One Year Later

iPLEDGE *from page 1*

isotretinoin was approximately 4 per 1,000 women, she said.

"In the interim, some sort of methodology [for evaluating success of the program] will be determined," said Dr. Thiboutot, professor of dermatology at Pennsyvania State University, Hershey. "The only information we have at the moment …is that the way the program is going to be evaluated is still under discussion."

The most significant change to come this year, in the meantime, will likely be an elimination of the 23-day lockout period for women of childbearing potential. With such a rule change, women who do not have their prescriptions filled within 7 days could undergo another pregnancy test and office visit and then get a refill without having to wait 23 days.

The FDA eliminated this lockout period last October for males and females of nonchildbearing potential, while promising that a change in this rule for females of childbearing potential would be "rolled out" in 2007. Last month, a spokesperson for Covance, the Princeton, N.J.–based company that manages iPLEDGE, confirmed that the company is "currently working on eliminating [the lockout]."

Dr. Thiboutot said she and other AAD leaders have been pushing for other changes as well—for instance, the incorporation of specific dates rather than time windows in the iPLEDGE online program—based on input from dermatologists who have communicated with the academy as well as a survey of 400 dermatologists taken this summer.

The poll showed that 95% were prescribing isotretinoin and that 90% of them were having difficulty with the iPLEDGE program.

Dr. Stephen Stone, who recently assumed the chairmanship of the academy's task force on isotretinoin, said the academy has a "seat at the table" that it did not have as iPLEDGE was being designed and implemented.

"The FDA is definitely listening to us," said Dr. Stone, immediate past president of the AAD and professor of clinical medicine at Southern Illinois University, Springfield. "My understanding is that iPLEDGE will be improved, at least in its ease of application."

Even with the elimination of the 23-day lockout period for men and women of nonchildbearing potential, "participation of these patients in the system is still overly complicated," he emphasized. "There still [needs to be] some liberalization of rules."

Dermatologists still are debating the program's effects on prescribing patterns. Dr. Noah Scheinfeld, of the dermatology department of Columbia University, New York, estimated last spring that the level of prescribing in his region had dropped by at least 50%. Last month, he said that estimate still holds true.

Dr. Elaine Siegfried, a dermatologist at St. Louis University who chairs the AAD's Environment and Drugs Committee, said, on the other hand, that the number of isotretinoin prescriptions dropped after implementation of iPLEDGE but now appears to be back up, approximately to where it was under the voluntary SMART (System to Manage Accutane Related Teratogenicity) program.

(The total number of prescriptions dispensed in the United States in the year after SMART was implemented had declined 23% from the previous year.)

According to Covance's data, while the number of prescribers and pharmacies activated has remained approximately the same in the last 6 months, the number of patients activated in the program has risen significantly, from 140,000 patients last June to more than 244,000 in December.

Calls into the AAD office, meanwhile, have continued to decline—a trend that AAD leaders say likely reflects changes made by Covance in the spring (the company added staff to its call center and made changes to its Web site, for instance, resolving some of the program's operational difficulties) as well as time needed to learn the system and delegate responsibility.

The average wait time for getting help from the iPLEDGE call center in December was 2 minutes, according to Covance spokesperson Laurene Isip.

"The program is definitely running light-years better [than it did at the start]," said Dr. James Del Rosso, of the department of dermatology at University of Nevada, Reno, and immediate past chairman of the AAD's Environment and Drugs Committee. "The situation is not perfect, but [it has] improved dramatically because of positive effort both at the academy level and the level of the individual dermatologist."

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DR. DEL ROSSO

Dr. Sharon Gardepe, who has a solo practice in general dermatology in Huntsville, Ala., called her legislators and the AAD soon after implementation about her concerns and experience with iPLEDGE.

She also created a handout listing local legislators to give her patients who complained about the program. "Giving them the list underlined the fact that it wasn't me," she said.

One year into the program, Dr. Gardepe said her hour-long phone calls to Covance are a thing of the past, but the requirement that prescriptions be picked up within 7 days and the rule that lab tests be conducted no sooner than 1 day before the office visit still result in "a lot of time spent troubleshooting."

"Some people are optimistic that we might be better able to work with [FDA and Covance], but I'm still skeptical [about the extent of future change]," she said.

Dr. Siegfried said such skepticism is understandable. "I really am optimistic. I do think that Dr. Walker [at the FDA] wants to build bridges," she said. "But in the end it's not her call—it's Congress."

The iPLEDGE program "was an incredibly political thing, and we doctors tend to be apolitical," she said. "We need to work not only to change what's happening now, but to work to prevent future bad outcomes."

Dr. Siegfried and other AAD leaders urge physicians to be vigilant and active. Isotretinoin, they caution, will likely be in the limelight this year, since Rep. Bart Stupak (D-Mich.) has announced he wants to hold a congressional hearing on the FDA's handling of the drug.

Dr. Siegfried said that she believes the decision to collect a full year of baseline data and then another year of comparison data before reporting pregnancy rates—rather than releasing iPLEDGE data quarterly, as was first anticipated—reflects the realization that "if the data were made public [along the way], and there's been one pregnancy, it will haunt us and we won't have the drug [at all]."

Dr. Stone said he too is concerned. "[iPLEDGE] will minimize the number of pregnancies by forcing people to go through the hoops, but I don't think we'll ever eliminate pregnancies," he said. "There is going to be a bottom line below which we cannot go." ■

Surgeon: Don't Scrimp On Initial Equipment

BY BETSY BATES
Los Angeles Bureau

LAS VEGAS — The most critical investments one should make in a new surgical practice are a quality surgical table, a top-of-the-line surgical light, and excellent surgical instruments, Dr. James M. Spencer said at the annual meeting of the American Society of Cosmetic Dermatology & Aesthetic Surgery.

"There are a lot of places in life to cut corners. Don't do it here," said Dr. Spencer, a dermatologist in private practice in St. Petersburg, Fla.

A dermatologic surgeon who only intends to do facial work might be well served by a top-flight procedure chair, such as those used by otolaryngologists.

However, Dr. Spencer prefers a high-quality surgical table and an adjustable, ceiling-mounted surgical light.

"Don't be cheap here," he reiterated.

Every surgeon has his or her favorite piece of equipment, and Dr. Spencer is no exception.

"The smartest thing I ever bought in my whole life was an Ellman Surgitron [electrosurgery unit]," he said.

Dr. Spencer noted that he has no financial interest in the Ellman Surgitron company or the recommended product.

Making a foray into surgical practice should be a careful and well-thought-out career move, cautioned Dr. Spencer, who serves on the clinical faculty of the Mount Sinai School of Medicine in New York.

"Why would another doctor refer to you because you took a weekend course?" he asked.

He advises doing a procedural dermatology fellowship, writing papers, doing research, and then, with some expertise to offer, arranging to do a grand rounds lecture at the local community hospital.

Dr. Spencer said young dermatologic surgeons are wise to take Medicare so that they can begin to build a referral practice for patients with skin cancer.

Family physicians often perform skin biopsies, but have a choice about where to send their patients for excisions and repairs.

"Get to know them," he suggested. ■

Essence of Ethical Marketing: Underpromise and Overdeliver

BY BETSY BATES
Los Angeles Bureau

LAS VEGAS — An ethical cosmetic practice should always "underpromise and overdeliver," said Dr. Michael A.C. Kane, a plastic surgeon in private practice in New York, at the annual meeting of the American Society of Cosmetic Dermatology and Aesthetic Surgery.

"Before" and "after" photographs, patients' testimonials, and catchy phrases such as "a facelift in a syringe" can all be misleading to the point of being unethical, Dr. Kane warned meeting attendees during his presentation.

"Computer imaging is the most dishonest of all," Dr. Kane maintained.

Most practices that utilize computer-imaging technology require patients to sign a statement saying that they understand "they're not going to look like that," he said. "Then why show it to them?"

Ethical marketing should feature realistic and representative results, Dr. Kane said.

Photographs should not be cherry-picked images from one's best results over a career, but should depict real results in consecutive patients undergoing similar procedures.

Patients should not be given a time-machine–type prediction of their results, such as "You'll look 10 years younger," because this promise can't be consistently delivered.

Superlative phrases used to characterize procedures or combination treatments often "way, way overpromise," Dr. Kane commented.

"Does anyone really think eight syringes of Restylane and Botox are the same as a facelift?" he asked.

As tempting as it is to entice patients with general statements suggesting that they will see dramatic results with minimally invasive treatments, it's misleading to make such blanket claims.

"Some people need the whole enchilada," he said. ■