unquestioning trust.” Moreover, while modestly reimbursing physicians for research-related services rendered beyond what would ordinarily be provided to the patient is acceptable, trial sponsors and participating physicians can circumvent any restrictions by “claiming to pay for the work involved in conducting the trial (rather than for recruiting patients), and then overestimating the amount of time required for each patient.”

As usual, patients are ahead of physicians on this issue. In a 1995 U.S. survey, approximately 90 percent of patients thought they should be told who paid for the study, 80 percent wanted to be told if the researcher owned stock in the company, and 85 percent wanted similar disclosure if the investigator was paid for each patient enrolled. For each of these questions, doctors recommended disclosure at somewhat lower rates. Similar disparities are apparent when doctors and patients are asked about the appropriateness of accepting knickknacks, free meals and trips to exotic locations from the pharmaceutical industry. When will the doctors catch up with their patients?

# Hormone Replacement Therapy

*In a book Public Citizen's Health Research Group book published 11 years ago, Women's Health Alert, the largest chapter was on hormone replacement therapy (HRT). By then, the evidence was clear that these drugs caused breast cancer, very serious doubts had been raised about their ability to protect against heart disease, and safer alternative drugs had been developed for osteoporosis.*

*The first sentence in this chapter began: "Female replacement hormones may someday be remembered as the most recklessly prescribed and dangerous drugs of this century."*

*Since the chapter was written, more and more evidence has accumulated linking these drugs with breast cancer and disproving the protective effect on heart disease. This has culminated in the study published in July from the government-funded Women's Health Initiative proving, beyond doubt, that the drugs do indeed cause breast cancer and, instead of protecting against heart disease, actually increase the risk of strokes, heart attacks and blood clots.*

*Below are excerpts from the 1991 Women's Health Alert chapter on HRT.*

Since the 1940s when estrogens were first manufactured cheaply and available by mouth, the story of their widespread use in treating women's "problems" is one of false promises, disregard for scientific evidence and the wishful thinking of women and their doctors that all female health problems can vanish with the magic of pills. It is a story of well-meaning doctors eager to please, and of women too easily sold the wonders of pharmaceutical cures. Unfortunately, years after women have been routinely consuming hormones, many of these otherwise healthy people have slowly been getting sick from estrogens.

In 1989 more than 3.5 million women were given estrogens for the symptoms of menopause—hot flash-

es, heavy sweating and vaginal discomfort. For the short term problems associated with menopause these women began hormone replacement therapy. However, while the symptoms of menopause usually subside in less than two years, a large proportion of these women will take estrogens, and probably progestins (a synthetic form of the naturally occurring female replacement hormone progesterone) indefinitely.

By today's questionable medical reasoning, these potent drugs should be given to perfectly healthy women, not to treat any disease, but to decrease the potential of disease—specifically osteoporosis and heart disease.

Replacement hormones were the "feminine forever" drugs of the 1960s and 1970s, guaranteed to keep wrinkles away, hair glossy and depression to a minimum. In the 1980s, these drugs were advertised as the cure for osteoporosis, the long sought-after answer to brittle bones. Now in the 1990s, estrogens are being touted as the solution to female heart disease. Whatever their mission, these recycled wonder drugs have securely found a permanent spot in the medicine cabinets of millions of healthy women over 45. But the dangers of hormone replacement therapy have been tragically underplayed by American doctors, the press, and of course the drug companies, who make hundreds of millions more dollars every time a new use for these drugs is found. Throughout the history of their application in American medicine, estrogens have proven to be as dangerous as they are helpful. As with so many medical products sold to American consumers, taking them has become a risk-benefit game; the difference here is that women are not making choices based on all the facts.

Ovarian hormones, especially estrogens, have been linked to breast cancer in animal studies since the 1930s. But if you ask your doctor if

they cause human breast cancer, you will probably be told the evidence is still "inconclusive" and "inconsistent," or that women are not the same as rats or mice.

You may have heard or read that if you take menopausal hormones you increase your risk of endometrial (uterine) cancer, heart disease, stroke, gallbladder disease, uterine fibroids, liver disease, and migraine headaches. If you combine estrogens with progestins, you will reduce your risk of uterine cancer, but may simultaneously be increasing your risk of heart disease and breast cancer. Progestins may also cause abdominal bloating, headaches, depression, or acne. You may also begin to menstruate again.

Many women do not realize that menopausal hormones are grossly overprescribed for extraordinary lengths of time—now longer than ever before—longer than anyone can scientifically justify. Unless you are considered at high risk for potential problems with the treatment, physicians today are more likely to downplay any harm and persuade you that without them you will prematurely expire or snap under the weight of old age.

Prescription practices for these potent drugs have subtly but dramatically shifted over time. Today, it is not up to women to prove they need hormone replacement after menopause. The burden is on women to prove they don't. So widespread is the use that many women may not be completely sure why they are still taking estrogens at age 60.

These two grandmothers are examples:

*I have been taking estrogens since I can remember. I don't know whether I'd still get hot flashes, but I don't want to find out.*

and

*I started taking estrogens 12 years ago when my surgeon prescribed them following my hysterectomy. I*

*was having terrible hot flashes then, and Premarin (the most widely prescribed estrogen) completely got rid of them. I'm still taking it, because somewhere along the line, I don't remember when, my doctor told me they would protect me against osteoporosis. I feel great and don't see a reason in the world I should stop taking that pill along with my vitamin every day.*

### **Hormones: Not Harmless Little Tablets**

Little pills that deliver hormones to your body are not simple vitamins or candy-coated aspirin. They are manufactured duplicates of substances that play amazingly diverse roles in females. Besides their role in maintaining reproductive cycles, estrogens alter lipid (fat) levels, metabolize carbohydrates, affect how blood coagulates, adjust blood pressure, and assist in calcium absorption, all of which are complex biological events.

When the natural supply of estrogen slowly diminishes after menopause, can its job all be "replaced" in a pill?

Obviously not. The enormous and complicated functions of hormones are not completely understood by science. Experts are still exploring the effects—both good and bad—of replacement hormones. There is still a lot to know about their long term risks, since long term use is relatively new. In fact, identifying which women will ultimately benefit from these drugs is still impossible, which is why their use is so general and widespread. There is an excellent probability that the vast majority of women receiving hormone replacement therapy will obtain no benefit at all while subjecting themselves to all the potential risks and side effects.

Since ovarian hormones have been known to promote cancer, the trend toward grossly overprescribing them can't be taken lightly. As Allan S. Brett a researcher from the New England Deaconess Medical Center wrote in a 1989 editorial in the *New England Journal of Medicine*, "phar-

macologic interventions are powerful symbols of the triumph of medical technology. Patients are likely to believe implicitly that the benefits of drugs clearly outweigh the risks." This can be a very dangerous assumption.

### **Cancer and Hormone Replacement Therapy**

In the United States in 1990, an estimated 150,000 new cases of breast cancer will be diagnosed in women and 44,000 women died of the disease. Because women of the "baby boom generation" are now reaching age 40, the number of breast cancer cases and deaths will increase substantially over the next 40 years. For this reason, even a small increase in the risk of breast cancer caused by menopausal estrogens will translate into a lot of lost lives.

As women in menopause by the hundreds of thousands are being given replacement hormones, that increased breast cancer risk is being further investigated now. But accumulated evidence over the past decade shows that if you use menopausal estrogens for a long time, you roughly double your chance of getting breast cancer by the time you are 75.

What's a long time? Let's briefly look at the scientific studies. While they go back earlier than this, the first reliable studies of women taking menopausal estrogens for longer than five years were published between 1977 and 1983. These were strikingly consistent in their findings, and overall, showed that women using the most commonly prescribed dose of estrogen (1.25 mg tablets at the time) for five or more years double their chance of developing breast cancer.

Four of the five studies found that the risk of breast cancer was highest in women who used higher doses of the drug, women who used the drug for a long period of time or both. In the first of these studies, researchers found that women using doses higher than .625 mg per day (the dose most commonly prescribed today)

were 2.7 times as likely to develop breast cancer 10 years after starting drug treatment as women who did not use the drug.

In the second study, researchers found that women who received any dose of menopausal estrogens for at least seven years had an 80 percent increase in breast cancer.

The 1981 study found that women who had surgical removal of the ovaries and estrogen replacement therapy increased their risk of breast cancer; dramatically the longer they were on estrogens. The risk worked out like this: in less than five years of estrogen replacement therapy these women had a 38 percent increased risk of breast cancer; at nine years, their risk had increased to 55 percent; and after 10 years it reached 70 percent.

In 1986, an expanded study of menopausal estrogen use showed that 20 years after first using estrogens, women had increased their risk by 50 percent.

But all these findings have been called "inconclusive" because other studies have shown little or no connection between breast cancer and menopausal hormones. Proponents of menopausal hormones are reluctant to implicate this wonder drug as a contributor to breast cancer, an admittedly complicated disease caused by many factors.

In 1989 at a meeting of the Food and Drug Administration Fertility and Maternal Health Drugs Advisory Committee in Washington D.C. leading researchers met to decide if the evidence over the last decade did indeed point to an increased risk of breast cancer in postmenopausal women.

Janet Daling from the Fred Hutchinson Cancer Research Center in Seattle called the question of risk "very tricky" to answer: "My conclusion would be that estrogen replacement therapy may have a modest effect on breast cancer risk, something in the range of 1.5 to 2.0 [times increased risk] in women who have used estrogens for long periods of time."

The committee was also asked to

review all the evidence and their conclusion was: "The committee's unanimous response is, while the evidence is not conclusive, some studies have reported an increased risk of breast cancer in long term use of estrogen replacement therapy."

Today, instead of getting only a prescription for estrogens, you will probably also get another little bottle, this one with progestins. You will take these for 7 to 10 days at the end of your cycle of estrogen pills.

In the mid-1970s, three striking studies found that taking estrogen by itself increases your risk of endometrial or uterine cancer from 5 to 14 fold. This news sent shock waves through the medical community, but in 1989 it was shown that by adding progestins, the problem of endometrial cancer was largely ameliorated.

Good news and bad news. It was somehow "hoped" by some doctors that progestin would also offer women some protection from breast cancer, despite the known differences between how each organ responds to hormones. However, not surprisingly, in the summer of 1989, a new study from Sweden suggested that progestins in combination with estrogen may cause more harm than good.

The study showed, once again, that women using estrogens alone for an extended period double their risk of breast cancer, but it also showed that when progestin was added there was no protection against breast cancer. Instead, the few women who used the two hormones together for more than six years had a higher risk of breast cancer than those taking estrogen alone.

The study has been criticized because the Swedish women who participated in it were given differently manufactured hormones at different doses than women typically get in the U.S. But one of the study's authors, Dr. Robert Hoover, Chief of the Environmental Epidemiology Branch of the National Cancer

Institute, says the results shouldn't make any hormone proponent feel vindicated. "It looks as though the cancer risk may be an estrogenic effect and not some nuance of the chemical structure of different estrogen compounds."

The results of the Swedish study, says Hoover, are not surprising.

*The fact that ovarian hormones might relate to increased risk of breast cancer is not on the bizarre fringe of biological reasoning. The biological plausibility was established 100 years ago, so new data which shows that women on replacement therapy have an increased risk is exactly what you would predict. You can argue about what level of risk there is, but the reasonableness of the observation is firmly steeped in biology.*

Arguing about the level of risk is what researchers are doing these days, which may be the reason that practicing physicians are told, and will tell you, that studies are inconsistent and inconclusive, so basically there is nothing to worry about. In fact, if you increase your risk of breast cancer, that is obviously something to worry about.

### **Getting Started on Replacement Therapy**

Why have women adopted the notion that menopause is a cruel consequence of being female, "one of nature's mistakes," an illness that needed to be cured? Menopause is not a disease. No one has ever died from it. It is a natural event that results in some temporary and some permanent changes for all women. Physiologically it's the time when a woman's ovaries stop functioning, a process that can take several years. The cessation of periods and the thinning and drying of the vaginal tissues are among the two most obvious permanent changes

associated with menopause. Hot flashes are temporary changes most women encounter. However, many other psychological conditions have been described as "symptoms" of menopause. Irritability, depression, anxiety, loss of sexual feelings, and an almost limitless list of other states are all attributed to it, but not proven to be caused by it.

Menopause is not the first time most women experience these symptoms, but they may be worsened at age 45 or 50 in a society that discriminates against aging women, promotes superficial notions of exclusively youth-related sex appeal and encourages everyone to answer all problems with a pill. Menopausal estrogens will not eliminate wrinkles, increase your libido, or ameliorate all the psychological conditions that come with growing older. Those hoped-for effects don't happen, plain and simple.

However a small number of disruptive and annoying symptoms of menopause may be alleviated by reintroducing estrogen as its own production is slowly reduced. Menopausal estrogens in low doses over short periods can eliminate hot flashes and night sweating associated with menopause. They can also reduce vaginal dryness. While useful for both problems, treatment seldom needs to continue for longer than several months. Most women are free of hot flashes in under two years and vaginal dryness can be treated with topical creams.

While some women do experience hot flashes that are incapacitating, more frequent is the experience of Dorothy, 50, a psychologist.

*The first time I felt one I thought I had forgotten to turn on the air conditioner. Now I can feel one coming and I know it's going to last a minute or so. Occasionally I have to take off a sweater, or wipe my brow but it never gets in my way. It's simply not a big problem.*

**OUTRAGE, from page 12**

ties. In an April 29, 2002, letter to all Academy members, Dr. Fred F. Castrow II, the Academy's president, cautioned dermatologists that "Social gatherings of this kind in combination with botulinum toxin treatments are inappropriate and potentially dangerous settings for patients. As such, I strongly discourage you from participating in these kinds of medical/social activities."

Thus, we were astounded when we heard that everyone with an email account through the Johns Hopkins School of Medicine (including students, faculty, residents and staff) had received an announcement on Johns Hopkins stationary for the Botox event with the title "It's Botox Night at Hopkins." Here was the pitch:

*Do you have fine lines and wrinkles that make you look older than you really are? Do you want to look younger without the cost and inconvenience of surgery? Curious what all the fuss is about Botox? Come join us after work for an infomation (sic) seminar including live demonstration of the many uses of Botox. Any interested in receiving Botox treatments may do so on the spot! Refreshments will be served and attendance is free. (Emphasis in original)*

The wording of the ad did not suggest an educational seminar so much as a sales pitch dressed up to look like an educational event. Real educational events at hospitals typically occur at lunchtime seminars or as grand rounds, not after hours with promises of drugs for the attendees. A truly educational seminar would have been entitled "The Safety and Efficacy of Botulinum Toxin A in the Treatment of Glabellar Lines," rather

than the blatant pitch "It's Botox Night at Hopkins." It is hard to imagine a patient education seminar on arthritis with "on-the-spot Enbrel injections" or a seminar on cancer with "on-the-spot chemotherapy."

Whereas the refreshments and

*"Any interested in receiving Botox treatments may do so on the spot!"*

attendance at the session were indeed free-of-charge, as advertised, injections were to be offered to prospective clients at a special rate of about \$100 per treatment. Presumably, this "introductory offer" would entice them to return to Hopkins for injections in a few months when the initial treatment inevitably wears off. The full price, typically five times that of the initial treatment, most likely would be charged for subsequent visits.

Dismayed that a respected institution like Johns Hopkins would permit so inappropriate an activity

*The wording of the ad did not suggest an educational seminar so much as a sales pitch*

under its roof, Public Citizen sent a letter to Edward D. Miller, M.D., Chief Executive Officer and Dean of the Medical Faculty at Johns Hopkins School of Medicine, strongly urging that "Botox Night" be cancelled. "With all the medical problems facing the U.S., and Baltimore in particular, can this be the most productive use of faculty members,' students,' or residents' time?" Public Citizen asked. "What social or medical purpose is served by marketing cosmetic procedures to healthy Johns Hopkins employees, particularly those who, based on their age, will have few signs of aging? Botox injections are medical procedures that should be delivered in a calm, private setting—not in the festive atmosphere this announcement appeared to contemplate."

The Public Citizen letter had immediate results. Although Botox Night was not cancelled, the University did call off its plan to administer Botox at the event. It also informed us that the university is drafting an institutional policy which will preclude similar events in the future.

Such gatherings, which market products under the guise of education, undermine the core educational mission of the university, debase the profession, and misdirect precious health resources that would be better spent treating disease than pandering to vanity. For this reason, Public Citizen has written to the Association of American Medical Colleges asking that it develop a national policy banning such blatant commercialism. As for Johns Hopkins, in instituting its planned policy prohibiting future Botox Nights, it may yet lead the nation, not only in medical science, but also in the fight to preserve integrity in medicine.

## “It’s Botox Night at Hopkins”

For the 12th consecutive year, Johns Hopkins Hospital has come in first in the *U.S. News & World Report* ranking of American hospitals. Ironically, one day before receiving this honor, Hopkins came within a hair’s breadth of disgracing itself by sponsoring a “Botox Night”, in which healthy people would have received on-the-spot treatments at reduced prices in a social setting.

Botox, also known as botulinum toxin A, is a chemical that, injected in small concentrations, reduces the ability of muscles to contract, thereby causing improvement in the appearance of “glabellar lines” (frown lines between the eyebrows). Since (and even before) the approval of Botox Cosmetic by the Food and Drug Administration (FDA) on April 12, 2002, Botox parties have sprung up all over the

*The American Academy of Dermatology went on record criticizing Botox parties.*

United States, typically in spas or upscale private homes, often featuring alcohol and on-the-spot injections with Botox. The procedure must be repeated, usually every three to five months, potentially providing a steady stream of patients (and income). The average cost of a Botox injection is \$497, according to a survey by the American Academy

of Facial Plastic and Reconstructive Surgery conducted between January and April 2002.

Although alcohol was not served at the Johns Hopkins event, one purpose of the party setting is to capitalize on the fact that people in large, casual settings get caught up in the moment and are easily influenced by persuasive speakers. Another is that since a vial of the very expensive Botox typically contains enough toxin for five injections and the contents must be discarded within four hours of the vial’s being opened, there is an incentive to gather enough people to use all the contents in one session.

Just two weeks after Botox was approved for cosmetic uses, the American Academy of Dermatology went on record criticizing Botox parties  
*continued on page 11*

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