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**Medical Innovation Bill: re-writing the law of clinical negligence**

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*J.P.I.L. 127* Lord Saatchi’s Medical Innovation Bill is designed to dispense with the Bolam test of whether a doctor’s treatment is negligent. He believes that the current law mandates adherence to standard practice and is an obstacle to medical innovation which, when removed, will lead to the finding of a "cure for cancer": In the face of opposition from medical and other bodies such as the BMA, MDU, MPS, the NHSLA and the Patients Association, he is driving the Bill through Parliament with the Government’s support. If this Bill becomes law, it will provide an indemnity to doctors in certain situations and deprive individuals of a right of redress when they or their loved ones are harmed by treatment which is not supported by a body of responsible medical opinion. Critics believe that the Bill is unnecessary because the current common law does not impede innovation. They are concerned that the Bill will have adverse ramifications for patient safety and even, perversely, for medical innovation.

**The Mission**

Lord Saatchi is a man with a mission: to cure cancer by re-writing the law of clinical negligence. Even before the Government had reported on a public consultation on his private member’s Medical Innovation Bill, he introduced a further version to the House of Lords where it received its second reading on June 27, 2014. At the time of writing the Government has indicated that it will propose amendments during the committee stage and Lord Saatchi has undertaken to accept them (although no amendments have yet been published).

The advertising guru’s late wife, novelist Josephine Hart, died of ovarian cancer in 2011. He has described the crushing experience of watching her deteriorate and die whilst conventional treatments failed to cure her and caused her further suffering. He claims that deaths due to cancers are "executions", treatment for cancer is "torture" and the lives of those who die of cancer are "wasted". He wants to speed up the search for a "cure for cancer" and believes that the greatest obstacle is the common law of clinical negligence. He aims to create an environment conducive to medical advancement by removing the threat of litigation from doctors who decide to provide treatment outwith the existing range of accepted treatments. The Saatchi Bill, as it is commonly known, provides an indemnity for doctors in certain situations. It substitutes the Bolam test of clinical negligence, which for decades has been applied flexibly and without undue difficulty, with a battery of statutory criteria which focus on the process of decision making rather than the substance of the treatment given.

Lord Saatchi and his supporters have claimed that opposition to the Bill comes from "greedy lawyers" who put "cash ahead of patients". In fact, opposition to the Bill from outside Parliament has been led by the medical profession, medical defence organisations, research bodies and patient groups. The legal community, perhaps fearing the *J.P.I.L. 128* expected backlash, has been largely silent. The British Medical Association ("BMA"), The NHS Litigation Authority ("NHSLA"), the Academy of the Medical Royal Colleges, the Medical Defence Union ("MDU"), the Medical Protection Society ("MPS"), AvMA, the Patients Association, the Motor Neurone Disease Association and the Academy of Medical Research, amongst others, have asserted that the Bill is unnecessary and have expressed significant concerns about its ramifications. The MDU has stated that the Bill is:

"aiming to solve a problem that doesn’t exist … it has never known of a case of medical innovation leading to a doctor being sued."

The Patients Association has warned that the Bill is a "huge threat to patient safety".
Undaunted, Lord Saatchi has dismissed the "fewer than 100" negative responses to the consultation by comparing them to the "staggering 18,655 people" who said "yes" to the Bill. In fact that was the number of people who expressed support for the Bill on the Saatchi Bill website and whose support was then channelled to the Government’s consultation. On this view, an individual doctor’s opinion is given the same weight as that of the BMA.

Within Parliament the Bill is now making rapid progress. Jeremy Hunt, Secretary of State for Health, has supported it, saying:

"We want to make sure doctors are not held back if they want to use pioneering treatments to offer a lifeline to dying patients."

The intention is to have the Bill enacted before the 2015 general election. In the House of Lords debate, opposition was voiced by Lord Brennan, Baroness Masham, Lord Turnberg and Lord Winston, who described the Bill as being of "colossal importance". But Lords Woolf and Mackay supported it and many other peers expressed great reassurance that such judicial heavyweights were advocates for the Bill.

Whether this Bill is likely to be the saviour of the terminally ill or a misguided and dangerous interference, it is legitimate to ask of it the fundamental question for any proposed legislation: what is the problem to which the Saatchi Bill is the proposed solution?

The current law

Lord Saatchi has exercised all his expertise in PR and media management to promote his Bill. The Daily Telegraph has campaigned vigorously in support. At the closure of the Government’s public consultation on the draft Bill Lord Saatchi claimed overwhelming approval for it, writing that "In democratic politics, perception is reality. If people perceive there is a problem, there is one".

Lord Saatchi has not stinted in his efforts to encourage the perception that there is a problem with the common law of clinical negligence. Current law, he claims, is preventing medical innovation, specifically in the field of cancer treatment. His article in the Health Service Journal in 2013 was headed: "Lord Saatchi: The law is killing patients". In The Daily Telegraph he wrote, "The road ahead to any innovation in cancer is closed by law". Speaking in the House of Lords he claimed that, "Current law is a barrier to progress in curing cancer".

The premise of the Bill is that litigation, or the fear of litigation, discourages innovative treatment. Evidence to support *J.P.I.L. 129* that premise is hard to find. The British Medical Association has said that it:

"is not aware of any evidence which shows that the possibility of litigation deters doctors from pursuing innovative treatments or that uncertainty exists over the circumstances in which a doctor can safely innovate without fear of litigation."

Cancer Research UK responded to the Government consultation by saying: "We have been unable to find evidence that fear of medical litigation is currently a barrier to innovation in cancer." The Association of Medical Research Charities wrote: "Through speaking to our members we are not aware that fear of litigation is a barrier to innovation."

Notwithstanding these and similar assertions by the National Institute for Health and Care Excellence ("NICE"), the MDU, the MPS, the NHSLA and many other representative bodies, Lord Saatchi has maintained that the current law of clinical negligence has an inherent antipathy to medical innovation:

"The law obliges the doctor to follow the status quo, even though he/she knows it leads only to poor life-quality followed by death. Science learns nothing from these thousands of deaths. Scientific knowledge does not advance by one centimetre, because the current law requires that the deceased receive only the ‘standard procedure’ — the endless repetition of a failed experiment."

In support of this thesis Lord Saatchi, speaking in Parliament, quoted case law: not the well-established authorities of *Bolam, Maynard or Bolitho*, but *Clark v MacLennan*, Crawford v Governors of Charing Cross Hospital and a text book on medical negligence authored by Nathan and Barrowclough published in 1957. He described *Clark* as an "important test case". It was a first instance decision in which Pain J. remarked that:
"It seems to me that … where there is a situation in which a general duty of care arises and there is a failure to take a precaution, and that very damage occurs against which the precaution is designed to be a protection, then the burden lies on the defendant to show that he was not in breach of duty as well as to show that the damage did not result from his breach of duty."

However, Mustill L.J. expressly "dissented from this approach" in the Court of Appeal in Wilsher v Essex AHA and few if any clinical negligence lawyers would regard Clark as relevant to current clinical negligence practice, let alone an "important test case".

Crawford was a pre-Bolam decision which has no relevance at all to current clinical negligence litigation.

Lord Saatchi did refer the House to the more important speech of Lord Diplock in Sidaway, saying:

"I hope that we can agree with Lord Diplock, who was looking for a better balance to be struck between therapeutic innovation and therapeutic conservatism. He warned of the dangers of so-called defensive medicine:

‘Those members of the public who seek medical or surgical aid would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well-tried method of treatment only, although its past record of success might be small, if he wanted to be confident that he would not run the risk of being held liable in negligence simply because he tried some more modern treatment, and by some unavoidable mischance it failed to heal but did some harm to the patient. This would encourage ‘defensive medicine …’.

Had he been an advocate in court, the Judge would have reprimanded Lord Saatchi for not completing the quotation:

‘... The merit of the Bolam test is that the criterion of the duty of care owed by a doctor to his patient is whether he has acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion. There may be a number of different practices which satisfy this criterion at any particular time. These practices are likely to alter with advances in medical knowledge. Experience shows that, to the great benefit of human kind, they have done so …’"

On July 15, 2013 Lord Saatchi said in the House of Lords:

"Will my noble friend consider the warnings of judges, including that of the noble and learned Baroness, Lady Butler-Sloss, that under current law no innovative work—such as the use of penicillin, or performing heart transplant surgery—would ever be attempted?"

This was an apparent reference to the decision of Butler-Sloss’s judgment in Simms, which he has often cited in the media as an example of how the current law impedes medical innovation. In fact her judgment demonstrates the precise opposite of what has been claimed. Simms was not a clinical negligence action but a "best interests" determination of whether previously untried treatment should be given to two young people who had variant Creutzfeldt-Jakob disease, contrary to the wishes of the NHS Trust. Perhaps controversially, the Judge deployed the Bolam test to give permission for the treatment. As Sir Robert Francis QC wrote in his response to the consultation on the Bill:

"It was not the law that stood in the way of innovative treatment in that case - it facilitated it by explicit reference to the Bolam test. Indeed the doctor wanting to provide the treatment was not deterred by the fear of litigation. He was inhibited by his employer."

Whatever else might be said about lawyers, we can spot the misuse of authority to support a bad point.

Lord Blencathra supported the Bill at its second reading on the grounds that patients should be permitted to consent to being guinea pigs for trying new treatments. Of course the current law does not prevent medical trials taking place in which thousands of patients participate. Would the current law protect a doctor from a finding of negligence if he carried out experimental treatment on a fully informed, consenting patient outside an established trial? The answer must be that: (i) a patient could only sue if they suffered avoidable harm as a result of the treatment; (ii) they could not sue on the basis of a failure to obtain informed consent if fully informed consent was given; but (iii) if no responsible body of medical opinion would condone the experimentation, the doctor would have been negligent. Is the law too restrictive in that respect? Even Lord Saatchi doesn’t appear to think so because the Bill provides that doctors shall not be permitted to treat patients for the purpose of
research unless the treatment is also in the patient’s best interests.\(^\text{19}\)

One issue of concern raised by Lord Mackay in the House of Lords debate on 27 June was that the \textit{Bolam} test cannot apply where there is no body of responsible medical opinion and that there will be no such body of opinion where treatment is truly innovative—there will be too few doctors who have experience of the treatment. In fact the \textit{Bolam} test has proved to be sufficiently flexible to deal with that situation. In \textit{Waters v West Sussex HA} [1995] 6 Med. L.R. 362 the Court applied the \textit{Bolam} test when dismissing a negligence claim where a neurosurgeon had deployed a "unique" technique and the patient suffered paralysis followi\(ng\) the operation. In \textit{Pollard v Crockard}\(^\text{20}\) Mr Justice Holland applied the \textit{Bolam} test where another neurosurgeon used a technique which was "previously unknown" in the United Kingdom. Again, the defendant was found not to have been negligent. Innovative treatment can be judged by experts in the relevant field as reasonable or rational, even if it has never before been tried on a patient.

Some of the Bill's proponents have said that it aims to "bring forward" the \textit{Bolam} test to the time when the decision is made. A doctor should know whether his decision is acceptable when he makes it, not years later when a judge considers expert evidence at court. This confuses the purpose of the law of clinical negligence which is to provide redress for harm caused when it ought not to have been caused: it is a compensatory not a punitive process. In any event, redress is afforded not when a doctor falls below an average standard of care, but only when he acts in a way which no responsible body of doctors would support. It might well be in the interests of all if the current law discourages a doctor from giving treatment when he is unsure whether any other doctors would condone it.

In the 57 years since the \textit{Bolam} decision, considerable medical advances have been made. The Saatchi Bill is not the result of a clamour for change from within the medical profession. The fact that some patients suffer terribly and die from conditions such as ovarian cancer is not a ground for criticising the medical profession or the law, let alone for changing the law. Nevertheless, even if the law has worked well, it is worth asking whether it is likely to be improved by the Saatchi Bill. To answer that question it is necessary to examine the detailed provisions of the Bill and their likely impact.

\textbf{Dispensing with Bolam}

The Medical Innovation Bill seeks to bypass the \textit{Bolam} test of whether treatment is negligent. Clause 1(2) of the Bill now provides:

"It is not negligent for a doctor to decide to depart from the existing range of accepted treatments for a condition if the decision is taken in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters."

The Bill does not apply to all cases of clinical negligence, only to treatment decisions. A surgical error would not be covered, for example. The courts would interpret the Bill's provisions with regard to the purpose of the Bill, stated in cl.1(1) to be to encourage responsible medical innovation. Nevertheless its ambit is wide.

The Bill applies only to doctors, not to nurses or other healthcare professionals, but a "doctor" is a person on the medical register and so includes general practitioners as well as specialists. It applies whether the doctor is acting within the NHS or in a private capacity, whether he is acting within or without a hospital, as part of a team or on his own.

Treatment of a condition is defined as "including a reference to its management (and a reference to treatment includes a reference to inaction)."\(^\text{21}\) It clearly covers conservative as well as invasive treatment, elective as well as emergency treatment and treatment of mental as well as physical conditions. "Innovative treatment" is not defined and cl.1(2) appears to apply to all treatment decisions, whether innovative or not.

The meaning of "accepted treatments" is not defined but it is likely to be interpreted as referring to the range of treatments which would be accepted by a responsible body of medical opinion. Treatment decisions currently considered negligent are those which depart from the existing range of accepted treatments. Under the Bill they would no longer be negligent, provided the decisions were taken in the prescribed manner \(\textit{J.P.I.L. 132}\). The Bill is clearly designed to change the law as to when a doctor is negligent.
The Bill’s provisions are not restricted to treatment of the terminally ill, to treatments which are experimental or to treatment which is a last resort when "standard" treatments have failed. It was surprising therefore to read Lord Woolf in \textit{The Daily Telegraph}:

"It is important to understand here that we are talking about a new law that will make a limited, but significant contribution in a small number of difficult cases. Maurice Saatchi, with the support of Health Secretary, Jeremy Hunt, and of the Government, is seeking to introduce legislation that will only apply to: (1) patients who are not responding to conventional treatments; (2) patients who give their consent to such innovation; (3) new treatments that are still at a experimental stage; (4) new treatments that hold out a real prospect of being able to help, both the patient and others in similar circumstances who come after them."

The Saatchi Bill is not targeted in that way.

\textbf{The decision-making process}

Provisions for determining whether the decision to depart from the existing range of accepted treatments has been taken via an accountable and transparent process, which allows full consideration of all relevant matters, are set out at cl.1(3):

"That process must include—

\begin{enumerate}
  \item consultation with appropriately qualified colleagues, including any relevant multi-disciplinary team;
  \item notification in advance to the doctor’s responsible officer;
  \item consideration of any opinions or requests expressed by or on behalf of the patient;
  \item obtaining any consents required by law; and
  \item consideration of all matters that appear to the doctor to be reasonably necessary to be considered in order to reach a clinical judgment, including assessment and comparison of the actual or probable risks and consequences of different treatments."
\end{enumerate}

Clause 1(3)(a) requires consultation with, but not the agreement of, "appropriately qualified colleagues". The question of what qualifications are appropriate is not answered. In the House of Lords, Lord Mackay stated that the process of consultation necessarily included having regard to others’ opinions. With respect, whether or not that is so, what the Bill does not require is agreement or consensus. In any event, indications are that the Government does not agree with Lord Mackay and will table an amendment requiring that treatment decisions must be agreed or supported by other doctors.

A “responsible officer” is defined by reference to Pt 5A of the Medical Act 1983. Clause 1(3)(b) requires notification not authorisation of the responsible officer. Many have questioned what useful purpose would be served by such notification.

Clauses 1(3)(c) and (d) re-affirm the present law of consent. Note that there is no requirement to elicit the opinions of the patient, only to consider opinions and requests they express. Following \textit{Sidaway} the common law effectively applies the \textit{Bolam} test to the issue of consent. So, \textit{Bolam} will continue to
apply to the obtaining of consent to treatment but not to the actual provision of the treatment. The impact of this on future litigation is considered below.

Clause 1(3)(e) is a subjective test: a doctor should consider matters he believes to be relevant to the decision in question, but those matters must include consideration of "actual or probable risks and consequences of different "J.P.I.L. 133 treatments". Presumably the "different treatments" to be taken into account should include the proposed treatment, but the extent to which other options must be considered is not clear.

Clearly the procedural requirements only fall to be considered if, under the current law, the decision to treat would be regarded as negligent. Otherwise, there would be no need for the Saatchi defence to be considered. So, a doctor might well consider all matters that appear to him/her to be relevant, obtain the consent of the patient, notify his responsible officer, consult with colleagues and still make a decision which no responsible body of doctors would support, even that no other doctor at all would support; under the Bill, that doctor would not be negligent.

Finally, cl.1(4) provides that:

"Nothing in this section—

(a) "permits a doctor to administer treatment for the purposes of research or for any purpose other than the best interests of the patient, or

(b) abolishes any rule of the common law in accordance with which a decision to innovate is not negligent if supported by a responsible body of medical opinion."

As to cl.1(4)(a), this is again a subjective requirement—did the doctor believe that the treatment was in the patient’s best interests? In his guidance on the Bill, the responsible parliamentary draftsman, Daniel Greenberg has written:

"The policy of the Bill is to support innovative treatment where the doctor is satisfied that it is likely to be in the best interests of the individual patient receiving treatment."

Were this requirement an objective one—was the treatment in fact in the interests of the patient—it would defeat the purpose of cl.1(2). Doctors are not found liable for giving treatment which is in fact in the best interests of the patient.

Mr Greenberg claims that cl.1(4)(b) preserves the Bolam test. I do not believe that it does. It preserves the common law rule as to what is not negligent, but not the rule as to what is negligent. Hence, a doctor who is not Bolam negligent will not become negligent if he fails to comply with the Bill’s process requirements. But a doctor who is Bolam negligent in relation to a treatment decision and who does comply with the Bill’s process requirements will no longer be negligent.

The impact on patients

If this was a Bill which, whilst unnecessary, would have no impact, it would be of less concern. However, as the Patients Association, AvMA and others have warned, the Bill risks undermining patient safety.

The Bill will prevent patients and their families from obtaining redress when harmed by treatment which no doctor would support, or which is irrational and irresponsible. Adherence to the Bill’s process requirements does not guarantee a rational, reasonable and responsible treatment decision. So it is that some critics have referred to the Bill as a "quack’s charter". Patients who are desperate to try treatments which are not evidence-based, or are untested or not supported by the medical community, may be the most vulnerable to exploitation. They may be the very patients who need the law’s protection; this Bill would significantly weaken that protection and prevent them from seeking compensation if they were exploited and injured. The Bill would provide a defence to doctors who, for
reward or otherwise, provide idiosyncratic treatment which has no rational basis and/or no support from other doctors.

As noted, the Bill’s protection of irrational or unsupported treatment is not restricted to innovative treatment of the terminally ill. The Saatchi defence provides immunity to doctors giving treatment in all manner of settings and to all manner of patients. There will be great attraction in seeking to rely on the Saatchi defence in a whole range of circumstances. The Bill seeks to ensure that treatment decisions are "accountable" yet it removes the opportunity for patients to hold doctors to account through the civil courts.

The impact on regulation

If passed, the Bill may also have ramifications for regulatory regimes. In the field of professional regulation, if a doctor is not negligent when providing treatment which no responsible body of doctors would support, then how can he be unfit to practise for doing the same? In its response to the Government's consultation, the General Medical Council ("GMC"), which regulates the conduct of doctors, stated that:

"Although the Bill aims to clarify and encourage good practice in responsible medical innovation we believe that it could have the opposite effect as well as unintentionally weakening the existing principles which we regard as fundamental to safe, effective patient care."

There is also concern as to how will the Bill sit with the regulation of new treatments, products and procedures? NICE has said the case for the Bill is "weak".

The impact on litigation

If there are greedy lawyers reading this article, who wish to put "cash before patients" they may wish to support the Saatchi Bill. It would be fertile ground for litigation in particular in relation to the interaction of the statute with the common law and the lack of clarity of terms such as "accepted treatment" and "appropriately qualified colleagues". As noted, the Bill seeks to preserve the current common law on consent to treatment. Thus the Bolam test remains effective in relation to consent but not in relation to whether the treatment decision was negligent. One can foresee particular focus in future litigation on the process of obtaining a patient’s consent to treatment which no responsible body of doctors would support.

Red tape

Responsible doctors making treatment decisions who are concerned about the risk of litigation will be faced with a new list of statutory requirements which they will be expected to meet. It can be foreseen that NHS Trusts and other employers will lay down guidelines for compliance with Saatchi. Authorised officers will be inundated with notifications. Doctors will be required to make a written record of consultations, notifications and considerations. New forms will be generated, filled and filed. New jobs created; new costs incurred. Where there is uncertainty as to whether a treatment is within the existing range of accepted treatments, the safest course will be to treat it as a Saatchi case and to ensure that the procedural requirements are fulfilled and documented. For example, doctors can currently prescribe off-label if it is in the best interests of the patient, and consent is given. Post-Saatchi, doctors prescribing off-label may well have to jump through several new hoops of red tape. This would have particularly serious implications for treatment decisions which have to be made urgently.

The impact on innovation

As several critics of the Bill have pointed out, there are many other more obvious barriers to innovation than the threat of litigation. But the Bill has nothing to say about funding, regulatory oversight of research and the introduction of new drugs and treatments, professional regulation, or about terms and conditions of employment which restrict what doctors may do. Further, the Bill applies only to doctors who treat patients, not to scientists or researchers who are central to the advancement of medical understanding. The idea that, freed from the shackles of threatened litigation, a lone doctor will find a cure for cancer is not one that seem to have chimed
with the scientific or medical bodies responding publicly to the Bill. Indeed the GMC has expressed concern that the Bill may actually "hinder responsible innovation." As the Bill progresses and amendments are made, it is foreseeable that the final Bill will lay more hurdles in the path of the medical innovator than currently exist. The Saatchi Bill may become the unfortunate paradigm of the legislative own goal.

Conclusion

Lord Saatchi has personal reasons for driving this Bill through Parliament but that should not prevent objective analysis of it by others. The Bill, rather like the treatment it seeks to promote, is not based on evidence. There is no substantial evidence that responsible medical innovation is impeded by the common law of clinical negligence. Worse still, the Bill is likely to expose vulnerable patients to increased risk. Whatever "protections" are written in to the Bill, they cannot effectively replace the current requirement that treatment should be rational and supported by a responsible body of medical opinion. If the Bill were revised to require that treatment decisions should be rational and Bolam reasonable, it would be rendered pointless.

Earl Howe, speaking for the Government at the Bill’s second reading said that “a necessary focus on patient safety must not stifle responsible innovation”. By supporting the Saatchi Bill it seems that the Government believes not only that patient safety and responsible innovation are in tension, but also that there has been too much emphasis on safety at the cost of a lack of innovation. The solution proposed by the Saatchi Bill is to prevent patients and their families from obtaining redress when ha

*N.P.I.L. 136* remed by treatment which no responsible doctors would support. It could soon become law.

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1. Debate on second reading.
3. The Sun, June 22, 2014.
4. Pace Association of Personal Injury Lawyers, which did publish a strong response as part of the Government’s consultation.


