Controversy rages over new contraceptive data

About half of the three million women in Britain who use the combined oral contraceptive pill were advised by the Committee on Safety of Medicines last week to switch to another brand, amid controversy about the way in which the new information was released. Evidence suggesting that use of two of the newer "third generation progestogens"—gestodene and desogestrel—is associated with an increased risk of venous thromboembolism was presented to the committee two weeks ago. As a result it decided to recommend that all users of brands containing the newer progestogens—Femodene, Femodene ED, Minulet, Triadene, Tri-Minulet, Marvelon, and Mercilon—should be offered the choice of switching to another brand and that these brands should be contraindicated in women who have other risk factors for venous thromboembolism.

Presenting the committee's decision at a press conference last Thursday, its chairman, Professor Michael Rawlins, said that early results from the World Health Organisation's task force on epidemiological research in reproductive health had suggested a possible association between the newer brands of the combined pill in July. The results prompted the committee to ask workers from another large international study, the European transnational study of oral contraceptives, to "expedite their results." Professor Rawlins also said that the committee had commissioned researchers using the general practice research database, which analyses data routinely collected from British general practitioners using the Value Added Medical Products (VAMP) system, to examine the link between the newer progestogens and venous thromboembolism. "The results of all three studies pointed the same way," said Professor Rawlins, "though the chance of a woman on the pill experiencing a thrombosis is small."

The committee thought, however, that the increased risk—estimated at 30 cases of venous thromboembolism for every 100 000 users a year, compared with 15 cases for every 100 000 a year in users of other brands—was sufficient to warrant it issuing an urgent alert to users and prescribers. A letter posted first class to all doctors and pharmacists in the United Kingdom on Wednesday evening was supplemented by a "fax cascade" to general practitioners from the regional directors of public health, who had been warned to expect an urgent message.

Over a million women are now worried about their pill

Mr Stephen Dorrell, the health secretary, backed the committee's handling of the matter but said that the government would review the incident to learn from it. In the House of Commons last Monday, Labour's health spokesman, Ms Harriet Harman, accused the government of complacency and incompetence over the announcement. Mr Dorrell responded that "the government has a duty to evaluate information on the safety of medicines as soon as it becomes available and to ensure that doctors and their patients are in possession of the information necessary to allow them to make choices about their health."

Scientists express disquiet

Meanwhile, the scientists on whose work the decision was based expressed their disquiet. Professor Walter Spitzer, the organiser of the European transnational study of oral contraceptives, flew to London from Canada to hold a press conference, at which he accused the committee of misinterpreting the results of his study and creating unnecessary fears among women.

Professor Spitzer was concerned that his study—a case-control study—which matches 980 users of the combined pill who have a cardiovascular event with 2200 controls recruited from the same hospital or general practice—should be interpreted with caution. "Women who have a deep vein thrombosis while on the pill are more likely to have it diagnosed, and, conversely, women who have had a deep vein thrombosis in the past are not recruited to the study. Women who

have had problems on one brand of the pill are more likely to be switched brands, and women who are at higher risk are more likely to be prescribed one of the newer brands which are being promoted as safer. Besides these factors there are statistical artefacts to be considered."

Dr Susan Jick, an epidemiologist at the Boston Collaborative Drug Surveillance Program, who is one of the investigators analysing the VAMP data, was also aggrieved at the way in which the committee had handled her data. "We sent our results in confidence to the committee, and they were released with absolutely no consultation. The whole decision is premature and based on insufficient information. We are quite distressed that our results are being used in this way."

These concerns seem to be shared by the European pharmaceutical regulatory bodies, as the British committee is the only body so far to have issued a warning. According to the medical director of the Association of the British Pharmaceutical Industry, Dr Frank Wells, the Committee on Proprietary Medicinal Products (the European equivalent of the Committee on Safety of Medicines) met last Wednesday and decided that the information should be evaluated further, but Britain's unilateral decision "took everybody by surprise."

Dr Wells denied that any of the players were financially motivated, though the decision will plainly hit the manufacturers of the third generation progestogens hard. "On medical grounds this might be the right

Headlines

Muslim law will allow organ transplants: The Muslim Law (Shariah) Council has issued a religious verdict, a fatwa, giving official approval for organ donation. The fatwa accepts that the medical profession is the proper authority to define signs of death and that brain stem death is a proper definition of death.

Labour party appoints new health spokesperson: Ms Harriet Harman has taken over the Labour party's health portfolio from Mrs Margaret Beckett. Ms Harman was a former shadow employment and health minister.

Branded medicines to be reviewed: The Office of Fair Trading is to review the agreement that allows drug companies to set minimum prices for branded non-prescription medicines.

UK health department bans temazepam capsules: From 1 January 1996 general practitioners will be unable to prescribe temazepam capsules, which are often misused by drug users. Other formulations of the drug will continue to be available.

Breast screening extended to older women: The UK government has announced that women aged 65 to 69 are to be included in a study in an attempt to reduce deaths from breast cancer. Three pilot studies will take place in the South Thames, Northern, and Yorkshire regions. The House of Commons health committee said in its report on breast cancer services that the upper age limit for the call and recall system should be extended beyond 64.

Russian doctors rekindle revolutionary flame: Russian doctors, alarmed by what they see as an imminent crisis in health care, have revived a prerevolutionary forum to campaign for political action. The forum, the Russian Pirogovsky Congress of Doctors, is due to meet next month after a 77 year break since the last time it convened, in 1918.

NHS will be leading provider of private care: The NHS will provide more private care in Britain than any other group by the end of the current financial year, according to the *Fitzhugh Directory*, an annual review of private health care. In 1993-4 St Thomas's Hospital earned more than £8.4m and the Royal Free Hospital £8.2m from private care.

decision, but the industry feels that the most important matter is that information is disseminated appropriately to those who need to know. I challenge the degree of urgency of these data, which should have appeared in a peer reviewed journal. A delay of one or two months would not have made a difference to patient safety." (see pp1111, 1112, 1162, 1172.)—DOUGLAS CARNALL, *BMJ*

Men can have free prescriptions at 60

Last week men in Britain aged 60 and over became entitled to free NHS prescriptions when the European Court of Justice in Luxembourg ruled on equal treatment of men and women. Until then, exemption from the prescription charge of £5.25 per item had been linked to the state pension age of 60 for women and 65 for men. Within hours of the court's ruling, the British government said that it had no option but to comply. More than one million men between 60 and 64 became exempt from prescription charges the next day. Refunds will be paid to those who were charged for prescriptions in the previous three months.

The cost will be £30m a year for lowering the age and £10m for the refunds. The health minister, Mr Gerald Malone, said that the money would come from the Department of Health's general budget and not from funds allocated to direct patient care. He told the House of Commons that he was surprised by the court's decision and did not accept that it was good, though the government had to comply.

The decision was a vindication of individual litigation by Mr Cyril Richardson, a retired lecturer now aged 66, who objected to paying for prescriptions while his wife, aged 62, was exempt. He claimed that such

discrimination was contrary to a European directive on equal treatment of men and women in matters of social security. The High Court in London referred the case to Luxembourg for a ruling. The government argued that exemption from prescription charges was a health, not a social security, scheme and that in any case there was a derogation for state pension age. The European court ruled that prescription charges were within the scope of the directive. Accordingly, the NHS regulations tying free prescriptions to retirement age were not consistent with European Union law.

The government will distribute posters and coupons to pharmacists and take space in national newspapers detailing how to claim a refund. Members of parliament who are sceptical about Europe saw it as "another humiliation" of Britain by the European Union, but a member of parliament for Labour said that it upheld the British tradition of an individual citizen fighting for justice. The government could have raised the exemption age for women to 65 but decided against doing so.—JOHN WARDEN, parliamentary correspondent, *BMJ*

US proposes radical reform of Medicare

The US House of Representatives has taken the biggest step in health reform since 1965 by approving an overhaul of the government's programme that insures elderly people in the US. By an almost rigid party vote last week the House approved a reform of Medicare that will place growth limits on the programme for the first time. The bill would save \$270bn (£171 000m) over the next seven years, holding growth to 6.5% a year rather than the 10% it has been running at in recent years.

"Nice one, Cyril"

EDWARD SYKES/THE INDEPENDENT

In contrast to the long campaign for health reform two years ago by President Bill Clinton, the Republican congressional majority has taken little more than six weeks to run the bill through Congress. Some health policy analysts have complained that experts have barely had time to read the legislation. The House version must be melded with the Senate's bill, which is expected to be voted on later this month. Little has been disclosed about the Senate bill except that it is likely to be less radical than the House version.

The House bill got a huge boost last week when the American Medical Association withdrew its doubts and gave full support to Speaker Newt Gingrich and his fellow Republican leaders. In a flyer sent to its members the association applauded the Republicans' promises that doctors' fees would not be cut severely, that malpractice awards for pain and suffering would be limited to \$250 000 (£158 000), and that almost all federal regulations of doctors' laboratories would be repealed. The Democrats said that the association had "sold out." They claimed that patients and hospitals would suffer so that doctors' fees could be maintained.

But policy experts have not yet identified who will be hurt most by the new limits. Most seem to think that hospitals will lose the most, and some hospitals, especially teaching hospitals, expect revenues to fall, forcing many to close.

The fundamental goal of the bill is to move elderly people away from fee for service payments to hospitals and towards prepaid health schemes in which doctors and hospitals are paid agreed capitation fees in advance—more similar to how Britain's general practitioners are paid.

President Clinton has promised to veto such radical reform as passed by the House. The Republicans, however, hope to include their reform of all government sponsored medical insurance (for elderly, disabled, and poor people) in one omnibus budget bill that will be almost impossible for the president to veto without sending financial markets into chaos.—JOHN ROBERTS, North American editor, *BMJ*

UK government will fund research into health variations

Fifteen years after the Black report identified a link between poverty and ill health in Britain the government has accepted an action plan to tackle variations in health and is to fund a multimillion pound research programme. This follows the publication this week of a report to the chief medical officer, Dr Kenneth Calman, by an expert group headed by his deputy, Dr Jeremy Metters. The report, *Variations in Health: What can the Department of Health and the NHS do?*, finds evidence of appreciable variations between occupations, the sexes, regions, and

The government accepts that some poorly paid jobs are linked with ill health

ULRIKE PREUSS

to which the Department of Health is not giving sufficient emphasis.

"What is now needed," the report says, "is for the NHS at local level to undertake a more systematic identification of health variations and to design and implement measures to tackle them. Future interventions must be rigorously evaluated, particularly for cost-effectiveness, and the findings widely disseminated."

The report proposes that the Department of Health should set specific objectives for reducing variations. It should work actively to encourage social policies that promote health and should conduct research into the needs of particularly vulnerable groups of the population and into the causal processes.

While not advocating a new "initiative," the group calls for much more explicit targeting of the issue within existing policies and activities. It adds: "The context is favourable. The department is leading a government-wide strategy to improve the nation's health and the NHS...has a stronger focus than ever before on identifying and meeting the needs of local populations."

The expert group found little practical guidance available on effective interventions to deal with variations in health. The likeliest explanation for observed variations is given as cumulative exposure to health damaging or health promoting environments, with other contributing factors such as social mobility, behaviour, use of health services, and genetic or biological factors. The weakness of the evidence, however, did not support the conclusion that nothing should be done but gave added weight to the need for further research. The target should be to improve the health of the least healthy groups so that it is closer to the level attained by the most healthy.

Announcing a £2.4m research initiative next year, the health secretary, Mr Stephen Dorrell, promised more formal links between the department and the research councils into variations in health, thus ending a

decade and a half in which the government has refused to acknowledge a direct link between social factors and health.—JOHN WARDEN, parliamentary correspondent, *BMJ*

Variations in Health: What can the Department of Health and the NHS do? is available from Department of Health Mailings, Two-Ten Communications, Building 150, Thorp Arch Trading Estate, Wetherby, West Yorkshire LS23 7EH.

South African placentas sold to French drug firm

South African hospitals have embroiled themselves in an ethical row after complaints by a rural hospital alerted government officials to the fact that state hospitals were disposing of human placentas by sending them to the French pharmaceutical company Pasteur Mérieux.

The original licence to export the placentas was granted in 1992 by the previous minister of health, Dr Rina Venter, who claimed that the contract she signed referred to "organic matter." She claimed that had she known that this included placentas she would not have signed the document. She said that the issue of disposing of human organic material had been debated at the time and that the then government (the National party) had believed that it should send the "material," but not for money. Each hospital that disposed of placentas received a token fee of 1000 rand (£180) as "an acknowledgement."

The present ministry of health has reacted strongly. A ministry statement said that the programme was "immoral" because "someone benefits and it removes something

from a woman's body without having the decency of informing her."

The practice was defended by Dr Steve Mendelsohn of Bocknek, the company that collects the tissue for export. He said that although women are not directly asked to donate their placentas, they sign a disclaimer that allows the hospital to dispose of waste material as it sees fit. Many of the women who give birth in state hospitals are illiterate and speak languages not spoken by the medical staff, who may, unusually, try to get properly informed consent on admission.

The placentas are used in the preparation of drugs to treat Gaucher's disease, which about 50 people in South Africa have. Of these, under a dozen are able to receive the expensive drugs.—PAT SIDLEY, freelance journalist, Johannesburg

Russia tries to reduce irradiation deaths

Russian citizens are to be issued with "radiation passports" to try to reduce the number of deaths due to overirradiation. In Moscow alone 8000 people die every year of cancer, radiation sickness, or reduced immunity directly related to too many x ray examinations, according to Dr Roman Stavitsky, a senior medical officer who heads a laboratory investigating the subject.

Dr Stavitsky blamed the thousands of deaths—which include deaths due to diseases related to cancer in subsequent generations—on faulty equipment, outdated attitudes to health care, inadequate training in hospitals and x ray departments, and inadequate shielding from radiation. Russians undergoing routine medical checks are exposed to radiation levels up to three times higher than those used in "civilised countries," he claimed. There are not enough health experts to cope.

When Russia was part of the Soviet Union all adults had regular lung x ray examinations to screen for tuberculosis. Although this practice was stopped a few years ago, over half of Moscow's adult population had an x ray examination of some kind last year.

Officials in the city health department say that a new health care system introduced in 1992 encourages x ray examinations and that the number of x ray procedures and examinations that are unnecessary has doubled.

Sergei Okhrimenko, deputy head of a city department that checks radiation sources, said, "We consider this a big problem, all the more so since it happens in a country which suffered the Chernobyl catastrophe."

The passports are the brainchild of Moscow's senior radiologist, Yury Varshavski, who plans to set up a new diagnostic and coordinating centre, which would enable people to keep a check on their exposure to x rays.—MIRANDA INGRAM, Moscow bureau chief, the *European*

Effect of air pollution on asthma is "small"

There is no good evidence that air pollution causes asthma, and current levels of air pollution play only a small part in exacerbating existing asthma, says a British government report. According to Professor Ross Anderson, the chairman of a subgroup of the Committee on the Medical Effects of Air Pollutants set up to examine the links between asthma and air pollution, "daily fluctuations in the levels of air pollution do correlate with hospital admissions and symptoms, but this accounts for less than 5% of the total number of episodes of asthma."

Although there is a consensus that the rise is real, the committee concluded that the trends are "not entirely clear" because of the difficulty in comparing the variety of survey techniques, age groups, and catchment areas. The available evidence points to an increase of around half over the past 30 years, though hospital admissions of children with asthma have risen 10 times.

Air pollution is one obvious possible culprit, but the evidence that it causes asthma is not strong. Levels of pollution from smoke and sulphur dioxide have fallen considerably in the past 40 years, following the introduction of the Clean Air Act of 1956, which greatly reduced the amount of coal burnt for domestic use. But levels of nitrogen oxide, volatile organic compounds, and particulates from vehicle engines have increased over the past 30 years. The evidence on trends in ozone levels is conflicting, with declining levels in urban areas and rising levels in rural areas.

Studies in animals provide some evidence that air pollutants may initiate asthma attacks. Nitrogen oxides, sulphur dioxide, and ozone at concentrations consistent with ambient exposure levels have been shown to

enhance the allergenic properties of airborne particles, but the committee advises caution in extrapolating these results to humans because there is no satisfactory animal model of asthma.

Chamber studies, in which human volunteers are exposed to atmospheric pollutants under tightly controlled laboratory conditions, show that air pollutants may cause acute narrowing of the airways in high doses, but there is no important response at levels currently prevailing in the air over Britain.

Epidemiological surveys show no association between the prevalence of asthma and areas with higher levels of air pollution, but five studies have shown a moderate and consistent correlation between asthma and exposure to traffic. It is possible, however, that social class and reporting bias may have confounded these results.

More research is needed, and the government is making £5m available for further exploration of the subject. Welcoming the report, the government's chief medical officer, Dr Kenneth Calman, said, "This is a technical document with a clear conclusion: that the rise in prevalence of asthma is unlikely to be the result of air pollution. It must be something else."—DOUGLAS CARNALL, *BMJ*

Asthma and Outdoor Air Pollution is available from HMSO, price £21.

Correction

Multiple sclerosis drug prompts rationing fears

An editorial error occurred in this story by Owen Dyer (14 October, p 969). Dr David Miller of the Institute of Neurology is inaccurately reported as estimating that about 40 000 of the 80 000 people in Britain with multiple sclerosis might benefit from interferon beta. Given the experience with the drug in the United States he believes that about 10% of people with multiple sclerosis might benefit.

Vehicle exhaust fumes are increasing along with asthma

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