

What do you suggest that we may do to make certain that we find a better pill or a safer pill or some other contraceptive because of difficulties you recite?

Dr. SPELLACY. There are metabolic changes that are still in debate. There are also areas of change that are very clear. For example, elevations of triglycerides, glucose, and insulin. These occur for most of the drugs in any population, studied in most laboratories, so you do not have to do a hundred thousand ladies to document this statistically.

What can we do to avoid this? Well, in Dr. Corfman's section they are pursuing other means of conception control, and this is certainly one approach but probably with a distant solution. We have an immediate problem and we do not want to wait for another 30 years for a solution so let us hope in the next 3 or 5 years we can switch these women to an intermediate drug as a preparatory solution. Research and development must be continued. Thus there may be three phases: (1) monitor our women on the current oral contraceptives, (2) develop a less toxic form of conception control as an intermediate solution, and (3) continue basic research for a new means of nondrug conception control.

Senator DOLE. What do we do in the meantime, do we continue to use the pill?

Dr. SPELLACY. This would be my phase 2 intermediate solution. We should abandon the use of the term "oral contraceptive." We should find the steroid(s) that will prevent pregnancy and that has the least amount of adverse effects. Although we do not know what happens if you walk this earth for 20 years with a high blood triglyceride levels, but it makes some of us uneasy. There are steroids that can prevent pregnancy and which allow women to walk this earth without high blood triglyceride levels. It would seem to me that the approach in the interim until better methods are available, would be to move in the direction of the use of safer steroids.

Senator DOLE. That is all I have.

Mr. GORDON. Doctor, someplace in your statement, I do not recall what page, you refer to a drug, chlormadinone.

Dr. SPELLACY. Yes.

Mr. GORDON. What kind of a drug is that?

Dr. SPELLACY. That is one of the many progestins, it is a synthetic progesterone-like drug.

Mr. GORDON. Is this connected with the minipill that was withdrawn from—

Dr. SPELLACY. It has been studied as a minipill.

Mr. GORDON. And is this a dangerous drug?

Dr. SPELLACY. Apparently if you are a beagle dog, female. The studies that we and others have performed in humans show very few effects of this steroid on metabolism as compared to, for example, estrogen or some of the other progestins.

Mr. GORDON. Is this now in any of the pills that are on the market?

Dr. SPELLACY. Yes; it is one of the sequential oral contraceptives which have been studied extensively, and I think this is probably a partial explanation for the fact that "sequentials" get branded as not having much effect on carbohydrate metabolism; that is, the ones studied contain that specific progestin. Again we come back to the importance of specifying what kind of progestin is involved in the oral contraceptive under study.