Prescribers Fume Over New Isotretinoin Program

BY BETSY BATES
Los Angeles Bureau

SANTA BARBARA, CALIF. — Who's responsible for iPLEDGE, the new, highly restrictive, mandatory registry for isotretinoin prescriptions?

A Vioxx-jittery Food and Drug Administration, noncompliant pharmacists, the American Academy of Dermatology, dermatologists, and other prescribing physicians are all at fault, Alan R. Shalita, M.D., declared at the annual meeting of the California Society of Dermatology and Dermatologic Surgery.

Dr. Shalita reported that isotretinoin prescriptions declined sharply in the year after the implementation of SMART (System to Manage Accutane-Related Teratogenicity), a voluntary patient registration/pregnancy prevention program, but

'No program will reduce the pregnancies to zero. ...We cannot regulate human behavior.'

DR. SHALITA

the pregnancy rate among women taking the drug stayed essentially the same, representing a failure of the profession to police itself and bring down the pregnancy rate, as the FDA had urged.

Doctors, pharmacists, and patients alike failed to comply with the central components of the voluntary program, he said.

When SMART was implemented in 2002, "we should have been getting monthly communications from the AAD," said Dr. Shalita, professor and chair of dermatology at the State University of New York Downstate Medical Center in Brooklyn. But there was "no communication, no reminders, no insistence, no effort to make our specialty more adherent to the [SMART] program."

AAD's position was to tell the FDA, " 'Leave us alone and we will do our thing,' when it was perfectly obvious we weren't doing our thing," Dr. Shalita said. Only in June, after iPLEDGE was announced, did the AAD assemble a group of thought leaders in acne to try to influence provisions in the final version of the program.

Diane M. Thiboutot, M.D., chair of the AAD's isotretinoin task force, responded to comments made at the meeting.

"The AAD has consistently opposed a mandatory registry program for managing the risks associated with fetal exposure to isotretinoin and has expressed this opposition to the FDA and the manufacturers of isotretinoin repeatedly. Once the decision was made that a registry was going to be implemented, the academy insisted on changes to the program to make it more workable and less burdensome for dermatologists and their patients," said Dr. Thiboutot, of the dermatology faculty at Pennsylvania State University in Hershey.

"The failure, in my estimation, of the academy to stand up in the face of this is almost criminal," said Sacramento, Calif., dermatologist John Kasch, M.D. "This represents a dramatic loss for the patients."

Richard Odom, M.D., of the University of California, San Francisco, placed blame squarely on the FDA for what he called a "huge, huge overreaction" to a drug that has caused 160 birth defects in 23 years.

Under the FDA's new mandatory program, physicians, patients, pharmacists, wholesalers, and manufacturers will be required to "pledge to follow the rules," Dr. Shalita explained.

Physicians who prescribe isotretinoin should have received registration materials in September, and patient registration began last month. Between now and Dec. 31, there is a transition period during which patients already on isotretinoin can continue to renew their prescriptions; mandatory compliance with iPLEDGE will be required as of Jan. 1, 2006.

Screening pregnancy tests (to determine whether a patient is qualified to enter the iPLEDGE program) can be done by the physician. The confirmatory pregnancy test and all subsequent monthly tests must be done by a CLIA-certified lab. If iPLEDGE fails to sharply reduce pregnancies, many worry that the drug will be lost.

"No program will reduce the pregnancies to zero. At the end of the day, we cannot regulate human behavior," he said.

Dr. Shalita disclosed that he is a consultant for Ranbaxy Pharmaceuticals Inc., which manufactures an isotretinoin product. ■