POLICY & PRACTICE

FDA Says Humira Ad Misleading

The Food and Drug Administration said that Abbott Laboratories downplayed the risks associated with the psoriasis therapy Humira (adalimumab) in an ad intended for dermatologists. The ad was misleading because it "suggests that Humira is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience," the FDA noted. The drug has many risks, including tuberculosis and invasive fungal infections, and its use should be carefully weighed, the agency wrote in a December letter to Abbott, which contended that the ad gave a full description of the drug's approved use only in small, "nearly illegible" text. Also, the patient pictured in the ad was not representative of approved users since the model showed only a small area of plaque psoriasis. The agency said Abbott should immediately stop the ads. A company spokeswoman said the ad was discontinued in October and that it will "work with the agency to address their concerns."

Phototherapy Copays Prompt Action

The National Psoriasis Foundation has written to insurance commissioners in six states to request that they encourage health plans to eliminate or reduce patients' copayments for phototherapy sessions. Members of a foundation task force on the issue—who are primarily dermatologists—decided to target commissioners in California, Massachusetts, Missouri, New York, Texas, and Utah. The foundation has received two responses, neither of which was very encouraging, said Sheila Rittenberg, the organization's senior director of advocacy and external affairs. The task force effort came after a failed attempt to convince 85 health insurers around the country to cut copayments, she said in an interview. Patients are paying anywhere from $5 to $50 per psoriasis-phototherapy session, and most need several a week, said Ms. Rittenberg. In some cases, she added, patients are being prescribed biologics because they can't afford phototherapy.

Colorings Must Be Declared

Many foods and cosmetics contain carmine and cochineal, but they have been hidden under the rubric of "artificial coloring" or "colors added." The FDA has ruled that manufacturers must clearly state on labels that carmine and cochineal are in those products. The final rule, published Jan. 5, is partly in response to a petition filed by the Center for Science in the Public Interest in 1998. The nonprofit advocacy group contended that because carmine and cochineal extracts—which give products red hues—come from insects, they were the most likely causes of dozens of allergic reactions. The FDA acknowledged that reactions and anaphylaxis have been associated with carmine- and cochineal-colored products, and the agency first proposed requiring disclosure of the two extracts in 2006. But the FDA has refused to ban the colorants. Manufacturers have 2 years to comply with the new labeling requirements.

2009 Predictions on Cosmetic Front

There will be an increase in horror stories about consumers having bargain cosmetic procedures, and Botox will finally get some competition this year, according to a list of predictions from the American Society for Aesthetic Plastic Surgery. The professional society said that the injectable botulinum toxin Reloxin should gain approval in 2009. The organization also said that noninvasive fat-removal techniques will gain credence as they are tested in clinical trials and that men will continue to be a growing segment of the market for cosmetic procedures. The society said its predictions are based on interviews with plastic surgeons.

—Alicia Ault

MANAGING YOUR DERMATOLOGY PRACTICE

Protect Your Data!

Last month I wrote about a dermatologist from the Midwest whose office was ransacked and then set on fire. I covered the steps necessary to file a timely and accurate insurance claim.

BY JOSEPH S. EASTERN, M.D.

No amount of insurance, however, will recoup one of his worst losses: the data on his destroyed computers.

Industry statistics show that fully 10% of hard drives fail in any given year and that 43% of computer users lose one or more files every year. Recovery of lost data, when it's possible at all, can be very expensive.

Despite that, a Harris Interactive study found that 35% of Americans admitted they never back up their computers. My guess is that the actual percentage is substantially higher. And amazingly, many people who have lost important, irretrievable data in a crash still refuse to do regular backups.

Why do so many of us neglect such a basic precaution? Because it's an annoyance and an inconvenience and takes too much time. Clearly, the only way to get many people to back up their data regularly is to make the process automatic.

Some computer companies have taken steps in that direction. Apple, for example, has a feature called Time Machine that backs up Macs to an external drive automatically. But that does you no good if, as happened to the Midwestern dermatologist, the fire that destroys the computers also incinerates the backup drives.

So, the first rule is to store your backup drives in a different location from your computers. Unfortunately, that's a pain, too, and external drives can be lost or stolen, creating a HIPAA nightmare. So an increasingly popular alternative is automatic remote backup.

There are several companies that offer this service: two of the most popular are Mozy (www.mozy.com) and Carbonite (www.carbonite.com).

(As always, I have no financial interest in any product or service discussed in this column.)

The cost is very reasonable. In fact, Mozy lets you store up to two gigabytes of data for free. Its basic package, which includes unlimited storage, costs $4.95 a month per computer. Carbonite is a bit cheaper ($49.95 per year, also for unlimited capacity), but Mozy is a little more customizable, and you can specify the files you want regularly backed up and when it will be done. Backing up an entire office costs more, depending on how many computers and/or servers you have, but it's still very reasonable and includes other services such as operating system and network share support.

The procedure is simple: You create an account and tell the service which files you want copied. Your first backup can take a long time, often days, depending on how much data you are sending and the speed of your Internet connection. After that, the program runs in the background, copying only those files that have changed since the previous backup. Files are encrypted before leaving your computer, and they remain encrypted at the service's data center, making them HIPAA compliant and, theoretically, accessible only to you.

To restore files, you open a sort of virtual representation of your backed-up files and click on what you want restored. You also can log into the Web site from any other computer and pick any file or folder to retrieve. If your computer is stolen or the hard drive is destroyed, you can go to a site to initiate a full restore to a new computer.

If you ever decide to terminate the service or simply want a hard copy of your data, Mozy will send you a DVD of all your files, for a fee.

Mozy's parent company, EMC, has announced a new subsidiary called Decho (www.decho.com), which it says will soon offer the same services for information that banks offer for money. Not only will you be able to store your data, you'll also be able to share it, move it around, put it to work, and access it no matter where you are. Such a centralized "information bank in the sky" could change the way we perceive and use computers. ■

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