POLICY & PRACTICE

Reloxin Approval Delayed

Ipsen and its marketing partner Medicis announced in mid-April that its botulinum toxin type A, Reloxin, (known as Dysport in Europe) would not be approved at the expected time. Instead, the companies reported in a statement that they were "in active labeling and risk evaluation and mitigation strategy discussions" with the Food and Drug Administration for both the therapeutic—cervical dystonia—and the aesthetic indications. Galderma owns European marketing rights for aesthetic uses, and Medicis owns the U.S., Canadian, and Japanese rights. The companies did not say when they expected final approval.

QVC Settles Over Cellulite Cream

The megaretailer QVC Inc. has agreed to pay $7.5 million to settle Federal Trade Commission charges that it violated commission orders dating to 2000 and made false and unsubstantiated claims about an anticellulite cream as well as three dietary supplements. The company's TV-shopping network made unsubstantiated claims that Lipofactor lotion could reduce cellulite, said the FTC statement. "Simply put, we aren't going to let QVC get away with this," said the acting director of FTC's Bureau of Consumer Protection, Eileen Harrington. QVC will pay $6 million for consumer redress and a $1.5 million civil penalty. And the FTC extended the order prohibiting the claims.

NIAMS Touts Stimulus Funds

The government's economic stimulus package offers new opportunities for dermatologic research, Dr. Stephen Katz, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), said on the agency's Web site. The stimulus funds are distinct from NIAMS's annual appropriation and will be managed separately, said Dr. Katz. Among the new programs is the Grand Opportunities initiative for projects requiring more than $500,000 per year. Other stimulus funds can be used to accelerate ongoing research. Application deadlines are in June and July, visit www.niams.nih.gov/Recovery/directors_go_letter.asp.

Lupus Research Gets Budget Boost

Congress has dedicated about $5 million to lupus research and education as part of the recently enacted fiscal year 2009 Omnibus Appropriations Act. The law, which was signed in March, includes $4 million to support the National Lupus Patient Registry, about $1 million more than in FY 2008. Congress provided another $1 million for health provider education aimed at improving early diagnosis and treatment of lupus and reducing health disparities. The Lupus Foundation of America specifically praised the health provider education initiative. Educational programs that improve the time to diagnosis are critical, the organization said, because more than half of individuals with lupus report that they had symptoms of the disease for at least 4 years and visited at least three physicians before receiving a diagnosis of lupus.

Path Outlined for Biosimilars

A bipartisan group of legislators has introduced a bill to promote approval of follow-on biologics, or biosimilars. The Pathway for Biosimilars Act (H.R. 1548) is designed to accomplish for follow-on biologics what the Hatch-Waxman Act of 1984 did for generic drugs. The legislation would set up a process within the FDA to expedite approval of new biologics that are based on existing products. However, the bill includes incentives for companies to continue to create innovative products, including 12 years of exclusivity for the original product.

Device Staff Decries FDA Politics

The FDA is a mess of politics, abuse, and misdeeds, according to members of the agency's Office of Device Evaluation, who sent a six-page letter to President Barack Obama in early April. The staff members called on the president to enact sweeping measures "to end the systemic corruption and wrongdoing that permeates all levels of FDA." They said that FDA managers have "abused their power and authority" and "engaged in illegal retaliation against those who speak out." The letter detailed a handful of events in the last few months but said that "the culture of wrongdoing is nothing new but is part of a long-standing pattern of behavior." The letter, with all of the signers' names redacted, was released at a congressional hearing.

Administration Posts Filling Up

The Obama administration has named officials to several top health care-related positions that do not require Senate confirmation, including the director of the White House Office of Health Reform, administrator of the Health Resources and Services Administration, and the new National Coordinator for Health Information Technology. Nancy-Ann DeParle, who ran Medicaid and Medicare under President Clinton, will now lead the White House office. Rural health expert Mary Wakefield, Ph.D., R.N., was selected to head HRSA, joining the agency from the University of North Dakota, Grand Forks. And internist David Blumenthal, former director of the Institute for Health Policy at Massachusetts General Hospital, Boston, will take the lead on creating a nationwide health information technology infrastructure.

—Alicia Ault

MANAGING YOUR DERMATOLOGY PRACTICE

Ready for the Red Flags Rule?

By now, you are probably aware of the Fair and Accurate Credit Transactions (FACT) Act of 2003 and its "Identity Theft Red Flags Rule," which require creditors to establish a program to prevent identity theft. The law will be enforced beginning this month, so if you haven't taken any action yet you'd better get cracking.

The law was originally aimed only at financial institutions, but the Federal Trade Commission, which is charged with enforcing it, subsequently decided it could apply to any group that would be considered a creditor, which the law defines as "any entity that regularly extends, renews, continues credit or arranges for the extension of credit."

BY JOSEPH S. EASTERN, M.D.

The FTC has specifically said that it will include medical providers in this definition "if [the provider] does not regularly demand payment in full for services or supplies at the time of service."

In other words, if you routinely bill patients for any portion of your fees, including the portions not paid by insurance carriers, you are considered a creditor under this law.

To comply with the law, the FTC says that you must develop a program that allows you to do four things: identify relevant red flags (more on that below), detect red flags, prevent and mitigate identity theft, and update your program periodically.

So what is a red flag? Basically, it is a warning sign that should alert your practice to suspicious activity that may indicate identity theft. The FTC guidelines list five categories of warning signs that should be identified and addressed:

- Alerts, notifications, or warnings from a consumer reporting agency or any entity that performs services on your "covered accounts."
- Suspicious documents.
- Suspicious identification documents.
- Suspicious activity relating to a "covered account."
- Notices from customers, victims of identity theft, law enforcement authorities, or other entities about possible identity theft in connection with "covered accounts."

Okay, so what is a "covered account?" It is any financial account used mostly for personal purposes that involves multiple payments or transactions, for which there is a foreseeable risk of identity theft.

The FTC says it is particularly worried about medical billing accounts because the theft of a patient's information to fraudulently obtain medical care can cause a variety of serious problems over and above those usually associated with identity theft, including exhaustion of the victim's health benefits and a potentially life-threatening corruption of medical records.

The law requires you to develop a written program appropriate to the size and complexity of your practice that spells out your responses to red flags and the preventive actions you plan to take if there is a breach or attempted breach of your database. The program should include appropriate staff training, as well as a plan for monitoring staff to ensure that they are all following the program.

You must update your program "periodically" (the law is no more specific than that) to reflect changes in risks to patients, ensuring that the program remains current and relevant as methods of identity theft change.

In other words, designing a program and putting it on a shelf to collect dust will not satisfy the law's requirements, nor adequately protect your patients.

If you employ a billing service and/or collection agency, or any other outside entity that has access to your covered accounts, you also must take steps to ensure that their activities are conducted using a reasonable identity theft program. This could be done through a written contract with the service provider, or by amending your existing HIPAA Business Associate Agreements.

Some states have their own additional rules that may need to be incorporated into your identity theft prevention program. Check with relevant agencies in your state regarding that possibility.

Violations of the Red Flags Rule can subject your practice to significant penalties—particularly if a patient suffers an identity theft that could have been prevented by your program, had it been properly implemented.

The exercise is not as onerous or time consuming as many assume. The American Academy of Dermatology points out that the law permits great flexibility, so if you determine that your practice has a low risk of identity theft, developing a program should be simple and straightforward, with only a few red flags to identify and deal with.

Medical practices and other businesses can find help online for developing their own programs. One good example, with a template that should be modifiable to fit most dermatology offices, is online at the California Society of Municipal Finance Officers' Web site (www.csmfo.org/index.cfm?fuseaction=DetailGroup&CID=2478&NavID=181).

The AAD also has more information at its site (www.aad.org/pm/_doc/FTCRedFlagsRulesFactSheet.pdf). ■

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