Antibiotics: Experts Question Value in Treating Colds; FDA Issues Ban on Use in Compounds

Because of a curious quirk in the drug laws, only five of the antibiotic "wonder drugs" that have come to play so crucial a role in medicine since World War II were ever subjected to government tests of efficacy for their intended uses. The five exceptions—penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin—were tested for both safety and efficacy. But subsequent additions to the list of antibiotics, or compound drugs utilizing one of the five, or one of their derivatives were either scrutinized by the Food and Drug Administration for safety alone, or—because of another gap in the law—permitted to go on the market without being scrutinized at all.

One result has been the promotion of a variety of antibiotic compounds for ailments for which some medical experts have long suspected they were useless. That needless use of antibiotics may diminish their effectiveness for an individual at critical times has been suspected for about 10 years. Concern has focused particularly on one possible source of overuse—the antibiotic preparations that allegedly soothe the sufferer from the common cold.

Medical skepticism about antibiotic treatment for colds was given official backing on 20 August, when the Food and Drug Administration released a report, submitted to it nearly a year ago, of a special panel on antibiotics, headed by Harry Dowling of the University of Illinois Medical School. The panel found "no acceptable evidence that any antimicrobial agent is of any value in the treatment of the common cold or of any other respiratory viral infection . . . [or] in preventing bacterial complications in patients with common colds who are otherwise healthy."

The Food and Drug Administration has taken two steps based on these findings.

1) On 23 July the FDA announced that producers of over-the-counter cold compounds, such as lozenges, nose sprays, and mouth washes, in which the antibiotic ingredient was said to act locally, had to prove the efficacy of their products. In the absence of medical proof of effectiveness these drugs—there are about 200 of them—will be taken off the market. The deadlines for proof are 6 September 1963 and October 1964, depending on when, and under what regulations the drug initially went on sale.

2) On 17 August the FDA announced to manufacturers of antibiotic compounds for prescription sale that it intended to remove their products from the market as well. The companies will have 30 days to offer objections before a final order is issued. The effect of this order will be to force doctors who now prescribe antibiotics in combination with analgesics, decongestants, antihistamines, or caffeine to prescribe an antibiotic alone. About 50 drugs, and about 20 firms, will be affected.

Manufacturers in both categories are known to feel that, whatever the final verdict on antibiotic treatment for colds, they probably cannot make an adequate case for their claims within the allotted time. It is a safe bet that many of the drugs will be off the market before the winter colds set in.

The ban on antibiotics is in accord with widespread, though not unanimous, medical opinion. But lest FDA's action be interpreted as a swift victory for scientific evidence, it should be noted that the utility of antibiotics in treating colds has been seriously questioned for at least a decade, and that the Food and Drug Administration had the Dowling committee recommendations in hand 10 months before it followed through. One FDA official ascribed the delay to a lag in "communications"; another, to the need to wait for the new drug laws under which FDA took action to come into effect. The fact is, however, that the new laws, permitting the FDA to evaluate the efficacy as well as the safety of new drugs, came into effect about the same time the Dowling committee report came in—nearly 1 year ago.

—ELINOR LANGER

Mental Health: House Committee Cuts Funds Proposed by Kennedy

The House Interstate and Foreign Commerce Committee has dealt harshly with President Kennedy's program for massive federal support for mental health activities, and with those who predicted it would glide easily through Congress.

The President proposed federal grants to states and private and public institutions over a 10-year period for: (i) construction of centers at universities and hospitals for research on and treatment of mental retardation; (ii) construction of community-based centers for the treatment of mental patients; (iii) contributions of up to 75 percent for staff salaries of the community centers; and (iv) training of teachers for handicapped, retarded, or mentally ill children.

The program did glide easily enough through the Senate. The Labor and Public Welfare Committee heard no opposing testimony, and the floor vote for the $848.5 million project was 72–1, with Nebraska Republican Carl Curtis standing alone.

The House committee, however, could not overcome a temperamental reluctance to pay the salaries of professional talent with federal funds. Congress has paid for "bricks and mortar" in many areas of general and medical education, and it pays for training grants and fellowships ungrudgingly enough, but it usually draws the line at actually supporting working talent. The result of the committee's total deletion of the $427 million slated for salaries of the staffs at the community mental-health treatment centers may be, as a disappointed Presidential aide put it, "shiny new buildings with inadequate professional staffs," for it is unlikely that many states or communities will be able to offer sufficiently attractive salaries out of their own resources.

The committee also chipped away at other edges of the program, reducing both the length of time grants can run without further congressional approval and the amount of money available for such grants. The un-grand total left by the Commerce Committee is about $238 million—roughly 30 percent of the Senate figure.

Though the administration may make some attempt to rescue its program, no real fight to restore the deleted funds is expected when the bill comes before the House. And any compromise reached between House and Senate, when the difference between them is so large, is unlikely to approach the Senate's upper limit. Although another $25 million may be added to the administration's overall mental health proposals from a separate provision, which comes under Social Security, to increase maternal and child health services and authorize grants for the care of prospective mothers with physical conditions likely to cause retardation of their children, the impact the President hoped to make on mental illness is bound to be rather drastically reduced.—E.L.