Department of Health

From the Rt Hon the Earl Howe P.C.
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Dear [redacted]

Re: Lord Saatchi's Medical Innovation Bill

Thank you very much for your letter dated 9th December 2014 in which you highlight an article from the Lancet Oncology dated 28th November 2014.

I have read this article with interest and am also aware of the letter published in the Times from a large number of senior oncologists. There are a large number of stakeholders who have raised concerns about the Bill. The Government has engaged with a number of these stakeholders to reassure them that the Bill does not remove any of the current safeguards in place to protect patient safety.

As you are aware, Lord Saatchi has identified the threat of litigation as a potential barrier to innovation, which is what prompted him to table the Bill. The Department of Health ran a consultation on the Bill from February to April 2014. This consultation revealed a significant diversity of views on the topic, including that some doctors do find the threat of litigation to be a block to innovation. It also revealed that many doctors do not and those doctors will be able to continue to rely on the existing common law.

The Government's position remains that it is supportive of the Bill since amendments were made to the Bill at Committee Stage on 24th October intended to ensure patient safety.

The Government's view is that the Bill does not apply a weaker test to a doctor's decision to innovate than the existing law of clinical negligence. The test of responsibility under the Bill is intended to be the nearest equivalent to the requirement under the Bolam test.

A key amendment made to the Bill at Committee Stage provides that where a doctor's decision to depart from the existing range of accepted medical treatments for a condition is taken responsibly, that departure is not negligent. As such, a doctor who acts irresponsibly is prevented from relying on the Bill.

In addition to this objective test of responsibility, the amended Bill requires doctors to "obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment", and to "take full account of the views obtained (and do so in a way in which any responsible doctor would be expected to take account of such views)." This means that a doctor will not be able to ignore those views or give them only minimal weight (such as only to note them), unless there are reasonable grounds for doing so. If a doctor were later challenged, the court would closely scrutinise how the doctor had taken account of the views expressed by other doctors. These provisions ensure that there is expert peer review of the doctor's proposal and that the doctor acts responsibly in taking account of that review.

A number of stakeholders and Lords have sought to amend the Bill to require that doctors obtain agreement to the proposed treatments by another responsible doctor. The Government has resisted such amendments for two reasons. Firstly, the Government considers this to be unnecessary as the provisions in the Bill already ensure expert peer review of the doctor's proposal. Secondly, such an amendment would create a risk of liability for the doctor whose agreement is sought.
Requiring another doctor's express agreement as part of the decision to carry out an innovative treatment opens up the possibility of a new negligence action against this second doctor. What's more, if that counter-signing doctor were sued they would not be able to rely on the Bill directly and the counter-signing doctor would not have any certainty about their legal position. This would discourage doctors from providing their views on the proposed treatment and may result in many innovating doctors being unable to meet the steps set out in the Bill.

You refer to the amendment made at Report Stage. This sets out the further steps which must be taken in addition to those in clause 1(3)(a) to (d) to ensure that the decision is taken in an accountable and transparent way. It requires doctors to record in the patient's notes details relating to: the views they have obtained from one or more appropriately qualified doctors; their decision to innovate; and the proposed treatment.

Department
of Health

This amendment does not remove any safeguards for patients and does not provide the doctor with any kind of immunity if they simply hear or record the views of other doctors. The doctor is still required to take full account of those views in a way in which any responsible doctor would be expected to do so. If the innovating doctor has to record the views of a doctor who does not support the proposed treatment, the innovating doctor is almost certain to be aware that he will be putting himself in a risky position as regards a possible negligence suit and would be highly unlikely to proceed.

Of course the doctor offering their opinion would want to know as much as possible about the patient before offering their opinion. Indeed, a doctor's professional integrity would be called into question if they were to give advice based on no, or only little, understanding of the patient's case.

On the point about the risk of increased litigation, it may be that overall litigation claims increase slightly as the new legislation is tested. However, this effect should only hold for a short time and longer term it may be that claims decrease because it will be clearer from the outset whether a doctor has acted responsibly (and thus not negligently) when using an innovative new treatment.

As I have outlined, the test of responsibility under the Bill is intended to be the nearest equivalent to the requirement under the Bolam test. As such the Bill should not have any impact on the likelihood of a successful claim in situations where a doctor has acted negligently.

I hope this letter has provided useful clarification.

Yours sincerely.

Earl Howe

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