



ity taken away and given to the politicians. Companies could meet directly with Troy and decisions would be made without input from FDA staff."

But whether the FDA's current model of business is driven by budget

constraints or political philosophy, many in the medical community are concerned about what they believe is a growing laxity in both surveillance and enforcement by the agency, said Avorn.

"Dan Troy came in saying the FDA was doing too much enforcement and that on his watch there would be less of that—and he followed through on his words," Avorn said. "This [minority report] is not just a fantasy of Waxman's." □

Report Reviews Secondhand Smoke Risks Some Scientists Question Risk Level

Bridget M. Kuehn

AT A JUNE 27 PRESS BRIEFING launching his new report on the ill effects of secondhand smoke, Surgeon General Richard H. Carmona declared that "the debate is over." But some scientists continue to question the magnitude and immediacy of cardiovascular and lung cancer risks attributed to secondhand smoke exposure.

The report marks the 20th anniversary of the landmark 1986 Surgeon General's report on the health hazards of secondhand smoke and reviews data amassed since then. More than 20 scientists authored the report and more than 40 scientists reviewed it. Among its conclusions are that children exposed to secondhand smoke are at greater risk of sudden infant death syndrome and exacerbation of existing respiratory disease (<http://www.surgeongeneral.gov/library/secondhandsmoke/>). The report also concludes that secondhand smoke has immediate effects on the cardiovascular system and causes coronary heart disease and lung cancer.

Publicity for the report emphasized that everyone is at risk.

The report "documents beyond any doubt that secondhand smoke harms people's health," Carmona said. "There is no safe level of exposure to secondhand smoke."

BANS EMPHASIZED

The report, which provides a review of the literature to date, presents no new information. But some of its conclusions go further than previous re-

ports. For instance, the new report concludes that ventilation systems and designated smoking areas cannot eliminate secondhand smoke exposure.

"Smoke-free environments are the most effective and efficient approach to protection," Carmona said.

Many antismoking and health organizations applauded the report's emphasis on banning smoking in public. So did some physicians, including Michael Siegel, MD, MPH, a professor of social and behavioral sciences at Boston University School of Public Health. Siegel, who has advocated in the past for such bans and researched the health effects of secondhand smoke in the workplace, said evidence that secondhand smoke poses a danger to workers in restaurants, bars, and casinos is strong and that the report should be a wake-up call for policy makers.

"It's time to protect these workers. There are no more excuses," he said. He also advocated campaigns to re-

duce smoking in homes. "We need to do a better job of educating people about what the hazards are and develop interventions to try to help them quit smoking or institute smoke-free homes," he said.

More controversial was the surgeon general's emphasis on the immediate risks of exposure to tobacco smoke, particularly acute cardiovascular and lung cancer risks. While there is a large body of evidence on the health effects of chronic exposure to secondhand smoke, the evidence for more immediate effects is small but growing.

Among the more immediate potential effects examined in the report was exacerbation of respiratory disease. "For infants, children, and adults with asthma or with more sensitive respiratory systems, even very brief exposures to secondhand smoke can trigger intense bronchopulmonary responses that could be life threatening," the report notes.



The Surgeon General's latest report on secondhand smoke emphasizes the risks of exposure, including lung cancer, heart disease, and respiratory problems.



Evidence from animal and human studies also indicates prenatal and postnatal exposure of infants to nicotine or other substances in tobacco smoke may affect the neuroregulation of breathing, apneic spells, and sudden infant death. The report also cited animal studies that suggest possible mechanisms by which such exposures could lead to sudden infant death.

CANCER, CARDIOVASCULAR RISKS?

Terry Pechacek, PhD, associate director for science at the Centers for Disease Control and Prevention's office of smoking and health, said there is no safe exposure level to any carcinogen and that the carcinogens in secondhand smoke are no exception. Exposure could lead to the DNA damage that causes cancer, he said, and each new exposure increases that risk.

The report notes a dose-response relationship between secondhand smoke exposure and the development of lung cancer, similar to the dose-response relationship between smoking and lung cancer. It cited evidence from animal studies that showed a higher incidence of lung tumors in mice and rats exposed to secondhand smoke for extended periods. The report also found evidence that secondhand smoke exposure leads to increased levels of metabolites of a tobacco-specific lung carcinogen in the urine of nonsmokers.

At a press briefing, the surgeon general also emphasized acute cardiovascular risks associated with exposure to secondhand smoke: "The evidence indicates that even brief secondhand smoke exposures can have immediate adverse effects on the cardiovascular system. This is especially true for persons who already have heart disease or who are at special risk."

The report found that animal studies indicate that exposure to secondhand smoke promotes atherosclerosis and it also concludes that even brief exposure to secondhand smoke causes blood platelets to become more sticky and leads to endothelial damage in humans.

Although the report states that "the immediate effects [changes in plate-

lets and vascular function] of even short exposures to secondhand smoke appear to be as large as those seen in association with active smoking of one pack of cigarettes a day," scientists have concluded that exposure to secondhand smoke produces 1% or less of the exposure associated with active smoking. This discrepancy, along with limitations related to studies and meta-analyses on the acute cardiovascular risks associated with secondhand tobacco smoke, have led some scientists to question whether the evidence for an acute heart risk is conclusive (Mitka M. *JAMA*. 2004;291:2690).

John Bailar III, MD, an epidemiologist and professor emeritus at the University of Chicago, has no doubt that exposure to secondhand smoke poses some cardiovascular risk and supports smoking bans based on the demonstrated hazards of exposure. But Bailar continues to be skeptical of the magnitude of cardiovascular risk found in some studies. In particular, a 1999 meta-analysis that found nonsmokers exposed to secondhand smoke had a relative risk of coronary heart disease of 1.25 (He J et al. *N Engl J Med*. 1999; 340:920-926).

"It doesn't make sense for the cardiovascular risk of secondhand smoke to be as high as one third of the the risk from direct smoking," he said. "That's a far bigger ratio than risk for lung cancer and it's hard for me to believe that it's real."

He also noted that the risks should be in proportion to the level of exposure. "I think there probably is a risk from any exposure, but from very limited exposure the risk would be equally limited," he said.

PUBLICITY QUESTIONED

Siegel questioned the surgeon general's comments and promotional materials from Carmona's office that emphasize the acute risks. "It's very misleading to suggest to the public that you can walk down a street and breathe in a few whiffs of smoke and be at risk of developing heart disease or lung cancer," he said. "It takes many years for these chronic diseases to develop, and there's simply no evi-

For Further Information

Medline Plus (<http://www.nlm.nih.gov/medlineplus/secondhandsmoke.html>)

American Cancer Society (http://www.cancer.org/docroot/PED/content/PED_10_2X_Environmental_Tobacco_Smoke-Clean_Indoor_Air.asp)

The American Lung Association (<http://www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=35422>)

US Centers for Disease Control and Prevention (http://www.cdc.gov/tobacco/ETS_Toolkit)

dence that a brief exposure is enough to cause chronic health problems."

He said he felt the publicity materials and coverage in the media distort the evidence laid out in the report itself.

Pechacek, who coauthored a 2004 commentary arguing that there is a growing body of evidence that acute exposure to secondhand smoke could precipitate myocardial infarction (Pechacek TF and Babb S. *BMJ*. 2004;328:980-983), maintains that the evidence is strong enough that physicians should urge patients with cardiovascular disease or respiratory problems to avoid all exposure to secondhand smoke. He noted that there are a large number of individuals who are unaware of the status of their cardiovascular health and may be at risk. He also said that parents need to get the unequivocal message that they should not expose their children to secondhand smoke.

But Siegel said he believes public health officials should be emphasizing the well-established risks faced by individuals exposed in the workplace or at home, instead of suggesting that everyone is at risk. "We're really risking our credibility [as public health professionals or officials] by putting out rather absurd claims that you can be exposed briefly to secondhand smoke and you are going to come down with heart disease or cancer. People are going to look at that and say that's ridiculous." □