No. 9

PARLIAMENT OF NEW SOUTH WALES

LEGISLATIVE COUNCIL

STANDING COMMITTEE ON SOCIAL ISSUES

CLINICAL TRIALS AND GUARDIANSHIP:

MAXIMISING THE SAFEGUARDS

Report Number 13

September 1997

TERMS OF REFERENCE

That the Standing Committee on Social Issues inquire into, and report on,

1. The appropriateness of those clauses of the *Guardianship (Amendment) Bill 1997* that were deleted by amendments in the Legislative Council. Particular reference should be paid to the adequacy of safeguards for people unable to consent for themselves gaining access to new treatments available only through clinical trials; and

2. That the Committee report by 1 September 1997.

CONTACT DETAILS

Members of the Standing Committee on Social Issues can be contacted through the Committee Secretariat. Written correspondence and telephone enquiries should be directed to:

The Director
Standing Committee on Social Issues
Legislative Council
Parliament House, Macquarie Street
Sydney New South Wales 2000
Australia

EMAIL: sociss@parliament.nsw.gov.au

TELEPHONE: 61-2-9230-3078

FACSIMILE: 61-2-9230-2981

September 1997

Standing Committee on Social Issues, Report No. 13

ISBN 0 7313 1340 2

COMMITTEE FUNCTIONS

The functions of the Standing Committee on Social Issues are to inquire into, consider, and report to the Legislative Council on:

- any proposal, matter or thing concerned with the social development of the people in all areas of New South Wales;
- the equality of access to the services and benefits including health, education, housing and disability services provided by the Government and non-Government sector to the people in all areas of New South Wales;
- recreation, gaming, racing and sporting matters; and
- the role of Government in promoting community services and the welfare of the people in all areas of New South Wales.

Matters for inquiry may be referred to the Committee by resolution of the Legislative Council, a Minister of the Crown, or by way of relevant annual reports and petitions. The Committee has the legislative power to:

- summons witnesses;
- make visits of inspection within Australia;
- call upon the services of Government organisations and their staff, with the consent of the appropriate Minister;
- accept written submissions concerning inquiries from any person or organisation; and
- conduct hearings.

COMMITTEE MEMBERSHIP

THE HON. ANN SYMONDS, M.L.C., AUSTRALIAN LABOR PARTY

CHAIR

THE HON. DR. MARLENE GOLDSMITH, M.L.C., LIBERAL PARTY

DEPUTY CHAIRMAN

THE HON. DOROTHY ISAKSEN, M.L.C., AUSTRALIAN LABOR PARTY

THE HON. JAMES KALDIS, M.L.C., AUSTRALIAN LABOR PARTY

THE HON. ELISABETH KIRKBY, M.L.C., AUSTRALIAN DEMOCRATS

THE HON. DOUG MOPPETT, M.L.C., NATIONAL PARTY

THE HON. PETER PRIMROSE, M.L.C., AUSTRALIAN LABOR PARTY

TABLE OF CONTENTS

CHAIR'S FOREWORD

Clinical trials involving human subjects have led to extraordinary advances in human health as well as appalling abuses of people's rights and dignity. The potential for abuse of subjects in medical research is heightened when an individual is unable to consent to their involvement in an experiment because their decision-making ability is impaired or diminished. They may, for example, have a pre-existing disability such as dementia or brain damage, or they may be unconscious or disorientated.

Recent revelations about the testing of vaccines on orphans in Victoria between 1945 and 1970 serve to heighten public anxiety about human experimentation, particularly involving vulnerable members of society.

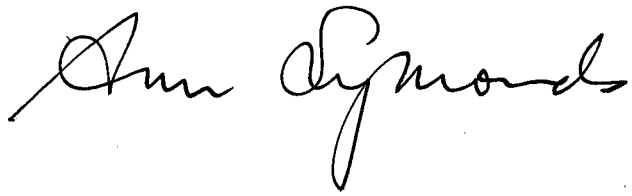
The Committee has been acutely aware of public concerns regarding human experimentation during its deliberations. While we acknowledge the ethical dilemmas posed by the involvement of people with decision-making disabilities in clinical trials, we do not believe these dilemmas would be eliminated by proscribing such research. The treatment available through a clinical trial may be the only or most promising alternative available to an individual. In such cases, it may not be in a person's best interests to deny them this opportunity.

This Report tackles important ethical questions raised by involving people with decision-making disabilities in a clinical trial, including the ethicality of administering a placebo. In doing so, it also provides an overview of guardianship law and principles in New South Wales and the regulatory framework for the conduct of clinical trials in Australia. The recommendations aim to facilitate access to clinical trials for people who cannot consent to their own treatment, at the same time as maximising the safeguards to protect them from abuse or danger.

I am extremely grateful to my parliamentary colleagues on the Committee for their dedication to this Inquiry. Members of the community play a critical role in the inquiry process. I would therefore like to convey my thanks to the many individuals and organisations who provided written submissions or evidence to the Inquiry.

My thanks are also due to the Committee Secretariat, in particular, Jennifer Knight, Committee Director for executive support and for writing a key section of the Report; Senior Project Officer, Beverly Duffy who worked within an extremely tight timeframe and coordinated the inquiry process, undertook the necessary research and wrote the four technical chapters of the Report; Heather Crichton, for undertaking the administrative elements of the Inquiry and for producing the final Report with great speed and precision; and my Research Assistant, Julie Langsworth for providing valuable editorial fine tuning. Robin Creyke from the Faculty of Law at the Australian National University wrote the second chapter in the Report on Guardianship Law in New South Wales and provided generous assistance to the Senior Project Officer during the course of the Inquiry.

I commend this report to the Government.



THE HON. ANN SYMONDS, M.L.C.

COMMITTEE CHAIR

SUMMARY OF RECOMMENDATIONS

RECOMMENDATION 1: (Introduction)
That the *Guardianship Act* provide for the conduct of clinical trials through the reintroduction of the clinical trial provisions in the *Guardianship Amendment Bill,* with additional amendments as recommended in this Report.

RECOMMENDATION 2: (Chapter Three)
That the *Guardianship Act* require the Guardianship Board to withhold consent for a clinical trial if it is not satisfied that adequate, independent monitoring arrangements are in place for the conduct of the trial.

RECOMMENDATION 3: (Chapter Three)
That the *Guardianship Act* ensure that the Guardianship Board can only consent to trials that have been approved by an Institutional Ethics Committee registered with the Australian Health Ethics Committee.

RECOMMENDATION 4: (Chapter Three)
That the Minister for Health request the Federal Minister for Health to ensure that the annual compilation of Institutional Ethics Committee Compliance Reports by the Australian Health Ethics Committee are publicly available.

RECOMMENDATION 5: (Chapter Three)
That the Minister for Health request the Federal Minister for Health to amend the *Statement on Human Experimentation* to require the inclusion of a subject representative on Institutional Ethics Committees.

RECOMMENDATION 6: (Chapter Three)
That the Minister for Health seek the support of the Federal Minister for Health for the amalgamation of small Institutional Ethics Committees as recommended by the Chalmers Review.

RECOMMENDATION 7: (Chapter Three)
That the *Guardianship Act* ensure that the Guardianship Board is informed of all variations to the protocol of any clinical trial it approves and that the Board reassess its original approval for such a clinical trial.

RECOMMENDATION 8: (Chapter Three)
That the *Guardianship Act* require the Guardianship Board, in the event of a variation to a trial protocol, to contact all "persons responsible" who have given consent to the participation of an individual in a clinical trial and provide them with the option to reassess their approval.

RECOMMENDATION 9: (Chapter Three)
That, any references to clinical trials in the *Guardianship Act* use the word "person" in place of the terms "patient", "patients" and "participants".

RECOMMENDATION 10: (Chapter Three)
That the Minister for Community Services reconsider the wording of section 45AA (2) in the *Guardianship Amendment Bill* to take into account the need to assess the potential benefits as well as the risks of participation in a clinical trial.

RECOMMENDATION 11: (Chapter Four)
That the proposed amendments to the *Guardianship Act* allow the administration of a placebo in clinical trials.

RECOMMENDATION 12: (Chapter Five)
That the independent review of amendments to the *Guardianship Act* (see Recommendation 17) specifically examine the experiences of "persons responsible" to whom the Board delegates consent for a clinical trial.

RECOMMENDATION 13: (Chapter Five)
That the Minister for Community Services instruct the Guardianship Board to produce a plain English guide to amendments to the *Guardianship Act* relating to clinical trials. This guide is to outline clearly the issues to be considered by the Guardianship Board and the matters that should be taken into account by a "person responsible" in deciding whether to give consent to the participation of an individual in a clinical trial. The guide should be produced in several community languages and distributed widely.

RECOMMENDATION 14: (Chapter Five)
That the Minister for Community Services request the Guardianship Board to conduct briefings for "persons responsible" who are requested to consent to the participation of an individual in a clinical trial.

RECOMMENDATION 15: (Chapter Six)
That, upon clarification of the legal position of Advanced Directives, the Minister for Community Services, in conjunction with the Minister for Health and the Attorney General, develop a public information campaign to encourage people to make Advanced Directives or to appoint an Enduring Guardian.

RECOMMENDATION 16: (Chapter Six)
That the *Guardianship Act* require the Annual Report of the Guardianship Board to include details of all clinical trials it has approved during the period covered by the Report.

RECOMMENDATION 17: (Chapter Six)
That the *Guardianship Act* require a review of any new amendments relating to clinical trials be undertaken one year after the proclamation of the Amendment Act relating to clinical trials.

RECOMMENDATION 18: (Chapter Six)
That the Minister for Community Services support the creation of an Appeals Division in the Administrative Decisions Tribunal to hear appeals against decisions of the Guardianship Board and ensure that members of the Division have a similar range of skills and expertise as the members of the Guardianship Board.

RECOMMENDATION 19: (Chapter Six)
That the Minister for Community Services instruct the Guardianship Board to conduct a series of briefings with Institutional Ethics Committees throughout New South Wales after the Amendment Act is passed to inform Institutional Ethics Committees of their responsibilities under the Act.

RECOMMENDATION 20: (Chapter Six)
That the Minister for Health recommend to the Federal Minister for Health that Institutional Ethics Committees include an item in their clinical trial application forms to establish whether an investigator has sought consent from the relevant guardianship authority in their state.

GLOSSARY

ADT	Administrative Decisions Tribunal
AHEC	Australian Health Ethics Committee
CTN	Clinical Trials Notification Scheme
CTX	Clinical Trials Exemption Scheme
IEC	Institutional Ethics Committee
NHMRC	National Health and Medical Research Council
TGA	Therapeutic Goods Administration

INTRODUCTION

CONTENTS:

BACKGROUND TO THE REPORT

The *Guardianship Amendment Bill, 1997* was introduced into the Legislative Council on 7 May 1997. One of the aims of the Bill was to allow the Guardianship Board, under certain circumstances, to authorise people with decision-making disabilities to participate in clinical trials.

A person with a decision-making disability is unable to make certain decisions for themselves because of a disability such as dementia or brain damage or because they are unconscious or disorientated.

During debate of the Bill, the Legislative Council voted that the clauses concerning clinical trials be deleted from the Bill to allow further public debate on the issue. On 2 June 1997, the Hon Ron Dyer, Minister for Community Services, referred an Inquiry into Clinical Trials to the Standing Committee on Social Issues.

The Terms of Reference for the Inquiry are:

- *The appropriateness of those clauses of the Guardianship (Amendment) Bill 1997 that were deleted by amendments in the Legislative Council. Particular reference should be paid to the adequacy of safeguards for people unable to consent for themselves gaining access to new treatments available only through clinical trials; and*

- *That the Committee report by 1 September 1997.*

RECENT DEVELOPMENTS

The *Guardianship Amendment Act, 1997* (minus the amendments relating to clinical trials) was passed on the 29 May 1997 and assented to on 2 July 1997. It is expected to be proclaimed and thus come into effect by the end of 1997.

However, as this Inquiry was required to consider aspects of the *Guardianship Amendment Bill* relating to clinical trials, we will at times refer to the Bill, even though we recognise the Bill has been enacted.

Readers will note that throughout the Report some witnesses refer to the Guardianship Tribunal while others talk about the Guardianship Board. This is because when the *Guardianship Amendment Act, 1997* is proclaimed, the name of the Guardianship Board will be changed to the Guardianship Tribunal.

THE INQUIRY PROCESS

During the course of the thirteen week Inquiry, the Committee received 58 submissions and took formal evidence from 19 witnesses. Those appearing before the Committee were drawn from a diverse cross-section including clinicians, professors of medicine, family members, ethicists, relevant non-government organisations and government agencies.

Given the relatively short time frame in which submissions could be received, the Committee feels this response demonstrates a significant level of public interest in the issue.

THE SCOPE OF THE INQUIRY

Several submissions and a considerable amount of evidence supported the notion that people with decision-making disabilities should be able to participate in clinical trials. However, concern was also expressed about the effectiveness of some of the safeguards designed to protect vulnerable people from exploitation or harm.

The Committee also heard a significant amount of evidence and received submissions from people who were totally opposed to the passing of the amendments relating to clinical trials. Their opposition stemmed from their concerns about the operation of the Offices of the Public Guardian and Protective Commissioner, and to a lesser extent, the Guardianship Board.

It is outside the scope of this Inquiry to investigate these concerns. However, as will be discussed in the Report, the Committee has responded by calling for greater accountability from these Offices.

Given the very tight time parameters for this Inquiry, a comprehensive literature review was not undertaken.

THE STRUCTURE OF THE REPORT

Chapter One is an overview of the framework for the regulation of clinical trials in Australia, including the relevant international instruments and Federal regulatory agencies. The role and function of Institutional Ethics Committees is considered in detail.

Chapter Two is a general introduction to the principles of guardianship law in New South Wales. It outlines the role of the New South Wales Guardianship Board and describes the appointment of guardians and financial managers. The final part of the Chapter explains the system in New South Wales for substitute consent for health care.

Chapter Three reviews the safeguards proposed in the *Guardianship Amendment Bill* which must be satisfied before the Guardianship Board can give consent for the conduct of a clinical trial. The Chapter discusses concerns raised by witnesses and in submissions concerning the effectiveness of Institutional Ethics Committees, the level of acceptable risk in a trial and whether the proposed safeguards prohibit the conduct of non-therapeutic research.

The ethical issues concerning the administration of a placebo to participants in a clinical trial are examined in Chapter Four. It is argued that the potential benefits available to participants in a clinical trial outweigh the potential disadvantages they may experience from receiving a placebo.

In Chapter Five, the Report examines a number of issues concerning the delegation of consent to the "person responsible". Arguments in favour of and against the delegation of consent are identified and discussed. The power of the Guardianship Board not to delegate consent or to overrule the decision of the "person responsible" is also considered.

A range of issues are considered in Chapter Six including: advanced directives and enduring guardianship, annual reports, development of protocols and appeals against decisions of the Guardianship Board.

CONCLUSION

The Committee supports the overall objective of the amendments relating to clinical trials that were excised from the *Guardianship Amendment Bill, 1997*. The Committee considers that people with decision-making disabilities should not be denied an opportunity to participate in a trial that may alleviate or even cure their condition. At the same time, legislation which aims to enhance access to clinical trials must also protect the rights and welfare of people who are unable to consent to their own treatment.

In order to satisfy these twin goals of access and safety, the Committee supports the reintroduction of the provisions relating to clinical trials in the *Guardianship Amendment Bill*, with certain modifications which aim to maximise the safeguards proposed in the Bill.

RECOMMENDATION 1:

That the *Guardianship Act* provide for the conduct of clinical trials through the reintroduction of the clinical trial provisions in the *Guardianship Amendment Bill,* with additional amendments as recommended in this Report.