"Our responsibility is not the direct supervision of the [drug] investigators," Dr. Ley said in an interview. "Our responsibility is to evaluate the data that come in to us. We can't be omnipotent or omniscient."

While the agency has never found occasion to reprimand Dr. Stough, its inspector, Dr. Alan B. Lisook, did make some "suggestions" earlier this year about "the lack of medical supervision of patients."

NOT ENOUGH SUPERVISION

"We told him we thought there should be more supervision," Dr. Lisook said, "and he admitted there was not as much as he would like because of the volume of drugs being tested."

This was virtually an acknowledgement by Dr. Stough that more tests had been undertaken than could be adequately overseen, but the F.D.A. did not require change.

The agency "frowns" on insufficient supervision, Dr. Ley said, but under present policies there are no specific minimum standards. In the gray area that results, frowning is about the limit.

Since between 25 per cent and 50 per cent of the phase one studies have been concentrated in Dr. Stough's hands, Dr. Ley was asked whether volume alone—quality aside—concerned his agecny.

"It's a red flag, there's no question about that," he replied. But the commissioner explained that neither law nor regulation permitted the agency to force a cut back in the number of studies assigned to a single man.

There is no step short of outright disqualification for obvious misconduct, Dr. Ley said. That is an action the F.D.A. has taken no more than a dozen times in its history.

SHORTAGE CHARGED

The drug companies contend there is a shortage of investigators, and Dr. Ley said that while he believed there were enough to study the "really new drugs," he wanted to avoid charges that the agency blocked progress.

"It's harder to get a driver's license in the United States than it is to get fatal drugs," complained Dr. William M. O'Brien, an associate professor of preventive and internal medicine at the University of Virginia. He added:

"To get a driver's license you have to take tests, show you know how to drive, and so on. For drugs, you just walk in the door and say, 'I'm an M.D. I want to test drugs.' It's fantastic. It's unbelievable."

It is difficult to measure the precise sums of money that the pharmaceutical industry has poured into Dr. Stough's operations, but a number of reliable clues are available.

Operating within at least nine separate corporations, the major one of which is Southern Food and Drug Research, Inc., Dr. Stough has a gross income in a good year probably approaching $1 million.

SMALL OVERHEAD

He has not carried a high overhead. His net income in Alabama in 1967 was nearly $300,000 (on a $500,000 gross), and his profit before taxes in Arkansas in 1966 was about $150,000.

The Alabama Medical Association's committee treated the drug manufacturers with circumspection in its report, suggesting that the companies could hardly police the state's prisons.

But it pointed out that the makers, as well as the Food and Drug Administration, had engaged in monitoring of the drug tests that might have been "too superficial and too remote to provide maximum safety."

The committee also found that in sponsoring Dr. Stough's tests the drug concerns had given "tacit approval" to his research. In this, it reported, the companies had "demonstrated some lack of discretion."

"Our companies are usually pretty careful about who they have doing phase one work," said Dr. C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association. "They aren't interested in guys who aren't doing a first-class job."

Mr. Stetler said that some concerns might make more rigorous over-all studies of potential investigations than others and that in some instances the day-to-day supervision "gets to be seemingly routine."