

sexual violence is contradicted by such methodological limitations, which do victims and health professionals a disservice.

We declare that we have no competing interests.

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Authors' reply

As noted by Céline Denis and colleagues, Natsal-3 is the first of the Natsal surveys to include questions on experience of sexual violence. Our decision to do so was guided by our adoption of a more holistic definition of sexual health that, in addition to the traditional domains of sexually transmitted infections and unplanned pregnancies, also includes sexual function and violence.¹ It is an important, and arguably overdue, addition to the survey that has provided valuable information on the scale of non-volitional sex in Britain and the need for action to address it.² We fully acknowledge that there is a range of experiences that constitute

sexual violence that we did not ask about, which is a matter of regret. When designing the questionnaire, about 5 years ago, sexual violence had not fully come to the fore as a topic of public health importance and new questions were required to compete with a wide range of topics traditionally included in the survey. This is certainly a section of the survey that we will seek to develop for Natsal-4.

We do not ask questions about sexual experiences at age 12 years or younger, whether consensual or otherwise, on the grounds that this is likely to be an overly sensitive area for (generalist) interviewers to deal with. Querying on the part of ethical review committees, even of questions probing sexual experience before 16 years of age, suggests that we would have had difficulty in obtaining ethical approval had we sought to do so.

We declare that we have no competing interests.

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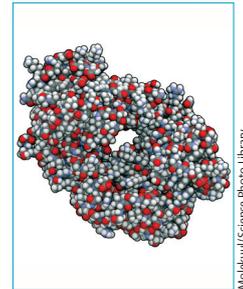
Product licences for alemtuzumab and multiple sclerosis

Alemtuzumab was licensed for the treatment of active relapsing-remitting multiple sclerosis in the European Union on Sept 17, 2013; and, to date, in at least three other countries (Canada, Australia, and Mexico) with several other applications pending. On Nov 13, 2013, the US Food and

Drug Administration (FDA) Advisory Committee voted by a majority that there is sufficient evidence for superiority of alemtuzumab over interferon beta-1a and that the safety profile of the drug does not preclude its approval. But on Dec 27, 2013, the US FDA decided not to license alemtuzumab on the basis that the sponsor, Genzyme, had not submitted evidence from adequate and well-controlled studies demonstrating that the putative benefits of alemtuzumab outweigh its adverse effects.

We write as clinicians who, since 1991, have assessed alemtuzumab as a potential treatment for multiple sclerosis, and as investigators based outside the USA participating in the clinical trials programme from 2002. We have complete confidence in the results of the phase 2 CAMMS223 study and phase 3 CARE-MS1 and CARE-MS2 studies, published in *The New England Journal of Medicine* and *The Lancet*.^{1–3} The FDA considers the decision not to mask patients with respect to randomisation, relying solely on rater-blinding for assessment, to have biased results in favour of alemtuzumab versus interferon beta-1a thereby undermining all clinical and radiological outcomes in each of these clinical trials. The FDA was informed from the outset that their recommendation of a double-dummy design with effective double-blinding is not possible for alemtuzumab because of its well-publicised and predictable acute infusion reactions.⁴ Almost no clinical trial in multiple sclerosis is effectively double-blinded and reliance on rater-blinding is routine in this context.⁵ Many commentators accept that alemtuzumab has easily cleared a hurdle that no other agent has even attempted, demonstrating superiority versus an active comparator in one phase 2 and two phase 3 clinical trials.

The decision made by the FDA now prevents patients in the USA from access to an important treatment option in multiple sclerosis that offers high efficacy with infrequent dosing;



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it risks those who obtain treatment outside the USA not benefiting from the effective and well-rehearsed risk management scheme; and it is likely to demotivate clinician scientists and the pharmaceutical industry from committing to future long-term multiple sclerosis research programmes in the USA if the Agency cannot be trusted to judge evidence objectively and in the interests of patients with a potentially disabling disease.

We would be surprised if people with multiple sclerosis living in the USA and their professional representatives acquiesce with insistence on trial design that cannot be applied with integrity to the treatment of multiple sclerosis with alemtuzumab, and we doubt whether they will leave unchallenged a decision that sidelines doctors and US citizens from taking informed decisions on treatment options for a disease that still has important unmet therapeutic needs. We urge the FDA to re-evaluate and revoke this decision.

ACol and ACom have received honoraria and travelling expenses for speaking at Genzyme-sponsored meetings. Genzyme have partly funded their research and made a donation to the University of Cambridge.

**Alasdair J Coles, Alastair Compston, on behalf of 70 signatories*
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See appendix for a full list of signatories

WHO disapproves Kochon prize for Tibetan TB Programme

The nomination by the Kochon selection committee of the Tibetan Tuberculosis Control Programme based at Delek Hospital, Dharamsala, India, for the Stop TB Partnership-Kochon Prize 2013 award—a prize worth US\$65 000—for its work for more than 30 years to control tuberculosis in Tibetan refugees is a recognition of an important public health work in a vulnerable population. It could be seen as a thoughtful and much needed investment into a vital organisation directly involved in saving the lives of hundreds of young patients with tuberculosis. This selection was in agreement with the 2013 Kochon prize theme “[Tuberculosis] in conflict and refugee areas”.

However, WHO Director General Margaret Chan disapproved this nomination and deprived the health-care workers and patients at Delek Hospital from a vital source of inspiration, hope, and funding, which could have all promoted excellence within the programme.¹ The Tibetan tuberculosis programme has been run with a very limited budget for decades, but achieved a 93% treatment success rate in 2012.

Tibetan refugees have one of the highest rates of tuberculosis in the world. The incidence of tuberculosis in the Tibetan population in India was 645 per 100 000 in 2012, whereas global incidence is 122 per 100 000 and India's incidence is 176 per 100 000.² Overcrowding, poor nutrition, migration, and exposure to different climate, language, and culture are important epidemiological, socio-environmental, and political factors that could explain the high disease burden in this population.

When decisions to honour and support leadership, innovation, and

achievement in global health in the poorest areas are surrendered to political influence, how confidently can we confide in, support, and implement WHO's magnanimous goals of poverty eradication, disease elimination, and universal health coverage?^{3,4}

As we accelerate work on the health-related Millennium Development Goals, we hope that social activism—through press and internet-based social media—will help global health organisations to make righteous choices⁴ and decisions so that matters such as public health and saving lives are not held subservient to politics and economics.

I declare that I have no competing interests.

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WHO's reply

The Delek Hospital has long been recognised within the tuberculosis community as providing excellent care for patients with tuberculosis and we applaud all who work there for what they have done in tuberculosis control. However, the Board of Directors of Delek Hospital is presided over by the Minister of the Department of Health of the exiled Central Tibetan Administration. This Board also includes several other Central Tibetan Administration members. The hospital is accountable to, and audited by, the Central Tibetan Administration. Despite the good