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Viagra: a botched test case for rationing

If it leads to a proper debate about rationing the decision on sildenafil will not be entirely bad

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The recent decision of the secretary of state concerning how sildenafil (Viagra) will be made available within the National Health Service[1] will have angered most men with erectile dysfunction and has caused grave disquiet among doctors.[2] In dressing up a rationing decision as a clinical one, the secretary of state has ended up with the worst of all possible worlds: a decision that makes no sense on clinical, equity, or cost effectiveness grounds and has alienated communities that need to be engaged if rationing is to be acceptable.

Sildenafil was licensed for use in the United Kingdom on 15 September 1998. The previous day the NHS Executive issued guidance about the drug, stating that ministers would be considering the evidence and drawing up substantive policy proposals within the next few weeks; as an interim measure, the Standing Medical Advisory Committee had advised that doctors should not prescribe sildenafil.[3] At that time most doctors complied with the interim guidance, explaining to their patients that a definitive ruling on the availability of sildenafil within the NHS would be made within weeks. However, it subsequently became known that the Standing Medical Advisory Committee (which advises the secretary of state on medical matters) had met in October and forwarded its advice to ministers in early November. Increasing frustration that definitive guidance was being delayed was inevitable, and in mid-December the chairmen of Council and the General Practitioners Committee of the BMA wrote to the secretary of state asking for the uncertainty to be resolved urgently. General practitioners had been finding that men whose treatment had been deferred when the interim guidance was first issued were returning repeatedly, asking their doctors for help, and increasing numbers of general practitioners were prescribing sildenafil on the NHS, in view of their ethical[4] and contractual[5] obligations to prescribe the drugs their patients need.

Doctors had been placed in an untenable position because of the inconsistency between the interim departmental advice and their professional obligations. At its December meeting the General Practitioners Committee had therefore decided that, unless the government's definitive decision was known before its 21 January meeting, it would issue its own guidance to general practitioners. The government's procrastination finally ended on the morning of that meeting, over 10 weeks after the Standing Medical Advisory Committee had provided its advice, when the secretary of state announced his intentions on BBC Radio 4's *Today* programme.

These proposals[1 6] have been seen as making a cruel, unethical, and inequitable distinction between "acceptable" and "unacceptable" forms of impotence, and the General Practitioners Committee firmly expressed the view that it is wholly unethical to distinguish between patients according to the cause of their erectile dysfunction.[2] Subsequent pronouncements by the secretary of state have made it clear that the choice of predisposing conditions allowing access to NHS treatment was made on solely financial grounds, in order to keep expenditure on treating impotence at roughly its current level. Indeed, it would be hard to justify on clinical or attitudinal grounds why patients with erectile dysfunction associated with prostatectomy, radical pelvic surgery, spinal cord injury, diabetes, multiple sclerosis, or single gene neurological disease should be eligible for NHS treatment, while those whose impotence is associated with arterial disease, hypertension, liver disease, renal failure, cerebrovascular accident, chronic obstructive pulmonary disease, thyroid disease, or hypogonadism[7] should not. Furthermore, while sildenafil is effective in treating erectile dysfunction whatever the predisposing clinical condition, it is less effective in at least two of the favoured groups than in men with erectile dysfunction of broad aetiology: among men with diabetes 59% achieved improved erections in trials (Price DE et al, Endocrine Society annual meeting 1998), while only 40-50% of patients with impotence after radical prostatectomy did so.[8] If the Department of Health's intention is to make some spurious, judgmental distinction between organic and psychogenic causes of impotence, it is salutary to remember that the cause of many peptic ulcers induced by *Helicobacter pylori* infection was once thought to be psychogenic.

The additional proposal that for certain patients sildenafil will be available only after specialist assessment[1] will necessarily result in increased outpatient waiting lists and increased costs for a treatment that it is well within the competence of most general practitioners to prescribe.

Notwithstanding the lack of any logical basis behind the government's proposals, and the secretary of state's extraordinary implication that the NHS is primarily for patients with life threatening or painful

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conditions,[1] it must be acknowledged that he has courageously admitted that the government is no longer willing to fund an NHS that adheres to its founding principles of comprehensiveness, universality, and access based on need, and has taken a decision that will at least ensure national consistency in access to sildenafil. While the BMA has long campaigned for increased funding for the health service,[9] it has also repeatedly stated that if the government and taxpayers are unwilling to provide the necessary resources, the government should be explicit about what the NHS will and will not provide, rather than leaving those judgments to individual doctors or to the accident of where patients live. The BMA has also broadly supported the proposal to establish a National Institute for Clinical Excellence[10] as a way of ensuring that the introduction of new and expensive drugs is managed in accordance with evidence on clinical effectiveness.

However, sildenafil is a decidedly effective drug, which is cheaper and more acceptable for patients than alternative treatments and highly cost effective in cost per QALY terms.[11] If the NHS cannot afford to fund the additional costs of such new treatments without rationing, it would surely be far better to look at withdrawing ineffective treatments elsewhere in the health service rather than inequitably denying access to the new treatment for many who would benefit, unless they can fund their own treatment.

The secretary of state's proposals for the introduction of sildenafil may be rationing but they are not rational. Perhaps they will, however, lead to the public debate about NHS rationing for which the BMA has long campaigned. That debate must include a rational consideration of need, clinical effectiveness, cost effectiveness, equity, and social values.[12]

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Gulf war syndrome

There may be no specific syndrome, but troops suffer after most wars

By the end of the Gulf War in February 1991 US, British, and Canadian forces had deployed about 697 000, 53 000, and 4500 military personnel, respectively, to south west Asia. The conflict required rapid mobilisation of coalition combat troops, and massive numbers of casualties were expected.[1] An extensive medical infrastructure and preventive medicine effort was deployed to support the troops.[2 3] During the operation service personnel were exposed to a wide variety of known and potential health hazards. These exposures included smoke from oil well fires, extremes of hot and cold weather, petroleum products and fumes, depleted uranium, pesticides, endemic infectious diseases, and other physical and psychological stressors. The preparations for war included training in chemical warfare, immunisation against certain biological warfare agents, and use of the nerve agent protection pill, pyridostigmine bromide.

Despite the arduous conditions, morbidity rates among US troops were lower than in previous wars.[4 5] Mortality was also much lower than expected. Altogether 372 deployed US troops died in 1990-1: 40% from combat, 52% from accidents (primarily related to training and motor vehicles), and 8% from illness.[6] Illnesses in Gulf War veterans have been a source of intense controversy on both sides of the Atlantic. Since 1991 many veterans and their families have voiced concerns about possible health consequences of their service, and many have complained of being unwell, reporting a wide array of medical complaints. Some veterans have alleged a conspiracy to deny the existence of Gulf War syndrome and to cover up toxic chemical exposures. Clinical manifestations have varied, though the most commonly reported symptoms have been fatigue, headaches, joint pains, rashes, shortness of breath, sleep disturbances, difficulty concentrating, and forgetfulness. Recent reports, including one in this week's *BMJ* (p 290),[7] have looked at the long term effects of these exposures. What do they tell us?

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In this issue Coker et al confirm these clinical observations in British Gulf War veterans.[7] Their report catalogues the examination findings of a large case series covering 1000 servicemen and women who voluntarily attended the Ministry of Defence's medical assessment programme. The programme uses a structured evaluation protocol that includes a comprehensive medical history, an exposure questionnaire, physical examinations, and extensive laboratory testing. Patients are referred to specialist consultants after the initial evaluation as needed. The participants reported multiple common medical symptoms, including affective problems (50%) , fatigue (42%), joint and muscle aches (40%), cognitive problems (26%), headaches (26%), respiratory complaints (24%), gastrointestinal problems (22%), sleep disturbances (21%),

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