

of thousand pupils in the course of a year to lectures on the "performing arts" at Lincoln Center for The Performing Arts. The participant from a "broad cultural area" was of course Lincoln Center—a reflection of grass-roots participation if ever there wasn't one. In fact, the project was not even

FDA Wins Round in Panalba Fight

Panalba, a combination of tetracycline and novobiocin, is off the market. The Food and Drug Administration (FDA) has won a round in its long battle to remove drugs officially declared dangerous or ineffective from the market.

The Sixth District Court of Appeals in Cincinnati on 27 February upheld the FDA's authority to force such drugs off the market without granting the manufacturer a public hearing. Even when the issue is efficacy alone, the court said, the hearing is still optional; the manufacturer must show reasonable grounds for requesting one before the FDA must grant it.

The Court gave Upjohn Company, makers of Panalba, a deadline of 9 March for appeal to the Supreme Court, after which Panalba had to be removed from the market. The Supreme Court recently refused to stay this ruling, although it may still decide later to hear Upjohn's appeal.

The ruling gave the FDA a green light on removing Panalba and about 90 other drugs found hazardous or ineffective by investigative panels formed by the National Academy of Sciences—National Research Council.

The NAS-NRC had reviewed anti-infective agents that combine one antibiotic with another in fixed ratios, or antibiotics with sulfonamides. In addition to finding about 40 of these drugs to be ineffective, the review panels judged about 50 to be dangerous. The mixtures held hazardous as well as ineffective are the "pen-sulfas" (penicillin and sulfa), the "pen-streps" (penicillin and streptomycin), and Panalba (tetracycline and novobiocin). The FDA initiated action against Panalba in May 1969, after receiving the NAS-NRC reports.

A long series of hearings, writs, and court actions began (*Science*, 29 August 1969). The drugs at issue in the suit were four preparations of Panalba and three versions of the antibiotic called Albamycin. Upjohn said about \$30 million a year in sales was involved, 12 percent of its domestic gross income.

Upjohn's main contention was that it had a "right" to an administrative hearing before the drug was removed, and that the physician had a "right" to prescribe as he wished.

The FDA argued that a hearing is available so long as the issue is efficacy alone, but that, in a case such as Panalba, a hearing would be considered only if Upjohn could supply reasonable grounds for requesting one.

FDA counsel argued that, while such hearings were being sought and conducted, the maker would be free to continue selling the drug. And Panalba was sold throughout 1969; on 11 March 1970, Upjohn recalled it and sales were stopped at the wholesale level.

The way is now open for the FDA to deal with other combination drugs. Its next legal step, to be taken within about 2 weeks, is to issue a final ruling on manufacturers' objections to its pen-strep and pen-sulfa order and on the request for a hearing. It is expected that the FDA will deny the request for a hearing and will demand immediate removal of the drugs.

Upjohn has told the FDA it will remove its pen-streps and pen-sulfas from the market in advance of final FDA action.

Charles Edwards, FDA Commissioner, expressed himself pleased with the promptness with which Upjohn acted to remove Panalba and the other tetracycline-novobiocin drugs from the market. "Upjohn's action, taken on their own volition, is a very responsible corporate action in the public interest," he said.—NANCY GRUCHOW

an innovation since Lincoln Center had been conducting the same program with its own money before the advent of ESEA and, after 3 years of Title III funding, repaired to its own finances again. Another project that received a Title III grant in New York City was a nature course for elementary school children, which was conducted by a society called Nature Trails for Youth. Whether Nature Trails for Youth reflects community participation or not is questionable; moreover, as it turns out, the society had been taking school children on nature walks in conjunction with a program within the Board of Education for some 40 years before the passage of ESEA.

The Lincoln Center and the nature walk projects are typical of what happened to Title III money in New York City. The bulk of it went to operate programs that a handful of prestigious and well-endowed organizations had previously conducted with their own money. The rest of the money was divided among about a dozen tiny experiments with exalted names, but which usually petered out after a year and were not picked up by any other education agency.

How well Title III in New York City reflects the nationwide experience is hard to determine, since in fact, no national evaluation of Title III has been made.

One Title III project which USOE officials single out among those which proved "very successful" was conducted by the Board of Education of Montgomery County, Maryland, an affluent suburb of Washington, D.C. The project was a "Summer Music Camp" designed to give musically talented students 2 weeks of concentrated music instruction in rural surroundings.

Although the "Summer Music Camp" received a grant in 1966, the first year of Title III's operation, it had actually been established in 1965 and financed by the parents of the participants. More importantly, because the "camp" was exclusively for already well-trained music students, it was primarily a program for middle- and upper middle-class children. Aware of the antipoverty thrust of ESEA, the USOE approved the project with the proviso that Montgomery County not ask for a second-year "continuation" grant. They didn't.

Instead, they submitted a proposal and received a grant for a project entitled "A Maryland Regional Center for the Arts." The center turned out to be the summer music camp expanded