Editorial

"Counter" Intuitive

Jeffrey M. Weinberg, MD

After starting to digest the disturbing news regarding the black box warnings for pimecrolimus and tacrolimus, I was stunned to hear news regarding the status of some of our other topical treatments. Specifically, there was a proposed change being considered by the Nonprescription Drugs Advisory Committee (NDAC) and the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) of the US Food and Drug Administration (FDA) in which topical corticosteroids would be available to patients over-the-*counter* instead of by prescription. Given the first piece of news, the second seemed a bit *counter*-intuitive. My first notion was that perhaps I had entered some bizarre alternate reality.

The American Academy of Dermatology (AAD) issued a statement in response to this proposed change. "The [AAD] is deeply concerned that if the FDA allows topical corticosteroids to be marketed over-the-counter instead of by prescription, patients could self-medicate without being monitored by their physician for serious side effects associated with long-term or improper steroid use," said AAD President Clay J. Cockerell, MD. "While weaker topical corticosteroids are available over-the-counter, we have seen some complications with their use. For the safety of patients, we urge the FDA to keep these stronger topical corticosteroids where they belong—behind the pharmacy counter as prescription medications."[1]

Fortunately, the NDAC and DODAC members agreed and voted 21-5 that any topical corticosteroid that causes hypothalamic-pituitary-adrenal axis suppression "under maximal use conditions" is not an appropriate over-the-counter switch candidate.[2] The committee noted that "potentially fatal adverse events related to adrenal suppression of cortisol from 'maximal use' of topical corticosteroids should preclude a prescription-to-OTC switch of those drugs."[2]

On February 15, 2005, on another issue, the FDA announced the creation of a new independent Drug Safety Oversight Board that will be responsible for the management of safety issues relating to FDA-approved drugs that are presently on the market.[3] The goal of this board will be to provide physicians and patients with emerging information about the risks and benefits of medications. In addition to institution of the Board, the FDA announced its intention to share drug safety information with the public sooner and more broadly and conveniently. This includes the launch of a new Drug Watch Web page and the dissemination of drug safety information sheets to healthcare professionals and patients.[3]

The creation of this Drug Safety Oversight Board is certainly a positive step. Hopefully, future decisions regarding the status of dermatologic drugs will be more judicious than the ones we have experienced of late.

The author reports no conflict of interest.

REFERENCES

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