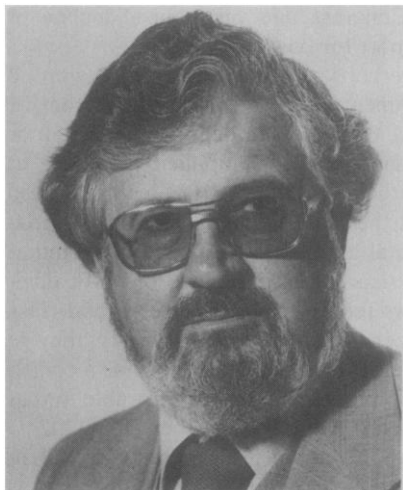


## FDA Caffeine Decision Too Early, Some Say

The Food and Drug Administration recently warned pregnant women to avoid or minimize their intake of caffeine because studies show it causes birth defects in animals. But whether caffeine has ever caused birth defects in human beings is still a big and troublesome question. The scientific evidence is "inconclusive," emphasized FDA commissioner, Jere Goyan. Nevertheless, the FDA has enough evidence to be concerned, he says.

The FDA expressly did not define safe levels of caffeine consumption because of the lack of data, so the choice is left largely up to the mother-to-be.



*Jere Goyan: No smoking, no drinking, and now no caffeine.*

Some physicians are worried that the FDA's warning may raise unnecessary guilt among women who already have babies with birth defects or may stir up undue fear in mothers-to-be. Women have already been cautioned by government agencies to limit their smoking and drinking while pregnant. "We must be careful to avoid creating an even more confused and skeptical public," says Allen Mitchell, a senior investigator for the Drug Epidemiology Unit of Boston University and an assistant professor at Harvard.

Says commissioner Goyan, "All the government is asking a woman to do is lay off alcohol, smoking, and caffeine. That is not taking anything away from the joy of pregnancy. Caffeine is

a drug that crosses the placenta and I can't see drugging a baby unnecessarily."

Vague as it is, the FDA's warning is premature, according to representatives of the coffee industry and some scientists. They believe that the animal data should have been supported by good studies on humans before a warning was issued.

Mitchell says that a wiser course of action would have been to announce the findings of the agency study and say simply that more studies would be done. Rather than calling the scientific evidence inconclusive, "I would have said that the evidence is not even strongly suggestive."

The agency study on caffeine was prompted in part by a petition in 1978 from a consumer group, the Center for Science in the Public Interest, which wanted warning labels on tea and coffee. Since 1976, its director, Michael Jacobson, has repeatedly urged the FDA to issue a notice about caffeine and has stirred up interest among the press.

The FDA study on caffeine, directed by Thomas Collins, is the largest that has yet been made on animals. Three hundred pregnant rats were force-fed at various doses. Offspring of mothers fed the equivalent of 12 to 24 cups of strong coffee daily were missing toes or parts of toes. The skeletal growth was slowed in animals whose mothers received the equivalent of two cups a day.

The possible relation between caffeine and birth defects has been studied for some 20 years, but many of the studies are flawed, says Collins. But even with the FDA study completed, the question remains: How relevant are animal studies to humans in teratology? "It's vague at best," says Mitchell.

The coffee industry contends that, because rats metabolize caffeine differently than humans do, animal data are not applicable in this case.

Jacobson, however, argues that there are studies on humans to back up the animal data that caffeine is a human teratogen. He says that at least two studies show that it is highly likely caffeine causes birth defects. FDA epidemiologists, looking at the same studies, differed, saying the experiments were poorly designed. The authors of one of the studies said, in a letter to *Science* (21 March 1980, p.

1296), that Jacobson was stretching their data. But Jacobson still holds fast to his original conclusion.

The problem of pinpointing a teratogen is further complicated by the fact that a host of factors bear consideration in an epidemiological study. Even then, a control group is hard to find because nearly everyone consumes caffeine, which is found naturally in coffee, tea, cocoa, and chocolate and is added to cola drinks and so-called "keep-alert" drugs.

Along with the caffeine warning, FDA announced a proposal to make the drug optional in cola drinks. By FDA definition, colas must contain caffeine.

The agency has asked the beverage industries to perform their own studies on caffeine and birth defects. Coffee manufacturers are already designing a large-scale study. FDA scientist Collins is continuing the second phase of his rat studies, examining the effects of caffeine when sipped by the animals. The results are expected next year.

## Sawhill Is Named Synfuels Chief

John C. Sawhill, deputy secretary of energy, has been named head of the Synthetics Fuels Corporation by President Carter. His appointment eliminates one of the chief weaknesses of the new multibillion-dollar program—the lack of a director (*Science*, 12 September 1980, p. 1208).

Sawhill, 44, will not be returning next year to the presidency of New York University, which gave him a leave of absence to work for the Department of Energy.

The Administration has looked for someone to fill the job since last spring but had difficulty in an election year. The President also appointed six others to serve on the board of directors.

Sawhill holds a doctorate in economics and finance and was a senior vice president of six financing companies at the Commercial Credit Company. He was also an associate director in the Office of Management and Budget. He has served as a director of Consolidated Edison, RCA, and Philip Morris.

**Marjorie Sun**