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U.S. Agencies Under Fire

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FDA Aiding Industry Most, An FDA Researcher Says

By MIKE MEYERS

The Food and Drug Administration is coming under increased attack from inside and outside the agency. But one of its biggest critics is inside.

The critic is Jacqueline Verrett, an FDA research biochemist whose studies are said to have disclosed the hazards of cyclamates.

Miss Verrett, who holds a Phd degree in biochemistry from Fordham University in New York City, joined the FDA in 1959 as a researcher a short time after leaving college.

SHE SAYS the FDA is doing more to benefit industry than it does to help the consumer. The regulatory agency, she says, is "in the untenable position of proving unsafe products which are already on the market."

Often the FDA unwittingly gives industry a hand by doing chemical research which should have been done by the company's own product testing division, at their expense, Miss Verrett said, in a telephone interview with The Press.

Though Miss Verrett said she wasn't personally involved in the incident, she said several months ago FDA officials rounded up many of their scientists for a crash two-day briefing on the then incomplete FDA findings on Red 2. A food coloring which has since been declared hazardous by the agency.

WHAT WAS the reason for the rush? The makers of Kooland wanted a quick FDA okay on using Red 2 coloring in their product, to avoid any later embarrassing and costly recall of Kooland from the shelves, Miss Verrett said.

From her experience, she contends the major handicap of the FDA is Congress limiting its powers and at the same time expecting the agency to do a mammoth job with neither the money, staff or organization to handle it.

Even when the agency devotes much staff and money to research problems such as cyclamates or hexachlorophene, "the industry exerts tremendous amounts of pressure on the FDA," Miss Verrett says.

During the FDA hexachlorophene probe, for example, an agency spokesman leaked preliminary findings which showed the chemical could be dangerous. The next day, a major drug maker stormed into FDA offices and demanded the spokesman be fired, she recalls. He wasn't fired.

THE FDA sometimes also faces less than-enthusiastic cooperation from business, Miss Verrett says.

Monsanto Co., for years the country's sole maker of PCBs, a toxic chemical used in heating and closed-circuit systems, some paints and pesticides, refused to disclose to the FDA just how much of the chemical was being dumped on the market, she says.

The chemical firm maintained silence even after PCBs had been identified as a dangerous contaminant in the milk of some cows, Miss Verrett says.

Detective work by the FDA traced the chemical back to the grain eaten by the cows, she says, adding the barns where the grain was stored had been coated with containing a PCB additive.

MISS VERRETT adds the FDA finally got the information by gleaning from an obscure chemical journal that contained production volume statistics.

"We have watched whole lines of product being built up without adequate testings. To be fair, we must realize some of these product have been around for years without an question of their safety," Miss Verrett says.

"However, pacifying and placatin statements by companies defending their products only on the basis that they've been o the market for 20 years doesn't mean they ar safe. After all, who's been looking for side ef fects all those years?" the FDA researche adds.

THE FDA ITSELF is sometimes guilty o "juggling figures and ignoring findings" o researchers, perhaps less out of any conspiracy with industry than from the way the FDA i run, Miss Verrett contends.

Under a recent reorganization of the agency FDA researchers are shut out of policy meetings where top-level FDA administrator discuss scientific findings, she says.

Miss Verrett says the exclusive "management approach" taken by the FDA in forming policy may contribute to confusion since the scientists aren't in the meetings to explain and interpret their findings.

"Basic down-to-earth scientific research is getting short shrift in the FDA," she says, adding "as a result we find ourselves workers from crisis to crisis" sometimes without a broad background of scientific data.

THE BEST WAY for consumers to be protected from useless or unsafe products is testing by an independent agency, not associated with either business or government," Miss Verrett suggests.

Industry sometimes tailors its research to suit its own ends and government bends to pressure, too," she says.

Nevertheless, Miss Verrett complains that at times her comments about the FDA have been distorted or taken out of context. The FDA administration of regulations under the right circumstances can be effective and responsive to consumers, she argues.

"I'm not out to provoke arguments with the administration, but sometimes it just doesn't

MONS 069877

News

File

Toxic Chemical

Scientists Discuss Effects Of PCB

DURHAM (AP) — Scientists from throughout the world gathered Monday in Durham to discuss the effects of the chemical PCB — a toxic industrial chemical — on human beings.

Dr. Atsuko Yamaguchi of Japan, who has studied human beings who ate food contaminated by PCB, said the chemical caused still births, birth defects, retardation of growth in young boys and other health problems.

Yamaguchi, a researcher for the Department of Public Health at Kyushu University, said there was an epidemic of a "peculiar skin disease which was later called Yusho" in 1968 in a Japanese town. He said it was traced to rice oil produced and shipped on a certain day.

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THE OIL was believed to have been contaminated with PCB which leaked from a heating pipe used in food processing.

PCB is a liquid with extremely high heat resistance. It is used in manufacturing when heat resistance is of primary importance such as in heating pipes and transformers. It has been used since 1930.

Yamaguchi said that of 13 pregnant women who ingested the rice oil, 10 delivered live infants, two delivered still-born infants and the child of one was dead from other causes.

The 10, he said, had "grayish, dark brown stained skin, nails and gingiva, and an increased eye discharge at birth."

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"AS THEY GREW older, the children's stained skin gradually faded. The majority of the babies were small for their periods of gestation," he reported.

Yamaguchi said, "Many patients with Yusho are still tortured by the disease even after more than three years. To cure them and prevent another epidemic, all possible worldwide cooperative efforts are highly desired."

Researchers attending the conference are from Sweden, Canada, the United States and Japan.

MONS 069878

PCB 'May Cause' Birth Defects

DURHAM (AP) — A Japanese researcher told a worldwide gathering of scientists yesterday that the industrial chemical PCB, used in food processing, is suspected of causing still births, birth defects and retardation of growth.

The researcher, Dr. Atsuko Yamaguchi, spoke to a convention of the National Institute of Environmental Health and Science.

PCB, polychlorinated biphenyl, was found earlier this year to have contaminated tons of fish meal processed at a Wilmington plant for use in feeding broilers, laying hens and hogs.

The toxic industrial chemical is a liquid that is highly resistant to heat. It is designed to be used in so-called closes systems, where it is not supposed to come into contact with food or feed. It has been used since 1930.

The contamination was found to be caused by a leak in a closed system at the Wilmington plant. The U.S. Department of Agriculture spent weeks trying to recall the meal from companies. There have been no reported cases of human beings becoming ill from this contamination.

Dr. Yamaguchi, a researcher for the Department of Public Health at Kyushu University, said there was an epidemic of a "peculiar skin disease which was later called Yusho" in 1968 in a Japanese town. He said the cause of the epidemic was traced to rice oil produced and shipped on a certain day.

The oil was believed to have been contaminated with PCB which leaked from a heating pipe used in processing the rice oil.

Of 13 pregnant women who used the rice oil, Yamaguchi said, 10 delivered live children, two delivered still-born infants, and the child of one was dead from other causes.

The 10 children born alive, he said, had "grayish, or dark brown stained skin and nails, and an increased eye discharge at birth. The majority of the babies were small for their periods of gestation."

Yamaguchi said, "Many patients with Yusho are still tortured by the disease even after more than three years."

Dr. Albert C. Kolbya, deputy director of the Food and Drug Administration's Bureau of Foods, said that in the United States "fish, primarily from fresh water locations, appear to be the primary source of exposure to PCB through foods.

"Most states having significant problems with fish contaminated by PCB have taken appropriate steps to restrict dietary intake by issuing public warnings and imposing other requirements," Kolbya sais.

● Kolbya also said that PCB gets into food through paper containers that contain the chemical and which are not removed from old bakery products before they are processed for feed.

"Recycled paper products may contain PCB in significant amounts," Kolyba said, "but the migration into contained foodstuffs usually is very minimal."

Day Care Center Opens

● *A new center has opened to give day care to children.* *See Page B1.*

● *The second article in the Christmas series is on Page B9.*

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