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Views & reviews

Soundings

Say no to Viagra

Judging by the recent success of Viagra (sildenafil) a visitor from outer space might conclude that what truly distinguishes man from other species is his desire to take pills affecting his reproductive functions. For here comes the sensational blue diamond shaped pill that for $7-10 (£4-6) inhibits phosphodiesterase type 5, maintains high levels of cyclic guanosine monophosphate in the corpus cavernosum, causes local vasodilatation and smooth muscle relaxation, and promises to revolutionise the love life of 140 million people in the world.

Studied in over 4000 people, including a 74 year old retired senator who had undergone prostatectomy, it helped some 60-80% of people suffering from erectile dysfunction—a condition well studied by plethysmography and an internationally agreed questionnaire and found to be organic in 58% of cases, psychogenic in 17%, and mixed in 24%. Sildenafil takes about one hour to act, but the manufacturer hopes to develop a pill that will induce instant gratification.

Yet already side effects abound. Sildenafil has caused headache in 16% of patients and flushing in 10%. It has made the price of the drug company's shares go through the roof. It has caused transient blue-green colour blindness, enough to alarm ophthalmological societies but not to put off those looking for the desired effect. Some doctors must have developed writer's cramp, given the 120 000 prescriptions written in the second week after the drug's release. A few patients had heartburn. A few health maintenance organisations and insurance companies noted dyspepsia, a symptom they partially relieved by announcing that they would pay only for medically documented erectile dysfunction and only for six tablets a month. This in turn caused heartburn and anxiety among investors and resulted in the stock staying temporarily on the roof and rising no further.

Demand, however, is still on the rise. From abroad I received a letter from an 86 year old widower asking me to reserve a supply of pills before they all sell out. The friendly drug detail man has generously given me two bottles of samples, which I will not send abroad but will quietly pass on to my patients, one tablet at a time, to determine in a truly scientific manner if the stuff really works.

Discovered by serendipity while being tested as an agent for treating heart disease, this modern elixir of love is expected to soon reach the black market and become a popular recreational drug, more popular at parties than even Ecstasy. Some women are now also beginning to complain that, officially at least, they cannot get the drug yet might benefit from it as much as men. Letters are also trickling in from disappointed men who may now be reduced to injecting themselves in the urethra with alprostadil.

Meanwhile one company tried to sell an alprostadil gel that may be applied externally, but Wall Street analysts were not impressed. Another company advertised a product called Veagra, but were forbidden by the courts to use that name. The internet also abounds with advertisements on natural herbal stimulants containing yohimbine and exotic ingredients such as muira puama and vamsa rochna. Try our natural herbs, they say, or consider relaxation by hypnography with professionally written compact disks that will cause a dramatic improvement during intimate moments. "Say no to Viagra" they further advise, for why indeed take an expensive drug that causes headaches, interacts with other agents metabolised by cytochrome P450, and that must never, never be taken with nitrates, of which a list a page long is given.

George Dunea, *attending physician, Cook County Hospital, Chicago, USA*

Personal views

Was the paper I wrote a fraud?

See retraction box p 1700

The sad thing is, it was a good paper about people with severe physical disability and how a coordinated approach can successfully meet their needs (*BMJ* 1993;306:95-8). One professor called it seminal. It was used as an empirical base to promote community care. I trumpeted the findings with gusto. But it has had to be retracted (retraction box p 1700) because my coauthor was struck off the medical register for research fraud and I am unable to vouch for the probity of the data used (28 February, p 647). It has been an unedifying experience putting my own scientific credentials into question.

Mark was a registrar and senior registrar in my department in Somerset when the survey was done in 1989. He was a reliable trainee and became a trusted friend and colleague. He was on the way to becoming accredited as a public health physician and was appointed lecturer and later senior lecturer at our local university department of social medicine. He was a success.

The survey was commissioned and designed jointly by our social services department and us. It was carried out in house. One hundred and eighty one severely disabled adults were interviewed in 1989 and underwent physical assessment. Mark supposedly carried these out. A year later he did without prompting what I believed was an imaginative addition. He reinterviewed by telephone those people who had been found to have unmet needs, to see whether their needs had been met in the intervening 12 months after

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the original assessment. The approach was able to show that many of the unmet needs identified were remediable at minimal cost and not based on some professional or patient wish list.

The results were fascinating. Those severely disabled people who were being seen only by their GP and community nurse had far more unmet needs than those who were also being seen by a social worker or who were in contact with a patient organisation. Here was empirical evidence of inadequate medicosocial assessment reported at just the right time to back the government's community care proposals.

When I heard that Mark was to appear before the General Medical Council we searched for the original data records. The original questionnaires and data sheets could not be found. The health authority has moved since the survey was undertaken and old files had gone from basement to basement. Not only was I unable to find the completed questionnaires but the computer files containing the coded results could not be found either.

I then tried to contact as many as possible of the original people who had had the follow up telephone interview. My purpose was to be assured that at least some would recall the telephone interview undertaken by Mark six years before. Mark gave me a list of these individuals. This act gave me confidence of his innocence. There were 75 people on Mark's list. They were those with unmet needs and who had responded to the telephone follow up survey out of the original 181 individuals. On the family health services authority's register, 36 were still living, 14 had died, two were known to have moved out of the county, and 22 could not be identified on the register. Of the 36 alive, telephone numbers were found for 18. The 18 were telephoned. Three did not answer. Of the remaining 15, 10 could not recall the original interview and physical examination which was undertaken in their own homes, the other five did remember the home visit, and none remembered the follow up telephone survey. Two individuals, who were very alert and receptive to my inquiries, were quite convinced that they had never had a telephone survey undertaken one year after the original. So I could find no one who could remember being telephoned and only a third could remember the original home visit.

Before the GMC hearing I was happy to assume that everything that Mark had done was true and accurate. Now, the rules of trust have changed. After the GMC ruling it has to be assumed that all his work is fraudulent until proved otherwise. So I confronted Mark over a pint of beer. I asked about the survey and suggested that it was important to know the truth for the benefit of science. A confession would not result in further detriment to him. Were the survey results fabricated? No, certainly not, was the reply. He spoke with the sad eyes of someone losing the trust of another of his few remaining friends.

There are public as well as personal consequences if the paper is a fraud. If it is not but is so claimed there is a loss to science if the paper is retracted when it is in fact honest.

Nationally, it is difficult to say what the effect of the paper has been on health care. The paper was used in the part I examination of the membership of the Faculty of Public Health Medicine.

Who knows whether it had an effect on the introduction of community care? It should have done—it was pertinent to the new multidisciplinary assessment arrangements that were being put in place jointly by social services and health authorities.

From a local point of view, it had a powerful effect on my own professional work. The paper gave me confidence to seek radical solutions to the way we assess and care for disabled people. We were able to push through some innovative arrangements such as the use of specially trained nurses to undertake assessments, the establishment of a consultant post in physical disability, and fully integrated arrangements, such as joint budgets, between social and health services. I felt confident enough about the work to present it at a conference at the Faculty of Public Health Medicine.

Fraudulent research cannot be prevented completely but perhaps we should be less trusting, especially if the results are spectacular. I will not coauthor an original paper again without scrutinising the original data. There needs to be a repository for the original survey records and computer files of published research for reanalysis.

We all cut corners to get things done. There is no clear cut distinction between slipshod work and fraudulent research. Where do I stand, where do you stand, on this continuum of probity?

Cameron Bowie, *emeritus director of public health, Somerset*

Whistleblowing or professional assassination

In the light of recent publicity over whistleblowing and disputes among consultants and against the background of the General Medical Council's performance procedures my own experience may be of interest.

A short time ago I was forced to stop work at the hospital where I had been consultant for 18 years. My professional competence was challenged by two colleagues, primarily on the basis of a small number of clinical cases that had been under my care during the previous five years. I was completely unaware of the concerns about my professional conduct until they were passed to the trust executive. I had, however, been aware of the enmity towards me. I was immediately forbidden any contact with patients and I spent a humiliating two and a half months at home, interspersed with frantic trips to the Medical Defence Union in Manchester. My reputation at the hospital was being damaged and there was a constant fear of misrepresentation in the press. I lost weight, could not sleep, and my family also suffered.

Finally, came exoneration. No prima facie case was established against me and it was back to work almost as if nothing had happened. Coping with this ordeal and re-establishing myself at work under such circumstances was possible only because of support from my family, friends, and colleagues. I assumed that this was a one off nightmare that had probably never happened before, but I learnt from a group which studied the cases of suspended doctors that out of over 100 more than 80% had been totally exonerated. Malice seemed to have been a frequent feature; many doctors had been off work for several years, and only a few managed to return to work in their own hospital.

From my experience and that of similarly affected consultants I would like to make the following observations. Firstly, while it is necessary for the safety of patients to speak up if a colleague is making dangerous errors or practising under the influence of alcohol or drugs, trusts and the GMC should appreciate that the process might not be genuine whistleblowing but systematic spying on a colleague with intent to damage.

Secondly, unless suspension is handled with considerable discretion it will be immensely damaging to the doctor, both personally and to his or her reputation. There is always the fear of local or national press coverage. Where there is genuinely reduced performance, inquiries should be made about personal, psychological, or physical pressures at the earliest stage. If enforced leave is unavoidable it should be arranged with sensitivity to avoid undue attention. There should be regular contact between the organisation and the doctor and his or her family—perhaps via the personnel department—in order to reduce the real risk of personal tragedy.

Thirdly, for the majority of the doctors who are ultimately found to have been falsely accused there should be a sincere expression of regret for the ordeal together with a formal, if discreet, acknowledgment of the fact that a malicious act, or at least a severe over-reaction, has taken place. Some attempt to restore the damaged reputation of the doctor should be made, especially as self esteem is bound to be shaken.

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Fourthly, patient care is almost bound to be damaged by the sudden removal of a competent doctor, especially if he or she is the only specialist in a particular field in a peripheral hospital.

Fifthly, the reputation of the hospital is likely to be damaged, if not by mischievous media attention then by gossip in the local medical and nursing fraternity, and public money is likely to be wasted to pay locums and legal fees.

Sixthly, clinical competence is not clearly defined and while gross incompetence is probably simple to recognise, the dividing line between the lower level of acceptable performance and just falling short of this theoretical line requires shrewd judgment and is largely guesswork. Putting a small, selected part of a consultant's work under the microscope by super-specialised professors will carry a high risk of dragging down the actual performance of a doctor of average competence to apparent incompetence.

The following factors need to be taken into account: the workload of the doctor, the supporting staff and facilities (or lack of), clinical areas where there are no clear guidelines or general consensus, and the variation in practice from conservative to interventionist. Errors can occur at both ends of this clinical spectrum. The very existence of audit recognises the fact that all of us make errors and excessive scrutiny of our worst cases would look bad for any of us.

Finally, those in authority who have to differentiate the genuine allegation from the mischievous and ignorant must always ask the crucial question, "Could this be malicious or at least a gross over-reaction?" If so, they should proceed with caution and include an informal response from the accused before proceeding. And there should be rapid, external medical advice at the earliest stage. Any allegations should be put to the accused doctor in the company of several senior consultants (perhaps the Three Wise Men). Before that, attempts should be made to speak informally to the doctor about the concerns. Any such concerns should have been brought up at audit meetings, where standards should be agreed and checks put in place to see if they were being achieved.

And surely there should be a substantial penalty, perhaps dismissal, for unsustainable, unnecessary, and damaging allegations—especially if the motive for the allegations was believed to have been personal. Otherwise we will have chaos.

Medicine and the media

Who killed Cock Robin?

Recently, pages of newsprint have been filled with heartrending tales of families who lost babies under the knife of the Bristol surgeons. This week's *Panorama*, the subject of an unsuccessful injunction application by the General Medical Council, alleged that the NHS system failed to prevent the deaths. Tony Delamothe looks at the fallout for professional self regulation.

After the GMC's decision came the recriminations, followed by the questions that won't go away. Firstly, why weren't surgeons James Wisheart and Janardan Dhasmana stopped from operating on young children once their poor results became widely known? Immediate colleagues, their employer, the Royal College of Surgeons, and the Department of Health all knew—or had been told—how badly they were doing.

The behaviour of each of these came under scrutiny in the days after the judgment. The *Guardian* said that the GMC had warned several consultant colleagues that their conduct might also be open to question (30 May); the *Independent* speculated that the forthcoming government inquiry would examine the involvement in the babies' deaths of up to a dozen senior consultants (1 June).

Why was the United Bristol Healthcare NHS Trust so slow to act? The *Daily Mail* suggested that its keenness to enhance its status by providing complicated paediatric surgery may have blinded it to the poor results. Defending his inactivity, the trust's chief executive, Dr John Roylance, said that he couldn't intervene in medical decisions—an argument rejected by the GMC. But Roylance did what he could to shore up the hospital's reputation by prevailing on an outside reviewer of paediatric heart surgery in Bristol to omit from his report his description of Wisheart as "a higher risk surgeon."

BBC Television's *Panorama* featured Sir Terence English saying that, when he was president of the Royal College of Surgeons, he had telephoned the Department of Health with his worries about the Bristol unit. This was intercut with an interview with the man to whom he had spoken (or to whom his message should have been relayed) denying it. As far back as 1989 the department was aware that Bristol was attracting fewer child referrals and had a higher operative mortality. Similarly worrying messages were passed back to the department several times over the next few years—without obvious effect. Will further inquiries and court cases shed more light on these matters?

Who killed Cock Robin?
I, said the Sparrow,
With my bow and arrow,
I killed Cock Robin.

Who saw him die?
I, said the Fly,
With my little eye,
I saw him die.

Who caught his blood?
I, said the Fish,
With my little dish
I caught his blood.

Whistleblower Dr Stephen Bolsin emerges as the hero of the piece. He began his dogged campaign to draw attention to the high mortality in 1990—and suffered the traditional fate of whistleblowers, ostracism and a collapse in earnings—after which he emigrated to Australia. Whistleblowers certainly earn their eventual canonisation by television, but it must seem poor recompense for the high personal price they pay.

Dr Bolsin's moral authority came over much better on television than it did in the newspapers—perhaps because the other players gave him so little competition. Although he dominated *Panorama*, we heard several sets of parents relating the fates of their children. All claimed to have been given an exaggerated estimate of the chance of a successful operation at the Bristol Royal Infirmary. Whatever the odds they were quoted, they all believed that their child would be one of the lucky ones.

Events finally came to a head with the death on the operating table of 18 month old Joshua Loveday in January 1995. A meeting of heart specialists and anaesthetists the night before had discussed whether Dhasmana should operate—and of those present only Bolsin apparently disagreed. Tipped off by Bolsin, the Department of Health tried to intervene, but to no avail. Bolsin's instinct before the operation—and that of several people interviewed on television and in newspaper—was to take the baby and run. No one did.

Like many of the disputed operations, the GMC inquiry went on far longer than usual and ended with the survival of the patient—in this case professional self regulation—seriously in doubt. According to the *Independent on Sunday*, the events mark "a watershed in the way medical practice is regulated in Britain" (31 May 1998). If future generations have cause to ask "Who killed professional self regulation?" then the complicated explanation might be summarisable in the single word " Bristol."

Tony Delamothe, *BMJ*