National Assembly for Wales / Cynulliad Cenedlaethol Cymru
Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol

Legislative Consent Memorandum: Medical Innovation Bill / Memorandwm Cydsyniad Deddfwriaethol: Y Bil Arloesi Meddygol
Evidence from Lord Saatchi - Member in Charge of the Medical Innovation Bill in the House of Lords – MIB 04 / Tystiolaeth gan Yr Arglwydd Saatchi – yr Aelod sy'n gyfrifol am y Bil Arloesi Meddygol yn Nhŷ'r Arglwyddi – MIB 04

NATIONAL ASSEMBLY FOR WALES

LEGISLATIVE CONSENT MOTION

IN RESPECT OF THE

MEDICAL INNOVATION BILL [HL] 2014-15

HEALTH AND SOCIAL CARE COMMITTEE INQUIRY

INTO THE LEGISLATIVE CONSENT MEMORANDUM

LAID BY THE MINISTER FOR HEALTH AND SOCIAL SERVICES

DECEMBER 2014

SUBMISSION OF LORD SAATCHI

SUBMISSION OF LORD SAATCHI TO THE INQUIRY

INTO THE LEGISLATIVE CONSENT MEMORANDUM

FOR THE

MEDICAL INNOVATION BILL [HL] 2014-15

Introduction

1. This submission is made, to the Health and Social Care Committee's Inquiry, on behalf of Lord Saatchi as the Member in Charge of the Medical Innovation Bill in the House of Lords.

2. The submission responds to the Legislative Consent Memorandum laid by the Minister for Health and Social Services in December 2014.

Legislative Competence of the National Assembly for Wales

3. Lord Saatchi—

   (a) understands that the position of HM Government is that the Medical Innovation Bill does not deal with matters within the legislative competence of the National Assembly for Wales,

   (b) also understands the contrary view of the Welsh Government set out at paragraph 12 of the Legislative Consent Memorandum, and

   (c) makes this submission on the basis that if the National Assembly is to debate the question of legislative consent it will want to have as clear an understanding as possible of the policy objectives of the Bill.

Purpose of the Bill

4. The purpose of the Bill is to give doctors and patients clarity at the point of treatment about what amounts to a responsible and lawful approach to innovation in medical treatment.

5. At present, the common law *Bolam / Bolitho* test requires doctors to wait and see whether they are threatened with legal or disciplinary proceedings if results from an innovative treatment turn out to be disappointed. At that point, the claimant patient and the defendant doctor each pay for two or more medical witnesses to go into the witness box, one to argue that the innovation was what a responsible body of medical opinion would have done and the other to argue the contrary. The arguments are played out in court and the judge decides between the two sets of witnesses. There is an inevitable element of unpredictability, as with all litigation.

6. The key policy driver for the Bill is to "bring forward" the *Bolam* test to the point of treatment. For the first time, the Bill summarises existing best clinical practice to articulate a set of principles by reference to which doctors and patients can determine with confidence and statutory authority, at the time when innovative treatment is offered, whether it is being offered in a responsible way.

Safeguards

7. The principles to be considered in determining responsible innovation include a series of safeguards designed to protect patients. The Bill has always contained a list of safeguards, but it has been re-fashioned during the course of the Bill's Parliamentary passage. In particular, the Secretary of State for Health commissioned Professor Sir Bruce Keogh, the Medical Director of NHS England, to draw up a revised list of safeguards, which was taken into the Bill by amendment at the Lords Committee Stage.

8. Principal among the list of safeguards is the requirement to obtain the views of appropriately qualified colleagues and to have regard to those views in a responsible professional manner. This is in effect the "responsible body of medical opinion" test used in *Bolam*, but brought forward to the point of treatment to enhance clarity and certainty.[1]

9. The other key requirements are transparency and accountability in decision-making around innovation. The latest version of the Bill includes a requirement for the patients' notes to include a record of the views of colleagues obtained.

Other details of the Bill

10. The Appendix to this submission includes a link to the Bill Team's Explanatory Notes to the Bill, which explains other details of the Bill.

Who wants the Bill?

11. The Department for Health ran a public consultation on the Bill in 2013/14. Over 20,000 individuals – including many patients and doctors – responded to support the Bill, based on many individual stories of the deterrent effect on innovation that the fear of litigation or disciplinary proceedings exerts.

12. Within the House of Lords, there has been strong support from all sides of the House, and from peers representing medical, legal and patient interests. Concerns raised early on in the Bill's passage have been met by amendments made in Committee and on Report. Proceedings so far have been entirely consensual, and it is hoped and cautiously expected that the same can be achieved for the Bill's final Lords' stage, Third Reading. The Appendix to this submission includes links to the debates on the Bill so far.

[1] The *Bolam* test is necessarily uncertain in the sense that it is applied only if and when a doctor is sued or charged with malpractice; and even when it is applied it is far from clear – for a recent illustration of its complexity see McGovern v Sharkey [2014] NIQB 117.

Data registration

13. Support for the Bill in the case of a number of organisations is conditional upon the Bill being amended to include provision for compulsory registration of the results of innovative treatment, positive and negative.

14. Lord Saatchi is strongly in favour of the inclusion of provision of that kind, which could result in the Bill being a major advance in the world of medical research. It is generally acknowledged by senior medical professionals that data arising out of innovative treatments could be of enormous benefit to patients and doctors, including being used to help determine which treatments should be tested by way of controlled clinical trial.

15. The introduction of a requirement for registration of the results of innovation would be an exciting breakthrough, replacing anecdotal evidence with a systematic database in a range of areas. Although structurally secondary to the primary purpose of the Bill – providing certainty and clarity in relation to responsible decisions to innovate – the creation of the database could be of at least equal practical importance for patients.

Opposition to the Bill

16. As recorded in the Legislative Consent Memorandum, a number of organisations have expressed concerns about the Bill. While some have been met by amendments in Committee or on Report, a degree of opposition remains, strong in some quarters.

17. In online commentary circles some of the strongest opposition has come from medical negligence lawyers. Leigh Day, in particular, have campaigned strongly and at considerable cost against the Bill. As noted above, the present system of uncertainty in the law makes it possible for medical negligence lawyers to advise large numbers of claimants to sue, not because there is clear evidence of malpractice but simply because the vagaries of litigation make it possible that the claimant's witnesses will be preferred to the defendants' on the day of trial. Much "no win no fee" or similar litigation is supported on this basis. When the Bill receives Royal Assent, the certainty which it brings will make it more difficult to bring wholly speculative claims: a doctor who has followed the transparency and accountability requirements of the Bill in a clearly rigorous and responsible way will be able to be confident of not being sued (while a quack will be more at risk of litigation or disciplinary proceedings, as he or she will be able to be shown as having failed to follow statutorily approved best clinical practice).

18. Apart from the concerns of the medical negligence legal sector about the loss of business, a number of legitimate concerns have been expressed about how the Bill will work in practice. The Bill team have worked with those expressing concerns to meet them through amendments tabled or to be tabled in the Lords.

Conclusion

19. Lord Saatchi hopes that the Committee will recommend that the Assembly should approve the Legislative Consent Motion.

20. Lord Saatchi and his advisers will be very happy to provide the Committee with any further information or assistance that would be helpful.

21. The Appendix to this submission provides links to additional sources of information about the Bill.

Daniel Greenberg
Parliamentary Counsel to the Bill Team
7th January 2015

APPENDIX

FURTHER READING

Bill as amended on Report - http://www.publications.parliament.uk/pa/bills/lbill/2014-2015/0070/lbill_2014-20150070_en_1.htm

Explanatory Notes to the Bill - http://www.publications.parliament.uk/pa/bills/lbill/2014-2015/0004/en/15004en.htm

2nd Reading House of Lords 27 June, 2014 - http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/140627-0001.htm#14062743000565

Committee Stage House of Lords 24 October, 2014 - http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/141024-0001.htm#14102458000643

Report Stage House of Lords 12 December, 2014 - http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/141212-0001.htm#14121229000622

Medical Innovation Bill Team Website - http://medicalinnovationbill.co.uk/

Frequently Asked Questions - http://medicalinnovationbill.co.uk/get-the-facts/