FDA Advisers: iPLEDGE Needs More Tweaking

Currently, there are about 20,000 calls a month to iPLEDGE call centers, a decline in volume.

BY ALICIA AULT

FROM A JOINT MEETING OF THE FDA DRUG SAFETY AND RISK MANAGEMENT AND DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEES

SILVER SPRING, MD. – The iPLEDGE risk management program for isotretinoin has reduced fetal exposure to the teratogen but still needs to be tweaked to reduce burdens on physicians and improve patient access, advisers to the Food and Drug Administration said.

Three versions of isotretinoin currently are on the market: Amnesteem, Sotret, and Claravis. The makers of those products said at the meeting that they were already planning on making changes to the iPLEDGE program in 2012. It's not clear whether the panels' suggestions would be incorporated then.

"I'm exceedingly impressed with what has evolved over time," said Dr. Wilma F. Bergfeld, professor of dermatology and pathology at the Cleveland Clinic and a temporary voting panelist on the Dermatologic and Ophthalmology Drugs Advisory Committee. She said that that it seemed that manufacturers, the FDA", physicians, and pharmacists were working together to make the program even better. "With everyone working at this, I believe the risk will go down."

Dr. Andrea Zaenglein of the departments of dermatology and pediatrics at Pennsylvania State University at Hershey said that while she was personally happy with the iPLEDGE program, it did constitute somewhat of a burden.

She said she spends at least 30 minutes counseling patients at the initial visit and then at least 15-20 minutes at each subsequent visit. Dr. Zaenglein, who spoke on behalf of the American Academy of Dermatology during the public portion of the meeting, said that the organization wanted to have more physicians participate in the ongoing evaluation of iPLEDGE. And, she said, the AADA hoped to have men and women of non-childbearing potential taken out of the registration process.

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Dr. Robert A. Silverman, past president of the Society for Pediatric Dermatology, said that Dr. Zaenglein's estimate on time spent counseling was conservative. He said he counsels patients over two or three extended visits, and that often he holds separate meetings with parents.

"After-hours discussion in my practice is not uncommon," added Dr. Silverman of Georgetown University, Washington. Still he said, isotretinoin "is a miracle drug that saves lives."

The dermatologists' concerns about physicians' burdens were echoed by the FDA panelists. The panelists noted that they were especially worried about what seemed to be a lack of understanding among patients and even physicians about birth control. Several wanted to see a clearer, more concrete presentation to patients on the relative merits and effectiveness of various contraceptive methods. They also asked for more data on why pregnancies were still occurring.

Dr. Eleanor B. Schwarz of the department of obstetrics and gynecology at the University of Pittsburgh strongly urged the panel to require more discussion among prescribing physicians and patients about birth control. She said that iPledge does not provide women and families with evidence-based guidelines on contraceptives. Noting that implants and IUDs are in the top tier of effectiveness, she said that these methods should be recommended as primary birth control for women of childbearing age who are taking isotretinoin.

Dermatologist and panel member Dr. Michael Bigby of Beth Israel Deaconess Medical Center in Boston said that he agreed that prescribing physicians – including dermatologists – should be given quantitative information on birth control methods.

For the year ending February 2011, 569,385 women of childbearing potential, 45,484 women of non–childbearing potential, and 620,012 men had enrolled in iPLEDGE since its inception in 2006.

The committee was first asked whether iPLEDGE is continuing to assure the safe use of isotretinoin. Overall, there have been 836 pregnancies since 2006; of those, 400 were terminated and 282 patients were lost to follow-up. A total of 45 live births were recorded; of those, 8 were children born with congenital anomalies.

In the year ending February 2011, there were 155 pregnancies, a decline from 186 the previous year, and 190 in 2008. Dr. Eric Davis, director of medical services for Mylan Pharmaceuticals, said that the pregnancy rate for iPLEDGE patients was 1.27/1,000, as compared with the 51/1,000 rate of unintended pregnancies in the general U.S. population.

James Shamp, director of risk management programs at United BioSource Corp., which helped develop iPLEDGE, said that analysis of program data had determined that some physicians were erroneously classifying women as being of non-childbearing potential. To mitigate against such errors, the iPLEDGE online system next year will include a "wizard" that will classify women as of childbearing potential or of non–childbearing potential based on a series of responses from the prescriber.

The panelists were also asked whether iPLEDGE was "unduly burdensome" for patients. FDA officials said that after iPLEDGE was introduced in 2006, there was a 29% drop in use by men and a 55% drop in use by women. Use among men recovered to pre-iPLEDGE levels within 7 months, but it took almost a year for usage to recover among women, according to Marta Wosinska, an analyst at the FDA Center for Drug Evaluation and Research. She said that iPLEDGE may have negatively affected patient access, but that the program also probably caused physicians to make more clinically appropriate prescribing decisions in certain cases.

Finally, the committee was asked to assess the burden on prescribers. According to data from Mylan, there are 14,444 registered prescribers in the iPLEDGE program, primarily with a specialty in dermatology (10,435, or 72%). Family physicians comprised the next largest group (2,095 prescribers 14%). Internists, ob.gyns., and pediatricians also were prescribers.

Mr. Shamp said that the program had become easier to manage for prescribers – a fact reflected by the declining volume of calls to the iPLEDGE call centers. Currently, there are about 20,000 calls a month, with an average hold time of a minute and an average time per call of just under 5 minutes, he said. ■

National Texting Program for New Moms Continues Growth

BY NASEEM S. MILLER

A nationwide texting program for new moms continues to grow in its second year, and an initial evaluation of the enrollees' feedback is showing promising results.

The public-private partnership called text4baby sends free educational text messages to expecting and new moms. The program now has over 260,000 enrollees, up from more than 150,000 in April.

With the advancement of technology and the widespread access to mobile phones, national agencies are trying to use tools such as texting to promote healthy behaviors.

The U.S. Department of Health and Human Services created a Text4Health Task Force in 2010, trying to "capitalize on the rapid proliferation of mobile phone technology and platforms, such as text messaging," and reach underserved groups, according to one of the agency's recent announcements.

Maternal and child health, domestic violence and sexual abuse prevention, tobacco control, emergency preparedness, and diabetes and asthma education are among the agency's texting projects.

Although it is too soon to tell whether such texting initiatives will improve health outcomes, positive feedback from women and physicians who use text4baby has turned some skeptics into believers.

"The overwhelming response was that the program brought information into their hands," said Dr. Yvette LaCoursiere, an assistant clinical professor in the reproductive medicine department at University of California, San Diego. She was involved in the multiagency partnership that conducted a small-scale evaluation of text4baby enrollees in San Diego.

Dr. LaCoursiere calls herself "a bit of a devil's advocate," and before conducting the survey she had some concerns. For one, she wondered whether the program was well received and whether it would create more work for physicians.

But she found out otherwise, she said.

With the goal of reaching women, especially those who are uninsured or underinsured, text4baby sends three free text messages daily to enrollees, many of

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which are relevant to their due date (nationally, around 46% of women signed up during their first trimester). It sends out phone numbers of relevant resources, and it alerts women of an outbreak or recall.

In the telephone survey of 122 text4baby users (roughly 10% of San Diego County's text4baby enrollees), 63% of the respondents said that the service helped them remember appointments or immunizations for themselves or their child, 75% said the messages informed them of "medical warning signs that they did not know," and 71% said the messages promoted a conversation with their physician.

More than half of underinsured respondents (53%) said they called a phone number that was sent in a text4baby message.

"The messages support the messages

'The [text4baby] messages support the messages ob.gyns. provide to their patients.'

DR. LACOURSIERE

ob.gyns provide to their patients," said Dr. LaCoursiere. "I tell my patients it's the text version of a [maternity book]."

Dr. LaCoursiere said that some of her physician colleagues who have signed up for the service have also "picked up some tips" from the messages.

To become more attractive to users and gather their insights, the messaging program is now trying to become interactive.

One of its first interactive projects was a flu module, which asked enrollees whether or not they were planning to get a flu shot this season.

Of the 31% of over 100,000 active text4baby users currently in the "pregnancy" or "new baby" protocol who responded, 40% said they had already gotten the shot, 29% said they were planning to, and 31% said they were not. More than half of those who said they were planning to get the flu shot requested a reminder provided by the module.

Such interactivity can help engage the users and also reinforce key health concepts, according to Dr. Carolyn B. Bridges, associate director of adult immunization at the Centers for Disease Control and Prevention, who spoke about the module at a recent briefing.

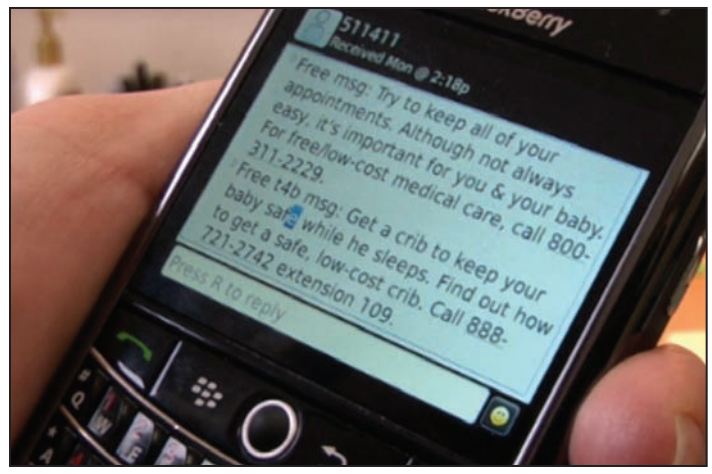
Text4baby, which is a program of the National Healthy Mothers, Healthy Babies Coalition, is planning to reach 1 million women by the end of 2012. The program was developed as a free tool to reach mothers across the nation and help reduce the risk of negative birth outcomes, according to the organization. With more than 28,000 infant deaths each year, the United States has one of the highest infant mortality rates among the industrialized nations.

While there are various texting projects underway, maternal and child health might have one of the more eager audiences.

"Pregnant women are hungry for knowledge," said Dr. LaCoursiere. "They want to learn how to be a good mom. So you have a population who's very interested in learning."

Text4baby is planning to release radio and television Public Service Announcements and increase its presence on social media in 2012, according to the program's organizers.

Several national evaluations are underway, and the results could be available within the next 2 years. ■



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A sample of text4baby messages is shown on a cellphone screen.