

Mr. DUFFY. Excuse me, Doctor, but just a casual reading of the FDA conclusions might indicate that that last sentence is still correct. Are you suggesting to us that the statement is not correct?

Dr. KASSOUF. I think I submitted evidence that this is, perhaps, not the best tested and certainly not the best reported drug. That is in my experience as a practitioner.

I do not think the FDA report says anything about birth control interfering with nature to any extent less than repeated pregnancies.

Mr. DUFFY. Maybe I was not specific.

Dr. KASSOUF. I am sure that that is a fact.

Mr. DUFFY. I was confining my remarks to the last sentence.

Dr. KASSOUF. The fact that the FDA report comes in 9 years later means to me these pills have not been studied more thoroughly than other drugs, and in addition evidence of their safety and effectiveness is not what the FDA report found.

If one reads the report and not the conclusion, one must disagree wholeheartedly with that legal statement. I am always suspicious when doctors make a legal statement. The conclusion said that they designated it legally safe. Why don't they make a medical judgment? In the report itself a death risk was documented and a risk of pulmonary embolism confirmed.

Mr. DUFFY. Would you agree with me, though, that the report—remember I am not a doctor and I cannot read this report the way you would, but I certainly can read the section of that report that gives the conclusion and that section says all things considered, the pill is safe.

Dr. KASSOUF. Of course you read what you want to read.

Mr. DUFFY. If you read your last sentence, which was the one I am asking you about it says “* * * evidence of their safety and effectiveness has been continuously confirmed.” This was published in 1966. In 1969 FDA says the pill is still safe.

Dr. KASSOUF. But it is still in circulation. If you read the FDA conclusion, you have one leg to stand on. If you read the rest of the report you have two legs to stand on, and if you read the report you will find a definite risk of clotting was established.

I do not interpret these two events in the same manner as you do, that evidence of their safety and effectiveness has been continuously confirmed. I think the FDA report tells us this after 9 years of concern. This particular committee has been at it 2 to 3 years, and finally they confirmed a risk. I do not think they found safety, they found a risk. This is how I interpret it.

If the patient asked me what did the 1969 FDA report find, I would have to tell them it found evidence of pill injury.

Mr. DUFFY. This will engage us, of course, in a discussion of what safety means, but I think the report did say that all things in balance, benefit versus risk, the pill is safe.

Dr. KASSOUF. I heard that discussion this morning, but everyone conveniently left need out of the benefit-risk ratio. Chloromycetin has a tremendous benefit-risk ratio, but I suggest you do not take it unless you desperately need it. Until you put need in that ratio, that conclusion is meaningless.

One other thing about that was discussed in the conclusion. It seemed convenient to invoke the idea of universal toxicity about drugs.