

## iPLEDGE problems pile up for patients, doctors

Patients crossing borders to get drug with less hassle

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**National report** — Sources say glitches in the Food and Drug Administration's online registry for limiting pregnancy exposures to isotretinoin have resulted in overburdened office staffs, locked-out patients and end runs around the system.



Dr. Thiboutot

Since registration became mandatory March 1, "There have been many reasons that patients may be having problems," says Diane Thiboutot, M.D., chairwoman of the American Academy of Dermatology's isotretinoin task force and professor of dermatology at Penn State University.

### Window shut

For starters, she says patients in various parts of the country who have been unable to get prior authorizations from their insurance carriers within the seven-day window the system allows have had to go without isotretinoin for 30 days.

Dr. Thiboutot tells *Dermatology Times* that if patients register but miss subsequent office visits, "Trying to re-establish those patients within the iPLEDGE system involves a call to the call center, and approval from someone at a higher level there. In some cases, that's been taking up to a couple weeks to accomplish."



Dr. Hughes

Similarly, Philip Hughes, M.D., reports that his practice hasn't been able to get isotretinoin for any female patients since March 1.

"The iPLEDGE program is basically locked up and says that the patient can't get it, even though one does everything properly," says Dr. Hughes, who practices in San Antonio, Texas, with his daughter, Elizabeth Tichy, M.D.



Dr. Tichy

"I have enrolled six patients in the silly program, and every one has been denied for various reasons," Dr. Tichy says.

For instance, she says the system kicked out a male patient because his pharmacy didn't stock the prescribed dosage and couldn't fill the prescription on time.

"We have people with a disfiguring disease that is both uncomfortable and socially disabling, especially for teenagers," Dr. Tichy says.

She adds that although she supports the program's goals, "I believe it's unethical to deny somebody a treatment when one knows they need it."

### Way around

To circumvent iPLEDGE, Dr. Hughes says one of his patients has purchased

isotretinoin from a Canadian online pharmacy that requires only faxed copies of iPLEDGE ID cards and prescriptions, plus a signed patient acknowledgment form, for verification.

A representative for the company, who declined to be identified, says its isotretinoin orders have risen 60 percent in recent weeks, though it's impossible to say if iPLEDGE accounts for the entire increase.

"The question is, is it legal? I feel safe because I'm doing everything properly" in terms of registering patients and writing prescriptions, Dr. Hughes says. "It's not my problem how they get them filled."

Clay J. Cockerell, M.D., says importing isotretinoin is theoretically illegal, "but people do it all the time. One of our concerns was that people are going to start getting isotretinoin (internationally) if they're having trouble getting it here."



If such patients don't meet the requirements for iPLEDGE, he says the AAD has a grave concern that U.S. physicians might, paradoxically, see an increase in women getting pregnant while on isotretinoin.

"The Canadian International Pharmacy Association (CIPA) issued a statement in 2002 that they would not sell (isotretinoin) to Americans, and the majority of CIPA members are following that dictate," Gord Haugh, CIPA's general manager, says. "Those that do ship isotretinoin follow strict controls which mirror requirements of the iPLEDGE program with respect to sales to women."

A spokesman for the Canadian Pharmacists Association says, "We don't track sales, and actively oppose cross-border/Internet pharmacies, which is a bigger issue."

### Other ways around it

However, Canada isn't patients' only alternate source of isotretinoin, Dr. Hughes notes.

Rather than go without, one of his patient who lives in Del Rio, Texas, has

traveled to a doctor in Ciudad Acuña, Mexico, who charges her \$30 to rewrite her prescription for filling there.

At \$99 for a 20-day supply, "I've already wasted \$400 on the medication," which would have cost \$3 monthly through her husband's military insurance, says the patient. "It's really working. The only problem is getting it," she laments.

### Static system

"The worst problem is that the system is static, and any errors found are presumably unable to be corrected quickly," says



Joel Schlessinger, M.D., a private practitioner in Omaha, Neb.

Since March 1, he adds, "We no longer have the ability to dispense isotretinoin to indigent patients through pharmaceutical assistance programs."

"The difficult part is explaining to patients that there's nothing one can do about this. It's not as though one can negotiate with the people involved," says Jeffrey M. Weinberg, M.D., assistant clinical professor of dermatology at Columbia University. "Very often, patients believe that if they stop (taking isotretinoin) briefly, it will ruin what they're doing, and they'll have to start over."

Fortunately, Dr. Thiboutot says, "The response at the call center for regular calls has been getting faster, which is definitely a step in the right direction."

Additionally, she says, the FAQ page that Covance (which administers the program) added to iPLEDGE's Web site has proven helpful.

A Covance spokeswoman says, "The iPLEDGE program has been making significant progress in resolving individual registration problems and responding to issues that arise. Since mid-March, we have been increasing call center staffing to manage the increased call volume."

Such efforts have produced an April call-capture rate averaging 90 percent, the spokeswoman says.

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Columbia University

dentified in size and scope," she says. "Because it contains new mandatory requirements, it's not surprising that it will take some time for prescribers, office staff and others involved to become accustomed to these new processes and procedures."



Dr. Weinberg says, "I have a tremendous amount of gratitude toward my office staff," particularly his nurse managers. "iPLEDGE has added up to 25 percent more work than they previously had. They find it very frustrating and taxing, but they do it because they know that it's for the benefit of patients."

Soon, adds Dr. Thiboutot, "We'll be getting to the point where women of child-bearing potential are finishing their therapy."

According to FDA rules, such women require pregnancy tests on the last day of dosing and 30 days later.

She says, "The AAD wants to make sure that the call center maintains the current staff level, because we're expecting new waves of phone calls as we move through each of these hurdles." **DT**

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