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THE "SAATCHI BILL"

Unnecessary, mistargeted, and will put vulnerable patients at risk

The Medical Innovation Bill is unnecessary, mistargeted, and will put vulnerable patients at risk.[1] In its response to the public consultation, the BMA said it "strongly believes that the draft bill should not become law."[2] I agree.

The bill's laudable aim is to promote responsible medical innovation, but the draft on which the government has consulted seeks to do so by providing that doctors who give treatment that no responsible body of medical opinion would support shall not be negligent.

The bill is aimed at the wrong target. As the Medical Defence Union said,[3 4] medical negligence law does not prevent responsible innovation. Doctors who act in accordance with a responsible body of medical opinion are not negligent, even if most other doctors would not support the treatment given (the Bolam test). Sir Michael misunderstands the judgment of Lady Butler-Sloss in Simms. Far from holding that the Bolam test obstructed innovative treatment, she deployed it to justify allowing untried treatment to be given to two patients with variant Creutzfeldt-Jakob disease. Whether that was a good decision or not, it cannot be used to argue that the current law impedes innovation.

LEFTERIS PITARAKIS/AP/PA

The bill has nothing to say about matters that have a real bearing on innovation, such as funding or regulation.

"Innovative treatment" is not defined, so the bill applies to all negligent decisions to treat, whether innovative or not. It does require that certain procedural steps should be taken by the doctor before making the decision, but, by definition, the decision would still be one that no responsible body of medical opinion would support. Contrary to some reports, the bill does not require other professionals to endorse the doctor's decision.

Surely there are better ways of promoting responsible innovation than by removing the right of redress to patients who are harmed as a result of treatment that no responsible body of doctors would support?

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Competing interests: I am a barrister practising in clinical negligence law.

1 Rawlins MD. The "Saatchi bill" will allow responsible innovation in treatment. *BMJ* 2014;348:g2771. (15 April.)
2 BMA. Legislation to encourage medical innovation—a consultation. British Medical Association response. http://bma.org.uk/-/media/files/pdfs/working%20for%20change/policy%20and%20lobbying/bmaresponselegislationencouragemedicalinnovation.pdf.
3 Medical Defence Union. MDU fears Medical Innovation Bill will confuse rather than clarify doctors'position. 2014. www.themdu.com/press-centre/press-releases/mdu-fears-medical-innovation-bill-will-confuse-rather-than-clairfy-doctors-position.
4 Medical Defence Union. Legislation to encourage medical innovation—a consultation. 2014. www.themdu.com/~/media/Files/MDU/Publications/Consultation%20responses/MDU%20response%20to%20consultation%20on%20Medical%20Innovation%20Bill.pdf.

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Wrong prescription for a badly formulated diagnosis

Surely it is reckless to interfere with something that "works."[1] Rawlins's logic seems to be that there is no legal impediment to innovation; there is "anecdotal" evidence of fear of law; and therefore we need more law (rather than simple reassurance, clear information, and financial stimulation).

This bill is the wrong prescription for a badly formulated diagnosis. Bad doctors guess and then justify themselves. Bad researchers set out to find what they know. That is how Saatchi's bill team operates: its PR campaign finds that lots of people agree. So what? This carries no weight because opinions do not change scientific facts. Good innovators and lawyers would pay more attention to the weaknesses and disagreement. It is insulting that one rich persuasive person with deep pockets, access and influence can bully the medical profession for not being innovative (enough). This is not a simple cultural debate—it is a category error for a grieving widower to suggest a new law because sadly neither he, nor any medical practitioner, could stop his wife dying. Law is not the first choice instrument to drive innovation, creativity, nuance, and shades of grey in the past or in other jurisdictions.

The bill just doesn't make sense. In our professional and academic practice we look for unconscious biases and make declarations of interest. We "follow the money" and ask "who benefits?" The only people who assuredly benefit from devising new law are barristers specialising in legislation or members of the bill team driving this project. Could Saatchi desist now that he has stirred up public discussion and confirmed that there are already no legal impediments? A foundation that supported innovation would be a more positive legacy.

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Full response at: www.bmj.com/content/348/bmj.g2771/rr/695556.

1 Rawlins MD. The "Saatchi bill" will allow responsible innovation in treatment. *BMJ* 2014;348:g2771. (15 April.)

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Unlikely to promote innovative treatments and could harm

The "Saatchi law" was drafted with the noblest of intentions but it faces serious hurdles in achieving the aim of promoting innovative treatments.[1]

Firstly, the bill needs to be reconciled with various mandatory EU directives on medicinal products.[2] As the Medicines and Healthcare Products Regulatory Agency states, the EU "Directive 2001/83/EC relating to medicinal products for human use" takes precedence over the UK Medicines Act.[3] Because "innovative treatments" and "research treatments" are virtually identical, this bill also needs to be reconciled with the EU directive on clinical trials.[4]

Secondly, the development of novel, innovative treatments has a high failure rate. Only one in 1000 new compounds that enter preclinical testing are estimated to make it to human testing and only a fifth of these receive Food and Drug Administration approval.[5] This is not due to any legal or financial hurdles—most novel drugs are just not good enough for clinical use. So the proposed law is unlikely to promote innovative treatments. Worse, it could harm patients by promoting the use of ineffective new drugs. Hence, unlicensed drugs, however innovative, should be tested in peer reviewed, ethically approved, clinical trials to obtain

scientifically credible information on safety and efficacy.

Thirdly, there is an important distinction between licensed and unlicensed drugs. Licensed drugs are likely to have good safety data so their use for unlicensed conditions is less risky. The legal safeguards proposed in the Saatchi law could end up curtailing the current widespread use of licensed drugs for unlicensed conditions.

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1 Rawlins MD. The "Saatchi bill" will allow responsible innovation in treatment. *BMJ* 2014;348:g2771. (15 April.)
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Author's reply

The current law is clearly confusing, even to lawyers. Poole and Bewley claim that the bill is unnecessary, and that the existing state of affairs allows for "responsible innovation" along the lines of the Saatchi bill. Lord Woolf—a former master of the rolls and a former lord chief justice—disagrees. In an article published on 24 April 2014, he stated: "what I do know about, from sitting as a judge, are the cases where doctors are sued for negligence because they have innovated in the treatment they offer, rather than following generally accepted medical standards."[1] The Saatchi bill will bring much needed clarity to an area of law that even the most eminent lawyers disagree about.

Sundar is confused about the scope of EU legislation on the use of drugs. A licence (marketing authorisation) is required before a drug can be provided for sale or supply; but, as I explained in my article, this does not pre-empt the provisions of Section 9 of the Medicines Act 1968 allowing doctors "to supply a medicinal product to a patient under his or her care."

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Competing interests: None declared.

1 Woolf H. Saatchi bill: your last chance to help. *Daily Telegraph* 2014. www.telegraph.co.uk/news/features/10785352/Saatchi-Bill-your-last-chance-to-help.html.

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Widespread criticism of the bill

McCartney argues that the "Saatchi bill" risks encouraging quackery.[1] Criticism of the bill is growing, despite appeals to the authority of various "respected clinicians" who helped to draft it. So far, critical organisations include:

Academy of Medical Sciences, Medical Research Council, and the Wellcome Trust
Academy of Medical Royal Colleges
Academy for Healthcare Science
Motor Neurone Disease Association
Royal College of Radiologists
Medical Defence Union
Cancer Research UK
HealthWatch (charity 1003392)

Additional responses include:

Robert Francis QC
General Medical Council
Royal College of Physicians
NHS Health Research Authority
Action against Medical Accidents
Association of Personal Injury Lawyers
Professor Michael Baum
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Competing interests: None declared.

The URLs for the statements are available in the letter on bmj.com.

1 McCartney M. Withdraw Saatchi's quackery bill. *BMJ* 2014;348:g2974. (29 April.)

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TARGETS FOR DEMENTIA DIAGNOSES

Initial specialist assessment is needed in suspected dementia

Brunet highlights the pressure on Herefordshire GPs to increase the number of diagnoses of dementia.[1] As the local memory clinic feels the strain, Herefordshire clinical commissioning group is trying to ease the bottleneck by encouraging GPs to make the diagnosis themselves. A recent newsletter stated that "adding a diagnosis of dementia does not require a referral to memory clinic, if the diagnosis is clear and treatment would not be beneficial."[2]

This is contrary to National Institute for Health and Care Excellence guidelines and the specifications for the "facilitating timely diagnosis" enhanced service,[3 4] which recommend referring patients with suspected dementia for a diagnosis to be made and specialist assessment of the subtype. This can guide possible treatment and enable access to the support and benefits that early recognition is claimed to provide.

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Competing interests: None declared.

1 Brunet M. Targets for dementia diagnoses will lead to overdiagnosis. *BMJ* 2014;348:g2224. (1 April.)
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Cite this as: *BMJ* 2014;348:g3160

The difficulty and dangers of diagnosing dementia

As Brunet rightly says, the diagnosis belongs to the patient.[1] That is precisely the problem in dementia, when the patient often has little insight and does not notice symptoms. The drive for GPs to increase diagnosis rates is admirable, but there are many unknowns and potential dangers.

Diagnosis in people with language barriers, no collateral history, chronic mental illness, epilepsy, hearing and visual loss, previous substance misuse, illiteracy, or a combination of these can be difficult.

The focus on memory symptoms narrows the focus on Alzheimer's disease and misses other common types of dementia. The failure of all cases of amnestic mild cognitive impairment to convert to Alzheimer's disease and the behavioural phenocopy variant of frontotemporal dementia illustrate the uncertainty of the diagnosis.

Many patients referred to my general or cognitive neurology clinic with dementia are a mixture of the worried well and those with

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depression, anxiety, insomnia, drug side effects, previous brain injury, and sleep apnoea—all treatable and easily missed if a diagnosis of dementia is already in place. Recently, despite having written about it with colleagues,[2] I have been unable to remove the label of dementia from patients who had previously been diagnosed by others but clearly did not have the disease (but some of the conditions above). Patients can be unhappy not to have dementia, possibly because the label allows much support. This is uncharted territory but will probably become common with this drive for early non-specialist diagnosis (although specialists get it wrong too).

Empowering patients' families and friends to express concerns, standing up for the vulnerable who cannot stand up for themselves, and appreciating diagnostic difficulties and the effect of comorbidity can improve care; solely increasing diagnostic target rates is unlikely to.

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Competing interests: I have been struggling to undiagnose people with no dementia but with a dementia diagnosis.

Full response at: www.bmj.com/content/348/bmj.g2224/rr/696133.

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2 Coebergh JA, Wren DR, Mumford CJ. "Undiagnosing" neurological disease: how to do it, and when not to. *Pract Neurol* 2014; published online 24 Mar.

Cite this as: *BMJ* 2014;348:g3162

Achieving quality of care in dementia by timely diagnosis

Brunet thinks that current interest in dementia will lead to harm and overdiagnosis.[1] This current awareness is a triumph for a concerted approach from patients, carers, the public, professionals, charities, policy makers, and politicians. There is great dissatisfaction with existing services, especially regarding delays in diagnosis and support immediately after diagnosis and throughout the illness. People involved in dementia practice and policy want to improve this situation so that patients with dementia, families, and carers feel supported at every stage of the illness.

Barely half of those with dementia have a diagnosis, so talk of overdiagnosis is surprising. It does a disservice to the estimated 300 000 people with dementia who, because of that lack of diagnosis, cannot access the support they need. Recognition of dementia enables support to be put in place and may prevent avoidable admission to hospital, longer stays, and admission to care in a crisis.

The diagnosis of dementia can sometimes be a challenge and all thoughtful clinicians would accept that occasionally they make an inaccurate diagnosis of dementia or its subtype. The solution to this problem is to improve education and the interface between primary and secondary care.

Incentives are not compulsory but do deliver investment for extra work. Primary care is under great pressure, so it is not unreasonable to provide a financial incentive if additional work is being done.

The debate around dementia is important and we look forward to a continued dialogue with colleagues of varied viewpoints, but we owe people with dementia and their carers a better quality of care. This can be achieved only by appropriate and timely diagnosis.

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Full response and competing interests at: www.bmj.com/content/348/bmj.g2224/rr/694634.

1 Brunet M. Targets for dementia diagnoses will lead to overdiagnosis. *BMJ* 2014;348:g2224. (1 April.)

Cite this as: *BMJ* 2014;348:g3199

Author's reply

Sleath has already experienced the unfortunate tendency for target setting to lead to perverse behaviours. Surely the recommendation for GPs to diagnose dementia without reference to the memory clinic has come about to satisfy targets rather than out of concern for patients? It is also an example of the disturbing disconnect that often exists between diagnosis and support. Coebergh rightly raises the added challenge of making a diagnosis of dementia in those with concomitant illness, and the difficulty of removing such a diagnosis, even when it is erroneous.

Burns and colleagues are wrong to say that I think the "current interest in dementia will lead to harm and overdiagnosis." I welcome the much needed attention that dementia care has received in recent years. It is specific policies that worry me, particularly the new concept of setting targets for diagnosis rates. I am disappointed that Burns and colleagues did not mention this central theme of the article or acknowledge the ethical considerations and potential harms of such a policy.

It is illogical to suggest that because some people with dementia are still undiagnosed, we should not consider the possibility of overdiagnosis. This seems complacent because not only are the estimates outdated and in dispute, but the presence of undiagnosed people in the community is of no consequence to someone who has been overdiagnosed—the existence of one does not exclude the possibility of the other.

We do owe patients with dementia better care, but this should be achieved by improving the services and support we provide, rather than by the untested policy of setting targets for diagnosis.

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Competing interests: I have received income from publications including *Pulse*, *Prescriber*, and the *Guardian* for writing and speaking.
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FAT AND OIL CONSUMPTION

Nutritional survey data are inaccurate

Micha and colleagues' paper is the latest of many articles attempting to investigate the diets of nations.[1] Its extended description of data analysis techniques may bemuse many readers. Surely authors of such statistical sophistication know what they are talking about?

But this research suffers from the same fundamental flaw as all such studies—the poor quality of the primary data on individual food consumption.

Although diet surveys vary in their methods, all rely on subjects telling researchers honestly what they eat. But such "self report" data are inaccurate. In the trade, the problem is called "under-reporting." In plain English, people lie.

Subjects respond normatively. They claim to eat a healthier diet than they actually do. These are white lies like we all tell every day.

Nonetheless, they are large lies. In the UK, separate research using a biomarker, "doubly labelled water," showed that adults under-report calories by 25%,[2] adolescents by 34%.[3] With soft drinks, subjects claim to drink a quarter of what manufacturers report selling.[4]

A review of the US national diet survey found that "data on the majority of respondents (67.3% of women and 58.7% of men) were not physiologically plausible."[5] Subjects claimed to eat less than is necessary to stay alive.

Readers receive no inkling of such problems. The "Methods" section describes much subsequent effort, but not how intake information was gathered. This appears in fig 1, which shows that all consumption figures come from self reports. Nor is under-reporting discussed, not even in the "Strengths and weaknesses" section.

No secondary data manipulations, no matter how sophisticated, can correct such gross flaws in the primary data.

The numbers presented for fat consumption are not credible. Given the limitations of diet surveys, no one knows the true figures, but these estimates are almost certainly wrong.

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Competing interests: None declared.

Full response at: www.bmj.com/content/348/bmj.g2272/rr/695522.

1 Micha R, Khatibzadeh S, Shi P, Fahimi S, Lim S, Andrews KG, et al; on behalf of the Global Burden of Diseases Nutrition and Chronic Diseases Expert Group (NutriCoDE). Global, regional, and national consumption levels of dietary fats and oils in 1990 and 2010: a systematic analysis including 266 country-specific nutrition surveys. *BMJ* 2014;348:g2272. (15 April.)
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Lack of evidence that saturated fat causes heart disease

From table 2 and the references of their systematic analysis, Micha and colleagues seem to recommend replacing saturated fatty acids (SFAs) with polyunsaturated fatty acids (PUFAs) to lower the risk of cardiovascular disease.[1] As support they refer to the joint WHO/FAO expert consultation from 2003, in which the evidence came from an American Heart Association consensus report. The only argument in that report came from the Nurses' Health Study, but from the tables in that study it seems that, after multivariate adjustment, including various types of dietary fats, the relative risk of coronary heart disease did not differ significantly between the different levels of dietary SFA intake.

Micha and colleagues also refer to Bradford Hill's criteria for causation, but the idea that saturated fat causes cardiovascular disease does not satisfy any of them.

For example, more than 25 cohort and case-control studies have shown that patients with coronary heart disease do not eat more SFAs than others. In seven studies, stroke patients had eaten significantly less.[2]

A meta-analysis of 10 cohort studies with more than 400 000 people found that high consumers of dairy products had a significantly lower risk of cardiovascular disease than low consumers,[3] and a thorough review of the associations between dairy products and

cardiovascular disease showed no evidence of harmful effects.[4]

A recent systematic review of 76 observational and experimental studies that looked at 530 525 patients found no association between increased intake of PUFAs or decreased intake of SFAs and cardiovascular disease.[5]

To recommend replacing SFAs with PUFAs without defining which type of PUFA is also questionable. This is because the dominant PUFA in processed food is omega 6, and food with a high omega 6 to omega 3 fatty acid ratio is associated with serious effects on human health.

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Competing interests: None declared.

Full response at: www.bmj.com/content/348/bmj.g2272/rr/695803.

1 Micha R, Khatibzadeh S, Shi P, Fahimi S, Lim S, Andrews KG, et al; on behalf of the Global Burden of Diseases Nutrition and Chronic Diseases Expert Group (NutriCoDE). Global, regional, and national consumption levels of dietary fats and oils in 1990 and 2010: a systematic analysis including 266 country-specific nutrition surveys. *BMJ* 2014;348:g2272. (15 April.)
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Authors' reply

We agree with Winkler that the interpretation of dietary data requires appropriate perspective, context, and recognition of strengths and limitations, as is true for any scientific research. But Winkler's concerns reflect only a partial understanding of the strengths and limitations of various nutritional assessment methods.

The interpretation and validity of individual level dietary data depend on the dietary assessment tool used (such as diet records, diet recalls, semi-quantitative food frequency questionnaires, tissue biomarkers) as well as the level of assessment required (such as individual intake *v* population or group mean intake) and the nutrient, food, or dietary pattern of interest. In relation to these considerations, various dietary instruments have different strengths and weaknesses, and their validity and reliability have been extensively documented.[1 2] Overall, the validity and long term reliability of food, nutrient, and diet patterns assessed by such instruments are reasonable, similar to other widely used measures such as blood pressure and blood cholesterol. Furthermore, when used to assess population means, as in our study (rather than to assess individual intakes), these dietary instruments have even stronger validity, especially when using diet records or recalls, which were the main instruments used in our analyses.

We agree that, in contrast to measurement of specific nutrients and foods, total energy intake is poorly assessed by dietary questionnaires. Thus, few nutritional experts recommend use of dietary questionnaires to assess total energy, and total energy was not an endpoint in our investigation. However, owing to correlated errors, total energy assessed by dietary instruments is useful for energy adjusting estimates of nutrient and food intakes to increase their validity. Consequently, we reported intakes of these key dietary fats and oils adjusted for energy.

We are familiar with Ravnskov's work and views on dietary fats and heart disease, and we appreciate his interest in our recent work. However, the aetiological effects of these dietary fats and oils on chronic diseases was not the subject of this manuscript, and Ravnskov and interested readers can review investigations on these topics by us and by others.[3-6]

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Competing interests: See www.bmj.com/content/348/bmj.g2272.

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