The drug had come into widespread use in other countries. In West Germany, where it was used primarily as a sedative, huge quantities of it were sold over the counter before it was put on a prescription basis. It gave a prompt, deep, natural sleep that was not followed by a hangover. It was cheap. It failed to kill even the would-be suicides who swallowed massive doses.

And there were the reports on experiments with animals. Only a few weeks ago the American licensee told of giving the drug to rats in doses 6 to 60 times greater than the comparable human dosage. Of 1510 offspring, none was delivered with "evidence of malformation."

In a separate study, one rat did deliver a malformed offspring, but the dosage had been 1200 times the usual one. Rabbits that were injected with six times the comparable human dose also were reported to have produced no malformed births.

Recently, the FDA publicly decried the "excessive contacts" made with its personnel by pharmaceutical manufacturers who are anxious to speed the agency's handling of new-drug applications.

MANY REQUESTS

So it was not at all surprising that dozens of contacts were made with Dr. Kelsey by representatives of the American licensee for thalidomide, the chemical name for the sedative. They had what they strongly believed was a clear and overwhelming case—but Dr. Kelsey delayed, and delayed, and delayed.

They visited her in her drably furnished, bare-floor office in an eyesore Tempo on Jefferson dr. sw. They phoned. They submitted a flow of reports and studies. It was apparent that substantial investments and substantial profits were at stake. And all of this was routine.

The application had come to Dr. Kelsey—simply because it was her turn to take the next one—in September, 1960.

The European data left her "very unimpressed." In an interview, she said she had "lived through cycles before" in which a drug was acclaimed for a year or two—until harmful side effects became unknown.

And, she said, she could not help regarding thalidomide as "a peculiar drug." It troubled her that its effects on experimental animals were not the same as on humans—it did not make them sleepy.

SAME QUESTIONS

Could there be danger in those few people whose systems might absorb it? Could there be a harmful effect on an unborn child whose mother took it? (In other countries obstetricians were innocently prescribing it as an anti-emetic for pregnant women.)

Dr. Kelsey regarded the manufacturer's evidence of thalidomide's safety as "incomplete in many respects." The drug was not, after all, intended for grave diseases, or for the relief of intolerable suffering, but primarily for sleeplessness, for which many drugs of known safety were already on the market.

All of this being so, she saw no need either to hurry or to be satisfied with the approach that, nine chances out of ten, it's safe. She was determined to be certain that thalidomide was safe ten times out of ten, and she was prepared to wait forever for proof that it was.

When the 60-day deadline for action on the application came around, Dr. Kelsey wrote the manufacturer that the proof of safety was inadequate. Perhaps with an understandable feeling of frustration the manufacturer produced new research data, new reasons for action. Each time a new 60-day deadline drew near, out went another letter: insufficient proof of safety.

UPHELD BY SUPERIORS

Dr. Kelsey's tenacity—or unreasonableness, depending upon one's viewpoint—was upheld by her superiors, all the way.

Although she takes her work seriously indeed, her contacts with applicants are, in her words, "usually amiable. We see their point, and they see ours. But the responsibility for releasing a drug is ours, not theirs." And that is the responsibility she would not forget.

In February, 1961, she chanced to read, in a British medical journal, a letter from a British doctor questioning whether certain instances of peripheral neuritis—a tingling and numbness in the feet and the fingers that is sometimes irre-