enberg, Fye, Burke, Wooster, John Knauss of the University of Rhode Island, and others to persuade the U.S. delegation and the 130-odd member nations of the United Nations that oceanography is worth preserving are not unlike the tedium faced by encyclopedia salesmen. For just as an encyclopedia salesman avoids suspicious looking houses on the block, the science lobby must avoid several pitfalls. The Russians, for example, have a big ocean research program, but will not wholeheartedly support the open research plank in the U.S. position, because they seek to identify with developing countries. The Defense Department also, because it must be able to continue its classified work of snooping and listening in all parts of the ocean, has interests almost directly opposed to those of the scientists. And these are only a few examples.

As to whether the lobby group can successfully navigate these, opinions at the moment are pessimistic. Fye pointed optimistically to last year's cruise along the west coast of Africa by a Woods Hole vessel. "We had the effective participation of all the African nations except one," he said. "The most important concern is for the nations themselves," he added. But Wooster was more gloomy. He pointed to the inertia of some European scientists who are unaffected by the

Physicians Who Falsify Drug Data

Among the many technical problems that entrammel the testing of new drugs, there is a simpler failing that enters in perhaps more often than might be expected—cupidity. Doctors in charge of investigating new drugs turn in fictitious data to the sponsoring drug companies and pocket the fees for studies they never conducted.

How often this happens is hard to say, except that probably only the outstandingly careless get caught. The problem is sufficiently serious that in 1967 the Food and Drug Administration set up a six-man Scientific Investigations Group headed by Frances O. Kelsey, the medical officer who prevented thalidomide from being marketed in the United States. Of the 50 or so physicians investigated by the Kelsey unit and its predecessor, 16 have been found to have supplied false data on drugs to the sponsoring companies and the government.

The erring physicians are usually no more than blacklisted by the FDA from testing further new drugs. Occasionally criminal proceedings are brought. Last month, a Louisiana grand jury indicted an associate professor of medicine at Tulane University, Wallace Rubin, for having submitted false reports on two drugs to two drug companies. FDA officials allege that the two drugs were apparently given to the same patients on the same days, in such a manner as to suggest that either one or both of the reports were fabricated.

Drug testing is a lucrative business. A sophisticated study of two dozen patients for 2 weeks may net an investigator $6500. If the investigator should elect to submit the same data to another sponsor, he will receive $13,000 for his 2 weeks' work. Several clinical investigators are known to gross more than $1 million a year from their testing programs.

Incentives of this order lead some physicians to take shortcuts. Sometimes data are fabricated from start to finish. "When our pharmacologists read reports concerning the negative findings in rat gall bladders and the testes of female animals, we are tempted to believe the investigator is cutting some corners," says Alan B. Lisook, the medical officer with the Scientific Investigations Group.

On one occasion the group's pharmacologist requested an investigator's slides for review and found he was able to assemble them in such a way as to represent serial sections of the liver of a single animal. Similar economy was attained by an investigator who applied to the FDA for permission to conduct clinical trials and was found to have performed all his preclinical work in a single animal—a rabbit, which, according to Lisook, went under the name of Ebenezer.

The Kelsey group has sometimes found paroled inmates and discharged mental patients reported as being treated in situ for weeks after their release. Concerned with the ethics as well as the validity of drug data, the group has uncovered consent forms of senile patients signed "X-(her mark)" and even some forms executed posthumously. On one occasion, the group questioned a set of women patients on their understanding of the consent forms they had signed and found the patients were not fully aware that they were even participating in an experiment.

Instances of outright fraud are less common than failure to keep proper records, excessive delegation of authority, and other administrative failings. The group's general criteria for investigating investigators are if a physician's data are of unique importance to the status of a new drug or if he has conducted an unusually large number of investigations on a wide variety of drugs. When an investigator is delisted, all drug companies who have ever used him are required to provide independent corroboration of his data, if the data are crucial to the standing of a drug.

In most cases of outright fraud, the investigator is deceiving both the sponsoring drug company and the government. Do investigators and drug companies ever collude to deceive the government? "There are companies who are not above hiring investigators who will give them the results they desire," Lisook believes. "This happens, but it is something you cannot prove beyond a reasonable doubt," says FDA attorney Eugene Pfeifer.

The Scientific Investigations Group has recently started a new program in which, instead of checking on individual investigators, they study the records supporting the introduction of new drugs onto the market. At the last count, 25 such studies had been completed, of which no fewer than five, or 20 percent, have uncovered matters sufficiently wrong to require official action, whether a reprimand or the barring of the physician from further investigations. Most of the cases involved failure to keep or provide complete records, rather than demonstrable wrongdoing.

The FDA is not unkind to those it catches fudging data. Last month's indictment is only the second that has ever been brought. And four of the 16 investigators barred from testing new drugs have been allowed back on the list.—N.W.