Data from transnational study of oral contraceptives have been misused

EDITOR,—The unpublished data from the transnational study of oral contraceptives have been misused and misinterpreted in Britain because of inexplicable haste and urgency not thought necessary by other major regulatory agencies. My colleagues and I do not agree that our findings justify the drastic actions taken in Britain, whereby a "Dear Doctor" letter was sent to doctors, warning that oral contraceptives containing desogestrel and gestodene are associated with an increased risk of thromboembolism (pp 1112, 1117, and 1172).¹ Doctors should be vigilant but not stampeded. Patients need not panic. In particular, the risk estimates in Britain are systematically lower than those in the four other European countries that participated in the study.

On 8 October my colleagues and I completed the analysis of venous thromboembolism in this study (the two other components examine myocardial infarction and stroke). Voluntarily, we briefed medical officers at the Medicines Control Agency and a subcommittee of the Committee on Safety of Medicines within two days. As we did with the German drug safety authorities, we shared the data in confidence, believing that this was in the public interest. To our dismay, without consulting the scientists who had provided the data after five years' fieldwork, the Medicines Control Agency and Committee on Safety of Medicines invoked our findings four working days later to justify sending out the "Dear Doctor" letter.

Unchallenged, that letter will effectively eliminate half of the oral contraceptives now on the British market. This effectively bans the drug while letting the committee off the hook about a banning decision. Despite Professor Michael Rawlins's attempt to mitigate the negative impact, its message seems to have caused a "pill scare," given the newspaper headlines the morning after. As a pharmacoepidemiologist and principal investigator of the study I believe that the associations shown do not justify haste in decision making. After one week's reflection my colleagues and I are uncertain whether the modest increases in the odds ratio for venous thromboembolism can be best explained by bias or as causally significant. Our statistical advisory group believes that five unavoidable biases might be driving the risks up spuriously. Moreover, conventional epidemiological wisdom holds that when drug safety is being considered, relative risks (such as odds ratios) should give way to absolute risks or attributable risks when they are available or can be derived. We presented attributable risks to the Medicines Control Agency and Committee on Safety of Medicines. They were very low, and yet the "Dear Doctor" letter states "twice the risk," an expression of relative risk that is both misleading and alarming.

Our results for venous thromboembolism are equivocal, being neither fully reassuring nor alarming. But I thought that the absence of danger or imminent danger afforded the opportunity to evaluate the results carefully and deliberately, to present them to scientific critique and feedback, and to submit them to a peer reviewed journal. The Medicines Control Agency and Committee on Safety of Medicines chose to short circuit the formal peer review process to make decisions about

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third generation oral contraceptives in the absence of a community health emergency. This is an unacceptable precedent, and I vigorously object to having our unpublished data used thus without the benefit of the investigators' interpretation of the findings or the assessment of disinterested peers.

Conversely, preliminary estimates of attributable risk in the myocardial infarction component of our study suggest that the newer progestogens may convey protection. Nevertheless, because of the adverse publicity we may not be able to complete the fieldwork to determine this. We intend to present our definitive findings on venous thromboembolism to scientific peers at the next annual meeting of the British Pharmacological Society.

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1 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.

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Medical aspects of fitness to drive

Unfit patients are a common and difficult problem

EDITOR,—I share Jo Alexander's concern about elderly people who continue to drive.¹ I agree that "if... elderly or sick drivers... steadfastly maintain that they are fit to continue it seems there is no way for a concerned third party to have the case reviewed before an accident occurs." Three cases in my own general practice have left me concerned about just this matter.

In the most recent case I received, in the same day's post as the issue of the *BMJ* containing Alexander's article, a letter from the Driver and Vehicle Licensing Agency (DVLA) informing me that "following satisfactory answers by your patient to a structured medical questionnaire he has been informed by the licensing authority that he or she may drive and that the licence is not subject currently to regular medical reviews, in order to remove unnecessary bureaucratic involvement with the case." This letter concerned a patient who had been wheelchair bound and house bound for many months with a deteriorating condition and whose spouse has recently developed

mental health problems because of his lack of insight into his problems generally. I took little comfort as a road user from the letter's continuing words: "Your patient was told that should the medical condition change so that the ability to control a motor vehicle becomes impaired, driving should cease and the DVLA be notified. It is primarily your patient's responsibility to report such changes to the DVLA."

In another recent case a patient who already had major limb problems had a stroke, which left him with contralateral hemiplegia and sensory impairment. He also had lack of insight into these neurological deficits and maintained that he was fit to drive his car.

The third patient had rapidly accelerating severe dementia; his inappropriate behaviours included telephoning various emergency services up to 20 times in a single night and physically assaulting members of his family. I witnessed him once leave his car parked across a street, blocking both directions of traffic, with the engine still running.

In the second and third cases I did my best to be proactive: I liaised with the close relatives, who arranged urgent sale or disposal of the car in question, but only at considerable emotional stress to themselves.

I agree with Alexander that there should be "a quick and reliable method for concerned people to have the fitness of drivers independently assessed before the worst happens."

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1 Alexander J. Drive on. *BMJ* 1995;311:269. (22 July.)

Enabling patients to drive is also important

EDITOR,—Jo Alexander expresses concern about the lack of interest by health care professionals in an elderly woman's medical fitness to drive.¹ This may not be an uncommon phenomenon. A more general interest in medical fitness to drive is recent, and many doctors are unaware of the regulations for medical fitness to drive and have never had any training in the matter.²

The simple linking of advanced age to dangerous driving is, however, unhelpful. If Alexander's concern is for the loss of innocent life on the road then alcohol, youth, speeding, and possibly testosterone should be targets, rather than old age. There is clear evidence that older people represent a low risk group³ but that those affected by diseases related to age represent a higher risk. Geriatricians on both sides of the Atlantic have written about methods of assessing medical fitness to drive, and referral for multidisciplinary assessment is appropriate in cases of doubt.⁴

A worrying trend for older people is that most of the literature is expressed in terms of who should not drive rather than in terms of enabling or rehabilitating people with illnesses related to age to drive more safely and easily. Less than 5% of the papers in my database of over 600 papers on the subject have an emphasis on enabling. If this trend is not reversed we risk our patients viewing us as police rather than as advocates. Patients with remediable conditions may not seek medical help if they fear that they may not be allowed to drive as a result of the consultation.