SHIFT IN DECISION MAKING URGED

He suggested that one possible solution to the problem of drug review would be to take the decision-making power out of the FDA's hands and give it to a peer-review committee of outside experts.

"It would be comparable to the procedure followed by the British Dunlop Commission," Dr. Freis declared. "The consultants would draw up the protocol, define the kind of evidence required, and then let the FDA working echelons implement the policy. The decision as to whether the protocol has been satisfied would be left to the peer authorities."

Another fundamental criticism of FDA policy came from Dr. Lasagna, who voiced concern that the FDA is showing a "growing tendency to involve itself in details of medical practice."

"For example, the FDA is now making efficacy ratings of drugs, as well as offering the recommended sequence in which drugs should be given. Legally, there is no basis in the Kefauver Amendments of 1962 for accepting or rejecting drugs because of comparative efficacy. The point is that the ultimate application of a drug is part science and part art. It is simply not possible, at long distance, to define a unitary way of treating each patient. The FDA is doing what the Dunlop Commission [of Great Britain] consistently refused to do: getting involved in matters of professional judgment and application."

Like Dr. Freis and others, Dr. Lasagna called attention to the many new drugs available in Western Europe but not here. "The argument has been made that the FDA is protecting us from drugs like thalidomide and that we are being spared poor drugs. In the United Kingdom at least, one can't point to any large number of new drugs that are poor and one can find a number of new agents that are clearly useful."

He cited the availability of carbenoxalone, the drug of choice in gastric ulcer management in Great Britain. "In a recent poll of United Kingdom experts," Dr. Lasagna said, "this was rated as therapeutic maneuver number one. If that is so, it means that our patients are being deprived of an important drug."

"We have one beta blocker in the United States," he noted. "There are several in the United Kingdom. And even the one that we have is not approved for use in high blood pressure or angina, although the evidence suggests that it could be of benefit for those indications."

Dr. Lasagna deplored what he saw as a growing tendency on the FDA's part to violate governmental neutrality in scientific controversy. "There is nothing in the Kefauver Amendments to justify the FDA's acting as an umpire when medical experts disagree," he stated. "This is pharmacologic Lysenkoism—a Government line in science. Here, in an area where angels fear to tread, a Government agency has moved with alacrity!"

WORRIED BY DECLINING APPROVAL

In New York, Dr. Gilman, who is chairman of Albert Einstein's Department of Pharmacology, said that he, like his colleagues on the committee, is "concerned with the declining instance of approval of new drugs."

"That decline," he noted, "comes at a time when our research capacities are improving." He added that he has received "a lot of mail lately expressing a similar sense of concern."

Dr. Gilman commented on the delays experienced in getting a new drug into the hands of the clinician. "A New Drug Application at present takes two to three years. It is certainly one reason why the Europeans have more new drugs on the market than we do," he declared. "We must recognize, however, that the FDA has been given tremendous responsibilities without adequate manpower to meet those responsibilities."

He added that he was "encouraged" by recent evidence that the regulatory agency is eager to move more swiftly in approving new drugs. The FDA has hired an industrial research firm to review its methods of processing such applications, Dr. Gilman disclosed. And, he said, just one week before the interview with MEDICAL TRIBUNE, he had been an invited participant at a two-day meeting of pharmacologists, industry, and FDA leaders called to review methods for organizing a prospective follow-up of the development of an NDA or an Investigative New Drug.