iPLEDGE at 6 Months

Acne remains the primary reason patients visit a dermatologist. A growing number of therapeutic options are becoming available, ranging from new combination topicals to photodynamic therapy and other laser- and light-source innovations. Despite these advances, there are still patients for whom the best therapeutic option boils down to one drug: isotretinoin. For these patients, there is no substitute. We are now 6 months into the iPLEDGE program, and based on personal experience, the future of this valuable drug is not bright.

The iPLEDGE program was implemented to reduce the number of pregnancies in women taking isotretinoin. Like most practicing dermatologists, I enrolled as a participant in this program. I have to admit, I find the program cumbersome and time consuming, with computer problems and delays, a 7-day purchase window, a subsequent 23-day "lock-out" period, and a 30-day period between office visits. My practice is quite busy, and neither I nor my staff has the time or energy to struggle with this program on a daily basis. The complications associated with iPLEDGE have resulted in a dramatic drop in the number of isotretinoin prescriptions I write. I am afraid this may be a national trend; the program may produce such a hurdle that the majority of dermatologists will stop prescribing the drug. The intended result of iPLEDGE, a drop in the number of pregnancies in women taking isotretinoin, will then result, not because of greater screening and counseling, but because the drug is simply not used.

Loss of this valuable drug would surely be a great disservice to patients for whom there is no alternative treatment. However, all is not lost. Dermatologists, especially through the efforts of the American Academy of Dermatology, are trying to improve the situation. In addition to direct contact with the Food and Drug Administration, dermatologists have enlisted support from several members of the US senate. Senators Dick Durbin (D-IL) and Judd Gregg (R-NH), along with colleagues from both parties, have written to the director of the Food and Drug Administration expressing concern about the features of this program that are obviously not working. With efforts such as these, it is still possible that the iPLEDGE program can be streamlined and improved so that unnecessary burdens are removed and patient access to this vital drug maintained.

The complications associated with iPLEDGE have resulted in a dramatic drop in the number of isotretinoin prescriptions I write. I am afraid this may be a national trend...

James M. Spencer, MD, MS
New York, NY