





Campaigners vow to fight on after report finds no link between hormone test and birth defects

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Campaigners have called for a judicial review after a UK government report found that hormone based pregnancy tests (HPTs) given to women in the 1960s and 1970s did not cause birth defects.

An expert working group of the Commission on Human Medicines, an advisory non-departmental public body sponsored by the Department of Health for England, found that after "an extensive review" of the evidence on the tests there was no "causal association between the use of HPTs . . . and birth defects or miscarriage."

Marie Lyon, chair of the Association for Children Damaged by Hormone Pregnancy Tests, said that she would carry on campaigning. "We are definitely going to challenge this, and we are going to ask for a judicial review," she said. She added that the working group had not followed the review's terms of reference to look at an association between the drug and the birth defects, instead looking at evidence for a causal link, she said.

The most widely used pill, given to women in the 1960s and 1970s to detect pregnancy, was Primodos, manufactured by the German drug firm Schering, since taken over by Bayer. Primodos contained a synthetic version of progesterone, norethisterone acetate, and a synthetic version of oestrogen, ethinylestradiol. Women took two pills over two days, and a bleed within a few days would indicate that they were not pregnant.

The pill was withdrawn over safety concerns and with the introduction of other forms of pregnancy testing.

Most of the scientific evidence considered by the working group was from the 1960s, 1970s, and early 1980s, including unpublished papers from Schering. The group also saw data

from a new study carried out by Neil Vargesson, senior lecturer in developmental biology at the University of Aberdeen, but did not consider this in the report because it had not yet been published.

Vargesson's study looked at exposure to norethisterone acetate and ethinylestradiol in zebrafish embryos. He said that he had detected some abnormalities and now needed to do further studies in mammals.

He told *The BMJ*, "From the outset we suspected what the working group's answer would be. The group was looking at scientific studies that are 30 to 40 years old. Some of the studies suggested a link and some didn't; in addition, there are not actually that many scientific studies available. So what should have been done is to fund new research using modern technology and imaging tools, and once that has been done they could have come to a definitive conclusion."

The working group's report said that women who had taken a hormone based pregnancy test and who experienced adverse outcomes of pregnancy should undergo a genetic test to see whether an underlying genetic cause could be identified.

Ailsa Gebbie, the group's chair, said, "Many women use these same hormones on a daily basis for contraception and heavy periods, who may experience an unintended pregnancy. So our findings are also very reassuring for them."

1 Commission on Human Medicines. Report on the Commission on Human Medicines expert working group on hormone pregnancy tests. Nov 2017. https://www.gov.uk/ government/uploads/system/uploads/attachment_data/file/659115/Report-CHM-EWG-HPTs_FINAL.ndf.

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