

Commission to Inquire into Child Abuse Act, 2000

Statement

Delivered at

Public Sitting

of

Commission to Inquire into Child Abuse

Division of Investigation Committee

(Ms Justice Mary Laffoy and Professor Edward Tempany)

held on

23rd January 2002

Commission to Inquire into Child Abuse,
Second Floor,
St Stephen's Green House,
Earlsfort Terrace,
Dublin, 2.

1. **Purpose**

The purpose of this public sitting of this division (the Division) of the Investigation Committee of the Commission to Inquire into Child Abuse is to explain the Commission's role in investigating vaccine trials. In this statement the Division will outline its understanding of its statutory functions, in other words, its terms of reference, in inquiring into vaccine trials. There will follow an outline by the Commission's leading Counsel, Mr Frank Clarke S.C., of the manner in which the Commission's legal team proposes to advance this module of the Commission's work.

2. **Commission to Inquire into Child Abuse Act, 2000**

The Commission to Inquire into Child Abuse Act, 2000 (the Act), which was enacted on 26 April, 2000, provided for the establishment of the Commission to Inquire into Child Abuse to perform the functions conferred on it by or under the Act¹. The Commission was established on 23 May, 2000. In addition to the principal functions which are conferred on the Commission by the Act² - to provide a forum for hearing allegations of, and to conduct an inquiry into, abuse of children in institutions from 1940 to the present time and to report on the inquiry – the Act³ empowers the Government by order to confer on the Commission and its Committees such additional functions or powers connected with their functions and powers for the time being as may be considered appropriate. By virtue of the Commission to Inquire into Child Abuse Act, 2000 (Additional Functions) Order 2001, (SI No 280 of 2001) (the

¹ Section 3(1)

² Section 4(1)

³ Section 4(4)

Order) additional functions in relation to certain vaccine trials, which involved children in institutions, were conferred on the Commission.

3. **Background to the making of of the Order**

Since the early 1990s three vaccine trials, which were conducted in the State in the 1960s and 1970s, have been the subject of media interest, which has given rise to public debate. Of particular concern has been the fact that some of the children who participated in the trials were resident in children's homes or orphanages at the time of such participation and questions have been raised as to the ethical propriety of the trials. In July 1997, the then Minister for Health gave a commitment in the Dáil to make inquiries in relation to the matter. The inquiries were conducted by the Chief Medical Officer of the Department of Health and Children, Dr James Kiely, who prepared a report entitled "Report on three Clinical Trials involving Babies and Children in institutional settings 1960/1961, 1970 and 1973" (the Report), which was laid before both Houses of the Oireachtas in November, 2000.

It being the view of the Minister for Health and Children that the matters dealt with in the Report required to be further investigated into, the Report was referred to the Commission on 13 November, 2000 to conduct such investigation.

As is recited in the Order, the Commission requested the Government to define the parameters of its investigation into the matters arising from the Report. After consultation with the Commission, the Order was made on

19 June, 2001.

4. **The Functions conferred on the Commission by the Order: Vaccine Trials**

By the Order, functions, which will be outlined later in this statement, are conferred on the Commission in relation to any vaccine trial which falls within either of the two categories of vaccine trials referred to in the Order⁴.

The first category comprises the three vaccine trials the subject of the Report, being the following trials:

- **Trial 1:** This was a trial in which fifty-eight infants resident in five children's homes in the State took part, which sought to compare the poliomyelitis antibody response after vaccination with a quadruple vaccine (diphtheria, pertussis, tetanus (DTP) and polio combined) with standard vaccines in use at the time which consisted of DTP and polio administered separately and at different sites. This trial was conducted between December, 1960 and November, 1961. The results of the trial were published in the British Medical Journal in 1962⁵.
- **Trial 2:** In one strand of this trial sixty-nine children resident in an orphanage in Dublin had blood taken. Twelve were subsequently administered intranasal rubella vaccine. In another strand of this trial, twenty-three children living at home

⁴ Article 3(a)(i) and (ii)

⁵ Antibody response in infants to the poliomyelitis component of a quadruple vaccine: BR. Med. J. 1962; i : 1098

in a rural area in the Midlands were administered the same vaccine. The purpose of the trial was to investigate whether there was a propensity for intranasally administered vaccine to spread to susceptible contacts, for example, pregnant women, and to estimate antibody levels and acceptability of the intranasal technique of vaccination. The trial was conducted during 1970. The results of the trial were published in the Cambridge Journal of Hygiene⁶.

- **Trial 3:** In this trial fifty-three children in “Mother and Baby” homes and children’s homes in Dublin and sixty-five children living at home in Dublin were administered vaccine to compare the reactogenicity of the commercially available batches of Trivax vaccine (diphtheria, tetanus and pertussis) and Trivax AD vaccine, with a vaccine of equivalent efficacy but, in relation to the pertussis component, of lesser potency. This trial was apparently conducted in 1973. The outcome of the trial was not published.

The second category is specified in the following terms in the Order:

“... any systematic trials of a vaccine or the mode of delivery thereof to test its efficacy or to ascertain its side effects on a person found by the Investigation Committee to have taken place during the period commencing on 1 January, 1940 and

⁶ “Trial of intranasally administered rubella vaccine”; J. Hyg. Camb. 1971; 69; 547-552

ending on 31 December, 1987, and to have been conducted in an institution, following an allegation by a person that he or she as a child in the institution was a subject thereof ... ”

The background to the inclusion of this category in the Order is that the publicity surrounding the vaccine trials issue generated communications to the Department of Health and Children by individuals who asserted that they had been in vaccine trials of the type being investigated within the Department, if not necessarily the three trials being investigated. At the request of the Minister for Health and Children the Commission indicated its willingness to investigate assertions of that type and to include in its inquiry any further trial, if its investigations should lead to a finding that such trial had occurred and involved children in institutions.

In order to come within the second category, a vaccine trial must fulfil all of the following requirements:

- (a) It must be a systematic trial of either the vaccine or the mode of delivery of the vaccine, the purpose of which is to test the efficacy of the vaccine or to ascertain its side effects on a person to whom it was intended to be administered;
- (b) It must have taken place in the years 1940 to 1987 inclusive, 1987 being the year in which the Control of Clinical Trials Act, 1987 was enacted;
- (c) It must have been conducted in an institution, which

expression is defined in the Act,⁷ as including “a school, an industrial school, a reformatory school, an orphanage, a hospital, a children’s home and any other place where children are cared for other than as members of their families”; and

- (d) There must be a finding by the Investigation Committee that such trial took place and was conducted in an institution during the years 1940 to 1987 inclusive, such finding following on an allegation by a person that he or she as a child, which word is defined in the Act⁸ as meaning “a person who has not attained the age of eighteen years”, participated in the trial in the institution.

The Commission, by public advertisement published in newspapers with circulation in the State and among members of the Irish community in the United Kingdom, has invited any person who alleges that as a child in an institution (for example, a children’s home or an orphanage) between 1940 and 1987 he or she was the subject of a vaccine trial to contact the Commission before 15 February, 2002. The advertisement will be repeated shortly. Every contact, whether as a result of the advertisement or otherwise, will be investigated and any vaccine trial which fulfils the requirements stipulated in the order will be inquired into.

It is possible that, in the course of investigations being carried out into vaccine trials, the existence of a trial which fulfils the requirements necessary to fall

⁷ Section 1(1)

⁸ Section 1 (1)

within the second category save that it has come to the attention of the Commission from a source other than the source stipulated in the Order – an allegation by a person that he or she as a child in the institution was the subject of the trial – may emerge. In that event, the Commission will give careful consideration to seeking from the Government an order under the Act⁹ empowering the Commission to inquire into such trial.

5. **The Additional Functions**

In relation to each vaccine trial which falls within either category provided for in the Order, the Commission has a twofold function, namely, to conduct an inquiry and to publish a report.

6. **The Inquiry**

The Order¹⁰ stipulates the nature of the inquiry to be carried out. It is an inquiry into the circumstances, legality, conduct, ethical propriety and effects on the subjects thereof of each vaccine trial which falls within either category provided for in the Order. It is the Division's view that, as such, it gives the Commission a broad, not a narrow, remit. In particular, it is the understanding of the Division that –

- The word “circumstances” comprehends all aspects of the trial, whether specifically alluded to or not, including the background to its inception, its purpose, and its outcome;

⁹ Section 4(4)

¹⁰ Article 3(a)

- The word “legality” connotes compliance or non-compliance with the regulatory regime, whether statutory (for example, under the Therapeutic Substances Act, 1932) or whether created by secondary legislation, which was in force at the relevant time;
- The “conduct” of a trial means all aspects of the implementation of the trial, including the devising of the protocol or plan in accordance with which the trial was to be carried out, the practical day-to-day implementation of the trial and the recording of the outcome of the trial.
- The expression “ethical propriety” connotes adherence or non-adherence to ethical norms and guidelines prevalent at the relevant time, both nationally and internationally, in relation to clinical research and trials involving human beings and, in particular, involving children; and
- The reference to “effects” on the subjects of a trial envisages both benign consequences and adverse reactions and consequences.

The foregoing analysis of the terminology of the Order which stipulates the nature of the inquiry is not intended to be exhaustive of all relevant factors

but merely illustrative of the Division's understanding of the parameters of the inquiry as defined by the Order.

In the case of each trial, the relevant factors will have to be considered, where appropriate, by reference to the acts and omissions of all persons and bodies promoting, funding, conducting, licensing or otherwise authorising, and facilitating the trial and all persons and bodies charged with responsibility for the person, health and well being of each child who participated in the trial. By way of illustration, in the case of the three trials the subject of the Report, it is envisaged that the Division will be concerned with -

- the conduct of the manufacturer of the vaccine,
- the conduct of the research body or institution and the personnel involved in the conduct of the trial,
- the conduct of the statutory and/or other regulator charged with responsibility for the regulatory regime in force at the relevant time,
- the conduct of any health, local or other public authority involved, directly or indirectly, with the trial,
- the conduct of the manager of the institution or other person with *de facto* responsibility for a child who, while in an institution, was a subject of the trial, and
- the conduct of each Department of State charged with responsibility for the health and well being of such child.

7. **The Report**

It is specifically provided in the Order that the inquiry mandated by the Order is to be carried out through the Investigation Committee, which is a committee of the Commission provided for in the Act¹¹. The reporting function of the Commission under the Order¹² is co-extensive with the reporting function of the Investigation Committee under the Order¹³. The scheme of the Order is that the Investigation Committee is required to prepare a report in writing of the results of the inquiry, specifying in it the determinations it has made in the conduct of the inquiry and furnish it to the Commission. The Commission's function is to prepare and publish to the general public a report in writing specifying the determinations made by the Investigation Committee in its report. In other words, the Division of the Investigation Committee conducting the inquiry into vaccine trials reports to the Commission. The Commission then publishes its report, but in so doing the Commission is limited to reporting determinations or findings made by the Investigation Committee.

8. **Personnel conducting the Inquiry**

As has been stated, it is provided in the Order that the investigative remit of the Commission in relation to vaccine trials shall be carried out through the Investigation Committee. Under the Act¹⁴ the Investigation Committee is empowered to act in divisions. When the Order was made, the composition of the Investigation Committee comprised the Chairperson and two ordinary

¹¹ Section 10

¹² Article 3(b)

¹³ Article 4

¹⁴ Section 11(6)

members. Because the two ordinary members were precluded, on the grounds of conflict of interest, from participating in the inquiry mandated by the Order, the Commission asked the Government to appoint an additional member of the Commission, who would be assigned to the Investigation Committee to participate in the vaccine trials inquiry. On 13 November, 2001, the Government appointed Professor Edward Tempany, a retired Consultant Paediatrician, as a member of the Commission. Professor Tempany has been assigned to the Investigation Committee. A division of the Investigation Committee consisting of the Chairperson of the Commission and Professor Tempany will conduct the inquiry and prepare the report thereon in accordance of the provisions of the Order and of the Act.

9. **Conflict of Interest**

All members of the Commission, including the members of the Division, are bound by a protocol on conflict of interest, which also binds the other statutory officers of the Commission, the inquiry officers provided for in the Act¹⁵, and the legal advisers. It is intended that any other advisers or consultants retained in connection with the vaccine trials inquiry will be bound by similar rules for identifying potential conflicts of interest and ensuring that an adviser does not become involved in any matter where such involvement would give rise to a conflict of interest. All members of the staff of the Commission are bound by similar rules.

The protocol and rules on conflict

¹⁵ Section 23

of interest are strictly enforced. The invitation already issued publicly by the Commission¹⁶ to all persons who are affected by its work is extended to the persons affected by the work of the Division namely, to bring to the attention of the Division any situation which it is believed may give rise to a conflict of interest. However, the Division wishes to reiterate the view already expressed publicly by the Commission that such a matter must be raised in writing with the Secretary of the Commission by the person who believes the conflict affects him or by his legal representative, who should clearly indicate the reasons why he believes there is a conflict. The Commission cannot act on media reports, second or third hand information, rumour or innuendo.

10. **Evidence**

The same approach will be adopted by the Division of the Investigation Committee in the conduct of the vaccine trials inquiry as is adopted by the Investigation Committee in relation to performance of its other functions. All witnesses who give evidence shall be required to give evidence on oath, as permitted by the Act¹⁷ In making its determinations the Division will –

- (i) apply the standard of proof applicable in civil proceedings in a court, that is to say, proof on the balance of probabilities, and

¹⁶ At the public sitting on 20 July, 2000

¹⁷ Section 22

- (ii) the determinations will be based only on evidence which would be admissible in a court, so that, for instance, in making its findings of fact, the Division shall not rely on hearsay.

11. **Public Hearings**

The Act¹⁸ provides that a hearing of the Investigation Committee at which evidence relating to particular instances of alleged abuse of children is being given shall be held otherwise than in public. Other hearings may, if the Committee considers it appropriate, having had regard to the desirability of holding such meetings in public, be held otherwise than in public. At this juncture, the Division does not foresee that any circumstances are likely to arise in which it would be appropriate to hold hearings of the Division *in camera*. Accordingly, the intention is that all hearings of the Division will be held in public. However, if any unforeseen factors emerge, the appropriateness of hearing particular evidence in public, having regard to such factors, will be addressed.

12. **Legal Representation and Costs**

It is recognised that every person or body whose conduct is impugned in the course of the inquiry or who may be materially adversely affected by a determination of the Division is entitled to legal representation in this process. It is also recognised that there are other interests to which it may be considered appropriate to grant legal representation having regard to the nature of the inquiry, for example, the public, or a section of the public which is the focus

¹⁸ Section 11(3)

of the inquiry. Applications for legal representation will be taken following the close of the Commission's Counsel's opening statement in relation to the three trials which have been identified in the Report. When all of the contacts from the public in relation to the possible existence of other trials which come within the Commission's remit have been investigated, a further preliminary sitting will be convened to apprise the public of the results of such investigations and the course the Division proposes to adopt in consequence. At that stage the issue of legal representation will be re-addressed, if necessary.

Currently, the payment of expenses, including legal expenses, of parties appearing before the Investigation Committee is governed by section 20 of the Act. That section empowers the Minister for Education and Science to make a scheme providing for the payment by the Commission of expenses incurred in relation to attendance before the Investigation Committee. A scheme is in place for the payment of the expenses of lay witnesses. Moreover, a scheme made by the Minister on 9 May, 2001 is in place for payment of legal costs and expenses incurred in respect of legal representation at the first phase of the proceedings of the Investigation Committee, which hearings are held *in camera*. At present there is no scheme in place under section 20 providing for the costs and expenses of legal representation at the proceedings of the Division, which it is intended will follow, in broad terms, a "tribunal" model of process.

However, by letter dated the 21 of January, 2002, the Department of Education and Science has advised the Commission as follows:

“In order to clarify matters I would like to inform the Commission that as a matter of policy it is proposed that all reasonable legal costs incurred by a person and arising from inquiries made by the Investigation Committee will be met from public funds. The Minister will propose the appropriate amendments at Report stage {of the Residential Institutions Redress Bill, 2001}”.

It is the Commission’s understanding that the amendment will provide for “taxed costs” in the ordinary sense in which that expression is used in inter partes matters. The Commission has been informed that the report stage of the Bill in the Dáil is scheduled for 20 February, 2002.

13. **Inquiry into Vaccine Trials, not Vaccines generally**

It is important that the public should appreciate that the functions of the Division relate to vaccine trials, the three vaccine trials the subject of the Report and any other vaccine trial which falls within the second category provided for in the Order. The common feature of the trials which the Division is empowered to investigate is that they were conducted on children in institutions. It is no function of the Division to investigate vaccines generally or the administration of vaccines to children in the past in any circumstances other than in the course of a trial conducted wholly or partly in an institution.

14. **Inquisitorial Process**

In conclusion, the Division wishes to emphasise the inquisitorial nature of the process. It is a fact finding process; not a process which is capable of giving rise to a determination of criminal responsibility or civil liability. However, it is a process which must be, and will be, conducted in a manner consistent with constitutional and natural justice. The *modus operandi* which will be adopted for this distinct module of the Commission's work, for gathering evidence, determining its relevance and presenting relevant sworn testimony to the Division, will ensure that every person or body whose conduct is impugned or is likely to be the subject of an adverse finding is afforded reasonable means of defending himself in the manner laid down by the Supreme Court in In Re Haughey¹⁹

¹⁹ {1971} IR. 217.