Policy & Practice

Sunscreen Label Delay Decried

Lawmakers are urging the Food and Drug Administration to release comprehensive sunscreen labeling that has been in the works for several years. Sen. Christopher Dodd (D-Conn.) and Sen. Jack Reed (D-R.I.) introduced a bill to require the FDA to issue final sunscreen rules by February 2009. The Sunscreen Labeling Protection Act of 2008 (S. 3425) is not the senators' first foray into the labeling controversy, as they have called for sunscreen rules since early 2006. "The FDA's current standards for sunscreen testing and labeling leave Americans with a false sense of security about whether their sunscreen protects them from harmful UVA rays," Sen. Dodd said in a statement. The senator said the legislation is supported by the American Cancer Society, the Melanoma Research Foundation, Citizens for Sun Protection, the Environmental Working Group, and sunscreen manufacturers Banana Boat and Hawaiian Tropic. Connecticut Attorney General Richard Blumenthal joined the senators, sending a letter to FDA Commissioner Andrew von Eschenbach calling for an immediate implementation of the rules proposed by the agency in August 2007. Mr. Blumenthal had petitioned the FDA to propose and implement sunscreen standards in May 2007.

FDA Seizes Hydroquinone

The FDA seized $24 million worth of unapproved drugs, including several hydroquinone cream products, from a St. Louis manufacturer. The agency took the action after an inspection of several plants owned by KV Pharmaceutical Co. The FDA determined that KV was not complying with a May 2007 notice requiring companies to stop manufacturing timed-release products containing guaifenesin and to stop shipping those products by November 2007. That notice was part of a larger effort by the FDA to begin removing unapproved drug products from the market. The FDA inspection found that KV was also manufacturing many other unapproved products, including hydroquinone 4% cream and hydroquinone 4% cream with sunscreen. KV issued a statement saying that the guaifenesin products had been manufactured by a company it acquired and that it was set to dispose of them. The company also said in a statement that it "will continue its cooperation with the FDA in bringing this matter to final resolution."

Survey: Only 15% Get Skin Exams

In a national survey, only 15% of American workers reported ever having a head-to-toe skin exam. Only 8% of those who had seen a physician in the past year reported having had such an exam, according to a study published in the July issue of the Journal of the American Academy of Dermatology. Researchers from the University of Miami and the University of North Carolina, Chapel Hill, analyzed data from the 2000 and 2005 National Health Interview Survey, an annual, in-person survey conducted by the National Center for Health Statistics. Based on their analysis, they estimated that 106 million workers have never been fully examined by a dermatologist or any other physician. Farm workers and blue-collar workers had the lowest screening rates. In 2005, only 2% of farm workers and 5% of blue-collar workers reported a skin exam in the previous 12 months, compared with 10% of white-collar workers. Blue-collar workers also had the lowest lifetime screening rates, ranging from 3% to 9%, compared with 11%-32% for white-collar professions. "The rate of reporting skin cancer screening was lowest for high-risk occupations most likely to experience increased sun exposures," wrote the authors. The research was supported in part by the National Institute of Occupational Safety and Health.

Stiefel Completes Acquisition

Stiefel Laboratories has completed its purchase of Barrier Therapeutics, a Princeton, N.J.–based company that has three topical products on the market, Xolegel, Vusion, and Solage. "Barrier's innovative products and pipeline are a very valuable addition to Stiefel," company CEO Charles W. Stiefel said in a statement. With the purchase of Barrier, Stiefel adds a development portfolio that includes products for onychomycosis, psoriasis, acne, skin allergies, and acute fungal infections. The family-owned Stiefel claims to be the world's largest dermatologic specialty pharmaceutical company. It does not publicly report sales or earnings.

Feds Scrutinize Generic Maker

India's Ranbaxy Inc., one of the top 10 generic drug makers in the world, is being investigated by various arms of the federal government for allegedly introducing "adulterated or misbranded products" into the U.S. market. The company's auditor, Parexel Consulting, is also under scrutiny. According to a subpoena for documents filed in the U.S. District Court for the District of Maryland by the Department of Justice and the U.S. Attorney's Office in Maryland, Ranbaxy submitted false information to the FDA on sterility and bioequivalence, covered up good manufacturing practice violations, and defrauded Medicare. Reps. John Dingell (D-Mich.) and Bart Stupak (D-Mich.) said that they will formally investigate the Ranbaxy situation. "If these allegations are true, Ranbaxy has imperiled the safety of Americans in a manner similar to the generic drug scandal we uncovered 20 years ago," said Rep. Dingell. "I would like to know whether FDA officials knew about these allegations and what, if any, action was taken."

—Alicia Ault

Managing Your Dermatology Practice

Adopt Guidelines for E-Mail Questions

I recently received a lengthy e-mail from a very worried woman. She claimed to be an established patient in my office, which I had no way of confirming because she did not sign her message. She asked many questions about sexually transmitted diseases and how they might affect her and a new boyfriend.

I was undecided on how to reply, or even whether to reply at all, so I posted my dilemma on the DermChat e-mail list to see how other dermatologists might handle such a situation. (DermChat and RxDerm-L were discussed in detail in my column of March 2004, which can be found in the archives at www.skinandallergynews.com.)

BY JOSEPH S. EASTERN, M.D.

Responses were all over the map—from "I never answer patient e-mails" to "What harm could it do, she's better off getting correct answers from you than incorrect answers from some 'advocacy' Web site"—and everything in between.

Clearly, this is a controversial issue that will only get more controversial in the future, so I decided to look at what has been published on the subject.

It turns out that, as early as 1998, two German investigators asked this same question and designed a study to address it (JAMA 1998;280:1333-5). Posing as a fictitious patient, they sent e-mails describing an acute dermatologic problem to random Web sites offering dermatologic information, tallied the responses they received, and followed up with a questionnaire to responders and nonresponders alike.

As with my informal survey, the authors found what they termed "a striking lack of consensus" on how to deal with this situation: Of the 50% who responded to the fictitious patient's e-mail, 31% refused to give advice without seeing the patient, but 59% offered a diagnosis, with a third of that group going on to provide specific advice about therapy.

In response to the questionnaire, 28% said that they tended not to answer any patient e-mails, 24% said they usually replied with a standard message, and 24% said they answered each request individually. The investigators concluded that "standards for physician response to unsolicited patient e-mail are needed."

Unfortunately, my DermChat survey suggests that, 10 years later, there is still nothing like a consensus on this issue.

In the interim, several groups, including the American Medical Informatics Association (http://134.174.100.34/AMIA%20E-mail%20Guidelines.pdf), Medem (www.medem.com/phy/phy_eriskguidelines.cfm), and the AMA(www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-478.997.htm) have proposed guidelines, but none have been generally accepted. Until such time as that happens, it seems advisable for each individual practice to adopt its own guidelines. For ideas, take a look at the examples I've listed, plus any others you can find. When you're done, consider running your guidelines past your lawyer.

Your guidelines may be very simple (if you decide never to answer any queries) or very complex, depending on your situation and personal philosophy, but all guidelines should cover such issues as authentication of patient correspondents, informed consent of those patients, licensing jurisdiction (if you receive e-mails from states in which you are not licensed), and above all, confidentiality.

Contrary to popular belief, ordinary unencrypted e-mail does not necessarily violate the Health Insurance Portability and Accountability Act (HIPAA). As I've noted many times, HIPAA allows you to handle medical information in just about any way you wish, as long as patients are informed of what you are doing and accept any associated risks of breach of privacy. As long as the Notice of Privacy Practices that you distribute to patients explains your e-mail policies, and each e-mail includes a standard confidentiality disclaimer, most experts say you will be HIPAA compliant.

If the lack of encryption and other privacy safeguards makes you or your patients uncomfortable, encryption software can be added to your practice's e-mail system. Rather than simply encrypting your e-mail, though, consider adopting Web-based messaging. Patients enter your Web site and send a message using an electronic template that you design. You (or a designated staffer) will be notified by regular e-mail when messages are received, and you can post a reply on a page that can only be accessed by the patient. Besides enhancing privacy and security, you can state your guidelines to preclude any misunderstanding of what you will and will not address online.

Web-based messaging services can be freestanding or incorporated into existing secure Web sites. Medem (www.medem.com), Medfusion (www.medfusion.net), and RelayHealth (www.relayhealth.com) are among the leading vendors of secure messaging services.

And the e-mail query that triggered all of this? I responded, but told the patient I could not provide specific answers to such personal questions over the Internet, particularly when they were asked anonymously. I said I would be happy to address her concerns in person, in my office.

And now, I'm writing my guidelines. ■

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