Line 5 assumes no induced abortions and the number of conceptions is computed as follows:

$$P=\frac{100,000\times 12}{8+4+80}=\frac{1,200,000}{92}\cong 13,000$$

$$P'=\frac{100,000\times 12}{8+14+80}=\frac{1,200,000}{102}\cong 11,800$$

The corresponding number of deaths is on the order of 2.5 per 100,000 women per year.

Line 6 assumes that all pregnancies are aborted out of hospital by lay abortionists. The number of pregnancies increases slightly, owing to the shorter gestation and post-gestational anovulatory periods.

$$P=\frac{100,000\times 12}{3+1+80}=\frac{1,200,000}{84}\cong 14,300$$

The expected number of deaths is 14.3 per 100,000 women per year.

In line 7, the same number of abortions is performed legally in hospitals and the number of deaths drops to 0.4 per 100,000 women or approximately one-seventh of the corresponding values shown in line 3 for no contraception but legal abortion, and in line 4, for oral contraception.

On the basis of this model, the following is my conclusion: In terms of the risk to life, the most rational procedure for regulating fertility is the use of a perfectly safe, although not 10 per cent effective, method of contraception and the termination of pregnancies resulting from contraceptive failure under the best possible circumstances, i.e., in the operating room of a hospital.

While comparable estimates of morbidity, associated with pregnancy and childbirth, abortion out of hospital and in hospital, and oral contraception, are not available, it is not unlikely that the pattern would be similar to that which has been demonstrated in terms of mortality.

Mr. DUFFY. Doctor, on the question of informed consent, while I don't have the package insert with me I have taken an extensive look at it from time to time in the past, and it really is quite horrendous when you read that long list of the risks and problems that a woman exposes herself to when she takes the pill. I note you felt it important that pill users be provided with this list in the process of arriving at their consent to use the pill.

My question is essentially this: The only opinion which meets Government standards that we have at this point as far as I know is an FDA study which concludes, after much study, that the pill is safe. Now, if we were to approach informed consent from a legal point of view—that is, a recognized risk which one must freely consent to—haven't we reached some important conclusions at this point? The FDA says the pill is safe. Only one of those items on the package insert has been documented to satisfy a legal standard and that is thromboembolism. So all of these things on the list that you are going to inform the woman about—all of these very grave and frequently remote risks—you only have one that has been documented to any sort of a legal standard. Even when you take this list and look at it in gross, the legal conclusion—the FDA study conclusion—is that the pill is safe. This poses substantial legal questions—on what are we going to base this informed consent at this point. You agree that we must have some legal standard to relate to.

Dr. HERTZ. Yes.

Mr. DUFFY. Otherwise from a legal point of view, from a medical malpractice point of view, from many other points of view, we would just be taking a stab in the dark. We may very well have people consenting to risks which do not, in fact, exist and thereby causing much needless anxiety.