

H. V. P.

(22)

[redacted]
Mathematics Division,
The University of Sussex,
Falmer, BRIGHTON, Sussex.

DC/CMF

MHB:AFG

13th November, 1967.

Dear [redacted]

Thank you for your letter of the 2nd November.

I am enclosing the remainder of the information that Mr. Fairbairn has been able to obtain from the various records. He believes that he may have a way of arriving at the percentage of pregnancies diagnosed hormonally and I would appreciate your comments on his suggestions.

The apparent correlation between the increase in congenital malformations and the sale of pregnancy diagnosis pills looks rather alarming. I appreciate that correlations can be misleading, but we are here dealing with a pharmaceutical product taken by pregnant women that may be capable of altering the chemical environment of the foetus and I think that we will have to be ultra cautious in this matter.

Since I last saw you I have had an opportunity to talk to Dr. Gal and found that her two groups were matched only in terms of the mothers physical characters. They were from different geographical areas, the normals being from Kingston and the mothers with malformed children from a much wider area covering several southern counties.

I doubt if it is possible to set up a trial of the size you suggest to look at the general population. The reasons for this are twofold: firstly, it would be a very large undertaking that might not give statistically satisfactory results even on completion, and secondly, it would draw widespread attention to the suggested side effect of the tablets and this in itself would probably prevent the completion of such a trial.

I will look forward to hearing from you when you have had an opportunity to consider the above comments and further data. Would you please let me have your account for this consultation at your convenience.

Yours sincerely,
CLINICAL RESEARCH DEPARTMENT,

[redacted]

[redacted]
15 Warriston Crescent,
Edinburgh, 3.

(84)

18th June, 1968.

Dear [redacted]

My Company has asked me to organise a study of women to whom hormone pregnancy tests have been administered.

In order for us to obtain statistically significant results, it would be necessary for us to collect at least 5,000 cases, and I wondered whether your group of 200 Research G.P.s. could possibly assist us in this matter. I think it would be better to leave details of the project to be discussed personally with you, but if you think there is any possibility of your College being able to help us, I will be very glad if you can suggest some alternative dates on which we could meet.

Kind regards.

Yours sincerely,

[redacted]
Medical Director.

AGP/RB

Schering A.G. Berlin,
Med. Wiss. Anal.

24th June, 1968.

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contraceptives. In the group taking sequential preparations they have so far located about 20 cases of abnormality and in the combined preparations group they have found 8. I was not told the size of the samples in each case and would emphasize that this information and all the above details were given to me on a quite unofficial basis and must, therefore, be treated as strictly confidential.

I explained to [] that we have a certain amount of teratogenicity data on the norethisterone acetate and ethinylloestradiol combination and he expressed interest in seeing this material.

I also informed him of our intention to mount a prospective study with the co-operation of the Royal College of G.P.s. and he kindly offered to help by recruiting the aid of Dr. [] and Professor [] on an unofficial basis.

The feeling of the Committee was, Dr. [] said, that they were "unhappy" about hormone pregnancy tests, but at present have insufficient information for any definite action to be taken.

I will, therefore, proceed with the plans for the prospective study, the first section of which will require negotiation with Dr. [] of the Royal College of G.P.s. and will keep you informed of progress.

3. Visit of Dunlop Committee Official to Berlin.

Dr. [] felt that it would be of help to us if he, or one of his executive officers, could visit Berlin for the purpose of holding discussions, not only with Dr. [] but also with those specialists responsible for the animal and human pharmacological studies which are carried out to provide evidence for the Dunlop Committee.

He stated that his lecture commitments were such that it would not be possible for him to visit Berlin, but he felt that his assistant, Dr. [], would be free to do so later this year. There would, however, be some difficulty in finding the necessary air fare from the Ministry of Health.

Dr. [] has dealt with many of our recent submissions, including SH 714, Proviron and Ablacton. In view of this, I tentatively accepted Dr. []'s suggestion and also mentioned that we would possibly be willing to assist with the cost of the air-fare.



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(25)

21st November, 1967.

[Redacted]
Schering Chemicals Ltd.,
Victoria Way,
Burgess Hill,
Sussex.

Dear [Redacted],

Thank you for your letter of 13th November, enclosing the data. I have had a look at the association between incidence of the malformations and the distribution figures. The easiest way to appreciate the relation is from a graph. I have plotted the logarithm of percentage incidence against the logarithm of distribution. I chose a logarithmic scale for the distribution figures because of their great range. It does not make a great deal of difference whether a logarithmic scale or not is used for the incidence; I have chosen to use a logarithmic scale again.

Because of the time lag in the assumed effect of the tablets I have plotted the incidence against the estimated distribution over the twelve month period which lags six months behind any given year. Thus I plotted the 1958 incidence against the average of the 1957 and 1958 distribution figures.

There is a strong correlation. The calculated correlation coefficient is 0.78. The high 1958 incidence figure, relative to the 1959 figure, suggests a high initial scatter and that it might be worth obtaining values for years prior to 1957. But the rise from 1961 onwards is distinctive.

I was interested in Mr. [Redacted] other figures but have not used them to make the test of association.

I think the present evidence is strong enough to demand a serious follow-up of Dr. Gal's findings. I hope to discuss this with you on the phone.

I have put in 7 hours work on this consultation.

Yours sincerely,

[Redacted Signature]