to Eli Lilly & Co., in an interview recorded last Nov. 6 by "This Hour Has Seven Days," a Canadian Broadcasting Corp. program.

"The effects of birth control pills have been studied possibly more thoroughly and for a longer continuous time on the same persons than any other drug."—G. D. Searle & Co., manufacturer of Enovid, the first oral contraceptive.

Among critics, there is a growing belief that the confidence of most of the medical profession in the pills is, at least in part, a result of inadequate information, wishful thinking and questionable scientific and statistical analysis.

In the Searle statement, for example, critics say the word "possibly" automatically raises questions about the quality of the testing.

They also make a more serious objection. (Because the pill studies have not been controlled, the data are less meaningful than that from scientific investigations made of other drugs in fewer people over shorter periods.

Apart from contraception, the pills are recognized to have purely medical uses for many women, such as treatment for abnormal bleeding not caused by benign or malignant growths. This is one of the reasons why none of the doubters, so far as is known, advocates taking the pills off the market.

In addition, the benefit/risk ratio is variable. It is at one level for a mother who may die if she becomes pregnant again and goes to a Planned Parenthood clinic, but who cannot be relied upon to use a mechanical method of contraception.

It is different for a woman who is willing to use a diaphragm but has been inspired by popular reports to ask her doctor for a prescription for the pill.

The advocates contend that the incidence of harmful effects is extremely low. But the fact remains that they have not established that the rate is low, or that it is even as low as they say it is, or that it is not actually many times higher than they say it is.

In addition, there is a widespread, resentful, "don't rock the boat" attitude in the medical profession.

Recently, one manufacturer said that if warnings about the pills are widely circulated, "literally *millions* of American women could be thrown into panic regarding the safety for *all* oral contraceptives."

Dr. Gregory Pincus, co-developer of the pill with Dr. John Rock, says it has yet "to be proved that there is a cause-and-effect relationship" between use of the pill and subsequent ill effects suffered by some.

DEGREES OF EVIDENCE

This is generally conceded. But those who keep speaking of lack of proof of a causal relation in regard to the pills, and many other drugs as well, fail to specify just what degree of evidence would in their eyes, constitute proof. One such is Dr. Joseph F. Sadusk Jr., medical director of the Food and Drug Administration.

The advocates imply that proof can be black or white, that it has a finality that all would concede.

Scientists recognize, however, that there is no proof—that evidence is in a gray area, that it is relative, that it boils down to sufficient data on *relative* risks. This is the kind of data on which persons charged with protecting the public health must judge the relative safety of all drugs. With a small chance of being wrong, they must decide whether the occurrence of adverse reactions is significantly more than would have arisen under normal conditions.

To insist upon certainty rather than compelling evidence of lack of safety is to risk the public health.

Dr. LeRoy E. Burney, while Surgeon General of the Public Health Service, has said that to wait for "proof" is "to invite disaster, or at least to suffer unnecessarily through long periods of time."

CHALLENGE AND RESPONSE

In the case of oral contraceptives, it has not been proved, and perhaps never can be, that they can cause, say, painful migraine—a possible indicator of more serious trouble in the bloodways.

But some women who had never had migraine get it on the pills, lose it when they go off the pills and get it again when they resume taking the pills.