References

- ¹ IARC Monographs, 21, 461-477, 1979
- ² Yager, J.D., Jr & Yager, R. (1980) Oral contraceptive steroids as promoters of hepatocarcinogenesis in female Sprague-Dawley rats. *Cancer Res.*, 40, 3680-3685

NORGESTREL (Group 3)

A. Evidence for carcinogenicity to humans

No data were available.

B. Evidence for carcinogenicity to animals (inadequate)

Norgestrel was tested in mice and rats, alone or in combination with ethinyloestradiol, by oral administration. There was no increase in the incidence of tumours in either species¹.

C. Evidence for activity in short-term tests

No data were available.

Reference

¹ IARC Monographs, 21, 479-490, 1979

PROGESTERONE (Group 2B)

A. Evidence for carcinogenicity to humans

No data were available.

B. Evidence for carcinogenicity to animals (sufficient)

Progesterone was tested by subcutaneous and by intramuscular injection in mice, rats, rabbits and dogs and by subcutaneous implantation in mice and rats. It was tested alone in mice and dogs; in rats and rabbits it was given in combination with other sex hormones. When given alone, progesterone increased the incidences of ovarian, uterine and mammary tumours in mice. Neonatal treatment with progesterone enhanced the

occurrence of precancerous and cancerous lesions of the genital tract and increased mammary tumorigenesis in female mice¹. Dogs treated with progesterone for four years at 1-25 times the luteal phase levels in that species developed mammary dysplasia and a dose-related incidence of mammary gland nodules².

C. Evidence for activity in short-term tests (inadequate)

Chromosomal abnormalities were induced in meiotic germ cells of female hamsters and of male dogs treated with progesterone *in vivo*, and in cultured human embryonic fibroblasts and renal epithelia treated *in vitro*. No anomaly was seen in human lymphocytes treated *in vitro*¹.

| | DNA damage | Mutation | Chromosomal anomalies | Other |
|----------------------------|------------|----------|-----------------------|-------|
| Prokaryotes | | | | |
| Fungi/Green plants | _ | | | |
| Insects | | | | |
| Mammalian cells (in vitro) | | | ? | |
| Mammals (in vivo) | | | + | |
| Humans (in vivo) | | | | |

References

OESTRONE (Group 2B) (See Oestrogens and progestins)

OXYMETHOLONE (Group 2A)

A. Evidence for carcinogenicity to humans (limited)

Although ten cases of liver-cell tumour have been reported in patients with aplastic anaemia, Fanconi's anaemia or paroxysmal nocturnal haemoglobinuria treated for long periods with oxymetholone alone or in combination with other androgenic drugs, a causal relationship could not be established¹.

¹ IARC Monographs, 21, 491-515, 1979

² Frank, D.W., Kirton, K.T., Murchison, T.E., Quinlan, W.J., Coleman, M.E., Gilbertson, T.J., Feenstra, E.S. & Kimball, F.A. (1979) Mammary tumors and serum hormones in the bitch treated with medroxyprogesterone acetate or progesterone for four years. *Fertil. Steril.*, 31, 340-346