rheumatic fever in 1944 and mitral valve repair for incompetence in 1985 was admitted in ventricular tachycardia without angina. He had started taking sumatriptan 30 days before admission. Each of the eight injections had been followed by "hot surges in the throat," and four of these were followed by a definite sensation of palpitation (up to 160 beats per minute). He required DC cardioversion and amiodarone to correct the arrhythmia.

A previous drug point showed that subcutaneous sumatriptan could produce ST elevation in susceptible subjects,¹ and a recent study has shown that vasospasm in patients with minor coronary artery stenosis can precipitate ventricular tachycardia and fibrillation.⁴

Our first patient would almost certainly have died without the prompt arrival of the ambulance service. The timing of her ventricular tachycardia in relation to the sumatriptan injection and the lack of previous or subsequent problems strongly suggest that sumatriptan induced her arrhythmia.

The second case is less clear in that there was a previous history of cardiac surgery, but eight separate administrations of the drug produced similar symptoms, which were shown to be due to ventricular tachycardia on hospital admission.

Thus we suggest that subcutaneous sumatriptan should be administered with caution and that, ideally, the first dose should be given while the cardiac rhythm is being closely monitored.

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- 1 Sumatriptan Cluster Headache Study Group. Treatment of cluster headaches with sumatriptan. *N Engl J Med* 1991;325:322-6.
- 2 Subcutaneous Sumatriptan International Study Group. Treatment of migraine attacks with sumatriptan. *N Engl J Med* 1991;325:316-21.
- 3 Willet F, Curzen N, Adams J, Armitage M. Coronary vasospasm induced by subcutaneous sumatriptan. *BMJ* 1992;304:1415. (30 May.)
- 4 Myerburg RJ, Kessler KM, Mallon SM, Cox MM, De Marchena E, Interian A, et al. Life threatening ventricular arrhythmias in patients with silent myocardial ischaemia due to coronary artery vasospasm. *New Engl J Med* 1992;326:1451-5.

EDITOR,—Concern has been expressed about the apparently high frequency of reactions after injection of sumatriptan to relieve migraine.^{1,2} We intend to follow up at least 10000 patients, identified by means of prescriptions, for about six months by using prescription event monitoring; we report here on the 1881 patients for whom questionnaires (green forms) have so far been returned.

The most commonly described symptoms include tightness in the chest; discomfort or pain radiating into the shoulders, arms, neck, or throat and sometimes accompanied by dyspnoea; palpitations; and an alarming sense of impending doom. A few doctors have written or telephoned to express their concern in addition to completing the prescription event monitoring forms.

In 25 of the 1881 patients the common factor has been tightness in the chest, with onset within one to 60 minutes after the injection; descriptions of this have varied from mild and tolerable in the light of the benefit obtained to severe and terrifying. Four of these patients also had dyspnoea. In a further eight patients the symptoms could have been confused with those of an anginal attack. Two patients experienced bronchospasm. One other patient, a comparatively healthy asthmatic woman aged 26, died suddenly; at postmortem examination the findings were entirely consistent with death from asthma and the relation to an injection has not yet been confirmed. Three patients developed tachycardia and two developed palpitations. Finally, one patient suffered an instantaneous syncopal attack after the first but not the second of

two injections. Only five of these 42 reactions were said to have been reported to the Committee on Safety of Medicines.

To be recorded in a prescription event monitoring study patients have to visit their doctor's surgery and complain about an event and the doctor has to enter it in the notes. Up to six months later the event then has to be considered to be sufficiently important to be transcribed on to a green form. Most events reported are not trivial. The incidence of this type of reaction in the series so far is 2.2%, which is unprecedented in numerous prescription event monitoring studies of more than half a million patients. Although we have seen no evidence of an unacceptable risk associated with sumatriptan in otherwise healthy patients, we believe that this drug should be prescribed cautiously for patients with a history of ischaemic heart disease, arrhythmia, or asthma.

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- 1 Willet F, Curzen N, Adams J, Armitage M. Coronary vasospasm induced by subcutaneous sumatriptan. *BMJ* 1992;304:1415. (30 May.)
- 2 Stricker BHC. Coronary vasospasm and sumatriptan. *BMJ* 1992;305:118. (11 July.)

** We sent these letters to Glaxo for reply

EDITOR,—Reports such as these cases of Dr Curtin and colleagues are taken seriously by the company, and we have followed up both cases.

Although the second patient experienced intense palpitations shortly after several injections, symptoms did not develop until after the third dose and did not occur consistently after injection. Similar attacks were recorded at times that were unrelated to treatment—in particular, the only documented episode of ventricular tachycardia occurred some six days after the last dose of sumatriptan. This protracted time lapse calls into question a direct causal relationship.

This patient had a history of rheumatic mitral valve disease, in which there is an established relationship with ventricular arrhythmias.² Underlying cardiac disease may therefore be a relevant aetiological factor.

In the first patient, a close temporal relationship was apparent, and the positive results of the exercise test and angiography support the authors' hypothesis of vasospasm superimposed on underlying coronary artery disease. The significance of hypertension in a woman of this age is unclear.

The reported occurrence of ventricular fibrillation is naturally of concern. Nevertheless, it constitutes an isolated event not otherwise identified in the entire clinical development programme or in subsequent international post-marketing experience, encompassing the treatment of an estimated 3 million attacks of migraine.

We appreciate the concern generated by this case report and are taking active steps to modify our prescribing information appropriately, in addition to continued investigation and close safety monitoring.

The preliminary data from Inman and Kabota's unit reports an incidence of adverse events which, although higher than for other drugs, is nonetheless entirely consistent with our own findings in clinical development. The potential for these symptoms is set out clearly in the sumatriptan data sheet; however, their nature and the associated use of an autoinjector will undoubtedly stimulate reporting. It is unlikely that previous prescribing events monitoring (PRM) studies with other drugs have been undertaken in comparable circumstances.

It should be emphasised again that, other than in exceptionally rare circumstances, there is no

relation between the chest symptoms described and cardiac dysfunction. Furthermore, our extensive database shows no evidence of acute asthma or bronchospasm, though it is possible that the chest tightness sometimes reported by patients may have been misinterpreted as being of asthmatic origin.

We therefore strongly refute Inman's comments regarding the need for particular caution in asthma; these seem to be based on a single death from asthma, in which the relationship to medication is unknown. In contrast, we emphasise our contraindication to the use of sumatriptan in patients with ischaemic heart disease and related cardiac disorders.

The "distress" referred to in the title of the letter is a reflection of the understandable anxiety associated with the chest symptoms reported. This clearly highlights the need for adequate explanation and advice at the time of prescribing.

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- 1 Kligfield P, Hochreiter C, Kramer H, Devereux RB, Niles N, Kramer-Fox R, et al. Complex arrhythmias in mitral regurgitation with and without mitral valve prolapse. *Am J Cardiology* 1985;55:1545-9.

Medical reports for courts

EDITOR,—Anthony Joseph's suggestions about "neutral" medical reports for courts¹ are based on prejudice. He alleges that "the dismal results" of the adversarial method "include a tendency to miscarriage of justice (often appallingly serious, as many recent appeal cases in the English courts have shown) and suppression of truth." The fact is that these cases were the product of distortion and suppression of evidence by the police. The legal system as such—that is, the conduct of the prosecuting lawyers and the process of trial at first instance—bears no responsibility.

In my opinion the notion that the evidence of the neutral expert is of higher quality than that produced by opposing experts subject to cross examination is naive. Why should it be so? Joseph says it promotes suppression of inconvenient facts. Plainly, inconvenient records may disappear. They will always do so from time to time. It is a fact of life unaffected by legal procedure. But an expert acting for a party adversely affected by the unavailability of documents will surely probe as intensely to ascertain their whereabouts (and in my opinion more so) as will the "neutral" expert.

The merits of the competing systems in relation to medical evidence may be capable of resolution by research. Let Joseph apply his mind to the appropriate methodology. As a mere lawyer, I am incapable of doing so.

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- 1 Joseph A. Medical reports for courts. *BMJ* 1992;305:479. (22 August.)

EDITOR,—J S Price identifies medicolegal reports in litigation arising from personal injury as potentially harmful to patients and believes that the system needs reform.¹ Price notes patients' distress at being evaluated by contemptuous doctors whom they perceive as being paid by the insurance companies to prove that they are malingering. But I doubt whether having the courts request and pay for reports would help.

The problem lies less in the arrangements for producing reports than in the product. If only the arrangements were altered patients could still face opinionated "psychogenic dismissal" by the same

medical mercenaries who currently perform the bespoke psychiatric hatchet jobs commissioned by the insurers. An allegation of malingering arising from the defence is distressing enough. To have one arise from the court itself, without the counterweight of prosecution evidence, would make patients fearful of the quality of justice they might expect at its hands.

Justice—and patients' emotional integrity—would be better served by introducing quality control of the reports, an initiative particularly necessary in the subjective realm of psychiatric opinion, not least because so many such opinions emanate from doctors unqualified in psychiatry. I suggest an independent panel of assessors, which should be multidisciplinary and include lay representation, to adjudicate on the admissibility as evidence of the psychiatric diagnostic opinions expressed in medicolegal reports. Opinions would be judged from two viewpoints: their conformity with publicly available diagnostic categories, such as those in the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised*³; and the sufficiency and cogency of evidence, of the kinds specified in the diagnostic criteria, adduced to support a proposed diagnosis. Reports using idiosyncratic categorisations or failing adequately to justify the patient's inclusion in the proposed public category would be summarily rejected and could not be used as evidence.

Effective, independent audit should resolve patients' distress. I have seen few defence psychiatric reports that would survive such vetting. To maximise doctors' accountability for their opinions, public records would be kept of their performance with the assessors. Doctors whose reports were consistently rejected would be publicly identifiable and would have either to retire from medicolegal work through loss of their ill deserved reputation or to clean up their act. Patients could rest assured that if a defence psychiatrist produced only idiosyncratic or unsubstantiated opinions this objectionable caricature of expert evidence could not damage their interests, only those of its author.

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- 1 Price JS. Medical reports for courts. *BMJ* 1992;305:254. (25 July.)
- 2 Ripper V. The mental state of dismissed patients: an enquiry into dismissal injury. I. A very peculiar practice. *Newsletter of the Society for Environmental Therapy* 1991;11:25-9.
- 3 American Psychiatric Association. *Diagnostic and statistical manual of mental disorders, third edition, revised*. Washington, DC: APA, 1987.

Paternal occupations of children with leukaemia

EDITOR,—My colleagues and I have found a few small numerical mistakes in tables II and VI of our case-control study of leukaemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria published in the *BMJ* in 1990.¹ These tables related to risks of leukaemia and non-Hodgkin's lymphoma in children with reference to mother's and father's ages at their child's birth and to father's employment and radiation dose during employment at the Sellafield nuclear plant. Tables I and II here show the amended results.

The original calculation of parental age was either one year lower or higher than it should have been depending on whether the parent's birthday was earlier or later in the year than that of the child. The new relative risks in table I are similar to, but generally larger than, the previously published figures. We have revised the estimates of radiation dose to take account of men whose periods of employment in the year of, or before, their child's conception did not cover complete calendar years.

TABLE I—Numbers of cases and controls with relative risks for leukaemia and non-Hodgkin's lymphoma in children by parental age at birth

Suspected risk factor	Type of control	Cases		Controls		Relative risk	95% Confidence interval
		Total	Positive (≥ 25 or ≥ 40)	Total	Positive (≥ 25 or ≥ 40)		
Leukaemia							
Mother's age (≥ 25 v < 25 years)	Area	52	34	351	227	1.00	0.54 to 1.86
	Local	52	34	344	227	0.94	0.50 to 1.77
Mother's age (≥ 40 v < 25 years)	Area	52	5	351	7	5.27	1.39 to 20.05
	Local	52	5	344	10	3.54	1.01 to 12.35
Father's age (≥ 25 v < 25 years)	Area	46	39	287	225	1.53	0.65 to 3.59
	Local	46	39	276	215	1.64	0.68 to 3.96
Father's age (≥ 40 v < 25 years)	Area	46	6	287	27	1.99	0.61 to 6.50
	Local	46	6	276	24	2.49	0.72 to 8.56
Leukaemia and lymphoma							
Mother's age (≥ 25 v < 25 years)	Area	74	51	492	324	1.11	0.66 to 1.89
	Local	74	51	484	326	1.04	0.61 to 1.78
Mother's age (≥ 40 v < 25 years)	Area	74	8	492	9	6.65	2.24 to 19.80
	Local	74	8	484	14	4.26	1.55 to 11.75
Father's age (≥ 25 v < 25 years)	Area	66	53	403	322	0.98	0.51 to 1.90
	Local	66	53	389	305	1.08	0.55 to 2.12
Father's age (≥ 40 v < 25 years)	Area	66	10	403	32	1.87	0.74 to 4.69
	Local	66	10	389	33	1.95	0.76 to 5.05

TABLE II—Numbers of cases and controls with relative risks for leukaemia and non-Hodgkin's lymphoma in children by timing of paternal employment and external ionising radiation dosimetry at Sellafield

Father's employment/radiation group	Type of control	Cases	Controls	Relative risk	95% Confidence interval
<i>Leukaemia</i>					
Total	Area	46	288		
	Local	46	276		
Dose record:					
Before conception	Area	8	34	1.76	0.71 to 4.35
	Local	8	40	1.40	0.50 to 3.94
At conception	Area	8	21	3.71	1.27 to 10.82
	Local	8	27	2.90	0.93 to 9.05
Total dose before conception:					
> 0-49 mSv	Area	3	18	1.20	0.34 to 4.32
	Local	3	26	0.77	0.20 to 3.00
50-99 mSv	Area	1	11	0.69	0.08 to 5.75
	Local	1	11	0.78	0.08 to 7.73
≥ 100 mSv	Area	4	5	6.30	1.52 to 26.03
	Local	4	3	8.38	1.35 to 51.99
Dose during 6 months before conception:					
> 0-4 mSv	Area	3	14	1.79	0.41 to 7.73
	Local	3	22	1.30	0.28 to 6.07
5-9 mSv	Area	1	3	3.62	0.33 to 39.97
	Local	1	2	4.60	0.37 to 57.83
≥ 10 mSv	Area	4	5	7.38	1.74 to 31.31
	Local	4	4	6.82	1.46 to 31.86
<i>Leukaemia and non-Hodgkin's lymphoma</i>					
Total	Area	66	404		
	Local	66	389		
Employed*:					
Before diagnosis	Area	11	73	0.95	0.45 to 1.99
Dose record:					
Before conception	Area	10	44	1.66	0.75 to 3.70
	Local	10	56	1.09	0.45 to 2.66
At conception	Area	10	29	3.09	1.25 to 7.65
	Local	10	40	1.90	0.73 to 4.97
Total dose before conception:					
> 0-49 mSv	Area	4	26	1.11	0.37 to 3.35
	Local	4	39	0.62	0.19 to 1.96
50-99 mSv	Area	2	13	1.16	0.25 to 5.48
	Local	2	14	1.04	0.19 to 5.60
≥ 100 mSv	Area	4	5	6.45	1.57 to 26.48
	Local	4	3	8.59	1.41 to 52.20
Dose during 6 months before conception:					
> 0-4 mSv	Area	5	18	2.31	0.72 to 7.36
	Local	5	29	1.27	0.37 to 4.35
5-9 mSv	Area	1	4	2.46	0.25 to 23.94
	Local	1	6	1.34	0.15 to 12.14
≥ 10 mSv	Area	4	8	4.41	1.19 to 16.39
	Local	4	6	4.50	1.08 to 18.78

*Only this amendment has been necessary for paternal employment results in table VI.¹

No cases and only a few controls were reclassified, and the new relative risks in table II are in general similar to, or a little higher than, the earlier figures.

We regret the changes but believe that they do not alter our interpretation of the study.

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- 1 Gardner MJ, Snee MP, Hall AJ, Powell CA, Downes S, Terrell JD. Results of case-control study of leukaemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria. *BMJ* 1990;300:423-9.

EDITOR,—We reported last year an analysis of a case-control study that we had conducted in three areas of northern England (West Cumbria, Gateshead, and North Humberside). Significant associations were found for childhood leukaemia and certain exposures of fathers before the affected children were born; these included exposure to "radiation." After the analysis was completed, review of the occupational histories reported at interview permitted classification of paternal radiation exposure as non-ionising or ionising and, for ionising radiation, into certain, "possible," or "unlikely." The numbers of fathers exposed to radiation were very small, but this aspect of the