

# iPledge off to a **bumpy** start

For those who use, prescribe and sell isotretinoin — an acne medication sold under the Accutane brand name, as well as in generic form — March 1, 2006 was about as dreaded and daunting as the Shakespearean Ides of March. That is because this date marked the implementation of iPledge — a mandatory registry and education program that regulates access to isotretinoin, which has been shown to cause serious birth defects.

WRITTEN BY **KENYA MCCULLUM**

**ACCUTANE, WHICH HAS** been on the market since 1982, has been a miracle cure for those suffering from severe recalcitrant nodular acne, a condition that causes pus-filled lesions to lodge deep within the skin, which can have devastating effects.

Because the drug is 90 percent effective, however, patients don't have to suffer these effects for long and after about six months of isotretinoin treatment; even the most severe cases of acne can be sent into remission.

## **A MIRACLE DRUG WITH A SERIOUS DRAWBACK**

Unfortunately, the miracle drug comes with a hefty price and can be catastrophic if it collides with childbirth. Studies have indicated that one-third of pregnancies exposed to isotretinoin end in fetal death, and some of the children that do survive are born with severe malformations, including missing limbs, brain or heart defects and mental retardation. These data do not account for all exposures, however, because many of the pregnancies end in miscarriage or termination.

## **EDUCATION EFFORTS**

In response to this tragic side effect, the Food and Drug Administration implemented

educational initiatives that included voluntary registries to decrease the number of pregnancies exposed to isotretinoin. However, the initiatives were deemed to be ineffective as the amount of exposures persisted: 2,000 were reported to the FDA. Additionally, when the generic forms of the drug were introduced to the market in 2002, multiple registries were created, making exposures more difficult to track.

Because of the failure of voluntary isotretinoin programs, the March of Dimes — an advocacy organization dedicated to preventing birth defects — proposed a single, mandatory registry program.

"Voluntary programs hadn't suf-

Mandatory Accutane registry leaves doctors and patients frustrated



ficiently prevented pregnancy exposures,” said March of Dimes medical director, Dr. Nancy Green. “This is a problem of enormous magnitude.”

In the latest attempt to decrease isotretinoin pregnancy exposures, the FDA approved iPledge, a mandatory educational program and registry. With the new system, in order for patients to get a prescription of the drug each month, they must produce two negative pregnancy tests and sign an iPledge card. In addition, doctors, patients and pharmacists must log on to the iPledge registry Web page ([www.ipledgeprogram.com](http://www.ipledgeprogram.com)) to confirm that the patient has been counseled on the risks of isotretinoin.

And this step of the program is where the problems began.

#### **iPLEDGE: HELP OR HINDRANCE?**

Prior to its March 1 debut, the American Academy of Dermatology (AAD) requested that the FDA delay iPledge until several glitches in the system — both technological and procedural — get resolved. Some of the problems the AAD wanted to see fixed

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include the confusing layout of the Web site; the fact that the prescription requirements for women of childbearing age are so similar to those for men and women outside of childbearing age; and sending passwords needed to log onto the registry via snail mail to doctors, which tend to arrive too late for a prescription to be filled.

Dr. Guy Webster, professor of dermatology at Jefferson Medical College in Philadelphia and AAD member, said the flaws with iPledge were caused because the company that designed it, Covance Inc., didn’t consult dermatologists. “It’s hurting patients and it’s making us crazy. They have no idea how a doctor’s office works.”

Green acknowledged that iPledge needs work, but she believes that the glitches will be resolved in the upcoming months. “We would

ask the dermatologists, the patients and the pharmacists to be patient with the system because it’s new,” Green said. “It’s cumbersome and I’m confident that can be (fixed).”

But dermatologists don’t accept this response and are concerned that difficulties with iPledge will force patients to explore other avenues for obtaining the drug.

“It trivializes what patients are going through by saying, ‘Eh, we’ll work it out.’ We have patients who are sick right now and they don’t want to hear, ‘Wait six months.’ They’re in the middle of treatment, and they need treatment now,” said Webster. “Even if it is just a glitch, what it’s really going to do is drive people to Canada, drive people to the Internet and drive people to Mexico. If you drain one end of the swamp, the other end is going to rise.” ■

