Like books, one should never judge a Bill by its cover. Later this week, the Medical Innovation Bill reaches Report stage in the House of Lords, but I would like to demonstrate that it is fundamentally flawed in its premise, it is unnecessary, it removes essential protections for patients, and it increases the risks of their exposure to maverick doctors. I believe it will undermine not only patients' safety but medical innovation and so will have precisely the opposite effect to that intended.

Under current law, a doctor is negligent if he or she acts in a way which no responsible body of medical opinion would support, or which is irrational or illogical—the so-called Bolam test, as refined in the case of Bolitho. The Bill would rewrite the law on clinical negligence and a doctor whose decision to treat would not be supported by any responsible body of medical opinion, or was illogical or irrational, would be able to call on a new Saatchi defence if they fulfilled the procedural requirements of the Bill. That is important: the Bill's protection of doctors applies if the procedural requirements are met. The Bill states:

"For the purposes of taking a responsible decision to depart from the existing range of accepted medical treatments for a condition, the doctor must...obtain the views of one or more appropriately qualified doctors in relation to the proposed treatment".

There is no requirement for the second doctor to have seen the patient or even read their notes, and no requirement for them to be independent. They could be working at the same private clinic. It is of little reassurance that the treating doctor must "take full account of the views" of the second doctor if the second doctor is in collusion with the first in that treatment, which may be unreasonable.

If the Bill is passed, we will put patient safety at risk and we will no doubt have to return to amend the legislation subsequently. Let me quote from a letter forwarded to me by a constituent who had met a visitor to my constituency who managed to convince him utterly that this individual's company had found a cure—a miraculous treatment—for cancer, but was being obstructed by a vast conspiracy in the medical community. In the letter, David Noakes, who describes himself as the chief executive of a biotechnology company, refers to a compound he calls GcMAF, which he describes as "a human protein, present in 5 billion healthy people, that removes a number of diseases, including terminal stage 4 cancer. It has no side effects." He attaches a couple of scientific-y looking papers, which have no bearing on proving its clinical effectiveness. Mr Noakes continues:

"It's always difficult to get feedback, but we have hundreds of superb results. In Guernsey, we treat over 100 people and...I have 50 successes including 10 excellent cancer results. We have perfect feedback in our German and Swiss clinics, where our 7 doctors reduce tumours at the rate of 25% a week".

He says that he cannot do it in the UK "because the law is so destructive."

Here is the bit that really worries me. Mr Noakes states:
"But we state that if you have terminal stage 4...cancer, have not had chemotherapy, and you do the" so-called "GcMAF protocol, you have an 80% chance of being cancer free in a year."

In other words, what the company is specifically saying to people is that they can look forward to that result if they do not have chemotherapy—it is actively encouraging people not to have evidence-based treatment and promising that it has a cure for cancer.

Mr Noakes says that "The pharmaceutical industry is not interested in"this treatment, because there is no profit in it."It is too cheap, and can't be patented".

He says: "The chemo lobby is so powerful it has changed British law so that doctors are only allowed to prescribe the poison of chemo for cancer when there are...better treatments."

He adds, specifically:"Lord Maurice Saatchi is trying to get that law changed with his Medical Innovation bill, but against so powerful a lobby"and so on. In other words, for this individual and the seven doctors to whom he refers, the Bill would be carte blanche. They see it as a Bill that would provide them with protections. The Bill specifically refers to medical practitioners and doctors as the people who can take this forward"not homeopaths or unregistered doctors. He says that he has seven doctors in his company. If one of those seven consulted another doctor in the clinic, it is highly likely that they would agree that this was an eminently sensible treatment.

Julian Huppert (Cambridge, Liberal Democrat)

I thank my hon. Friend for giving way and for securing this debate on an important subject. It is a shame that more people are not in the Chamber to discuss it. There are some very real concerns. Does she agree that people who are terminally ill may be desperate for treatment, and that simply makes them prey to people who may be unethical, who may be trying to push the envelope, and who may be doing things that would harm them but that sound quite good?

Sarah Wollaston (Totnes, Conservative)

I agree with my hon. Friend. In my constituency a medically qualified individual attempted to set up a cancer conference. It had to be pointed out that under the Cancer Act 1939 it is not legal to advertise cures for cancer. The Bill would allow people to circumvent the Cancer Act. How easy is it to get a reference to a miracle treatment planted into a magazine article, for example? This is the real danger here. While the Cancer Act protects people against blatant advertising, it does not provide protection against the back-door advertising that we already see. What is to stop individuals who are absolutely desperate"as my hon. Friend has said"going to doctors with articles saying, "This is a cure. I want you to refer me to this clinic."

Julian Huppert (Cambridge, Liberal Democrat)

I will try to resist the temptation to intervene too often. Does she agree that this is not just about cancer? We have already had homeopathic doctors, who may practise medicine as well as homeopathy, claiming that they have powerful treatments for Ebola that the World Health Organisation will not let them work on. The Bill would open the door for all sorts of quacks who will do serious harm in the name of medical innovation.

Sarah Wollaston (Totnes, Conservative)
I agree. I thank my hon. Friend for making the point that this is not just about cancer treatment but about a wide range of surgical treatments and therapies for any number of conditions.

If the Bill is about reducing medical litigation so that doctors are free to undertake innovative treatments, why do those who are involved in medical litigation say that there is no need for it? The Medical Defence Union, the Medical Protection Society, even the NHS Litigation Authority, are clear that the law, with the Bolam and Bolitho tests, is well established. They feel that the Bill could increase uncertainty. The MPS briefing says:

"Fundamentally, current law allows doctors acting responsibly to innovate, and this Bill is unnecessary. The time has come for the debate to shift towards improving education about the present law, rather than confusing the law through a new piece of legislation." That is another point that is worth bearing in mind.

Far from promoting medical innovation, the Bill could undermine recruitment to genuine clinical trials. If someone had been persuaded by the likes of the doctors in the letter that I read out that there was a miraculous treatment for their terminal cancer, why would they wish to be enrolled in a clinical trial and be part of a randomised trial? If they could circumvent that and go along to a private clinic, why would they do that? Medical research does not just answer the question about whether a treatment works; it also helps answer the question whether a therapy or procedure has serious side effects. The history of medicine is littered with good intentions and innovations that seemed like a good idea but turned out to have disastrous side effects.

I think, for example, of the use of 100% oxygen for premature babies, which led to blindness, or the use of steroids after head injury, which might have seemed like a good idea at the time but led to many, many deaths until it was realised that it was a dangerous innovation. There is an assumption that all innovation must be good innovation, but much innovation can be dangerous.

The randomised double-blind trial has been one of the greatest advances in medical science and has provided enormous protection for people. I look back at my time in medicine. Fairly soon after I qualified in 1986, I was a junior doctor on the Hedley Atkins breast unit. The newly appointed consultant is now Professor Sir Mike Richards, who is one of the country’s foremost and respected experts in cancer, formerly the cancer czar. He does not think the Bill will protect patients. We need to listen to the opinion of those who have serious concerns about such Bills. When I was working on that cancer unit in the 1980s, very many of the patients who did not survive at the time would survive today going to the same unit with similar conditions. That is because we now know what the best treatments are. We know that not from a series of unlinked anecdotal treatments, but because of former patients who were enrolled in clinical trials.

The accusation sometimes made is, "Aren't clinical trials just experimenting on people?" Far from it. There seems to be a benefit for everyone taking part in a clinical trial, even those who are not receiving a treatment that turns out to be more effective. If the Bill is passed and undermines enrolment in clinical trials, we will be doing a grave disservice to medical innovation, and it will be to our great shame to have done so. I would like the Minister to address that point when he responds.

That is a fundamental flaw in the Bill. There is also a fundamental flaw in the premise that separate anecdotal treatments can progress medical research. Interestingly, clause 1(5)
states:

"Nothing in this section permits a doctor to carry out treatment for the purposes of research".

In other words, it specifically precludes the treatments being linked in any way, so we will learn nothing from these treatments. Lord Saatchi’s premise is that his Bill will advance medical knowledge, but there is no evidence that it will advance medical knowledge an inch because we will not be able to answer that fundamental question about whether there are unintended harms from the treatments or any long-term benefits.

Where will the evidence be of benefit from those "innovative treatments"? Will the Minister look carefully at that, and be clear in responding? The list of bodies opposed to the Medical Innovation Bill is very long—the Academy for Healthcare Science, the Academy of Medical Royal Colleges, the Academy of Medical Sciences, the Medical Research Council, the Wellcome Trust, Action Against Medical Accidents, the Association of Medical Research Charities, the Association of Personal Injury Lawyers, the British Medical Association, the British Pharmacological Society, Cancer Research UK, the Good Thinking Society, Healthwatch, the Medical Protection Society, the Medical Defence Union, the Motor Neurone Disease Association, the National Institute for Health and Care Excellence, the NHS Health Research Authority and the NHS Litigation Authority.

Richard Francis QC, one of our most respected national authorities on patient safety, opposes the legislation. I think that we ought to reflect carefully on his words:

"If there is misunderstanding then it should be corrected by guidance, not by legislation which exposes vulnerable patients to unjustified risk and deprives them of remedies when mistreated by those who have no acceptable justification for what they have done."

Those are very serious words indeed. The legislation is also opposed by the Royal College of General Practitioners, the Royal College of Physicians, the Royal College of Psychiatrists and the Royal College of Radiologists. That is an important list.

There is a powerful lobby in favour of this legislation that purports that those who oppose it are somehow dinosaurs.

I urge the Minister to read the letter from 100 leading oncologists that was published in The Times on 13 November, which states:

"We devote our professional lives to treating patients with cancer and advancing research that contributes to finding more effective treatments for cancer. We neither want nor need Lord Saatchi’s bill. We do not believe that it will help our patients or future patients. We are dismayed that the bill is being promoted as offering hope to patients and their families when it will not make any meaningful difference to progress in treating cancer.

The law of medical negligence does not hinder our work or prevent innovation. There have been significant advances across all the modalities of cancer treatment over recent decades. There was no call for this change in the law from the medical profession. The current law already allows us to use off label drugs and to try new treatments when they are in patients’ best interests.

We are concerned that rather than promoting responsible scientific innovation in the treatment of cancer, the Medical Innovation Bill will actually encourage irresponsible experimentation.
producing nothing more than anecdotal 'evidence', at the potential expense of causing serious harm and suffering to patients, their families and carers. Innovation is best carried out within the discipline of controlled clinical trials, not by individual doctors acting on a whim."

I think that sums it up well.

Were we to title the Bill correctly, it would be called the medical anecdote Bill. We should be saying that it makes provision in relation to anecdotal treatments in medical treatment. If we titled it correctly, there would be no question whatsoever of its having Government support. I urge the Minister in the strongest terms please not to give the Bill Government backing. To do so, I think, would be to our great shame. We would undoubtedly have to return to amend it. It would put patients at risk, and it would put recruitment to clinical trials and genuine innovation at risk.

I look forward to hearing the Minister's response and about the many good things the Government have done to promote genuine innovation. I will not detain the House by offering that list now, because I know the Minister has done more than anyone I can think of in the House to promote true medical innovation. I therefore hope he will recognise that the Bill would do quite the opposite, and ensure that it does not progress.

Sarah Wollaston (Totnes, Conservative)

Lord Saatchi has said that 20,000 people support his Bill, but if people are asked whether they are in favour of medical innovation, they are likely to answer yes, and if the same people are asked whether they are likely to support medical anecdotes, I think they are likely to say no. Sometimes the answer depends on the question being asked.

Sarah Wollaston (Totnes, Conservative)

Does the Minister accept that a doctor who uses such innovative treatments within the NHS is protected under existing law and that we do not need new legislation to make them available to patients?

Sarah Wollaston (Totnes, Conservative)

Does the Minister accept that that cannot happen under the Bill, and that those things will remain a series of unlinking anecdotes? In medical science and for the safety of patients no one will be able to track whether there were unintended consequences or benefits, and it will not advance the cause of medical innovation whatsoever.

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