in their relations to the four other commissioners. Previously, meetings of the commissioners were run much in the fashion of a graduate seminar, with Seaborg presiding but not dominating. "He'd bend over backwards to bring all the other commissioners in on a discussion, as well as key staff," one observer recalls. "An issue would be discussed many times, worked through to some practical solution. He was very cautious, very patient, and often will-

Briefing

FDA's "Prudence" on Hexachlorophene

The Food and Drug Administration (FDA) last week announced sweeping restrictions on hexachlorophene, the antibacterial agent to which the public is now exposed through some 400 different products ranging from soaps to cosmetics and vaginal deodorants. "The only prudent course is to reduce the total human exposure to hexachlorophene," explained FDA Commissioner Charles C. Edwards.

The FDA's handling of the hexachlorophene affair affords in several respects a notable case study of regulatory action. If the FDA had not allowed the use of hexachlorophene to mushroom in the absence of adequate safety data, the situation would not have arisen in which millions of consumers are being exposed daily to a potentially brain-damaging chemical. Moreover, the various regulatory positions adopted by the agency appear to be markedly out of phase with the scientific data on which they were presumably based. The results of crucial experiments indicating that hexachlorophene causes lesions in the brains of rats were made available to FDA decision-makers in April 1970 and were communicated in preliminary form as early as July 1969 (*Science*, 19 November 1971). Yet as recently as 10 November 1971 agency spokesmen said there were no plans to seek an outright ban on hexachlorophene, only to require certain products to carry warning labels.

The only new evidence that appears to have come to light between then and last week's restrictions is a study submitted to the FDA on 19 November by Winthrop Laboratories, in which newborn monkeys washed daily for 90 days with a 3 percent hexachlorophene solution were found to have developed brain damage similar to that observed in rats. There is no immediately obvious reason why such a study, a necessary confirmation of the rat data, was not required or instituted by the FDA 21 months ago, when the rat experiments were first reported. (These experiments were carried out by FDA scientists based in Atlanta, Georgia, but because of the agency's protracted delay in granting permission to publish, the data have reached the public domain only in the last few months. In published documents, the FDA misleadingly refers to this data as a "recent" study.)

Few drugs are totally free of risk, but in most instances the risks are far outweighed by the benefits. Such is not the case with many of the uses of hexachlorophene; a report by the Drug Efficacy Study Group of the National Research Council, which was released last month by the FDA, concludes that hexachlorophene preparations are "lacking in substantial evidence of effectiveness for . . . the broad claim as a vaginal douche, in the treatment of chronic eczema, in irrigating or cleansing wounds and burns, and as an 'aid to personal hygiene.'"

An *FDA Drug Bulletin* issued last month gives the impression that this important study is of recent origin by stating that it was published by the FDA on 8 December 1971. In fact, the study has been in the FDA's possession for nearly 3 years, since April 1969.

The market for vaginal deodorants, most of which contain hexachlorophene as the principal active ingredient, has grown from nothing 5 years ago to a business worth $53 million a year and involving 24 million women. Probably more than half of this growth has occurred since mid-1969, by which date the FDA knew both that hexachlorophene was ineffective as a vaginal deodorant and that it was potentially damaging to mammalian brains.

The FDA has the strictly legalistic defense that vaginal deodorants are a cosmetic, and cosmetics, unlike drugs, are not required by the Federal Food, Drug, and Cosmetic Act to be proven safe and effective prior to marketing. The hexachlorophene incident seems to have stimulated an important reinterpretation of this *caveat emptor* policy. In a statement to be published this week in the *Federal Register*, the FDA professes, "It is fundamental that no manufacturer of a consumer product has the right to place that product on the market without first substantiating its safety. . . . In the case of a cosmetic, although the act does not require FDA approval prior to marketing, it necessarily contemplates that the manufacturer has obtained all data and information necessary and appropriate to substantiate the product's safety before marketing."

Because this has not been the case for hexachlorophene, the FDA found it necessary last week to ban the use of hexachlorophene as an active ingredient in cosmetics (it may be used as a preservative at a level no higher than 0.1 percent) and to require that soaps and other skin cleansers containing more than 0.75 percent hexachlorophene be available by prescription only. All antibacterial ingredients used to replace hexachlorophene in cosmetic compounds must be adequately tested for safety prior to marketing, failing which the packet must bear a prominent warning.

This regulatory action, which will safeguard the millions of consumers who use vaginal deodorants and high concentration hexachlorophene cleansers, is the direct—albeit long delayed—consequence of work by the scientists at the FDA's toxicology branch in Atlanta (the branch has since been transferred from the FDA to the Environmental Protection Agency). The scientists are Renate D. Kimbrough and Thomas B. Gaines, who first discovered the brain-damaging properties of hexachlorophene when they fed it to rats. These results were confirmed and extended by August Curley and Robert E. Hawk, also of the Atlanta toxicology branch. It is presumably indicative of the value placed by the FDA on good science that these scientists have not yet received any word of official praise or recognition for their achievement.

In a review of the hexachlorophene question made available to the FDA in May 1970, Kimbrough concluded "At the present state of our knowledge, the unnecessary use of concentrated hexachlorophene should be curtailed." Some 21 months later, Commissioner Edwards has acted on Kimbrough's advice.—N.W.