Editorial

iCHANGE

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It appears that we have started to turn the corner in our difficult relationship with iPLEDGE™. The US Food and Drug Administration (FDA) approved labeling revisions for isotretinoin on October 3, 2007. These revisions incorporate modifications to iPLEDGE, the drug's risk management program. Although it seems we have been dealing with the program for a lot longer, iPLEDGE was first introduced on March 1, 2006, as a stringent preventative approach against fetal exposure to isotretinoin.[1]

Several changes have been made to the iPLEDGE program. The following modifications went into effect on December 2, 2007: (1) some patients will be allowed more time between receiving and filling a prescription; (2) patients who do not fill their prescription in the prescription window will now be able to requalify to obtain a new prescription; and (3) condoms, with or without spermicide, have been added to the program's list of acceptable secondary forms of contraception.[1] For all patients, the prescription window (time between receiving and filling a prescription) formerly was 7 days, which started on the date of an office visit. According to recent modifications, the prescription window was extended from 7 days to 30 days for males and females not of childbearing potential; for females of childbearing potential (FCBP), the 7-day prescription window was changed to start on the date of specimen collection for pregnancy test, rather than the date of an office visit. In the past, FCBPs with prescriptions more than 7 days past the date of an office visit were unable to get a prescription for an additional 23 days, at which point they were required to start the process from the beginning by visiting their healthcare provider. The modifications to iPLEDGE eliminated the 23-day lockout for FCBP; patients may now return to their physician to start the qualification process again (except for the first prescription).[1]

It is interesting to note that the FDA recommendation for these changes occurred after it was reported that 122 women participating in the iPLEDGE program became pregnant in 2006.[2] According to a report conducted by isotretinoin manufacturers, more than 305,000 individuals registered to use the drug in 2006, including 137,415 FCBPs. Seventy-eight women became pregnant while taking isotretinoin; 8 became pregnant within 1 month after they stopped taking the drug; and 10 already were pregnant before taking isotretinoin, including 2 women who had pregnancy tests falsified. There was no information available for 26 pregnancies. Most of the 122 pregnancies were a result of women not adhering to their birth control plans.[2] A similar number of pregnancies were reported before the FDA tightened regulations on isotretinoin, but before iPLEDGE, the number of actual pregnancies in patients taking isotretinoin was unknown, making comparisons difficult.[3]

We should thank the American Academy of Dermatology for its dedication in working with the FDA to improve iPLEDGE. These modifications in the program are certainly welcome and will hopefully reduce the burden on our patients and staff. Most importantly, the increased flexibility will help to facilitate increased and uninterrupted access to a vital acne therapy.

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