

Virtual Mentor

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Ethical Issues in Dermatology

From the Editor

- Dermatology and the changing face of medicine** 493
Kelly A. Carroll

Educating for Professionalism

Clinical Cases

- Prescribing a teratogenic medication** 495
Commentary by Jeffrey M. Weinberg

- Dermatology lab referrals: cash cow or ethical trap?** 499
Commentary by Jane M. Grant-Kels and Barry D. Kels

- Dispensing cosmeceuticals from the office** 503
Commentary by Michael H. Gold

Medical Education

- Pharmaceutical support of dermatology residency electives:
slippery slope or synergy?** 509
by Alfred T. Lane

- Funding of dermatology residencies by the pharmaceutical
and medical device industries: what are the ethical ramifications?** 512
by Michael J. Franzblau

Journal Discussion

- The benefit and burden of ancillary professionals in dermatology** 514
by Seemal R. Desai

Clinical Pearl

- The ABCs of melanoma: expanding
basic screening and education** 517
by Cory L. Simpson

Law, Politics and Society

Health Law

- Accutane and the evolution of a warning** 520
by Lee Black

Policy Forum	
iPLEDGE: a report from the front lines of dermatologic practice	524
by Clay J. Cockerell and Diane M. Thiboutot	
Medicine & Society	
The influence of controllable lifestyle on medical student specialty choice: a dermatologist’s perspective	529
by Jack S. Resneck, Jr.	
History of Medicine	
<hr/>	
Lessons in dermatology research: protecting vulnerable research participants	533
by T. Howard Stone	
Op-Ed	
<hr/>	
Adding burden to burden: cosmetic surgery for children with Down syndrome	538
by Ann K. Suziedelis	
Medical Humanities	
<hr/>	
Birthmarks	541
by Faith L. Lagay	
Resources	
<hr/>	
Suggested readings and resources	545
August Contributors	
<hr/>	
About the contributors	552
Upcoming Issues of <i>Virtual Mentor</i>	
<hr/>	
September: Humanist Approaches to Care at the End of Life	
October: Thresholds of Parental Competence	
November: The Illness-Poverty Relationship	
December: Ethics of International Medical Volunteerism	

Virtual Mentor

American Medical Association Journal of Ethics
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From the editor

Dermatology and the changing face of medicine

It is more than just a play on words to say that dermatologists represent the changing face of the medical profession. As this issue of *Virtual Mentor* demonstrates, the advances dermatologists have embraced in their clinical practice and professional milieu place them at medicine's "cutting edge."

Practicing at medicine's cutting edge is fraught with ethical questions and challenges to professionalism. This month's clinical cases and commentary examine three situations that raise ethical red flags. The use of isotretinoin for treating severe acne is one example because the drug can cause birth defects if taken during pregnancy. The FDA-approved iPLEDGE program for managing this risk is so burdensome to physicians, patients, pharmacists and manufacturers that its critics fear dermatologists will refuse to prescribe the treatment despite its demonstrated efficacy. The dilemma of how onerous regulations can be before they become disincentives to valuable therapy is also explored in the policy forum and health law sections of the journal.

As the number of conditions physicians can diagnose and treat effectively increases, so do the number of tests available. Dermatologists are high-volume users of pathology services for diagnosis of cutaneous melanoma, other skin cancers and nonmalignant skin lesions. As such, they are courted by large interstate pathology labs that offer bargain prices (at times, lower than the amount insurers will reimburse) to dermatology clinics and practices that maintain a certain volume of business. Case two discusses the ethical dilemma these offers pose. Physicians who are being squeezed by high malpractice liability premiums on one side and generally low reimbursements on the other may be tempted to bill insurers for as much as they will pay, even if it exceeds the lab charges.

With a burgeoning market for cosmeceuticals and a variety of other enhancing products, dermatologists and dermatologic surgeons are well-positioned to contribute to the debate about the ethics of enhancement. How do we quantify the value of increased self-confidence or an improved sense of personal identity? How should physicians handle medical enhancements for minors? This month's third clinical case examines the guidelines for ethical sales of cosmeceuticals from a physician's practice, and a poignant and thoughtful op-ed challenges the wisdom of parental decisions to alter the facial characteristics of their children with Down syndrome through plastic surgery.

Dermatologists also confront questions about the role of the specialty within the larger profession. Long before 2003 when resident work hours were limited to 80

hours per week, dermatology was known for offering and respecting quality of life—both at work and at home. As the importance of balance in the life of physicians rose to the forefront of professional concerns in the 1990s, so did the rate of residency applications for dermatology, to the point that this specialty is now widely considered one of the most competitive. As the author in the medicine and society section explains, the cause and effect relationship between quality of life and selection of medical specialty is more complicated than it first appears.

In addition to analyzing the state of the specialty, contributors to this issue demonstrate that dermatology continues to push the envelope. Two medical education articles defend opposing positions on dermatology's experimental attempt to ameliorate residency shortages by accepting support from the pharmaceutical industry. The journal discussion elaborates on an article about managing the increased liability that dermatologists incur when they delegate clinical responsibilities to nonphysician health care professionals in their practices. The answers tested here may one day supply a fix for a labor shortage in other specialties.

A chapter from dermatology's past is retold in the history of medicine section and represents the downside of being a leader in the field. Clinical trials of new skin products were conducted starting in the 1950s and continuing into the 1970s at the Holmesburg prison in Pennsylvania. The inmates who volunteered and were paid for their participation in the studies were not fully informed about the risks involved in the experiments. These trials contributed to the growing awareness of the ethical hazards inherent in using members of vulnerable populations in research and led to the codification of protections for human research subjects. Finally, a fictional cautionary tale, Nathaniel Hawthorne's "The Birthmark," is explicated in the medical humanities section.

Yes, practicing at the cutting edge of medicine can be precarious. One of the best tools for improving the likelihood of benefit from an experiment is open and honest debate about the risks and rewards, background of the research and conflicts of interest, (real and potential). The authors in this issue contribute significantly to the important ethical debates arising from the professional and clinical "trials" facing dermatology today.

Sincerely,

Kelly A. Carroll
Fellow, Institute for Ethics
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Clinical case

Prescribing a teratogenic medication

Commentary by Jeffrey M. Weinberg, MD

Dermatologist Michael McIntyre enters the examining room and greets his patient, Reina Sharpe, and her parents. Reina is 14 years old and has been a patient of Dr. McIntyre's for about a year. Anxious about beginning her freshman year of high school in a few weeks, Reina expresses frustration over her worsening acne. Dr. McIntyre recognizes that Reina's condition has progressed from a moderate form of acne vulgaris to inflammatory acne, observing the development of nodules and signs of early scarring. At her initial visit to his office, Dr. McIntyre prescribed a topical antibiotic combined with benzoyl peroxide. However, over the last three months he has added oral antibiotics to her treatment regimen.

Reina tells Dr. McIntyre that one of her soccer teammates, Melissa, used to have bad acne too, but it has gotten better since she started taking Accutane (isotretinoin). Reina asks if Dr. McIntyre can put her on that medication. Mr. and Mrs. Sharpe express concern at Reina's request, and ask to speak to Dr. McIntyre in the hallway. Outside the examining room, Mrs. Sharpe says that she has read that Accutane can lead to depression and would also require that her daughter begin taking birth control pills. The Sharpes reiterated the feelings about birth control pills that they shared with Dr. McIntyre when he initially offered it as a stand-alone treatment alternative for acne. They feel that Reina is too young to be on "the pill," and besides, birth control of any kind is not permitted in their faith tradition. Mr. Sharpe adds that money is not an issue, and they would be happy to pay for laser surgery or dermabrasion to improve Reina's scars.

Dr. McIntyre is concerned that the oral and topical antibiotics are not treating Reina's acne effectively and that the preferred next treatment step would be to prescribe isotretinoin. However, that is a difficult therapy regimen, one that requires monthly office visits and strict oral contraceptive use and carries the possibility of side effects. On the other hand, he does not believe that Reina should have to rely on laser surgery to fix scars that could be prevented by isotretinoin treatment.

Commentary

This case is a microcosm for the recent controversy over isotretinoin. From a medical point of view, the drug is certainly the therapy of choice for nodulocystic acne, especially if there is a risk of permanent scarring. The introduction of isotretinoin in 1982 was a major advance in the treatment of severe acne. The drug is

highly effective and is not associated with serious adverse events for the vast majority of those who use it.

One of the major concerns in the use of isotretinoin is pregnancy prevention. Prior to the approval of the drug, premarket studies in animals showed high rates of central nervous system defects and facial malformations after gestational exposure [1]. Within months of the introduction of isotretinoin into the market, severe malformations were reported in infants of women taking the drug [2]. Approximately 40 percent of infants exposed to the drug in the first trimester have serious birth defects. In addition, children exposed in utero who do not develop a major malformation may still be affected by cognitive deficits [1].

Early risk management efforts

In 1988, the FDA, in conjunction with the manufacturer of isotretinoin, developed a Pregnancy Prevention Program to increase awareness of the teratogenicity of the drug. This program included written informed consent and a commitment by women taking the drug to use two contraceptive methods simultaneously. Despite this program, reports of fetal exposure continued during the 1990s [1].

The next risk management program was implemented in 2002. This program, in four variants known as SMART, SPIRIT, ALERT or IMPART, depending on the manufacturer of isotretinoin, had several features: pregnancy tests, two forms of contraception, a qualification sticker on the prescription, survey participation, patient consent forms, a letter of understanding signed by a physician and patient education.

Next, in February 2004, the FDA advisory committee reported that compliance with these elements of the risk management program had not been universal [3]. In fact, Roche, one of the manufacturers of the drug, reported an increased number of cases of pregnancy among isotretinoin users after SMART was introduced. In all, Roche received 150 reports of pregnancy cases prior to SMART implementation and 183 afterward. Although there was a slight decrease in the number of women who were already pregnant before starting isotretinoin, no improvement was reported in baseline pregnancy testing, monthly pregnancy testing or birth control methods [4].

The iPLEDGE program

The latest program was introduced in March 2006. It is called iPLEDGE and is quite complex. Utilizing an Internet-based system, iPLEDGE requires the registration of all wholesalers who distribute isotretinoin, all health care professionals who prescribe isotretinoin, all pharmacies that dispense isotretinoin and all patients, men and women, who take the medicine.

The program is rigorous for both the patient and physician. Female patients cannot obtain or fill their first prescription unless they meet the following requirements: initial screening, two negative blood or urine pregnancy tests with documented results verified by the prescriber and registration in the password-protected system. Female patients with child-bearing potential also must commit to using two forms of

contraception during the course of therapy and for one month before and after taking the drug. The patient is required to have a negative pregnancy test result every month throughout this period, and to report the test results as well as verification of the two methods of contraception being used. This information must be entered by the prescriber into the iPLEDGE system.

The advantages of the new program include the following: the unification of four risk management programs into one; the potential to drastically reduce or eliminate pregnancies among women taking isotretinoin; increased survey participation; a change in behavior of physicians, pharmacists and patients who have not complied with previous rules; assurance that only qualified physicians will prescribe; and, most importantly, assurance that this drug will remain on the market for patients with severe acne who need it.

There are also several potential disadvantages. No program is likely to reduce pregnancies to zero; some pregnancies will always occur. The iPLEDGE program requires physicians to shoulder a big administrative burden, and the risk remains that an underground trade in the drug via Internet and foreign sales could grow as patients become frustrated with a more restrictive system. Many physicians may decide not to prescribe the medicine if this safety process becomes more cumbersome. The worst consequence would be that patients who need isotretinoin would not be able to obtain it.

iPLEDGE and the minor patient

The case described above is a difficult one for the dermatologist. Of course, in the case of a minor, the parents have the final say. But it is incumbent upon the dermatologist to educate the parents as much as possible, especially in light of all of the negative stories about isotretinoin that are being disseminated by the press. The link between isotretinoin and depression, for example, has never been firmly established. Chia et al. performed a recently published study to determine whether patients with moderate to severe acne who were treated with isotretinoin experienced significant increases in depressive symptoms over a three-month to four-month period compared with patients who received “conservative” acne therapy [5]. A total of 132 subjects, aged 12 to 19 years, with moderate to severe acne were enrolled. Depressive symptoms were assessed using the Center for Epidemiological Studies Depression Scale (CES-D), a standardized self-reported instrument.

A total of 101 subjects completed the study. At follow-up, CES-D scores (adjusted for baseline CES-D score and sex of patient) suggestive of clinically significant depression were no more prevalent in the isotretinoin group than in the conservative therapy group. In addition, the incidence of new onset of depressive symptoms was not significantly different between the treatment groups. The authors concluded that the use of isotretinoin in the treatment of moderate to severe acne in adolescents did not increase symptoms of depression. Interestingly, treatment of acne either with conservative therapy or with isotretinoin was associated with a decrease in depressive symptoms [5].

In our case, Dr. McIntyre should review the truths and fictions regarding isotretinoin with the family, and reemphasize the potential physical and psychologic sequelae of her condition. He should also point out that abstinence is one of the acceptable forms of pregnancy prevention, in the case of lifestyle choice such as religious practice. If the parents do not agree, he should at least try to leave the matter open for further discussion if Reina's acne does not improve.

Despite all of the difficulty inherent in the use of isotretinoin, I urge clinicians to stay committed to the treatment of acne and to make the extra effort to provide isotretinoin to those who need it.

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Related articles

[iPLEDGE: a report from the front lines of dermatologic practice](#), August 2006

[Accutane and the evolution of a warning](#), August 2006

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Clinical case

Dermatology lab referrals: cash cow or ethical trap?

Commentary by Jane M. Grant-Kels, MD, and Barry D. Kels, MD, JD

Dr. Adam Vinaver emerged from an exam room at the Metro Dermatology Group's downtown office and spoke to Joan, a lab technician. "Would you see that this biopsy sample gets on the fast track, please? It's from a local lifeguard, and I think he's got a problem here, maybe a serious one. We need results fast."

"OK, I'll send it off. Did you hear about the new lab we're going to be using?" said Joan.

"New lab?" he asked.

"It's one of the boss's bright ideas," she said.

Dr. Vinaver soon learned that the clinic was about to contract with a giant out-of-state lab and would start sending its pathology samples there because the fee schedule was more favorable to the clinic. With a volume discount, the clinic could pay the lab \$40 per sample and get the lab pathologists' interpretation of the path slide promptly. Since most patients' insurers were reimbursing at close to \$120 for lab analysis, Metro could conceivably collect \$80 on every test.

Dr. Vinaver foresaw some problems, not least an ethical conflict of interest. He knew he'd have to confront the group's senior partner on this one, because if there's one thing Jim Swoboda was serious about, it was the cash flow that made the clinic a going concern and a leading group practice in the region.

Dropping by Jim's office, Adam spoke up. "I think we're asking for trouble with this lab referral deal. It almost looks like a kickback to me."

Dr. Swoboda countered, "Well, Adam, it's not illegal if we set it up right—I'm running it by our lawyer today at lunch. He'll look at all the angles for me. We have to work the system and this is one way to do it. There's decent money in this."

"You're not worried that we'll be tempted to do more tests to get the volume discount and make more money?" Dr. Vinaver asked.

“I’m not telling you to do something a patient doesn’t need, but when the opportunity arises, take it.”

“Jim, I know you’re a good businessman, so look at the risk. We could be getting into a serious conflict of interest here. How will it look? Besides, what happens when the insurers get wind of this? We know our local lab is fast and accurate. Who are these other guys? I’m asking you to wait until we can think it through.”

Commentary

We would encourage the Metro Dermatology Group to continue to utilize the local laboratory in which the group partners have confidence, due to its proven track record of speed, accuracy, service and availability for discussion of problematic cases. Large regional and national laboratories may have a roster of pathologists with indeterminate reputations and uncertain credentials. In addition, a switch to pathologists in a large regional or national laboratory might result in less-than-optimal pathologist-to-clinician communication and require clinicians to adapt to a new and unfamiliar terminology.

We would also caution Dr. Swoboda to insure that the Metro Dermatology Group will not run afoul of the federal “Anti-Kickback Statute” which states in relevant part:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program...shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both [\[1\]](#).

Obligations of the dermatologists

The ethical obligation of the dermatologists is to choose the lab in which they have the greatest confidence. We are aware of situations in which certain dermatologists use a cookie-cutter lab for some or all of their patients due to financial incentives but then consult with a high-quality laboratory for biopsies performed on their close friends and family members. This almost certainly represents unethical behavior and perhaps illegal behavior if the offending dermatologist realizes financial gain from the arrangement [\[1\]](#).

Obligation of the pathologists

The ethical obligation of the laboratory pathologists is to demand working conditions that permit them to perform within, or to even surpass, the standard of care. Therefore, if laboratory management were to request volume or speed inconsistent with accurate diagnosis, its pathologists would be ethically obligated either to

demand amelioration of the situation or to terminate their employment with the lab. In addition, the pathologist requires a quiet work area that is conducive to concentration as well as the ability, for example, to order as many “deeper” (deeper cuts into the paraffin-embedded specimen block to ensure the absence of additional material pathology) and specials (various stains that highlight additional diagnostic clues) as he or she deems necessary. Finally, group conferences during which cases are shared and reviewed by several pathologists enhance the quality of the sign-out process (sending slides out for microscopic examination and differential diagnosis) on more challenging cases.

Profit vs. patient care?

When physicians are required to see more patients per hour than they feel they can examine thoroughly or sign out more slides per day than they feel they can evaluate accurately, the need for profit has compromised patient care. If the work day extends beyond the time when the physician feels alert, profit motives may have compromised patient care. Unfortunately, we believe that 21st-century American medicine has probably reached the point at which the need for profit seriously threatens patient care.

As much as we disapprove of the course Dr. Swoboda wants to pursue, we understand his predicament. It is the rare clinician who can offer patients all the time and compassion they need and deserve while still producing sufficient revenue to service ever-expanding practice costs and meet personal income requirements. Moreover, the era of fee-for-service medicine is essentially at an end except for rare “boutique” or “concierge” practices. Therefore, many providers in their late 50s and early 60s may choose to leave the ethically challenging, pressure-cooker environment that managed care and governmental controls have created. This situation does not augur well for American medicine or Americans who require the ministrations of the healing arts.

Critique of options

The solution is not finding legal ways to cheat insurers. A better solution would be a return to fee-for-service medicine or hourly reimbursement similar to that demanded by attorneys. In that way, ever-expanding practice overhead could be transferred to the purchaser of the service. The CPT coding system has contributed to a business environment in which revenue is dependent upon volume rather than quality. Yet we seriously doubt that insurers or the government will ever allow physicians either to charge an hourly fee like experienced litigators or to return to fee-for-service medicine with a transparent disclosure of astronomical practice costs. Unfortunately, even if a single-payer system were to be adopted, the increasing overhead costs and medical-legal pitfalls inherent in the practice of medicine would not necessarily be adequately addressed.

Nevertheless, unethical behavior must be avoided because such behavior corrupts the profession, impairs patient trust and, most importantly, may cause patient harm. Disciplines such as internal medicine and pediatrics continue to struggle financially

because of the meager value placed upon face-to-face, doctor-to-patient time. Those physicians in subspecialty fields such as dermatology are more fortunate because of their ability to include cosmetic and procedural “profit centers” in their practices, thereby allowing them the luxury of providing moral, ethical and legal—as well as reasonably compensated—care.

Reference

1. 42 USC §1320a-7b.

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Clinical case

Dispensing cosmeceuticals from the office

Commentary by Michael H. Gold, MD

Mrs. Schweppe had just finished seeing her dermatologist, Dr. Fletcher, and was in the process of making an appointment to follow up about her eczema treatments when her eye caught three non-descript bottles with gold writing displayed on a short platform.

“Angie,” Mrs. Schweppe asked Dr. Fletcher’s secretary, “what are these bottles?”

“These are our special sunscreens and moisturizers,” Angie answered. “Are you currently using any special sunscreen on your face?”

“Well, no,” Mrs. Schweppe answered. “I mean, I always use an SPF 15—or 30 if I’m in the garden—but I usually buy whatever is on sale at the pharmacy.”

“Perhaps you should talk to Dr. Fletcher about the product before he meets with his next patient. Most of the doctors in the practice recommend this sunscreen to all of their patients, but if Dr. Fletcher hadn’t mentioned it, maybe it’s because it would interact badly with your eczema medication.” While Angie went to find Dr. Fletcher, Mrs. Schweppe read the short pamphlet that showed before and after pictures and offered testimonials about the benefits of the lotions.

“So, Marie,” Dr. Fletcher warmly greeted her, “Angie tells me that you’re interested in some of our products.”

“Well,” Mrs. Schweppe began, “they just caught my eye and I wondered if it was something new that I should be using.”

“I can tell you that the sunscreen here offers you the protection of SPF 30, moisturizes very well and never leaves your face feeling dry or oily like some of the mass-marketed products can. It’s much gentler on the skin.” Dr. Fletcher picked up the “tester” bottle and allowed Mrs. Schweppe to feel and smell the lotion.

“Do you think that this is something I need? How much is it?” she asked, clearly impressed by what she had seen so far.

“It’s kind of expensive, which is why I hadn’t mentioned it to you before. I think that it’s great and that it can only help your skin, but what you use now probably gives you the minimum protection that you need.”

“Well, if it’s so expensive here, maybe I can find it cheaper at a discount store or pharmacy.” Mrs. Schweppe offered.

“Unfortunately, you can’t get it anywhere else in the state—we have an exclusive contract with the manufacturer. We’re currently trying to expand their distribution but that could take months. The good news is that you don’t need a prescription. It’s about \$35 a bottle and each bottle, if you use it everyday, will last about a month. I can assure you, however, that your face will be well protected when you’re in the garden if you use this lotion. Also, we can offer you a better deal if you buy several months’ worth today.”

“I suppose I should get it then,” Mrs. Schweppe said with a hint of reluctance in her voice. “It’s almost impossible to cover my face completely when I’m in the sun and with the increase of skin cancer that you hear about on the news, you can never be too careful.”

“That sounds great. How many months’ worth can Angie get for you?”

Commentary

The dispensing of cosmeceutical products from physician offices has become a standard practice in the majority of dermatologic and plastic surgery offices across the United States. I comment on the case presented here as a dermatologist who has been dispensing cosmeceutical products in my office setting for the past 15 years and who has lectured extensively on what I have always described as the “ethical” dispensing of cosmeceutical products. By that I mean that, while I have always made nonprescription products available in my dermatologic clinic, I have never made patients feel obligated to purchase them.

During the past 15 years the nonprescription skin care business has expanded rapidly, as anyone walking into any pharmacy or looking at the cosmetic counter of any department store can see. Sales of skin care products have reached billions of dollars per year, and it seems to me that dermatologists and plastic surgeons, those physicians who spend the most time dealing with skin care concerns and issues, are in the best position to recommend the most appropriate skin care product or regimen to their patients. I refer to this as a “one-stop shopping” platform for dermatologists and plastic surgeons. We understand skin better than any other group and, if dispensing of nonprescription skin care products is done ethically, I find no reason the practice should not continue to grow and thrive.

There are both strong advocates of and vocal opponents to the concept of dispensing products from clinical offices. One look at the guidelines of the professional societies and you can get an understanding of the ongoing debate. A brief summary of the

relevant opinion from the *Code of Medical Ethics* of the American Medical Association states:

1. Physicians may sell health-related goods at cost, provided that they take adequate precautions to assure that patients are not pressured into making purchases. Products sold should be evaluated for their scientific validity.
2. Physicians may ethically advise the use of and provide free health-related non-prescription goods from their offices.
3. Physicians should not participate in exclusive distributorships [1].

The Code of Ethics of the American Society of Plastic Surgeons, however, states that “In the practice of medicine, a physician should receive professional income only for...sale of medically-related products approved by the physician” [2], which seems to be at odds with the AMA’s position.

And finally, the American Academy of Dermatology declared in 1998, “dermatologists who dispense in-office should do so in a manner with the best interest of their patient as their highest priority, as it is in all other aspects of dermatologic practice” [3].

Clearly, we have three different opinions from three vocal medical organizations. This discordance led to considerable debate in the world of medical sales and marketing. Articles and commentaries for and against the practice of dispensing cosmeceutical products have appeared in the dermatologic literature. Some thought we were putting our integrity at stake [4-6] while others felt that making skin care products available to patients was an extension of our everyday dermatologic business [7, 8]. This is where the word “business” entered into our medical vocabulary, at least for me.

The practice of medicine is a business, no matter which specialty one is in. I believe strongly that every one of us entered the field of medicine with the primary mission of taking care of patients to the best of our abilities. This does not alter the fact that, in the real world, the majority of us are involved in the business operations of a medical practice; the degree to which this is true varies from physician to physician, group to group and specialty to specialty, but almost always with the physician in charge.

The practice of dermatology puts the patients’ concerns right in front of our eyes, and our goal is to help those patients maintain healthy skin. This is in part the reason for the influx of cosmetic products and procedures into our practice. In many cases dermatologists have played crucial roles in developing or in refining these techniques so that now a broad range of skin care products essential to healthy skin maintenance is available and sought after.

My office is set up so that patients have the opportunity to see, examine and buy skin care products. Sales are handled at our Medi-Spa, located adjacent to but separate from my practice space. Brochures that explain many of the products and their

potential benefits are available in our reception area. After I examine a patient, I routinely ask about his or her skin care routine. If the patient is using appropriate agents on his or her skin, no matter where they were purchased, I will review those products with the patient and make sure they are being used correctly. With patients who are not using skin care products and who I think would benefit from a non-prescription skin care routine, I explain the kinds of products and ingredients I think will work best for their skin. I then refer them to the Medi-Spa for further evaluation. The patient receives a copy of my suggestions to take to the staff at the Medi-Spa who proceed to supply further explanation of the products we are recommending.

No coercive sales techniques

At this point, let me digress. Although I may have recommended that the patient go to our Medi-Spa and learn about the skin care products we have, I never insist that patients go there, nor will their decision affect their future treatments or care. All personnel in the Medi-Spa environment are licensed medical aestheticians or massage therapists who have received thorough training about the skin care products we sell. We offer numerous products in a variety of price ranges. We also have “testers” of every product we sell. Moreover, we offer samples when patients are financially unable—or unsure as to whether they actually want—to make the purchase. I consider these procedures—and my staff’s training—essential elements in ethical dispensing of products from the clinical setting.

The case at hand

The case before us raises several questions: who should be in charge of the explanation of the skin care product to the patient? Should the dermatologist profit from the sale of the products? And should the dermatologist be an exclusive retailer of it? I’ll answer these in order. Explaining skin care products to the patient should be the job of a medical professional, whether a physician, nurse practitioner or physician assistant, or skin care professional such as an aesthetician. Receptionists and other untrained staff should not explain or sell skin care products in the office environment.

The answer to whether it is ethical for a dermatologist to generate a profit from product sales is a definite yes, but many would be surprised to learn that very little profit is ever realized from this business in the typical physician’s office. Inventory controls, staffing needs and other factors reduce the actual profits seen in the physician-office dispensing marketplace, so some markup on the price paid for the product is expected.

Markups of skin care products vary greatly. Most physicians generally mark products up from 50 to 100 percent of the cost paid. The rule in our office is to make sure our prices are competitive with the retail environment around us and to be sensitive to the supplier’s recommended selling price. By keeping ethical concerns in mind, I am comfortable with how our office functions.

The last question deals with the exclusivity of the product and whether being an exclusive retailer may be perceived as coercion. In the many years I have been selling skin care products, I have come across very few instances in which a physician has been given exclusive rights to a skin care product or line of products—that usually doesn't make good business sense for the skin care company. So consumers have a choice of vendors in most locations. On the other hand, so-called "private labeling" of skin care products is a booming business. It allows a physician to appear to have an "exclusive" product, although that same product exists in many other places with "exclusive" labeling of other physicians. This becomes somewhat tricky, and physicians should inform patients that they are using a so-called private-label supplier. As I have stated, there are very few truly exclusive arrangements, and very few physicians are in a financial position to create their own unique skin care line.

The ethical dispensing of nonprescription skin care products is a useful tool for promoting maintenance of healthy skin to our patients who are in need of this service. We are specially trained physicians and skin care professionals who know more about the skin than the majority of people who currently recommend skin care products to consumers. The dispensing should be done in a nonthreatening manner, keeping the best interests of the patient as the number one goal.

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Medical Education

Pharmaceutical support of dermatology residency electives: slippery slope or synergy?

by Alfred T. Lane, MD

The mission of the Department of Dermatology at Stanford University is “sustained leadership in scientific investigation, patient care, and in training future leaders of our specialty in an environment that fosters creativity and synergy.” To fulfill this mission we have always tried to offer our residents an opportunity for at least one month-long elective to stimulate their interest in a new area of investigation. We expect that funding from hospitals for clinical dermatology training will eventually be earmarked for residents’ clinical activity only, a circumstance that could destroy our elective training opportunities.

One of our creative residents developed a well-organized and supervised elective at Connetics Corporation, Palo Alto, Calif., a local pharmaceutical company that specializes in producing drugs for skin diseases. His elective focused on product development and organization of clinical dermatological trials in an industry environment. The resident described the experience as outstanding, saying that it gave him broad exposure to clinical trial design and implementation. The pharmaceutical company indicated that having an enthusiastic dermatology resident on site greatly improved their employees’ motivation and helped them to connect with the patient-focused side of drug development.

As a result of that elective experience we began discussions with Connetics requesting that they fund one resident position so that we could always afford to offer a resident elective. From the very beginning, both the Department of Dermatology and Connetics clearly understood that no resident would be required to spend the Connetics-funded elective time at the company.

The dermatology department vigilantly maintained the integrity of its actions throughout the entire process. The independence and control of the Stanford Residency Program was maintained. At the time of the initial discussions the dean of the school of medicine was a founder and active member on the company’s board of directors. For that reason, although he was informed of the dermatology department’s plans to examine the possibilities of an industry-funded elective, the dean was neither consulted nor asked to give an opinion on the arrangements.

Principles of residency funding

From the department's point of view, this was an opportunity to develop a totally new type of educational program. The guiding principle was that the funding be given as a gift with no controls attached. It was designed to cover the full salary and benefits of one resident position for three years. Matching and selection would be done by the program according to the method we already had in place. Although the funding would allow our program to accept one more resident, no position would be specifically designated as the industry-funded one, and the industry donor would have no involvement in the selection process. The elective position would operate like other training at our institution, with 11 months of work each year and one month for vacation and academic meeting time.

The elective month was to be offered equally to all of the residents in the dermatology program. During the elective month the resident could undertake any research project approved by a faculty mentor and our residency program director. The project could be associated with the gift-giving pharmaceutical company, any other pharmaceutical company or another academic institution. The goals and objectives for the elective at the pharmaceutical company were structured to produce a deeper appreciation and understanding of the drug development and approval process. The educational goals and objectives were approved by the Stanford residency program director.

As chair of the Department of Dermatology and residency program director at the time, I took full authority and responsibility for developing this program. I had no consulting, contracting or other financial relationship with Connetics at that time or subsequently. The program was approved by the Stanford Graduate Medical Education Review Committee and Accreditation Council for Graduate Medical Education. In September 2001 Connetics sent a letter committing support for one dermatology resident position from July 1, 2003 through June 30, 2006. An initiating gift of \$100,000 was received before December 31, 2001, and the new position was assigned during winter term 2002. Subsequently additional unrestricted gifts were given and a new agreement promised to continue the program through June 30, 2009.

Since the start of the new elective, residents have spent 33 months in the program: fourteen one-month electives were spent at the pharmaceutical company; five one-month electives were spent at an academic medical center other than Stanford and the remaining 14 months were taken at Stanford-affiliated facilities.

Twice a year, staff members from Connetics attend resident educational conferences. During one of the conferences early in the academic year, these company representatives present the goals and objectives of the educational elective program to our residents. At the end of the year the pharmaceutical company's staff dermatologists are invited to a conference at which all residents present a review of their elective activities for the year. All participating residents are supervised by a board-certified dermatologist. In July 2005, one dermatology graduate resident was hired as a full-time senior medical director of the pharmaceutical company, after

having been pursued by many other pharmaceutical companies. Each resident who participates in the pharmaceutical company elective signs a waiver which protects the intellectual property of the pharmaceutical company.

Results of the industry gift program

We believe that the industry gift has enabled a much-desired elective program to become a reality. The residents who have taken the pharmaceutical elective praise it as a unique learning opportunity. Residents who have used their elective to explore other areas believe that the small periods of specialized focus motivates them toward academic careers. Five of our six graduating dermatology residents this year will continue in full-time academic pursuits while the sixth will take a part-time academic position.

We have completed the first three years of funding, and to date we have not found that our residents or faculty are indebted either “in subtle or in very direct ways” [1]. The positive experiences that our residents have reported during the pharmaceutical company-sponsored elective definitely directed them to greater academic pursuits and better understanding of dermatological drug development. We are aware of the risks of this type of an experience, but have not seen that our residents are “conditioned ... to prescribe that company’s products preferentially” [1] since we focus on the use of generics in our residency program. This innovative program offers our residents supervised experiences in the pharmaceutical industry as well as in other areas of academic dermatology.

As a result of the successful funding of this program and a recognized need for additional dermatologists, the American Academy of Dermatology has used pharmaceutical donations and other funds to support 10 residency positions throughout the United States. The 10 positions were selected with a goal of generating additional dermatologist positions in programs that have a potential to develop physicians who would practice in underserved areas.

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Related article

[Funding of dermatology residencies by the pharmaceutical and medical device industries: what are the ethical ramifications?](#) August 2006

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Medical Education

Funding of dermatology residencies by the pharmaceutical and medical device industries: what are the ethical ramifications?

by Michael J. Franzblau, MD

A proposal to accept funding for dermatology residencies by the pharmaceutical and medical device industries has been before the officers and board of directors of the American Academy of Dermatology for possible action for the past two years. A pilot program is already under way [1].

For the purposes of discussion, I will assume that a real shortage of dermatologists exists in the United States. This conclusion is not clear-cut, since as recently as 1994 a projected excess of physicians—particularly specialists—on the order of 165,000 was predicted [2, 3]. At least one study has produced evidence that a shortage of dermatologists now exists [4]. There are concerns that the study may be flawed, but it is in part the basis for the proposal now being presented to the academy.

The funding for residency programs draws upon the resources of individual departments of dermatology and the federal government. The specific formula is derived from Medicare payments to teaching institutions. Federal aid is limited and, hence, so are the number of residency slots that a specialty department can afford.

The perceived shortage of physicians has led medical educators to look beyond the government for additional funding for more residency slots. The question then becomes whether funding of residencies—in dermatology or any specialty—by pharmaceutical and medical device companies presents a conflict of interest. The question should be a matter of concern to residency program directors, dermatologists and all physicians throughout the country.

The ethical practice of medicine in the United States is founded on the following familiar principles: non-maleficence, beneficence, distributive justice and respect for autonomy. Here, I would define respect for autonomy as a physician's responsibility to the individual patient. As a corollary, no third party, whether an employer, a commercial entity or a governmental agency should interfere with the patient-physician relationship, which must remain pure.

In my view, no commercial pharmaceutical or medical device company can be expected to fund any enterprise unless it will reap a benefit from that sponsorship. Whatever safeguards are put into place—such as pooling industry resources so that

recipients are not indebted to a single, known funder—are unlikely to overcome the overt or covert influence that the pharmaceutical and medical device industries will exert on the teaching and research activities of any participating department of dermatology that accepts their funds.

I believe that there must be a firewall between industry and dermatology. If the public thinks dermatology is for sale, we will lose the trust of the most important individual in a sacred relationship—the patient.

It seems to me that society should assume the financial burden for the postdoctoral training of physicians. If this means additional allocations of funding by the governmental route or from private sources that do not create a potential conflict of interest, we will all benefit. To put into jeopardy collective trust from the public we serve is a price I do not wish us to have to pay.

No one can serve two masters. Dermatology must reinforce its belief in autonomy as a cornerstone of the ethical practice of medicine.

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Related article

[Pharmaceutical support of dermatology residency electives: slippery slope or synergy?](#) August 2006

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Journal Discussion

The benefit and burden of ancillary professionals in dermatology

by Seemal R. Desai, MD

Nestor MS. The use of mid-level providers in dermatology: a liability risk?
Semin Cutan Med Surgery. 2005; 24:148-151.

Medicine is a rapidly changing discipline. Practices common 20 or 30 years ago are obsolete today. Complex tasks formerly performed by physicians are now delegated to other members of the medical team. For this reason, medical students and residents must learn about the medical liabilities of practicing in today's high volume, cost-conscious, health team-dependent environment.

In his article on the use of mid-level professionals in the field of dermatology, Mark S. Nestor, MD, a professor from the University of Miami's Miller School of Medicine in Florida, outlines the roles of ancillary practitioners in dermatology and the degree to which the physician for whom they work is accountable for their actions [1]. Both nurse practitioners and physician assistants are becoming an integral part of the specialty. A shortage of dermatologists, ever-increasing patient volumes and changes in the number and types of in-office procedures are some of the reasons for this pattern [2].

Supporting roles

The duties of these nonphysician clinicians go beyond such rudimentary tasks as taking histories or conducting basic exams; they may extend to prescribing medication and even participating in some office surgical procedures [3]. Much of their training is the responsibility of the physician, and the critical point Nestor makes is that "the dermatologist in most cases can be held legally responsible for the acts of their physician assistant or nurse practitioner" [2].

Dermatologists are entrusting more and more clinical tasks to physician assistants and nurse practitioners as revealed by the huge number of patient visits these staff members handle annually—39 million in a typical year during the 1990s according to statistics compiled by Adele R. Clark (a physician assistant herself) and her colleagues in "The Emerging Role of Physician Assistants in the Delivery of Dermatologic Health Care" [4]. During these visits ancillary staff perform biopsies and surgeries and prescribe narcotics.

As with all surgeries and prescriptions, things can go seriously wrong and create liability. Nestor shows that problems can occur if a physician assistant or nurse practitioner provides services that don't meet the standard of care because of the staff member's inadequate experience or supervision [5]. It is the physician's responsibility to guard against lapses and provide for clinical and ethical best practices.

Physicians shoulder the ultimate responsibility

Despite the potential for problems, a good team working together can serve patients better and faster than a physician on his or her own, so mid-level care providers are likely to become and remain a valuable feature of almost all dermatology practices. Given these practice changes, it is important that the medical doctor demonstrate continual oversight and responsibility for ancillary staff. Nestor makes clear again and again that, as long as mid-level assistants continue to provide care for patients, the physician is liable for their actions and any allegations of malpractice that may arise due to their lack of adequate training. He goes on to highlight ways in which physicians can attempt to reduce their liability risk. They can, and should, for example,

- Seek better ways to instruct and train the nurse practitioner or physician assistant in methods of biopsy, excision or even some cosmetic procedures.
- Insure that community standards for care are met or exceeded.
- Teach procedures carefully and make sure they are mastered by assistants.
- See all new patients or new problems before deciding whether to delegate the treatment plan to an assistant.
- Make sure patients feel they are getting better care because of assistants—not being screened out from seeing a “real doctor” [6].

Of course, no matter how well the physician trains his or her staff, it is virtually impossible to duplicate the three intensive years of highly specialized post-graduate residency that are required for board certification in dermatology [3], so the dermatologist must remain the responsible party.

The American Academy of Dermatology and other state and specialty societies emphasize that the role of ancillary professionals in caring for patients with dermatologic disease should always be undertaken with the highest ethical, moral and safety standards [5]. Again, no matter whom patients see during a clinic visit, or to whom they speak when calling the dermatologist's office, the responsibility to ensure the highest medical and ethical standards in the patient's best interest remains with the physician.

A resident's perspective

As a new resident in dermatology, I read Nestor's article with particular interest, not only because of challenges I may face once I complete residency, but also and more importantly because of the way the practice changes Nestor describes will affect my patients. It is clear that increasing numbers of patients and the requirements of managed care are placing greater demands on dermatologists. It is critical that

residents be made aware of these changes during their training, a time when young physicians gain the knowledge to practice safe, sensitive and ethical medicine. Though the majority of a resident's learning comes through interactions with attending physicians and their patients, nurse practitioners provide valuable insight and experience. In many cases, a nurse practitioner or physician assistant has more years of service with the practice or academic institution than the physicians. They may have well-established patient bases within the dermatology office setting, and with that patient base often comes a wealth of useful experience with academically challenging and valuable diagnoses. For me, these are just a few of the tangible benefits of learning from all members of the care delivery team.

Readers of Dr. Nestor's article may have questions—as I did—about this growing practice trend in the field of dermatology. As a resident, I wonder whether patients will continue to receive the highest level of care with the utmost attention to safe medical practices. How will the fact that so many of our nation's states are in medical liability crisis and fighting for tort reform affect the ability of dermatologists to continue incorporating assistants into their clinics?

Through my clinical encounters with mid-level professionals as a medical student and resident, I have discovered that they provide vital and important services to dermatology medical teams and, more importantly, to our patients. Dr. Nestor does an excellent job of outlining the challenges facing our specialty and the role of the nurse practitioners and physician assistants. Reading his article gives one a better understanding of the role, liability and obligations of dermatologists and their nurse practitioners and physician assistants. I believe that through the synergistic work of the physician and mid-level professional and nursing staff our patients will continue to receive better care than they otherwise would.

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Clinical pearl

The ABCs of melanoma: expanding basic screening and education

by Cory L. Simpson

Cutaneous melanoma originates from uncontrolled proliferation of melanocytes, pigment-producing cells within the basal layer of the epidermis, and is the most lethal form of skin cancer due to its propensity to metastasize to distant organs. Despite decreasing incidence of other malignancies due to research and public health efforts, the number of invasive melanoma cases continues to rise, claiming around 8,000 lives in the U.S. annually [1]. The growing burden of this disease underscores the need to educate the public and health care professionals about screening methods.

Unlike tumors of internal organs, melanoma is often readily recognizable thanks to its external location and distinct pigmentation. Thus, many malignant lesions can be identified and excised at an early stage, increasing the likelihood of long-term survival for those with this form of skin cancer. To provide a simple and memorable method for distinguishing a malignant pigmented lesion from a benign nevus, Friedman et al. put forth the ABCD mnemonic in 1985 [2]; however, a fifth letter has recently been added to the screening acronym [3], which now reads as follows:

Asymmetry,
Border irregularity,
Color variegation,
Diameter greater than 6 mm and
Evolution.

The newest criterion, evolution, refers to the tendency of a lesion to change visually over time, e.g., to alter in shape, size or coloration, but the term also encompasses the emergence of associated symptoms like itching or pain. Benign lesions tend to remain stable, so noticeable changes in the characteristics of a nevus should raise suspicion that the lesion is malignant. Using these criteria, patients are encouraged to perform a skin self-examination (SSE) regularly to identify pre-invasive melanoma. This practice is especially important among those possessing one or more risk factors, including:

1. Intense sun exposure,
2. History of blistering sunburns, especially during childhood,
3. Light complexion,
4. Presence of typical and atypical nevi,
5. Personal history of melanoma or other skin malignancies,

6. Family history of melanoma [4].

Robinson and Turrisi recently reported that verbal explanation of the ABCDE criteria and demonstration of SSE techniques significantly improved the ability of patients to correctly identify suspicious lesions [5]—anyone can use a ruler to measure diameter and a magnifying glass to examine coloration and borders of nevi. This study suggests that providing simple instructions for melanoma screening would equip at-risk patients with tools to determine when to seek medical attention and confirms that efforts to educate the public in conducting a SSE would not be in vain.

Furthermore, training in skin cancer screening methods must improve within the medical education curriculum to enable budding physicians to differentiate benign from malignant nevi. An alarming report by Moore et al. indicated that most U.S. medical students feel ill-prepared to conduct proper skin examinations, with only 28.2 percent of students reporting that they felt “somewhat skilled” or “very skilled” in examining a patient for skin cancer and nearly 70 percent agreeing that the skin examination was under-emphasized in their clinical training [6].

Finally, a broadened melanoma awareness campaign is necessary to educate the *entire* public about screening practices. The campaign must reach members of minority populations who are often neglected due to the low prevalence of malignant nevi among individuals with darker skin. In a recent study from Miami-Dade County [7], the investigators found that people of African and Hispanic descent were more often diagnosed with melanoma at a late stage and exhibited poor survival compared to Caucasians. Thus, it is important that public health officials and health care professionals make an earnest effort to dispel the notion that melanoma is a disease that affects light-skinned individuals only and to teach the ABCDE acronym to *all* patients.

As suggested by Geller et al. in a recent editorial, achieving a meaningful improvement in melanoma detection at a curable stage will likely require a national initiative to educate physicians and patients about proper skin examination [8]. Indeed, cooperative efforts by the medical and public health communities to teach the ABCDE screening method may be the key to curtailing the discouraging increase in the burden of melanoma.

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Health law

Accutane and the evolution of a warning

by Lee Black, LLM

Informed consent is a well-established doctrine in the field of medical liability law. The duty to obtain informed consent stems from the principle that a patient should have information that is necessary to deciding upon a course of treatment. For a long time, the unpredictabilities of medical science impeded the acquisition of proper informed consent [1]. The last century, though, has seen a tremendous increase in the ability of physicians to anticipate most or all of the risks associated with a given treatment or procedure.

The requirement that physicians obtain informed consent prior to treatment now extends to the dispensing of pharmaceuticals because of the wide-ranging side effects that many drugs have been found to exhibit. The responsibility to warn patients of risks rests with the prescribing physician rather than with the manufacturer of the drug; the manufacturer has the responsibility to provide the physician with appropriate information [2]. A physician who fails to warn a patient or a manufacturer who fails to warn physicians of risks associated with a particular drug may incur liability for that error.

Accusations that the duty to obtain informed consent was not fulfilled have resulted in far-reaching efforts to strengthen the informed consent process. Such allegations concerning the prescription acne medication Accutane (known generically as isotretinoin) triggered an evolution in the warning provided to patients about the drug.

When Accutane was first released, its manufacturer strongly suspected that it could cause birth defects if women took it while pregnant or at the time of conception. Hoffman-LaRoche, the drug's manufacturer, maintained that it had no solid evidence in human subjects but that teratogenicity had been observed in rats. The warning provided to patients in 1982 noted this fact, instructed patients to use an effective form of contraception while on Accutane and recommended the use of contraception for one month after discontinuation of the therapy [3]. Accutane was also labeled as a "Category X" drug, meaning that it should not be used while a woman was pregnant. The 1982 warning was sufficient to inform users of the dangers and to aid the manufacturer in avoiding liability, according to the Florida Supreme Court.

Even though the 1982 warning was sufficient at the time, later reports of abnormalities of human fetuses prompted a change that made the warning more stern [4]. While many of the recommendations remained essentially the same, the new warnings listed each of them in a separate paragraph to improve clarity. In subsequent cases, courts again held that the warnings were sufficient, noting that they provided enough information to inform the plaintiffs of the harms they ultimately experienced.

Perhaps because of the frequency of lawsuits over Accutane and the claims that the patient-plaintiff had not been fully informed by the physician or that the patient-plaintiff had not been cautioned about the possibility of contraceptive failure, the warning provided prior to initiating Accutane therapy was changed again. By 1995, it had become more explicit, and patients were required to initial each paragraph in the warning to show that they had read it [5]. Because of the required initials, patients were no longer able to claim that the physician failed to inform them of the risks associated with Accutane. The warning included more detailed information on the requirement to use birth control—including a statement that any form of birth control can fail—and required patients to state that they were not pregnant and would not become pregnant for at least 30 days after completing Accutane therapy.

This did not prevent a patient from filing a lawsuit against Hoffman-LaRoche claiming its failure to sufficiently warn was the cause of her child's abnormalities. Most interestingly, *Banner v Hoffman-LaRoche* was based upon the failure of abstinence and the failure to warn of the possibility that this method of contraception was unlikely to be successful in certain circumstances. The court noted in this case that the manufacturer should not be held liable for failure to warn of a risk already known, i.e., that having sexual intercourse would make abstinence ineffective as a form of contraception.

Lawsuits continued to be filed, and the informed consent requirement and the warning about the effects of Accutane have become more explicit and rigid. In March of 2006, the iPLEDGE program was instituted to further reduce the incidence of birth defects caused by Accutane (as well as further solidify the legal ground of physicians and manufacturers of isotretinoin). Participation in the program is required for both female and male patients, as well as physicians and pharmacists [6]. Patients must also sign Patient Information/Informed Consent forms and to agree to follow program steps.

In addition to providing even more detailed information to patients than previous warnings, iPLEDGE introduces strict requirements for obtaining Accutane. A patient must agree to use two forms of contraception—and provide proof of use. The program specifies primary and secondary forms of contraception. Female patients must take a pregnancy test in order to obtain the medication and before receiving each prescription refill. Participation in the program is mandatory for all parties in the process: patient, physician, pharmacist, pharmaceutical wholesaler and

manufacturer. The purpose of the program is to ensure, with more certainty than ever, that a woman will not become pregnant while taking Accutane.

In sum, there has been a clear pattern of change in the warning accompanying Accutane over the past two decades. As lawsuits progressed, even without success, warning mechanisms evolved to meet many of the legal complaints. As the responsible government agency, the FDA had oversight of postmarket problems throughout this period, and in 2004 its advisory committee recommended more stringent regulation [7]. While the first warning had been very general, merely informing of the possible effects and recommending contraception, informed consent requirements were gradually strengthened, eventually obligating patients to sign their initials as proof of a proper warning. The need for two forms of contraception became explicit, and a statement of the possibility that contraception can fail was added. With the introduction in 2006 of the iPLEDGE registry program, agreed upon by FDA and industry, contraception and pregnancy tests are prerequisites for each one-month prescription. The possibility of the failure of contraceptive methods—abstinence included—is incorporated into the informed consent process for Accutane.

Informed consent is both a legal and an ethical requirement. Both share the intent that patients make informed decisions regarding treatment, but demands that satisfy the legal standard may not always satisfy the ethical standard. Hence, in the case of Accutane, although the courts found that the 1982 warnings satisfied the legal requirements, sensitivity to ethical standards prompted further revisions to the recommendations for informed consent. Moreover, it is apparent from the Accutane experience that patients do not always understand what they are told or may, in hindsight, feel as though their decision was not based on all appropriate information. The evolution of the warning provided to Accutane patients illustrates how continuing concerns brought about by legal battles can lead to a new understanding of what exactly “informed consent” is.

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Policy forum

iPLEDGE: a report from the front lines of dermatologic practice

by Clay J. Cockerell, MD, and Diane M. Thiboutot, MD

March 1, 2006 marked an historic turning point in the practice of dermatology in the United States. On this date, the iPLEDGE program—a mandatory program for managing the risk of birth defects linked to isotretinoin—replaced a voluntary predecessor initiative notable for its reliance upon a yellow sticker placed on prescriptions to indicate the patient was qualified to receive the medication.

In retrospect, the timing of the program launch was unfortunate. Most U.S. dermatologists were in San Francisco, Calif., attending their annual scientific meeting during the first week of March. At the meeting, a technical assistance desk staffed by employees of Covance, Inc. (a vendor selected by the isotretinoin manufacturers to design and operate the iPLEDGE program) was mobbed by concerned dermatologists seeking help for themselves and on behalf of their patients.

Nearly six months later, iPLEDGE remains a source of concern for dermatologists, their patients, pharmacists, lawmakers, FDA officials, the drug companies sponsoring the program and Covance. This article provides basic information on the iPLEDGE program and why it was created and a summary of the professionalism and ethical issues that make iPLEDGE a very hot topic of debate today.

iPLEDGE basics

The iPLEDGE program is not the only mandatory risk management program for drugs approved by the U.S. Food and Drug Administration. It is, however, the largest such program established to date and for this reason is being monitored closely by all concerned stakeholders, including dermatologists. Dermatologists account for approximately 85 to 90 percent of isotretinoin prescriptions, making them the specialists most directly impacted by the new program.

How iPLEDGE works

It is essential to know that this program is mandatory for prescribers, patients, pharmacies and wholesalers/distributors, in effect, all stakeholders in the distribution loop for this medication. No exceptions are permitted; obtaining this medication outside of the iPLEDGE program is prohibited, although it is possible to obtain it from numerous online “Internet drug stores.” The goal of the program is to prevent fetal exposure to isotretinoin, a known teratogen. To achieve this goal, the program tracks all isotretinoin transactions. This is a monumental undertaking since

isotretinoin is more widely prescribed than other medications that are subject to mandatory risk management programs. According to unofficial reports by Covance, at least 95,000 patients were registered with iPLEDGE in the first month after the program launch. By contrast, approximately 65,000 patients were registered in the STEPS program for thalidomide (on which iPLEDGE is modeled) between 2001 and 2004, according to testimony presented to the FDA in February 2004.

Before they can prescribe isotretinoin, physicians must register and then activate their status in the iPLEDGE system; this two-step process initially confused many prescribers and caused delays in their ability to prescribe isotretinoin. All isotretinoin patients—females of childbearing potential, females not of childbearing potential and males—must register with the program. There are no exceptions for age, gender or off-label or sporadic use of the medication for maintenance therapy. All patients receive counseling during monthly office visits on birth defects, adverse psychiatric events and basic safety precautions such as not sharing medication and taking the medication as prescribed. The counseling and other aspects of the visit are confirmed with iPLEDGE by dermatologists or their staff by computer or phone call. Notification of the office visit triggers a 7-day window in which the patient must pick up the prescription. Patients who fail to pick up the prescription during this 7-day window are barred from obtaining a new prescription and in effect “locked out” until the next office visit which must take place 30 days after the previous office visit. The 7-day window for picking up the prescription, the subsequent 23-day “lockout” and the 30-day gap between office visits are controversial aspects of the program which are unworkable in practice, create burdens for patients and their prescribers, and ultimately disrupt therapy for many patients across the nation.

Females of childbearing potential are subject to additional, mandatory requirements. Before she receives her first month’s supply of pills, a woman in this category must obtain a negative diagnostic pregnancy test and a negative confirmatory pregnancy test in synch with her menstrual cycle and must have been on a primary and secondary form of birth control for 30 days. Abstinence is a recognized form of contraception. A negative pregnancy test, contraceptive counseling (in addition to the counseling applicable to all patients) and passing a quiz on program basics are mandatory for being given a “green light” to receive each month’s supply of medication. After a female of childbearing potential completes her course of therapy, she must get a pregnancy test, continue her chosen birth control for 30 days after taking the last isotretinoin pill, obtain a final pregnancy test one month after taking her last pill and furnish that result to iPLEDGE. Pregnancy testing must be conducted by a certified laboratory.

The iPLEDGE program collects this sensitive health information on all female patients of child-bearing potential, keeping it confidential yet following up with prescribers and patients directly in cases, for example, of a positive pregnancy test result. In such cases, therapy is discontinued immediately. Subject to her consent, the pregnant patient is interviewed by teratology experts to determine the root cause of pregnancy. While the program does not provide information on options for handling

the pregnancy, the pregnancy registry will track the case. If there is a live birth, the infant is tracked for two years. Elective and spontaneous terminations of pregnancy are also recorded. At this time there is no publicly available data on the incidence of pregnancy since iPLEDGE was launched.

The previous paragraphs offer a cursory overview of salient iPLEDGE program features for patients and their prescribers. A detailed explanation of program requirements can be obtained by visiting the iPLEDGE Web site [\[1\]](#).

Why iPLEDGE was created

The program exists because a small number of women became pregnant while taking isotretinoin. Since 1988, voluntary initiatives that became more elaborate over time did not produce a noticeable change in the pregnancy rate for women taking this medication. The caveat with any assessment of the pre-iPLEDGE pregnancy rate is, of course, that the available statistics are the result of voluntary reporting and therefore incomplete and of doubtful accuracy or utility. Regulatory concern with the safety aspects of isotretinoin therapy culminated with a joint meeting in 2004 of the FDA's advisory committees—the Dermatologic Drugs and the Drug Safety and Risk Management—at which the framework for today's iPLEDGE was approved. The four drug companies that manufacture the medication (Roche Laboratories, Inc., Mylan Pharmaceuticals, Inc., Barr Laboratories, Inc. and Ranbaxy Laboratories, Inc.) formed the Isotretinoin Products Manufacturing Group (IPMG) that sponsors iPLEDGE and ultimately selected Covance to design and operate the program. In August 2005, the FDA approved the program design and timetable sponsored by the IPMG. At the request of the American Academy of Dermatology (AAD) and pharmacy groups, the original effective date of December 31, 2005 was pushed back to March 1, 2006. To no avail, the AAD requested additional time and pilot testing of the program when it became apparent during the transition period that there were significant concerns about the design and performance of the program.

Professionalism issues

Reports from dermatologists and their patients indicate that the design and performance of iPLEDGE leads to disruptions in therapy. A list of concerns presented by dermatologists is available at the AAD Web site [\[2\]](#). The overriding issue is that the program has forced dermatologists to alter the way they practice medicine in the conduct of isotretinoin therapy without regard to their training, expertise or the safety and effectiveness with which they handled isotretinoin cases before the advent of iPLEDGE. The administrative burdens of the program have proven to be difficult for many practices, but particularly so for solo and small practices, for non-electronic practices and for practices with few isotretinoin patients. Indeed, a number of dermatologists no longer prescribe isotretinoin as a result of the iPLEDGE program, thereby limiting patient access to the treatment. In these ways, the program compromises the patient-physician relationship and the practice of medicine.

Ethical considerations

Laying aside persistent disagreements over the necessity of iPLEDGE, many serious ethical issues remain and will certainly be debated over the upcoming months and years. Putting isotretinoin—but not all teratogens—into a mandatory, restricted distribution program is arguably selective and discriminatory—and especially so in the absence of reliable pregnancy rate data for this particular medication. Access to isotretinoin is limited by iPLEDGE, in some cases for patients qualified to take the medication but discouraged by system errors and the performance of the program in general or by a scarcity of dermatologists in their community who are willing to prescribe the medication. Is this a desirable or appropriate situation? Finally, the crux of the matter is patient responsibility. In a free and open democratic society such as ours, great responsibility comes with great liberty. The availability of this valuable, effective medication means that females of childbearing potential must take personal responsibility for avoiding pregnancy while taking this medication. The fairness of subjecting female patients who are not of child-bearing potential and male patients to the burden of this risk management program is questionable since fetal exposure is not and never will be an issue with these patients. Is it fair or right that all patients who need this medication should be forced into iPLEDGE because of the handful of women known to have become pregnant on this medication?

Looking down the road

Metrics data to evaluate the iPLEDGE program are expected to be publicized later this year. Meanwhile, the AAD is conducting a survey of its members to learn more about the impact of the program on the practice of dermatology. Survey results will be released by September 2006. The survey and comments and suggestions from dermatologists and their patients are helping the academy with its ongoing effort to improve iPLEDGE so it is more workable and less burdensome for patients and their prescribers. For more information on the AAD's actions in response to the iPLEDGE program, readers are invited to visit the AAD Web site [2].

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Medicine and Society

The influence of controllable lifestyle on medical student specialty choice: a dermatologist's perspective

by Jack S. Resneck, Jr., MD

The field of dermatology is frequently cited as a beneficiary of recent trends among medical students to seek careers with more controllable lifestyles. Indeed, while the number of dermatology residency positions in the U.S. has remained relatively static at about 300 per year for more than three decades [1], the number of applicants has continued to climb [2]. A little bit of data and overwhelming anecdotal evidence suggest that the quality of those applicants only gets higher [3]. Students who have not performed at or near the top of their medical school classes often don't bother to apply, and many of us who serve on residency admission committees struggle to comprehend board scores and deans' letters that place so many of our applicants among the top one to two percent nationwide. We are constantly delighted (and bewildered) by how much these applicants have already accomplished in professional and other venues before seeking dermatology residencies.

A few other specialties described as "lifestyle-friendly" have reported similar experiences, particularly radiology [4], ophthalmology [5] and anesthesiology [6]. Meanwhile, an increasing number of general surgery residency programs are not filling their slots [7]. Primary care fields also have struggled to attract medical school graduates. The proportion of family practice residency positions filled by graduates of U.S. allopathic medical schools decreased from 73 percent in 1996 to 45 percent in 2005 [6, 8].

Many have suggested that a quest for a manageable lifestyle—defined as having control of professional hours and thereby having more time for family, leisure and avocational pursuits—is what's driving the stampede out of primary care and general surgery [7, 9-11]. Students entering dermatology, radiology, ophthalmology and anesthesiology cited lifestyle as being more influential in their career choice than did students who chose most other specialties [12]. Practicing as a physician in a field that has benefited from increasing interest, I can only hope that applicants are drawn to dermatology by far more than lifestyle considerations. The situation does, however, raise some basic questions. Should dermatologists feel guilty about their specialty's current popularity? Is there anything wrong with valuing life outside of clinical work?

Influence of lifestyle on specialty choice

Influence of lifestyle on specialty choice may represent a larger societal trend [13]. A growing body of evidence has noted the contrast between the attitudes towards careers exhibited by the baby boomers (born 1945–1964) and the generation Xers (born 1965–1980) [14]. Generation Xers are commonly described as having a desire for autonomy and flexible schedules, placing more emphasis on friends and family than on material success, and harboring some cynicism about larger organizations [15–17]. Members of this generation who are physicians may see the practice of medicine as only one part of their identity. Baby boomers, who are described as having a strong work ethic and loyalty to their employers [18], criticize generation Xers for their lack of commitment to their careers.

The appearance of generation X in the physician workforce has been accompanied by a dramatic increase in the number of women entering medicine. The majority of entrants to dermatology residency programs are now women, leading to a steady rise in the number of women in practice [19, 20]. Some have suggested that the shifting gender balance in medicine has brought about the increasing popularity of more lifestyle-friendly specialties, but this is not supported by the evidence. While women in dermatology do work fewer hours during their child-bearing years, both women and men in medicine have shown similar rates of migration away from careers with less controllable lifestyles [2, 21]. Contrary to what might be expected, a greater percentage of women than men actually choose careers with uncontrollable lifestyles [2, 21].

In some cases, perceptions of work hours may not be accurate. Some dermatologists take ER calls, teach, perform research and work many more hours than alleged [22]. Nevertheless, it is true that dermatologists are working fewer hours than they did in the past [23], and, compared with specialties which by their nature involve a great deal of night and weekend time devoted to work, dermatology is certainly more flexible. This may be one of the factors leading to extremely high levels of job satisfaction among dermatologists. In one study, dermatology had the fourth highest proportion of “very satisfied” physicians of all specialties [24]. In a recent large survey, practicing dermatologists reported extremely high satisfaction levels (mean scores greater than 4 on a 5-point scale) with their careers, income and work-life balance [23].

Even to the extent that generational differences may be influencing specialty choice, an increasing desire for a controllable lifestyle may be only one of many factors. Medical students currently flocking to dermatology may also be influenced by their perceived personality fit with the specialty, skill-fit with the specialty, role models, clerkship experiences and anticipated income. Generation Xers might also be less influenced by pressures within medicine that have held specialties with intense work-hours to be more prestigious.

If controllable lifestyle is a driving factor, it is difficult to uniformly judge generation Xers (of whom I am one) who value their families and their interests outside of work

and who choose specialties like dermatology (which I chose as well). On the other hand, many of us in generation X would like to have primary care doctors and general surgeons to care for us as we age. If we're going to replace the baby boomer doctors in those "lifestyle-unfriendly" specialties as they retire, we need to think carefully about how to redesign medical training, medical careers and health care delivery systems so that family physicians and general surgeons will have satisfaction levels as high as those of dermatologists. Maybe that will help ensure that members of "generation Y" or the "millennial generation" will choose those careers in the future.

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History of Medicine

Lessons in dermatology research: protecting vulnerable research participants

by T. Howard Stone, JD, LLM

“The money was good and the money was easy.” He first tried a deodorant test. He chose the one he thought had the least chance of harming him, and says it was funny watching other prisoners smell his armpits and look for signs of irritation. He was a bit uneasy that the underarm lotion was unlabeled, but the \$25 he received each week smothered his concern. He went on to test hand and body lotions and soon realized the program’s full financial potential. “Three or four tests at a time could mean real easy money. Foot powder tests and deodorants would bring you \$100 per month, and hand creams a buck a day. You could be making \$300 to \$400 a month.”

Prisoner interview, in Allen M. Hornblum’s “Acres of Skin: Human Experimentation at Holmesburg Prison.” New York, NY: Routledge; 1998:6

Legacy of early dermatology research

Allen Hornblum’s book, “Acres of Skin,” accented by numerous personal interviews of experiments conducted from the 1950s to the 1970s at Philadelphia’s Holmesburg Prison, is one of the few historical accounts of the extensive and dubious use of prisoners as subjects in dermatology studies of agents used in popular skin care products, some of which—such as Retin-A (tretinoin)—are in wide use today. The lessons learned from Hornblum’s account should resonate any time dermatology research involves people who may be deemed vulnerable as research subjects.

In 1976, profound concerns about prisoners taking part in human research studies—including those testing new dermatology agents or products—were expressed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its report, *Research Involving Prisoners* [1]. Some of the National Commission’s concerns were based upon findings that money appeared to be a strong motivation for prisoners to take part in the studies. As the result of its deliberations and concerns, the National Commission, which had been charged by the U.S. Congress to study and make recommendations about the protection of human subjects not already subject to federal regulation, advised Congress and the Secretary of the U.S. Department of Health, Education and Welfare (predecessor to HHS) that research involving prisoners as subjects should be significantly restricted. These recommendations, adopted in federal regulations and still in effect today, essentially prohibit investigators from using prisoners in the types of dermatology

research that so commonly relied upon them in the past [2]. Other federal, state and local agencies—even some that may not be subject to the federal regulations referred to above—as well as some of the most prominent professional associations with interests in prisoners, also specifically prohibit the use of prisoners as subjects in such research [3]. For example, under federal regulations pertaining to the U.S. Department of Justice Bureau of Prisons, research projects “must not involve medical experimentation, cosmetic research, or pharmaceutical testing” [4]. Laws and standards such as these could reasonably be interpreted to prohibit dermatology research that uses prisoners as research subjects.

The legacy of the early dermatology studies in prisons has important implications for today’s medical student interested in a dermatology research career. For one, any research on prisoners may be subject to intense scrutiny, given the highly regulated environment and historic concern about studies that involve these populations. Second, people who are similarly situated to prisoners may be no less vulnerable as subjects in dermatology research, particularly when it comes to understanding their participation in research and their risk versus reward.

Lessons for dermatology research

Investigators should be aware of the multitude of federal and state regulations as well as professional standards that will be invoked if they choose to include prisoners as subjects of research. The most recognized federal regulation, which includes what is called the Common Rule and Subpart C and applies specifically to prisoners [5], is just the beginning. Investigators should note that Subpart C of the federal regulation is essentially an embodiment of many—although not all—of the ethical issues considered by the National Commission. Other federal regulations, including those promulgated by other federal agencies such as the FDA and the Department of Justice, must also be considered, as should the laws of the states where research may take place. In studies conducted across multiple sites, the laws of two or more states may apply. Investigators may also be required to demonstrate that their research adheres to professional standards or other general ethical guidelines, such as the World Medical Association’s Declaration of Helsinki—a requirement for studies published in the *Journal of Investigative Dermatology* [6]. Ethical guidelines such as the Declaration of Helsinki are particularly sensitive to protecting persons who may consent under duress to taking part in research, a concern which intuitively would have special application to prisoners as research subjects [7].

Dermatology research now spans a vast field of scientific inquiry—from molecular genetic studies of carcinomas to clinical trials involving eczema—that requires increasing numbers of patients with specified medical conditions to serve as research subjects. And like prisoners generally, prospective subjects in dermatology studies may be disadvantaged as the result of their socioeconomic status and may lack the educational or literacy skills sufficient to provide properly informed consent for taking part in research. As the risk or complexity of dermatology research increases, the need to protect such disadvantaged subjects becomes more pronounced.

For example, the lure of obtaining cash or similar pecuniary benefits was considered by the National Commission as the “overriding motivation” among prisoners for taking part as subjects in research [8]. Current federal regulations impose almost no substantive restrictions upon providing nonprisoner subjects with such benefits, other than to require that research review boards insist upon “additional safeguards” if some or all of the subjects are “likely to be vulnerable to...undue influence.” The National Commission defined “undue influence” in its Belmont Report as “an offer of an excessive, unwarranted, inappropriate or improper reward or other overture...” [9]. Often economic disadvantage is viewed as rendering a prospective subject “vulnerable to undue influence.” Payment for taking part in dermatology research is not uncommon and may range from one-time payments of \$25 for a single visit to payments of \$400 or more for repeat visits in research on topical creams for psoriasis, for example, Phase III research on investigational drugs for severe chronic plaque psoriasis, or research on atopic dermatitis [10]. If federal regulatory provisions and the underlying ethical principles pertaining to the protection of economically vulnerable subjects are to have meaning, investigators may want to consider examining the possible influence that such payments may have upon subjects’ motivation for volunteering as research subjects.

Prospective subjects in dermatology research who are educationally disadvantaged may also be vulnerable. Often, as was the case for many prisoners in early dermatology research, economic disadvantage is concurrent with educational disadvantage, which compounds the vulnerability of research subjects. It can diminish a person’s ability to fully understand and appreciate his or her participation in research—particularly research risk—which may in turn undermine informed consent. Educational disadvantage among prospective research subjects also has profound consequences for investigators. It may jeopardize a subject’s ability to adhere to a research protocol, with obvious consequences for effect size, adverse events and study results. Complex or cutting-edge dermatology research raises the stakes even higher. For example, genetic research examining familial or hereditary risk for psoriasis or melanoma is now under way at dermatology research centers across the U.S. The collection of genetic samples for such studies raises a host of ethical and social issues, and an understanding of both the research and the related ethical and social issues may be especially challenging for an educationally disadvantaged person. In studies such as these, ascertaining subjects’ knowledge of basic genetic concepts, including heredity and genetic predisposition, may be one of several prerequisites for informed consent. Other prerequisites may be addressing the possibility that subjects think their own risk for disease, such as melanoma, will be definitively ascertained by taking part in genetic research and establishing whether investigators will share genetic test results or findings with subjects.

As a threshold matter in designing and implementing their research, dermatology investigators should always consider the likelihood that their studies will attract disadvantaged persons, the explanations for that attraction, the impact that the recruitment of disadvantaged persons may have on obtaining effective informed consent, and the steps that might be taken to protect disadvantaged research subjects.

Some useful preliminary steps might include examining whether disadvantaged persons believe that taking part in a study will improve or guarantee access to treatment, whether the studies are actually being confused with treatment and whether recruitment takes place in predominantly disadvantaged communities. Equally important is the effect of payment upon subjects' decision to volunteer. As stated in the 1979 Belmont Report, "the economically disadvantaged" should be protected against the danger of participating in research "because they are easy to manipulate as a result of their illness or socioeconomic condition" [11]. Protecting human subjects should be the primary concern of every investigator. However, in light of the dubious history of dermatology research involving prisoners, special precaution in research involving all vulnerable persons as research subjects is well-advised.

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Op-ed

Adding burden to burden: cosmetic surgery for children with Down syndrome

by Ann K. Suziedelis, PhD

Expectant parents dream of giving birth to a beautiful, robust and “perfect” baby. In reality this does not always happen. When things go wrong there is sometimes nothing parents can do to ameliorate the condition of their afflicted child. For others, the imperfections are so slight that they barely affect the child’s leading a normal life. It is a specific group caught in the middle of this spectrum—high-functioning children with Down syndrome (DS)—who evoke the ethical question discussed here. That is, is it ethical for parents to subject children with DS to purely cosmetic surgery that offers no medical benefit for them before the children are old enough to give any informed and freely considered assent?

As the mother of a “perfect” child, I can only imagine that it is a crushing frustration for parents of high-achieving boys and girls with Down syndrome to see how tantalizingly close their offspring come to functioning as their peers do. It is understandable that some of these parents, fearing their children will be waylaid at the start by their distinctive features, might choose purely cosmetic surgery at an early age in an attempt to make them more visually acceptable. These parents focus on the importance of first impressions—if their children look like the other kids, they argue, they will have a better chance of being accepted after the behavioral and emotional differences of Down syndrome become apparent.

I cannot fault parents for wanting to protect their children from the stigma of not meeting subjective standards held by ignorant people regarding “acceptable” appearance. Though we may not agree with them, it is not hard to understand why these parents seek to erase what they believe to be triggers of prejudice by “fixing” their children’s faces as soon as possible. Nevertheless, pursuing this course raises both practical and ethical questions. Practically, we must ask if the surgery, which carries physical risks without medical benefits, provides the intended good effect. Ethically, we must consider whether the benefits outweigh the burdens. The surgeries in question are performed under general anesthesia and often include resection of the tongue, lifting of the bridge of the nose, removal of fat from the neck, placement of implants in the cheekbones and removal of the distinctive folds of the eyelids.

From a practical perspective, there is studied reason to question whether well-intentioned deception-by-surgery actually does erase the vulnerability of the child with Down syndrome. Most people recognize the facial characteristics of DS and are immediately signaled that the child will be more vulnerable, a bit slower and sweeter, a bit needier. While the child's features may alert bullies that they have found a target, kind people are alerted instead to be more understanding. Those distinctive features thus seem to invite loving care as much as they do discrimination [1]. Further, we must inquire—again in the face of a small child's subjection to medically unwarranted surgery—whether bullies and other intolerant persons will be any kinder if their recognition of the child as a target is merely postponed. This is a particularly telling question in light of research that shows little correlation between DS features and discrimination [2]. Still, if for the sake of argument we suggest that people who treat these children badly are indeed triggered by their facial features, we must consider findings that, while parents report being pleased with the results of surgery [3], independent reviewers discern “no improvement” in the appearance of children with DS who have undergone cosmetic surgery” [4].

Toward a more tolerant society

Ethically, I am most concerned that cosmetic surgery moves the onus from the “normal” person's moral obligation to be tolerant to the small shoulders of children with DS, requiring them to endure the fear and pain of surgery in hopes of stemming the intolerance of others. The position of the National Down Syndrome Society in the United States is that the focus should be on inclusion and acceptance of the children as they are and not on subjecting them to surgical intervention simply to make them more pleasing to others [5]. The slogan of Down Syndrome South Africa is “Count Us In,” and that organization suggests that surgically altering the facial features of the child with DS runs counter to prevailing efforts to nurture societal acceptance for these children just as they are [6]. Finally, in light of today's move toward involving young children in their health care decision making, I point out the serious ethical error of subjecting any child to a purely cosmetic procedure with no medical benefit before he or she can offer or withhold assent, much less consent. If it is expected that the child with DS will, with age, be able to decide for him or herself whether the benefits of surgery would outweigh the burdens, the parents should seriously consider waiting until that time. If, on the other hand, the child is not sufficiently high achieving for one to reasonably believe that that day will ever come, then the ethical strictures against cosmetic surgery to “normalize” the child intensify.

In light of objective evidence that purely cosmetic surgery does not accomplish any real benefit for children with DS, I believe that the only ethical course is to wait until a particular child achieves decision-making maturity sufficient for the task. Given that surgery does nothing to address the syndrome per se, it is impossible for me to justify ethically the risks and suffering visited on the child when the decision is made by others. He or she will remain a person with Down syndrome, with or without the surgery, still subject to the discrimination of the ignorant and intolerant. It is those persons who should accommodate the child with Down syndrome, not vice versa.

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Medical humanities

Birthmarks

by Faith L. Lagay, PhD

“In the latter part of the last century, there lived a man of science—an eminent proficient in every branch of natural philosophy” [1]. These opening words to Nathaniel Hawthorne’s short story “The Birthmark” are packed with clues about what readers are in for. Hawthorne’s “last century” has a specific referent, the 1700s, but on their own the words evoke the indefinite once-upon-a-time past of fairy tales, and the next two words—“there lived”—reinforce the expectation that a tale is about to begin, one that may take place on the border between the natural and the supernatural, perhaps one with a moral or lesson, probably one that is not about the everyday affairs of actual people.

Readers with knowledge of the history of philosophy know something more about a key figure in the tale. Natural philosophy and metaphysics were the two branches of ancient Greek philosophy. The former—of which Hawthorne’s protagonist is an “eminent”—was the ancestor to modern science and hence to medicine. We soon learn that this eminent’s name is Aylmer, which suggests the alchemy and sorcery that characterized natural philosophy in the centuries before it became modern science, long before the 1700s. Aylmer is just that sort of natural scientist. He believes that members of his craft ascend step by step until finally the best practitioners lay hands upon the very secrets of creation.

The tale

The plot of “The Birthmark” is simple and heavy with symbolic meaning. Its climax is foreseen by Aylmer’s wife, Georgiana, and grasped by first-time readers in the early pages of the tale. Here is the summary. Though devoted to his science, Aylmer “washed the stains of acid from his fingers and persuaded a beautiful woman to become his wife” [1]. No sooner had he married Georgiana, however, than he became preoccupied and then obsessed with a small birthmark on her cheek. It was the shape and size of a tiny hand—a pygmy hand. Before long, Aylmer shuddered at the sight of the mark and decided to apply the knowledge and skills of natural philosophy to ridding Georgiana of the “visible mark of earthly imperfection” [2]; he would correct “what Nature left imperfect in her fairest work” [3].

Georgiana was taken aback by Aylmer’s loathing of the mark, about which few before him had voiced dislike. Some had seen it as the print of a tiny fairy hand pressed there at Georgiana’s birth “to give her sway over all hearts” [4].

Nevertheless, Georgiana agreed to the plan, telling Aylmer that she could not be happy unless her husband removed the mark that distressed him so. But she knew from the first mention of the idea that “the stain goes as deep as life itself” [5]. “Spare me not,” Georgiana said, “though...the birthmark take refuge in my heart...” [3]. And she was correct. The fatal hand was in fact “the bond by which an angelic spirit kept itself in union with a mortal frame” [6]. Even Aylmer’s “brute” laboratory assistant Aminadab knew this. Said Aminadab, “If she were my wife, I’d never part with that birthmark” [7]. And with Aylmer’s successful removal of the mark, “the parting breath of the now perfect woman passed into the atmosphere...” [6].

The romantic tradition

Hawthorne is—along with “Moby Dick” author Herman Melville—the best known of America’s mid-19th-century romantic writers. Like the British romantics, the most famous of whom are the poets Byron, Shelley, Wordsworth and Keats, the American romantics wrote of a nature that reflected the handiwork of its creator. Nature in romantic literature is moral; it bears symbolic meaning, and humans who challenge it with inadequate respect for the immanent power of the divine generally learn painful lessons in humility. At some level, Aylmer appears to have sensed this. As heir to the long line of alchemists who sought the universal solvent by which gold might be “elicited from all things vile and base,” Aylmer believed that it was within human power to discover the long-sought medium. But he also believed that “a philosopher who should go deep enough to acquire the power would attain too lofty a wisdom to stoop to the exercise of it” [8].

And after

It would be disingenuous to suggest that the moral of Hawthorne’s cautionary tale should apply to the present-day pursuit of bioscience. Hawthorne placed his story in the latter part of the century preceding his own to cast a penumbra of more ancient abracadabra over Aylmer’s deeds. Medicine has challenged natural forces and processes directly and successfully since Aylmer’s time. Hawthorne himself probably witnessed the final attempts of physicians to cure patients by restoring nature’s healthy balance of the four humors—yellow bile, black bile, blood and phlegm—through bleeding, purging and administration of herbal potions. With the rise of experimental medicine in the mid-1800s the benefits of outsmarting nature began to outweigh the harms. Discoveries and advances over the next century and a half would produce immunizations, transfusions, antibiotics, organ transplants, and the promises of molecular, genetic and bionic medicine.

Correspondingly, nature has come to be read far less symbolically in post-romantic literature. Today a white whale might be thought of as a menacing killer because of the species to which it belonged but not because its whiteness represented the unknown or the “heartless voids and immensity of the universe,” “the white, colorless, all-color of atheism from which we shrink” or “the depths of the milky way” [9]. In *post-romantic* literature, a rose is a rose is a rose. (In *post-modern* literature, even *that* is up for grabs.)

A lesson for post-romantic times?

Does the tale of Aylmer's hubris hold any lesson for contemporary readers or physicians—other than “don't treat family members”? I think it does. Hawthorne meant for his readers to disapprove of Aylmer's attempt to master nature. Today's readers disapprove of Aylmer also but probably not for that reason. Had Georgiana been ill, we would have hoped that Aylmer's craft could cure her. No, we dislike Aylmer for being dissatisfied with a woman who pledged her love and entrusted her life to him, a woman whose inner—indeed, whose surface—beauty he could not see. *We dislike Aylmer for destroying the good in pursuit of the perfect.* In Hawthorne's metaphorical language, “the parting breath of the now-perfect woman” came simultaneously with her achievement of that unnatural state [6]. A related lesson for bioscience lies in the truth that our attempts to correct one of nature's flaws may do greater harm to one of nature's successes. The core purpose of medical research, of course, is to see that such harms do not occur as the result of well-intentioned interventions.

Unfortunately for the bearers of birthmarks, medical science has not perfected a one-time treatment for congenital capillary malformations like Georgiana's. Nor have most members of society come to accept visible birthmarks without staring or feeling sorry for their bearers. The vascular malformations that allow blood to pool below the skin's surface and thus produce what is colloquially referred to as a port wine stain are thought to result, in turn, from deficits in the nerves responsible for vasoconstriction [10, 11]. Hence, single laser interventions, which target the capillaries and not the perivascular nerve deficit, do not usually succeed in clearing the birthmark once and for all. Vessels in the affected area with insufficient innervation fill again with blood. This vascular-system explanation of birthmarks and the difficulty in making them disappear lends an aura of prescience to Hawthorne's symbolic use of a hand-shaped birthmark that grasped Georgiana's heart.

As for society's response, the good news is that the fading of symbol-rich romanticism in the 160 years since Hawthorne wrote has deprived nature's imperfections of their magical import. We no longer assume that a port wine stain, cleft lip or clubfoot is nature's superficial clue to a person's supernatural powers or spiritual flaws. We can only hope that acceptance of the marks themselves will eventually follow.

Conclusion

Few people today equate natural beauty with moral worth; few would insist that no natural flaw be tampered with because nature and nature's creator wanted its bearer to be marked just so. But 21st-century medicine has achieved many of its advances by heeding and applying another central lesson of “The Birthmark”—until we understand the deepest connections of surface signs, from birthmarks to behaviors, it is foolish and perhaps arrogant to attempt to change them in our pursuit of perfection.

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