

To the Health Select Committee
Parliament Buildings, Wellington

Submission on the Public Health Bill

Introduction

1 - This submission is from NZORD - the New Zealand Organisation for Rare Disorders, 125 Cuba St, Petone.

2 - We wish to appear before the committee to speak to this submission. Contact details are: John Forman, Executive Director Ph 04 566 7707 Mob 027 240 3377 Email exec.director@nzord.org.nz

3 - NZORD was established in 2000 following a conference of more than 30 rare disorders support groups. Our network now includes 135 groups.

It was established to;

- help those affected by rare diseases and their families find essential information
- assist small support groups to operate more efficiently
- monitor rare disease issues and promote public debate of those issues
- contribute to the formation of public policy
- support research partnerships for treatments and cures

4 - NZORD operates in partnership with officials, professionals and researchers, and with the groups within our network, to promote improvements to health services and policies. We have advocated on and contributed to reports, publications and debates about:

- Genetic modification and biotechnology
- Improvements to Genetic Services and ante-natal screening programmes
- Folate fortification of food to prevent neural tube defects
- Approval and funding of pre-implantation genetic diagnosis
- Expanded newborn metabolic screening and establishing newborn hearing screening
- Medicine regulation and funding in New Zealand
- Human tissue collection and use, including Guthrie card storage
- Development of a Medicine Strategy for New Zealand
- Promotion of a Carer Strategy with government

5 - NZORD is a Charitable Trust with a nine member board, chaired by Chris Hodson QC. We receive funding from the Ministry of Health, the Lottery Grants Board, the Todd Foundation, TG Macarthy Trust, JR McKenzie Trust, the Deane Endowment Trust and other occasional funders.

Submission Summary

6 - We are pleased that the Bill extends the focus of public health to include non-communicable diseases. We agree with the statement that NCDs "...are now the major cause of avoidable ill-health, disability, and premature death in New Zealand." A public health response is clearly warranted.

7 - While we commend the proposed framework in Part 3 of the Bill to address specific risk factors, the concept of non-communicable diseases is too narrowly constructed. There is a serious omission from the Bill in its failure to recognise the significant total burden of disease in the collective impact of rare disorders and genetic disorders on the population.

8 - Rare disorders (most of which are genetic) affect around 8% of the entire population - a number roughly equivalent to the entire Pacific population of New Zealand. This Bill is the ideal opportunity to bring New Zealand's legislation and policy up to date with leading initiatives in the US and European Union where rare disorders are recognised as a significant public health problem.

9 - We propose that the Bill should be amended by adding an additional section to clause 79 to make it clear that the collective impact of rare diseases is a matter for public health action (in addition to the personal health needs that they generate), and that the review provisions in clause 88 of the Bill are also amended to ensure that specific steps are taken to address rare and genetic diseases by way of comprehensive action plans to address service development, research, screening programmes, information provision, and similar matters.

10 - We note the reference to potential genetic screening under register-based programmes, but consider this is a far too limited response to the impacts of genetics on the health of the population. Genetics needs to be incorporated into a comprehensive public health response to rare disorders (and relevant common disorders) in a way that addresses a full range of research, service and information matters, of which screening is just one part.

11 - As an alternative to changes to clauses 79 and 88, it may be preferable to provide for a suitable public health response to genetic and rare diseases in a separate sub-part to Part 3 of the Bill, giving interpretation, principles and reporting requirements specific to genetic and rare diseases.

12 - We consider it essential for a suitable provision to be made for these diseases to avoid continuing neglect of the essential health needs of the affected population, and to address the inequities in access to health services and the increasing disparities in their health status.

13 - An example of the continuing neglect of this important area of health policy is the fate of the National Health Committee's report on Molecular Genetic Testing in New Zealand (2003). There were recommendations for urgency in upgrading our genetic services to an acceptable baseline, yet nearly 5 years later there has been no action taken by the Ministry of Health, nor the District Health Boards, to implement the recommendations of this report.

14 - This Bill is an opportune time to set a framework for good public policy on rare disorders and associated genetic services. Our suggestions are:

- a. That the Bill recognises rare diseases as a significant public health issue.
- b. That there is provision for an individual or group with responsibility and authority to coordinate policy relating to rare diseases.
- c. That the Bill should mandate the implementation of the "Molecular Genetic Testing in New Zealand" report as a first priority action item.

General Commentary on rare disorders and genetic disease

15 - Rare disorders need to be recognized as significant burdens to public health, and considered for inclusion in the public health bill for appropriate prioritisation and action.

- a. Rare disorders affect 1 in 2000 (EU definition), or fewer than 200,000 Americans (US definition, which is approximately 1 in 1400). New Zealand does not have a definition as we have no policy, no priority and no budgets.
- b. 80% of rare disorders have identified genetic origins. Genetics is strongly indicated as the cause of a significant majority of those not yet clearly identified as to origin.
- c. Rare disorders are often multi-symptom and require a wide range of services across the health, disability and social services sectors.
- d. “Relatively common conditions can hide underlying rare disorders – e.g. autism is a major symptom of Rett Syndrome, Fragile-X, Angelman, Adult PKU, Sanfilippo disease.....” (From European Commission, 2007)
- e. There are approximately 6000-8000 rare diseases. While these conditions are individually rare, the collective impact of them amounts to approximately 8% of the entire population being affected by a rare disease.
- f. For every affected person, on average two other people in the household are also affected, (often profoundly so, given the severity of the rare disease) – For inherited conditions more than 1 child in the household may be affected; for parents, roles fall outside the “norm” with extensive medical, behavioural, and physical demands in caring for their children.
- g. Rare disorders are often life-long and severe. They align significantly with chronic diseases which are also recognised as another significant burden on health systems, yet the connections are often not made by policy makers.
- h. The Public Health bill is an ideal opportunity for parliament to give some guidance and direction about this very important area of health need.

16 - Other nations and international agencies recognise the health impact of rare disorders/genetic disease.

- a. "In Canada it is estimated that [single gene disorders] account for up to 40% of the work of hospital-based paediatric practice" (Scriver 1995)
- b. "Genetic services that are introduced for the control of genetic diseases should provide a strong platform for the application of genetic technology to a broader range of public health challenges." (World Health Organization, 2005)
- c. The EU is considering a single, unified approach on rare disorders, due for public consultation in Feb 2008: "There is probably no other area in public health where the collaboration between the 27 different national approaches can be as efficient and effective as [rare disorders]" (European Commission, 2007)
- d. The establishment of the Office of Rare Diseases within the National Institutes of Health (USA) fosters education, research, and facilitates collaboration between families and clinical researchers, including international collaboration.
- e. Bringing New Zealand's approach to rare diseases on par with other nations and WHO recommendations is consistent with the Bill's "Statement of Public Policy Objectives": "that international health obligations are met."
- f. The International Genetic Alliance has published guidance for governments and health administrators on the approach they should take to rare disorders and the development of genetic services, in order to work towards equitable outcomes for the populations affected by these diseases.

17 - Problems with current exclusion of rare and genetic diseases from the Public Health Bill: They do not feature anywhere else in Government health strategies!

- a. Persons with rare diseases/ genetic conditions are not included as target groups of individuals with chronic conditions (National Advisory Committee on Health and Disability, 2007).
- b. Genetic diseases are considered low priority in the Health Research Council funding scheme. (Rare disorders are not mentioned at all.)
http://www.hrc.govt.nz/root/HRC%20Policy/Research%20Policy/Research%20Portfolios/Research_Portfolio_Strategies.html
- c. In fact, the HRC defers the study of gene disorders to the New Zealand biotechnology sector, which is a fragile, market-driven enterprise and in NZ, primarily focused on agricultural products (Helm, 2008).
- d. Rare disorders are not a priority area under the Ministry of Health's "Health Targets" <http://www.moh.govt.nz/healthtargets>
- e. Rare disorders are not prioritised as our public health system is burdened with other categories of non-communicable disease – such as tobacco addiction. A 1997 report by Brian Easton, estimated that without tobacco's direct and indirect costs, there would have been an extra \$785 million dollars that could have been used for other purposes (Easton, 1997).

18 - Genetic Services. Their importance in this debate.

- a. The National Health Committee in its report, "Molecular Genetic Testing in New Zealand" (Sept 2003), cites that "clinical genetics services in New Zealand are not well-resourced", and that our numbers of trained clinical geneticists and genetics counsellors are "...well-short of international standards" to provide suitable care. The Ministry of Health has so far taken no action on this report.
- b. Our primary health strategy provides important gains for general health in the population through early intervention, but this strategy is limited by an absence of training and experience in genetics to enable primary health practitioners to do more than symptomatic treatment for genetic diseases.
- c. One solution to this problem is a strong specialist genetic service with the capacity to diagnose, identify risk, initiate treatments and to educate and support primary health professionals in ongoing clinical care – all supported by quality specialist services to back them up or take over when appropriate. It has been nearly 5 years since the National Health Committee's report. Continued delay in implementing this puts families with genetic and rare diseases at a severe disadvantage in health provision.
- d. The result of this neglect is a growing disparity in health status, driven, not by socio-economic status or ethnicity, but by genetic makeup.

19 - Registers, register-based programmes, and screening: Newborn screening and antenatal testing/screening.

- a. New Zealand was a world leader in newborn metabolic screening in the 1960's, but in recent years lagged behind other programmes in terms of the number of conditions screened for. Since the introduction of the tandem mass spectrometer in 2006, the National Screening Unit has been able to expand newborn metabolic screening from 7 to 27 conditions. However significant lobbying was needed to obtain this result as there was no clear responsibility for who is to evaluate, fund and implement such programmes as new possibilities emerge. Similar problems occurred with the implementation of newborn hearing screening, ante/natal HIV screening, and others.
- b. We urge Parliament to initiate in this Bill a review of screening programme criteria and decision-making processes to ensure that emerging opportunities for screening (currently Fragile-X, Lysosomal Diseases, some Immune deficiencies and others for which the technological capacity is rapidly advancing), are captured early, decided upon quickly and, if appropriate, implemented promptly.
- c. The option of including genetic screening was discussed in the Explanatory Notes (pg 38), but not elaborated further in the Bill itself. The National Cervical Screening Program (NCSP) – which is well described in the Bill – may provide a useful framework in the design of a rare disease diagnostics / genetic screening programmes.
- d. The Bill expresses concerns about the Guthrie test (as a form of genetic screening), particularly in regard to the storage and use of medical samples and individual privacy rights. However, the very same issues are discussed in principle for the NCSP in Part 2, clause 26 (Retention of health information), clause 39 (Duty of confidentiality and authorised disclosure), and clause 53 (Certain information not to be disclosed).
- e. The World Health Organization (WHO) states that “screening programmes need to be supported by public education and regulatory structures to empower individuals to make informed decisions and to ensure that people are protected against discrimination as a result of their test results.” (WHO, “Control of Genetic Disease”, 2005). We think the NCSP can provide a framework for developing a wider rare disease diagnostics / genetic screening programme.

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