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Malone, Ruth E

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FDA's toothless tiger and its "lost pleasure" analysis

Ruth E Malone

In 2009, amidst much fanfare, the United States Food and Drug Administration (FDA) was given the authority to regulate tobacco products when Congress passed the Family Smoking Prevention and Tobacco Control Act. Ostensibly, the Act provided the FDA with the legal authority to regulate the manufacturing, distribution, and marketing of tobacco products. There was a frisson of hope in some circles that at last, the process begun in the 1990s when David Kessler first attempted to regulate tobacco and was legally stymied by an industry lawsuit would finally come to fruition—and the makers of the world's most deadly consumer products would be brought to heel in the interest of consumer protection. In practice, however, the Act remains a fairly toothless tiger, defanged perhaps by its own "ingrained culture" of bureaucratic caution—a caution based on awareness of the many political and legal minefields surrounding its mission, and the tobacco industry's effectiveness at influencing federal policymakers.^{1 2}

While some were skeptical from the start that any significant tobacco control regulation will ever be forthcoming at the federal level, the FDA's economic

calculation of the effects of proposed graphic warning labels on the value of the "lost pleasure" when smokers manage to finally free themselves from the shackles of nicotine addiction was enough to make skeptics' bile rise higher. One would think it embarrassing for FDA to argue with a straight face that ending addiction to deadly products that most smokers want to quit using should be calculated as a cost due to the value of their "lost pleasure," creating temptations to quote from among the dozens of economist tropes suggesting that the discipline occupies an alternate universe. One wonders about regulatory capture, given the long history of tobacco industry manipulation of science and influence on regulatory agencies. Or it could be just another form of created "controversy," the time-worn industry strategy for delaying and weakening any regulation that might be effective. Whatever it was, it didn't pass the laugh test, although a widely read cartoonist made it the "butt" of a Sunday comic strip feature (*see page 120*).

Regrettably, one can't simply howl with laughter and make an analysis like this go away, even if it deserves to be laughed off the docket. In this issue, a group of world-class economists whose work is grounded in the science of real life revisit the issue and argue that the FDA's analysis "substantially underestimated the benefits and overestimated the costs, leading the

FDA to substantially underestimate the net benefits" of the warning labels.³ Their analysis has important implications not only for the warning label issues, but for other efforts to assess the economic impact of tobacco regulations, in the U.S. and worldwide. One can only hope that those in charge at the FDA will read it carefully and act on it.

Even if they do, however, with a Congress now firmly in Republican hands, it is highly unlikely that health-promoting legislation *or* regulation will emerge at the federal level in the near future. Thus, the tobacco control community must focus its energies at the state and local levels, from which US leadership in progressive tobacco control policy has historically always arisen. Meanwhile, the US (with some state exceptions) continues to fall further behind many other countries in enacting new measures to reduce tobacco's hideous toll.

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Correspondence to Professor Ruth E Malone, Department of Social and Behavioral Sciences, University of California, San Francisco, San Francisco, CA 94118, USA; ruth.malone@ucsf.edu

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