

of Science and Technology. For one thing, the committees of the Domestic Council which have been set up are likely to concern themselves with some questions of science and technology which would normally have fallen in the purview of OST—the development of an energy policy, for example. And for another, much of the work of OST during the past two years has been concerned with the relationship between investment in research and development and general economic policies. Such questions would presumably fall into the area of responsibility of Mr Shultz and the proposed Department of Economic Affairs.

These considerations, coupled with the fact that Dr Edward David and Dr John Baldeschwieler, the Director and Deputy Director of OST respectively, both left the White House earlier this month, have increased speculation that OST will be scrapped. One possibility which is now being voiced is that some of the staff of OST will be moved over to the Office of Management and Budget, while others may serve on the staffs of the committees of the Domestic Council. No plans have been announced, however, and members of OST are anxiously awaiting news of their future.

SCIENCE POLICY

Help for Kennedy

by our Washington Correspondent

A BILL was introduced into the House of Representatives last week which could greatly influence the prospects for Senator Kennedy's National Science Policy and Priorities Act. Numbered HR 32, the bill proposes essentially the same programmes and objectives as Kennedy's bill (which is numbered S 32), but attempts to overcome one of the chief objections that has been raised against Kennedy's proposals—that they would undermine the responsibility of the National Science Foundation to foster basic research.

Introduced by Representative Alphonzo Bell, a Republican member of the Subcommittee on Science, Research and Development, the bill would create two new agencies within the National Science Foundation—the Civil Science Systems Administration which Kennedy proposes and a Science, Research and Education Administration. The idea is for the Civil Science Systems Administration to sponsor applied research and development to solve urban problems, while the Science, Research and Education Administration would be concerned with the support of basic research and education. An important part of Bell's proposals is that the latter agency should receive at least 40 per cent of NSF's total budget and that

no funds could be transferred between the two branches of NSF.

Bell says that he has introduced the bill to meet objections raised during hearings on Kennedy's bill conducted by the Subcommittee on Science, Research and Development last year (see *Nature*, 239, 302; 1972). But his bill retains the proposal that spending on civilian science and technology should equal that on defence science and technology, and calls for a total expenditure of more than \$1,000 million over three years. It would therefore probably be vetoed by President Nixon if it were passed.

DRUG LICENSING

FDA at Law

by our Washington Correspondent

THE US Supreme Court has decided to resolve a legal conflict between the Food and Drug Administration and the several drug manufacturers who have challenged the FDA's procedures for taking ineffective drugs off the market. The future of the FDA's drug control programme could well hang on the court's decision.

The Supreme Court will review five cases which have recently been tried by lower courts and which turn on the question of whether the FDA is obliged to hold public hearings when it bans supposedly ineffective drugs. Also at issue is the scope of the provision in the food and drug laws which requires drugs to be effective and the role of the courts in deciding manufacturers' appeals against FDA actions. The Supreme Court is expected to review the cases in the spring

OBSESITY

Amphetamine Ban

IN spite of legal challenges to its procedures for ordering ineffective drugs off the market, the Food and Drug Administration has decided to stop the sale of anti-obesity products which combine amphetamines with other drugs. The agency believes that such combinations are no more effective than amphetamines alone, and has already taken steps to prevent their manufacture by asking the Department of Justice to eliminate production quotas for the products. Last month, the FDA warned that even amphetamines alone are of only marginal value in the treatment of obesity, and several witnesses before the Senate Select Committee on Nutrition and Human Needs urged that the combination drugs should be banned (see *Nature*, 240, 436; 1972).

and to hand down a decision by June.

The basis of the court cases is an amendment to the food and drug laws passed by Congress in 1962. Before then, the FDA had power to remove from the market only drugs judged to be unsafe. The 1962 amendment, however, gave the agency the power to require that drugs be effective as well as safe and the FDA set in train a review of the efficacy of the 4,000 or so drugs that it had then approved.

The review, carried out by the National Academy of Sciences, has already led the FDA to withdraw approval for more than 1,300 drugs. Such numbers would clearly be difficult, if not impossible, to handle under the agency's standard regulations for removing products from the market, which provide manufacturers with the right to a public hearing if they wish to contest the FDA's actions. The agency thus published new regulations in 1969 for dealing with supposedly ineffective drugs which, in short, give manufacturers the right to a public hearing only if they can provide substantial scientific evidence to show that their product is effective.

In one specific case, a drug called Lutrexin, the FDA ordered the manufacturer to withdraw the drug from the market because the NAS had found it to be only "possibly effective". The manufacturer asked for a public hearing, which the FDA denied, and the case then went to a court of appeals. The upshot was that the court ruled against the FDA, and the FDA subsequently appealed against the decision to the Supreme Court on the grounds that it would require the agency to hold public hearings on nearly all its cancellation orders. The FDA argues that such a requirement would cause a massive log-jam and effectively block the whole programme.

Another case being reviewed by the Supreme Court involves the question of whether the FDA has the power to ban from the market drugs which it has not specifically approved in the first place—the so-called "me too" drugs. Such drugs were allowed on the market without specific FDA approval because they have identical, or very similar, formulae to other drugs which had already been approved as safe.

The FDA claims that if it orders one drug off the market because it is ineffective, all others with the same formula should meet the same fate. A court in Philadelphia backed the FDA last year, but a court in Virginia ruled that federal courts and not the FDA must decide whether "me too" drugs could be ordered off the market under the 1962 amendment. This is another of the nuts the Supreme Court must attempt to crack.