

Dear all of you

Hopefully you will forgive me for using friendly language but in my working life I have spent a lot of time with less-abled people so I know your problems well.

Before outlining the history of HPT, I would like to pay tribute to your late mothers and mothers who lived with the knowledge that using HPT may have damaged you, their children. Both your mother and her GP were in all probability reassured by the manufacturer that this diagnostic test could not harm a developing embryo.

My scientific critics always assumed that I had set out to prove that HPT was harmful. In fact, that couldn't have been further from what really happened: the effects of HPT were completely incidental findings and allowed many other very useful observations.

As a younger doctor, when my clinical job interfered with my maternal responsibilities, I decided to switch my interests to paediatric research. I accepted a post as a Hydrocephalus Research Fellow and the possible reasons for Spina Bifida. I found there were very many aspects to investigate in these areas: too many to consider readily. My husband, who worked at the Institute of Computer Science at University College, suggested collaboration and we were at least amongst the first to be able to take advantage of this approach. We had access to the powerful computers in the University of London, and these facilities allowed me to widen the research and to interview both the parents of affected children.

Along with many other questions, I asked them about the medications that were being taken. One of the fathers corrected his wife, pointing out that in addition to the list that she had described, she had been given HPT to diagnose her pregnancy.

I was a clinical paediatrician, so I had to look up the composition of HPT. I was very surprised that, in the course of a single test to find out if they were pregnant or not, women were being given massive doses of female sex hormones.

I believed then, and still believe, that if a woman was in fact pregnant, such large doses of hormones could damage the early development of her embryo. My senior tried to reassure me that this test had been in use for a long time.

This reassurance did not satisfy me, and I sought the opinion of Dr Richter, a Director of one of the units in the Medical Research Council – the MRC. Dr Richter thought that my hypothesis or discovery was of the utmost importance and provided explanations for many congenital malformations. According to him, damage caused by HPT was much more frequent than damage caused by Thalidomide. This was because HPT was given for diagnostics purposes whereas Thalidomide was given for therapeutic purposes – largely to counteract morning sickness. Because HPT inflicted more damage, Dr Richter advised me to contact the then Safety of Drugs Committee at the then Department of Health and Social Security – the DHSS.

My paper of my findings was published in 1967 in the Medical Section of 'Nature'. I wanted to be very precise about the issues, so I included a short paragraph in the manuscript that suggested that because HPT and oral contraceptives had similar chemical compositions (although the amount of hormone differed), they might have the same effects on a woman taking oral contraceptives while already pregnant. This brief observation was my own downfall.

Following the appearance of HPT in 1967, I received a visit from Dr Alan Pichford, the then Medical Director, and Dr Michael Briggs, the then Research Director, of British Schering Limited. They asked for details of my findings, and eventually I provided them with a copy of my questionnaire through which my study had revealed the harmful effects of HPT.

Thereafter, they invited me to a further meeting – at a restaurant – which was also attended by Dr Ursula Lachnit, the Medical Director of Schering AG in Berlin.

Dr Pichford appeared to be a person of integrity, who wanted to clarify many aspects of HPT. Unfortunately, I formed a different impression of Dr Briggs, who subsequently obtained a chair in one of the Australian Universities as well as acting as a chief adviser to the World Health Organisation on female sex hormones.

However, he eventually lost his Professorship because it later turned out that he had falsified his publications: instead of carrying out proper research, he simply responded to any publications from his desk. Brian Dear of the Sunday Times gave details of his downfall in two articles.

After giving a lecture at the Institute of Child Health, at which I set out my observations on HPT, I was invited by Dr Cedric Carter to join him at his Department, the MRC Clinical Research Unit at the Institute of Child Health. However, after only 3 months, I was dismissed using my HPT publications and my wish to continue research into its actions as the pretext.

When Dr Briggs visited me at my new post, I introduced him as a courtesy to Dr Carter. Oddly, Dr Carter then advised Dr Briggs that while I was in his employment at the time, I would not be permitted to publish any article on HPT – he referred to it as "silly". That was sufficient for Dr Briggs to invite me to renounce my article on HPT and to write a joint article in the British Medical Journal. He made a similar move on behalf of the World Health Organisation, where David Elstein had reviewed HPT and Dr Briggs expressed the opinion that HPT only harmed individuals but if oral contraceptives, which had a similar chemical composition to HPT, were withdrawn, it would be a national, international and world-wide disaster.

I could not understand why my publication caused such an upheaval in our Government departments and also in the World Health Organisation. However, it turned out subsequently that my article in Nature had coincided with a drive by the Department of Health and the World Health Organisation to encourage women to accept oral contraceptives as a birth control method.

In hindsight, it is difficult to understand why HPT was considered to be such a threat to oral contraceptives – it's most unlikely that my paper on HPT could have been the cause.

It is also difficult to understand the reason that Schering loaded GPs with huge amounts of medical samples of HPT – if they wanted to advertise oral contraceptives, HPT was a bad example. Of course, there were differences between HPT and oral contraceptives: the hormone content in the oral contraceptives was much less than in HPT, and the names of the products were also different – oral contraceptives were sold under the names of Gynovlar and Minevlar whereas HPT was sold as Primodos in England and as Diogyon in Germany.

Schering's policy seems to have been questionable, not only because of the points noted previously, but because they did not emphasise sufficiently that their HPT was the weakest amongst the available HPT products. This was important because the use of the other – 'stronger' – products was usually fatal to an embryo and would lead to abortion, whereas Schering's 'weaker' product damaged the embryo and led to the birth of a malformed baby. This, together with the widespread availability of the product through the medical samples, effectively resulted in Schering's product being considered the more harmful.

Dr Lachnit invited me to Schering in Berlin. Apart from having a very pleasant time – I was accommodated in a very smart hotel in the Tiergarten – Dr Lachnit took me to the Opera and to the Olympic Stadium. She even offered to arrange for me to visit East Berlin which I declined because, although I had recently become a British citizen, I well remembered how the East European governments had treated some of their citizens.

On my return, I believed that I could not have achieved anything through discussions in Berlin, but even then, Schering subsequently made modifications to the limited discussions that we did have.

Later, as part of my travelling fellowship, I visited Berlin again. Someone had told me that, if I was still interested in HPT, I was invited to go to a Dr Spielman's flat where there was to be a gathering of other people similarly interested in the subject. I do not know if whether those people formed an HPT Association at the time, nor do I know what eventually happened there such a long time ago. I lost contact with Dr Spielman who subsequently joined the Health Ministry, and so I don't know what happened afterwards.

I realised that I was not strong enough to fight off this level of opposition from these organisations and certainly not enough to fulfil my Hippocratic oath – which I took twice, once in Hungary and then for a second time after re-qualifying in Edinburgh - to look after patients to the best of my ability.

I therefore approached Lord Ashley who was an MP at that time and who had a wonderful reputation for helping disabled people in many ways.

Lord Ashley established the original Association here in England for victims of HPT, but I wasn't clear how the members of its Board were selected. Certainly, my impression was that they were not the sort of people who would regularly read Nature – or other medical publications. I tried to support the Association, but the Board members seemed to think that they knew more about congenital malformations than me.

For some unknown reason, the Association's solicitor selected only individuals with heart problems for the first test cases, leaving out all other deformities. Nothing could persuade him that this was an inappropriate approach; it was as if HPT had not even been found to be a factor in or related to other deformities. It turned out subsequently that all the offspring of the members of the Board had heart defects.

In the meantime, many other studies were completed and many of them confirmed my findings, including both studies by the Safety of Drugs Committee itself.

Mr Moyle, the Minister of Health at the time, asked me to carry out a review of the relationship between HPT and the cases of congenital malformations. As I was not a statistician, I approached Brendon Kelly OBE for assistance. Brendon Kelly was the Director of the Statistical Unit of the Medical Research Council at the time. He carried out an analysis of the available studies and found results that were even more significant than those reported by the authors themselves. However, this was not enough for the DHSS, who continued not to believe me despite their own study confirming my findings. Both of the reports appeared in the British Medical Journal, and both of them confirmed my findings.

At this stage, the Safety of Drugs Committee still had not taken any action in spite of the fact that health warnings had already been issued in many other countries. In fact, it was only in 1975, after Oliver Gillie's article in the Sunday Times, that the Safety of Drugs Committee issued a warning of the risks of using HPT. As you can see, this warning was only issued 8 years after I first published my findings – a huge delay during which time HPT continued to be used and many more babies with deformities were born. The Committee issued a second health warning in 1977, which was most unusual practice for the Department of Health.

The original Association closed in 1982, but nobody had the courtesy to tell me. It is still not clear to me what it achieved, if anything. I felt they let me down but, more seriously, they let down the victims damaged by HPT. I believe that nobody cared or had any thought for these victims until the new and present Association was established.

It is very gratifying that the current Association is so pro-active, and that it makes excellent use of the many more forms of communication, such as the Internet, that are available today to spread knowledge of its successes and advances many of which I am delighted have taken forward or built on my own achievements.

I'd like to pass my formal thanks to Jason Farrell of Sky TV, who put me in touch with Karl Murphy and his mother Pamela. After meeting them, I feel most reassured that, after a long, long period of inactivity, the well-being of HPT victims is in very good hands.

I promised Karl that if he needs anything from the past, he could count on my help. I would be more than honoured if the current Association would indeed like my help.

In certain respects my activities regarding HPT were unsuccessful, but perhaps the fact of you gathering here today is a way of recognising that all my efforts in the past have not been in vain.

I only wish that your joint effort with our new HPT Association will reach a successful conclusion.

Before closing, I would like to offer my help in any way that is useful, although my knowledge is more dated now. If this would be any help, please don't hesitate to contact me.

I'd like to wish all of you good health and many many successes in the future.

Isabel