# Health & Science

PUBLIC HEALTH . CLINICAL ISSUES . PATIENTS

# Renewal sought for drug approval user fee law

Some observers are urging Congress to seek a proper balance between federal and drug company funding of the FDA.

SUSAN J. LANDERS

Washington A growing chorus of former FDA commissioners, medical journal editors, researchers, clinicians and consumer groups are voicing concern about the reauthorization of a 15-year-old law that allows pharmaceutical companies to contribute a large portion of the Food and Drug Administration's drug approval budget in exchange for quick review of their products.

Their message is that agency funds should come solely from federal coffers and not in the form of user fees from the same industry the FDA regulates. These experts are urging Congress via letters and journal articles to eliminate the Prescription Drug User Fee Act or substantially alter it.

The user fee, they charge, is a funding mechanism that threatens the integrity of the drug approval system and even could affect the agency's already shaky safety procedures by pushing for fast approval of possibly dangerous drugs.

But Congress is intent upon reaffirming the measure, calling it a "must-do piece of legislation," according to a spokesman for Sen. Mike Enzi (R, Wyo.), ranking member of the Senate Health, Edu-

cation, Labor and Pensions Committee. It is currently being considered as part of a larger bill . Without congressional action, the law will expire Sept. 30.

PDUFA supporters — who include the FDA commissioner and pharmaceutical companies —contend that the fees paid by the firms are as necessary now as they were when the law was first enacted in 1992 to help speed drug approvals. They would like to hang onto those funds, which would amount to nearly \$400 million next year, \$87 million more than last year when the fees accounted for about 40% of the FDA's total human drug program.

Under the current law, user fee amounts are rene-Continued on page 31

### Editorial cartoon exhibit

# Smoking is the butt of their humor



STEPHANIE STAPLETON AMNEWS STAFF

he themes are varied, brought to life by a multitude of images — from the fat cat tobacco executives to kids attracted to Joe Camel's cool.

All are part of "Cartoonists Take Up Smoking," an exhibit curated at the University of Alabama Center for the Study of Tobacco and Society in Tuscaloosa that is built around the work of a core group of 55 cartoonists addressing tobacco issues spanning nearly the last half century. It also features artifacts such as the original newspaper headlines that inspired the drawings, an original copy of the 1964 Surgeon General's Report on Smoking and Health, and a display of the Kent Mironite filter that contained asbestos and was advertised as safe and pure enough to filter air in hospitals.

With such items, the exhibit seeks to detail the nation's ongoing struggle with tobacco in general and cigarettes in particular. "The wide-ranging controversies sur-

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# TOBACCO COMPANIES RESPOND TO THE SHADDILLION FLORIDA LAWSUIT!!! THEY POEK NOT SEEK NOT TILEY ONLY SEEK NOT TUSTICE... ONLY MONEY!! THEY POEK NOT TILEY ONLY SEEK NOT TUSTICE... ONLY MONEY!! THEY POEK NOT TUSTICE... ONLY MONEY!! THEY ONLY SEEK NOT TUSTICE... ONLY MONEY!! TO MAIN MARS!! TO MARS!! T



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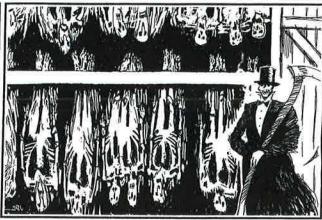
Taking on the big guys

Cartoons from Gary Brookings (Richmond Times-Dispatch, 1996), Kevin Kallaugher (Baltimore Sun, 2000), and Rob Rogers (Pittsburgh Post-Gazette, 1998) lampoon the relationship between the states and Big Tobacco while also raising public awareness of the lawsuits brought against the nation's largest tobacco companies to recoup the health care costs of treating smoking-related illnesses.

ART COURTESY OF THE UNIVERSITY OF ALABAMA CENTER FOR STUDY OF TOBACCO AND SOCIETY

### Editorial cartoon exhibit





J.D. Crowe, "Cash crop I and II," unpublished work drawn for the show

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rounding tobacco are captured in the cartoons, from the misguided quest for a safe cigarette to the targeting of tobacco advertising to women and minority groups," explained Alan Blum, MD, in a statement. He founded and directs the center and decades ago began the memorabilia collection it now houses.

The highlighted cartoons cover a broad swath of public opinion. Some convey adamantly antismoking messages, while others are critical of this crusade. Anyone can be a target - Big Tobacco, finger-waggers, lawyers, politicians and even smokers. The artwork has power - using humor to deconstruct the intricacies involved.

Dr. Blum, also a University of Alabama professor of family medicine, began developing this exhibit in 1995. But his fascination with the intersection of tobacco and popular culture dates back to the 1950s, when, as a child, his father encouraged him to begin the collection. As his stash grew, so did his opposition to smoking. By the time he went to medical school in the 1970s, he assumed everyone would be against smoking. He soon learned this wasn't the case. In 1977, he founded an anti-smoking group, Docs Ought to Care. He kept collecting and now describes his efforts as "a daily biopsy of this issue."

Dr. Blum views the role of cartoonists in the tobacco debate as pivotal. Nationally, he said, cartoonists have had a herd effect. "When they took on Joe Camel, they laughed Joe Camel out of existence." But they also have had significant impact on advancing local clean indoor air laws and smoking bans - affecting opinions of voters



Ben Sargent, Austin American-Statesman, 1998

as well as mayors and other local officials.

"Cartoonists Take Up Smoking" debuted in 2004 at the Ann Tower Gallery in Lexington, Ky., in conjunction with the Assn. of American Editorial Cartoonists annual convention. Most recently, it appeared at the National Museum of Health

and Medicine in Washington, D.C., and in the Nebraska State Capitol Rotunda in Lincoln. Its next stop is this month at the Buffalo Niagara International Airport in New York. For more information about this and the center's other tobaccorelated exhibits, e-mail ablum@cchs.ua.edu. •



Chip Bok, Akron Beacon Journal, 1998



Matt Davies, Journal News, Westchester, New York, 2000