Tobacco Law Gives FDA Unprecedented Power

BY MARY ELLEN SCHNEIDER

Public health advocates are applauding a new law that gives the Food and Drug Administration unprecedented authority to regulate the sale, marketing, and ingredients in tobacco products.

President Obama in late June signed into law the Family Smoking Prevention and Tobacco Control Act (H.R. 1256), which gives the FDA the power to regulate the levels of tar, nicotine, and other ingredients in tobacco products. The law does not give the FDA the authority to ban tobacco products, but it does give the agency broad authority to regulate labeling, packaging, and advertising of such products.

During a White House Rose Garden signing ceremony, President Obama said the law would "save lives and dollars" and would aid health reform efforts by reducing tobacco-related health care costs.

The law bans the use of cigarette additives or flavoring such as strawberry or grape that many public health advocates have said has been used by tobacco manufacturers to make smoking more appealing to minors. The law also prohibits tobacco companies from using descriptors such as "light" or "mild."

Additionally, the bill calls on the FDA to consider fast-tracking the approval of new smoking cessation products. The new law also aims to prevent youth smoking by placing restrictions on outdoor tobacco advertising within 1,000 feet of schools and playground, as well as sponsorships of entertainment and sporting events.

Cigarette packs themselves will also be designed to deter smoking. Under the law, about half of the front and back of the package will be taken up by the warning label. Manufacturers will be able to choose from a selection of warnings such as "WARNING: Smoking can kill you" or "WARNING: Cigarettes cause cancer."

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The measure signed into law by President Obama drew praise from the American Medical Association.

These types of restrictions will help chip away at some of the ways tobacco companies have successfully created an aura of "cool" around smoking, said Danny McGoldrick, vice president for research at the Campaign for Tobacco-Free Kids.

Physician groups hailed enactment of the new law. "The new law represents an important break from the past, as it signifies broad acceptance that nicotine is a drug harmful to people's health," Dr. J. James Rohack, president of the American Medical Association, said in a statement.

"This is great news for family doctors," said Dr. Ted Epperly, president of the American Academy of Family Physicians. "To now have this kind of statement coming out in terms of control of tobacco products is a huge shot in the arm for the health of America."

Dr. Epperly said he hopes the attention from this new law will spur physicians to make it routine to ask patients about smoking and follow up with advice on quitting. The AAFP has its own program—"Ask and Act"—which includes tools and information on prompts for physicians to ask about patients smoking, coding for cessation counseling, and resources for patients who want to quit (www.aafp.org).

For those physicians who think they do not have the time, Dr. Epperly pointed out that it doesn't have to be the physician who asks about smoking, it can also be a nurse or medical assistant. He also advised physicians to be patient about seeing results from patients. "I've had multiple patients who aren't ready yet to stop smoking. But I always remind them, 'I'm here for you if and when you decide [to quit],' " Dr. Epperly said.

The American College of Physicians also praised the new law. Dr. Joseph W. Stubbs, ACP president, said it was "high time" the government began to regulate tobacco products, which contribute to so many chronic illnesses. Dr. Stubbs said he hopes that the law will lead to stronger efforts related to smoking cessation.

One of the ways the FDA will be able to use its new authority to assist in smoking cessation is by regulating the ingredients in tobacco products. But finding the best way to do that may take some time, said Erika Sward, director of national advocacy for the American Lung Association. For example, under the law the FDA is gaining the authority to reduce the amount of nicotine in cigarettes but scientists don't yet know if that would only lead people to compensate by smoking more, she said.

Aside from the concrete elements of the law, Ms. Sward said she hopes the law will also help people understand that tobacco addiction is powerful and that most people can't quit "cold turkey."

It's important for physicians to talk to patients repeatedly about the need to quit smoking, she said. ■

FDA Announces Transparency Task Force

BY JOYCE FRIEDEN

In one of her first public acts at the Food and Drug Administration, new commissioner Dr. Margaret Hamburg announced that the agency aims to be more transparent about its daily work and decision making process.

"Over the years, complaints have been made about FDA's lack of transparency," Dr. Hamburg said in early June. "The agency has been referred to as a 'black box' that makes important decisions without disclosing them. The agency can and should communicate in a way that provides more transparency, not less."

The commissioner said it was her goal that the public looks first to FDA for trustworthy and useful information about drugs and devices.

"On President Obama's first day in office, he pledged to strengthen democracy . . . by creating an unprecedented level of openness" in government," Dr. Hamburg noted. "This will be an agency-wide effort charged with figuring out how to make the FDA and its processes more transparent to the public."

The transparency task force will include the directors of all FDA centers as well as the agency's associate commissioner for regulatory affairs, its chief counsel, and its chief scientist. Its first meeting was held June 24; another will take place in the fall. All meetings will be open to the public. The task force "expects to submit a written report to the commissioner about 6 months from now," according to FDA principal deputy commissioner and task force chair Dr. Joshua Sharfstein.

Being clearer about why the agency decides things a certain way is one area of interest for Dr. Sharfstein. "People don't understand why the FDA may have done something or not done something," he said. "In many cases, the agency has an explanation, but you don't necessarily hear that explanation very clearly."

Dr. Hamburg said she expects that a wide range of recommendations could emerge from the task force's work. Some recommendations "will be in areas that we can implement swiftly, but there may be other types of information that will take more time, and there may be some area where we have limitations within the current law and need to examine whether appropriate changes can and should be made," she said.

Both Dr. Hamburg and Dr. Sharfstein emphasized, however, that a balance will need to be struck between providing more information and the appropriate use of confidentiality. "We recognize that there are other policy goals besides transparency, and one of the other questions is what information should remain confidential," Dr. Sharfstein said. "The secret formula for how to make X pill may be legitimately confidential information."

Another balancing act will come in terms of clinical trials, Dr. Sharfstein continued. "What is the argument for different amounts of data [being disclosed] at different points in the drug development process, and on the other side, what are the confidentiality concerns and the reasons for them?"

The call for transparency comes at a time when FDA already has a backlog of requests under the Freedom of Information Act. Asked how she planned to handle personnel needs at a time when the agency is behind in its work, Dr. Hamburg said: "When the recommendations come in, I will work with the task force and others on implementation. Some activity may result in more work, and some may result in decreased work. If we make more information available, there may be fewer Freedom of Information Act requests and citizen petitions." ■

The Federal Register notice announcing the task force's formation is available online at www.federalregister.gov/OFRUpload/OFRData/2009-12902_PI.pdf. Comments on the task force's mission are being accepted through August 7.

Hamburg Lists Priorities for FDA

WASHINGTON — Regulating overseas drugmakers who export their products to the United States will become a bigger focus of the Food and Drug Administration, FDA Commissioner Margaret Hamburg said at the annual meeting of the Endocrine Society.

"Food and product safety is a very compelling concern to me," said Dr. Hamburg, who was confirmed in mid-May by the Senate. "For FDA to re-enter our modern, global world is a high priority. … When you look at the number of facilities overseas all around the world that are manufacturing both drugs and food, it's a huge and growing challenge."

Like Dr. Francis Collins, a possible candidate for the office of director of the National Institutes of Health, who addressed the meeting the previous day, Dr. Hamburg called for more collaboration between her agency and the pharmaceutical industry. "Regulatory science is an essential yet still underdeveloped field," she said. "It's my hope to see expanded efforts in this area."

Dr. Hamburg also called for improving conditions for the agency's scientists. "We must be able to recruit and retain the best crop of scientists, and give them the facilities and opportunities they need," she said.

—Joyce Frieden