

# THE RULES OF RETRACTION

Years after the antidepressant Seroxat was banned for under-18s, **Melanie Newman** reports on calls for withdrawal of a paper supporting its use in adolescents

**Y**ears after regulators banned Glaxo-SmithKline's antidepressant paroxetine (Seroxat) for under-18s, two academics are fighting for a paper claiming the drug is safe and effective for adolescents to be withdrawn.

The 2001 paper in the *Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP)*<sup>1</sup> concludes that paroxetine is "generally well tolerated and effective" for treatment of major depression in adolescents.

The paper gives a misleading impression of the trial's results and the journal should retract it, say Jon Jureidini, associate professor of psychiatry at the University of Adelaide, and Leemon McHenry, lecturer in philosophy at California State University.

The efficacy claim was based on just 15% of the trial's outcomes, they argue.

The academics' stance is supported by internal GSK documents released during personal injury lawsuits against the company. The documents show that company employees and public relations advisers also saw the trial data as having failed to prove that the drug worked in adolescents.

Despite this, JAACAP's editors maintain that as the paper contains no inaccuracies and negative findings

are included in a results table, there are no grounds for its withdrawal.

"Evidence about medicine will be reliable only if the sponsor company and investigators design, conduct and report the results of clinical trials with integrity," say Jureidini and McHenry.

The cases of rofecoxib,<sup>2</sup> rosiglitazone,<sup>3</sup> and gabapentin<sup>4</sup> have shown how marketing objectives can influence scientific testing.

The pair believe that journal editors are too reluctant to retract papers when the extent of this influence is revealed. Editors are "jeopardising their scientific standing and moral responsibility to prescribers and patients," by failing to retract, they argue.

A recent Thomson Reuters analysis<sup>5</sup> of journals covered by its *Science Citation Index Expanded* showed that retractions increased 10-fold between 1990 and 2008, but remained rare events against the numbers of articles produced each year.

In 1990 five out of 690 000 journal articles produced were retracted, compared with 95 retractions out of 1.4 million papers published in 2008.

The International Committee of Medical Journal Editors (ICMJE) advises retraction

in cases of scientific fraud or where an error is "so serious as to vitiate the entire body of work,"<sup>6</sup> implying that this approach should not be used in cases of debate as to whether data have been interpreted correctly.

The National Library of Medicine, perhaps the most authoritative source of advice on retraction, also defines the circumstances when retraction may occur fairly narrowly:

it advises that articles may be withdrawn because of "pervasive error or unsubstantiated or irreproducible data" due to either misconduct or honest error.

Last year the Committee on Publication Ethics (COPE) widened the scope for retraction, advising editors to retract if "they have clear evidence that the findings are unreliable." The COPE guidelines stressed the main purpose of retraction: to "correct the literature and ensure its integrity" rather than to punish miscreant authors.

Despite this many academics continue to equate withdrawal of a paper with misconduct so editors are reluctant to retract without extremely strong evidence of wrongdoing. The threat of legal action weighs heavily, especially on the smaller journals. Liu's research<sup>7</sup> associating higher retraction rates of some high impact journals with lower standards of pre-publication review may also mean editors see retraction as reflecting badly on their stewardship.

Three journals were warned about convicted fraudster Erich Poehlman by his university, which had uncovered evidence of data fabrication. Two of the journals refused to retract Poehlman's articles.<sup>8</sup>

Jureidini says: "I've been surprised how hard it's been to get editors to take action to improve the quality of their journals. They prefer to turn a blind eye."

Study 329, a study of 275 adolescents, was one of three clinical trials conducted by SmithKline Beecham (as GSK was then known) in the mid 1990s.

Study 329's results showed that paroxetine was no more effective than the placebo according to measurements of eight outcomes specified by Martin Keller, professor of psychiatry at Brown University, when he first drew up the trial.

Two of these were primary outcomes: the change in total Hamilton Rating Scale (HAM-D) score, and the proportion of "responders" at the end of the eight week acute treatment phase (those with a  $\geq 50\%$  reduction in HAM-D, or a HAM-D score  $\leq 8$ ). The drug also showed no significant effect for the initial six secondary outcome measures.







# The Bribery Act: what it means for you

The new UK Bribery Act makes recipients of bribes liable for prosecution as well as those offering inducements. **Clare Dyer** examines the implications for doctors

Lapdancing club outings, centre court tickets at Wimbledon, greyhound racing—these are all treats enjoyed by doctors a few years ago courtesy of one of the UK's largest drug companies. The company, Abbott Laboratories, was censured by its industry body, the Association of the British Pharmaceutical Industry (ABPI).<sup>1</sup> But from April 2011, any company providing such activities could be prosecuted under the new Bribery Act and end up with a criminal conviction. And so could the doctors who took advantage of the hospitality on offer.

## What does the Bribery Act do?

The act, which comes into force next April, overhauls the UK's archaic corruption laws, replacing them with one of the strictest pieces of anticorruption legislation in the world. It is mainly aimed at curbing corporate corruption and creates a new corporate offence of failing to prevent bribery.

## So how does it affect doctors?

Not only is it an offence under the act to offer someone a financial or other advantage with the intention to induce that person to perform an action improperly, but it is also an offence to request, agree to receive, or accept such an advantage.

As Tony Lewis and Alison Dennis of the law firm Field Fisher Waterhouse wrote in a recent article on the act: "A recipient in the UK who is bound by the General Medical Council code on good medical practice will arguably commit an offence by accepting hospitality breaching that code, even if the hospitality is outside the UK and even if he is unaware that he has breached the code."<sup>2</sup> And the advantage is not limited to hospitality; the offences are widely drawn. "Bribery can take many forms," the UK attorney general, Dominic Grieve, observed in a speech in September to the World Bribery and Corruption Compliance Forum.<sup>3</sup> One case currently under investigation by the GMC involves allegations that doctors carrying out a clinical trial received company shares and large consultancy fees.

## Who will enforce the act?

In England and Wales, the Serious Fraud Office and the Crown Prosecution Service. They are drawing up joint guidance for prosecutors which, when available in the New Year, will help clarify

what factors will influence a decision whether to prosecute. Similar steps are being taken in Scotland and Northern Ireland. As the attorney general pointed out in his September speech, the guidance will not spell out which activities will or will not result in prosecution. Every decision will be taken on a case by case basis.

## How can I stay on the right side of the line?

The attorney general also affirmed that hospitality and promotional activity "are not illegal per se and the act is not intended to clamp down on legitimate expenditure of this type." While it was clear that "lavish" hospitality could be a bribe, he did not think it would be too difficult to distinguish what was bribery from what was not. Ultimately, however, it would be for a jury to decide.

The GMC has not produced any specific guidance on the act, but its guidance on good medical practice includes sections on probity, conflicts of interest, and doctors' relationships with the drug industry. It also refers doctors to the Medicines and Healthcare Products Regulatory Agency's blue guide on advertising and promotion of medicines in the UK, which deals with gifts, hospitality, sponsorship of research posts, study visits, and the like. GMC guidance says that a doctor who has been sponsored by a drug company to speak at an educational meeting should declare that fact at the meeting and it should be disclosed in the published proceedings.

Where gifts or hospitality are concerned, Robert Amaee, head of the anticorruption domain at the Serious Fraud Office, said: "We'd look very much at whether it was part of a legitimate commercial transaction or whether it strayed into the 'lavish.'" He points to the code of practice of the ABPI and to examples cited by Transparency International, the world's leading anticorruption non-governmental organisation. Transparency International's guidance discusses gifts, hospitality, and expenses and gives two scenarios involving doctors and the drug industry.<sup>4</sup>

In the first, a UK branch of an international company provides meeting rooms for the monthly meeting of the local regional GP sub-

committee. Transparency International says the company should not provide lunch or display promotional literature. No more than coffee and biscuits should be provided, and the details and expenses should be properly recorded in the books. In the second scenario, a drug conference abroad, "lavish expenditure" such as excessive accommodation, dinners, and goody bags would not be acceptable. The event arrangements should be modest, and doctors should be required to attend all the conference events.<sup>4</sup>

These strictures tie in with the ABPI code of practice for the drug industry, which comes into force in its newly revised form on 1 January 2011.<sup>5</sup> Companies will no longer provide branded promotional items to healthcare professionals. They will also have to declare payments

to doctors for services including speaker fees, advisory boards, and consultancy and sponsorship for attendance at meetings, although individual doctors will not be named.

The code was under revision before the Bribery Act loomed, but the act's tough requirement on companies to put adequate measures in place to prevent bribery will mean that doctors are less likely in future to be offered improper inducements. And,

as Mr Amaee says, "In reality, most people will know what is and is not acceptable—it's largely a matter of commonsense."

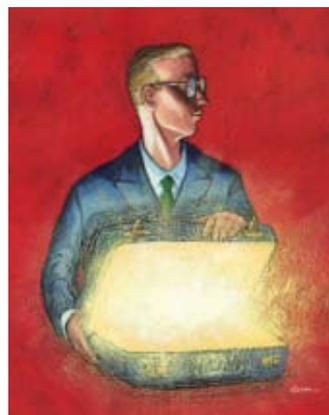
Clare Dyer legal correspondent, *BMJ*, London WC1H 9JR, UK [ClareDyer@aol.com](mailto:ClareDyer@aol.com)

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# Rape: a long lasting weapon

The war in Bosnia was the first time the United Nations had been faced with mass rape as a weapon of war. Fifteen years after the Dayton Accords peace agreement, **Sophie Arie** talks to doctors in Sarajevo and discovers a culture of denial



VII PHOTO/ANTONIN KRATOCHVIL/UNFPA

In the summer of 1992, Sreko Simic, one of Bosnia's leading gynaecologists, worked without electricity, anaesthetics, or oxygen and with only a skeleton staff, to keep delivering babies at Sarajevo's University Hospital while the city was under siege.

The number of pregnancies his department dealt with dropped dramatically, and the numbers asking for abortions rose, he recalls. And then in the late summer of 1992, some months after the war began, the women who had been raped started to appear.

"Most of them came alone, at night, so no one would see them," the 83 year old gynaecologist recalls.

"They were silent and full of shame and hatred. Often we would treat them but they would not speak. Some asked for abortions. Others gave birth and then rejected the child."

## Lost victims

Fifteen years later, and Dr Simic is still working at the University Hospital, a drab building with a few lost looking members of the public in its bare and gloomy entrance hall and many staff smoking under a tree outside.

"I never saw any of those women again," says Dr Simic. He does not recall treating any women since the war for gynaecological problems caused by the rapes.

In fact, many of the estimated 20000 women and men who were raped or sexually abused during the war,<sup>1</sup> often by gangs and often repeatedly over months, have not seen a doctor or any sort of mental health expert since.



Left: A survivor of the war visits a support network in Sarajevo. Far left: A resident of Gorazde recounts her experiences during the war

appetite and are not fit to work. Some had crosses carved or burnt into their skin by their attackers.

Their families suffer too. Children who witnessed their mothers being raped have grown up to be highly unstable teenagers or young adults. And husbands who survived are usually aware their wives were raped but have never discussed it. Couples can no longer have normal sexual relations, and in many cases both are too debilitated to work and their families have disintegrated or are dysfunctional. An unknown number of children born from the rapes have grown up in orphanages unwanted by anyone.

“The problem is that by ignoring the health of these people for 15 years, the problems are growing not shrinking,” says Jasna Žečević of Vive Zene, a therapy and rehabilitation centre in Tuzla, the third largest city in Bosnia and Herzegovina.

On top of their initial trauma, many rape victims have to live with the fact that their accused rapists may still be at large. Others have relived their trauma by giving evidence at the International Criminal Tribunal for the former Yugoslavia. And many who were raped or traumatised in other ways simply do not understand that their health problems may be related to their state of mind. Although there are no reliable figures available, local records in different parts of the country show rising numbers of suicides among war victims, according to Ms Žečević.

“In Bosnia, people take medication easily,” she says. “Before you see a doctor, you take a pill. People only come to us after trying every other route they can.”

Vive Žene has four fully qualified therapists and four junior therapists. The number of people coming to the centre, which also deals with domestic violence, is rising.

And yet, the donations from government and the international community on which these organisations depend are harder to secure every year.

“The public and the state say that the war is over and we must focus on the economy,” says Dr Žečević. “And the donors don’t want to invest in healing people. It takes such a long time.”

CTV, in Sarajevo, has 6000 people on its books but only €600 (£500; \$800) a month for drugs. It sometimes struggles to fill its one general practitioner position, despite offering the same salary

For 15 years since the Dayton Accords brought an end to the war on 14 December, those who were raped—mainly Bosnian Muslim women who were attacked by orthodox Christian Serbs—have battled in silence with depression, post-traumatic stress disorder, anxiety, insomnia, and debilitating psychosomatic problems.

Under the Dayton Accords, the country was carved into two ethnically distinct entities and an extremely complex, multilayered government structure has made it extremely hard to reach a nationwide consensus even on simple matters, let alone sensitive ones.

“Nobody has made this a priority,” admits Saliha Djurderija, Bosnia’s assistant minister for human rights and refugees. “Now the problem is three times bigger than it was because nothing has been done for so long.”

Since the war, the government of the Muslim dominated Federation of Bosnia and Herzegovina, where most of the rape victims now live, says it has opened 48 mental health centres with World Bank funding and trained staff to deal with torture victims, war veterans, and civilians with post-traumatic stress disorder. But it has not developed psychiatric services specifically tailored to the needs of rape victims or for those traumatised in other ways by the conflict in which at least 100 000 people were killed.<sup>2</sup>

According to Amnesty International, there is roughly one mental health centre for every 50 000 people. Medical students do not receive any special training in dealing with war

victims, and there has been no concerted effort to sensitise the public or state health workers to the mental problems war victims have.

“Speaking honestly, I would not talk about rape myself in the official healthcare system,” says Dubravka Salčić, a leading psychiatrist with years of experience in the public health service. “People feel too stigmatised. They do not want to expose themselves as victims.”

#### Non-governmental help

Dr Salčić runs the Centre for Torture Victims (CTV) in Sarajevo, which is one of a handful of non-governmental organisations that provide expert care for victims of rape and other war traumas in a discreet and sensitive setting.

CTV receives new inquiries all the time, adding to the thousands of war victims already receiving therapy and legal advice at its small, upper floor apartment overlooking the Miljacka river. There are comfy sofas, plants, and raspberry coloured thick pile rugs in every room.

“The trauma can be healed, but it’s very difficult,” says Dr Salčić. “The needs are immense for long term treatment. How can you heal repeated rape?”

Most rape victims are single mothers who lost their husbands during the war. They experience insomnia, permanent headaches, chronic backache, and ongoing gynaecological complications. Some have stomach ulcers and loss of

PHOTO: ANTONINI KRATOCHVIL/UNFPA

as the state health service, because most medical professionals prefer to work in more cheerful areas of medicine. And the centre is currently unable to accept new clients as it is not sure it will receive the same level of funding for the coming year.

“There are constantly newcomers and you have to make a decision who to help,” says Sumeja Selimbeogiv who was CTV’s in-house GP until recently. “Do you help the person who’s new or the one who’s been coming for 10 years? There was never enough (money) to do both.”

The government contributes only 1% of the total costs for the kind of services CTV provides, according to Amnesty.

To an extent, that is understandable. The country has struggled to rebuild its economy since the war and has been hard hit by the current global financial downturn. The health system relies mainly on insurance contributions from those with jobs (unemployment is around 40%), and in 2009 that meant a total health budget of only 1.4bn Bosnian marks (£600m; €700m; \$940m) for the estimated 2.6 million citizens of the Federation of Bosnia and Herzegovina.

Many people think that there is also political resistance to spending money on healing the wounds of the war—in large part because of the different opinions of the different ethnic groups who run the country.

**Compensation**

For a long time the government of the Muslim dominated part of the country, the Federation of Bosnia and Herzegovina, claimed that it should be Serbia that pays the cost of compensation and rehabilitation of war victims, including rape victims.

Only in 2006, was a law finally passed awarding rape victims official victim status and the right to financial compensation of €260 a month. Before then, only those who had been able to show that their bodies were more than 60% damaged by injuries inflicted during the war were eligible for incapacity benefit. There were mixed views on whether rape victims deserved income support.

“If you were only raped two or three times, it was not considered a big deal,” said Ms Djuderija. “If it happened repeatedly then some agreed that caused higher psychological damage which could prevent you from being able to work.”

All rape victims are now entitled to financial support and medical help if they make a statement confirming they were raped and if they produce documentary evidence that they were in a part of the country where these crimes were committed during the war. But in many cases the claim process is slow, and in some parts of



A woman returns to Miljevina, the site of her rape

VII PHOTO/ANTONIN KRATOCHVIL/UNFPA

the country the support does not materialise because of lack of funds. The number of people currently receiving financial support is between 1700 and 1800 according to the human rights ministry; non-governmental organisations say the true figure is more like 500.

Bakira Hasecic is one of the rape victims who has battled hardest for recognition. On a sofa in a cramped office of her organisation, Women Victims of War, on the outskirts of Sarajevo, she chain smokes and cries as she talks of her anger that accused rapists are still living freely. She can even see some of them on Facebook. She says that those detained at the Hague for trial by the international tribunal receive better healthcare than the victims who attend to testify and who depend on the Bosnian state for their healthcare needs.

“We feel that they would like for all of us to disappear, to go away,” she says.

By 2009, the International Criminal Tribunal had prosecuted only 18 cases that included charges of rape or sexual violence and the Bosnian courts had convicted only 12 defendants of the war crime of sexual violence, according to Amnesty International.<sup>1</sup> Rape is so hard to prove that Ms Hasecic fears there is a growing will to call an amnesty so that the past can be left behind.

In its annual *State of the World Population* report, published in October, the UN Population Fund (UNFPA) warned of the danger of failing to protect women from war crimes and urged that they be included much more in efforts to avert conflict and rebuild countries after conflicts.<sup>2</sup>

The scale of the atrocities committed in Bosnia and then in Rwanda in the 1990s led to the UN passing a resolution in 2000 urging governments to protect women from rape and work much more with women to heal trauma

after a conflict.<sup>3</sup> But UNFPA observed that the resolution has achieved little. Rape is widespread in Sudan and eastern Congo now. And Bosnia has failed to heal the wounds of the war and continues to be paralysed by ethnic division.

But Bosnia is not high on the priorities of the international community. UNFPA has spent “close to nothing” on this problem since the war, according to an official, largely because it has hoped the state would tackle it. It now plans to invest more in this area. . It now plans to invest more in this area. According to the Federal Health Ministry, the Swiss government has recently provided three years of funding for a mental health reform project.

“Bosnia for us has been really a pilot. It was the first time the UN was faced with a situation of mass rape being used as a weapon of war,” says Upala Devi, an expert on the implementation of the UN resolution at UNFPA headquarters in New York. “Based on our achievements—or lack of—in the past 10 years (since the resolution came into force) we are now making more efforts to address the issues of women, peace, and security,” she says.

The *State of the World Population 2010* report focuses on the obligation of states to protect civilian women in wartime and recognise the importance of tackling the psychological trauma caused by rape. A new UN body, UN Women, launching in January 2011, will no doubt attempt to achieve this. But in the case of Bosnia it might be too late.

Sophie Arie is a freelance journalist, London, UK [ariesophie@yahoo.co.uk](mailto:ariesophie@yahoo.co.uk)  
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## COMMENTARY

## What interventions work for victims of conflict related rape?

Recent reports from the Democratic Republic of Congo highlight the ongoing use of rape as a weapon of war and illustrate how the effects of rape may extend beyond the individual.<sup>1,2</sup> War rape is defined as “a deliberate and strategic decision on the part of combatants to intimidate and destroy ‘the enemy’ as a whole by raping and enslaving women who are identified as members of the opposition group.”<sup>3</sup> Rape is a sinister tool used to inflict terror and control for a range of political objectives. These include establishing territorial ownership, damaging community cohesion and morale,<sup>4,5</sup> ethnic cleansing, and genocide (for example in Rwanda<sup>6</sup> and Bosnia-Herzegovina).<sup>7,8</sup>

Rape has both acute and long term physical and psychological effects on the individual. Psychological responses to trauma in the immediate and longer term include feelings of powerlessness, worthlessness, and self disgust, as well as depression, suicidal thoughts, post traumatic stress disorder, sexual dysfunction, social phobia, and recurrent feelings of shame.<sup>8-10</sup> Destroyed

relationships and enforced, unwanted pregnancies cause further distress and propagate the effects of the attack to the next generation.<sup>11</sup> Wider effects of being raped, often repeatedly, as part of conflict include those resulting from the systematic infliction of physical and mental torture; the degradation of recipients, their families, and their community; and the loss of social identity. Although rape is traumatic in all cultures, interventions to alleviate the immediate and long term suffering of those affected must be sensitive to societal differences.

Guidelines for dealing with sexual violence in humanitarian emergencies include short term psychological interventions.<sup>12</sup> However, the emerging consensus is that practical, rather than emotional, interventions are most constructive in the immediate aftermath of trauma. Practical help—be it medical, economic, social, or the restoration of law, order, and justice—can also have important emotional benefits.<sup>13</sup>

But what about the longer term impact? Rape in any context is a very traumatic experience, and the subsequent psychological distress

experienced may be complex and long lasting. But where rape has been systematically used as a weapon in conflict, ongoing stigma and marginalisation of the victims are likely to have mental health consequences that are particularly difficult to treat.<sup>12,14-17</sup> The psychological effect of the physical outcomes of rape, such as HIV infection, disfigurement, infertility, and incontinence, also last long after conflict has ended and aid agencies have gone. Moreover, children born of rape may face discrimination and abandonment, resulting in their also experiencing long term physical and psychological consequences.<sup>18</sup>

Although there is acknowledgement of the need to provide long term support for rape victims in conflict settings,<sup>11</sup> the capacity of local mental health support may be limited, particularly in areas with economic difficulties that may still be experiencing conflict and whose priorities may continue to be food, water, medical care, and security. Post-conflict initiatives do exist, such as the Liberian non-governmental organisation THINK (Touching Humanity In Need of Kindness) and *Vive Žene* in Bosnia and Herzegovina, although international efforts rely in the long term on cooperation with the governing authorities. However, as in the case of Bosnia-Herzegovina, political will may be slow to catch up or reluctant to deal with controversial issues.<sup>17</sup>

Long term support for victims of war rape may be challenging because of reliance on the availability of international aid, political sensitivities, and the relationship between humanitarian and local institutions; however, there are additional difficulties in providing lasting care. Psychological interventions may be undermined by the reluctance of victims to come forward or to discuss their experiences because of stigma.<sup>12,14,19,20</sup> Furthermore,

Western models that focus on the effects on the individual may neglect the effect on men unable to protect their women or on a community that puts great importance on the virtuousness of their women. As such, interventions that increase resilience, such as rebuilding community cohesion, and which address sociopolitical factors framing the context in which such atrocities occur, are essential prerequisites for any psychological treatments to be effective in the longer term.<sup>13</sup>

Western intervention occurs in the context of diverse cultural norms and has to take into account such variation—for example, the use of traditional healers, reliance on close family and community social bonds to deal with problems, religious beliefs, and societal taboos.<sup>20</sup> It is imperative to recognise that Western concepts of trauma and mental health may not translate to other cultures and that symptoms viewed as signs of post traumatic stress disorder and depression, for example, may be viewed differently elsewhere.<sup>20-22</sup> Indeed, the legitimacy of international mental health humanitarian interventions has been questioned.<sup>23</sup>

To establish long term care for victims of rape, agencies need to work with local healers, health workers, religious services, and schools so that they are able to recognise symptoms of psychological distress, provide appropriate, culturally sensitive care, and help reduce stigma.<sup>15,20,24</sup>

Charlotte Woodhead, PhD student, King's Centre for Military Health Research, Institute of Psychiatry, King's College London, UK  
Simon Wessely, professor of psychological medicine, King's Centre for Military Health Research, Institute of Psychiatry, King's College London, UK  
[simon.wessely@kcl.ac.uk](mailto:simon.wessely@kcl.ac.uk)

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Training materials used in the evaluation of rape