need to retreat from a blind obsession with a regulatory “process” and “correct” procedures to the use of sound clinical judgment based on all relevant information and common sense, on a case by case basis. A good example is the regulatory clock, in which agencies guarantee to provide an approval within a timeframe embedded in regulations, and which has probably done more harm than good. The recommendation that “the clock should be stopped” is timely in an environment that pressurises regulators to bring drugs to market faster.

Among the more far reaching recommendations are those that place more responsibility on sponsors and investigators to prove that it is necessary to perform a clinical trial in humans. Even more wide sweeping is the emphasis on openness in development and regulatory and ethical review, and a burial of the sacred cow of proprietary information. Even so, the expert group was reluctant to grasp some of the more prickly nettles. These include advocating a single integrated and publicly accessible database in conjunction with the World Health Organization and resisting the claims that more emphasis on safety threatens the swift delivery of lifesaving drugs to the bedside and forces research overseas. A closer look at the contributions of pharmaceutical research to improving global health might draw a different conclusion. Although witnesses emphasised the word “unprecedented,” this does not mean that it won’t happen again.

The concerns and recommendations of the expert group about the rapidly changing environment of research are commendable. Concerns include the commercialisation of research and its loss from clinical and academic centres; the prevalence of inexperienced and small start-up biotechnology companies reliant on venture capital; lack of training and adequate facilities; and the failure to plan for and deal with adverse events. The new ethical guidelines from the royal colleges will lend a supporting voice to some of these aspects of the report.^{12 13}

Will the report of the expert group make a difference? That will depend on the quality of the

public debate and the responses to the consultation, the deadline for which is 14 September. It will also depend on the degree of resoluteness that the group displays in recommending the need for a more fundamental inquiry and action, the extent to which the affected parties embrace their vision, and the willingness of those parties and the Department of Health to implement them fully.

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What to tell patients about radioiodine therapy

Avoid close contact with other people, don't try to conceive, and take your radiation certificate when flying

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In this week's *BMJ* Gangopadhyay and colleagues report the case of an unfortunate patient who activated an airport radiation detector six weeks after receiving radioiodine ¹³¹I therapy and was consequently subjected to intense examination and interrogation (p 293).¹ No clinical practice guidelines cover this type of problem. So, on current evidence, how should doctors advise patients who are about to receive radioiodine therapy?

Each year radioiodine is administered to 10 000 people for hyperthyroidism in the UK.² After injection or ingestion, radioiodine initially concentrates in the thyroid gland and then circulates through the bloodstream, with 80% excreted renally. While the radioactive urine is stored in the bladder, until it is voided, the gonads are irradiated: after an adminis-

tered dose of 750 MBq of ¹³¹I the testes receive a radiation dose of 17-19 mGy and the ovaries 28-31 mGy.³

To reduce the risk of any radioactive germ cells causing irradiation of the fetus, the Department of Health Administrations of Radioactive Substances Advisory Committee (ARSAC) recommends that male and female patients should be advised to avoid conception for four months after treatment.⁴ The American Thyroid Association suggests a period of 6-12 months.⁵ Also, although currently no evidence shows that treatment is associated with an increased incidence of infertility in women,⁶ men should be warned that they may have a reduced sperm count and temporary infertility for up to two years after therapy.⁵ We can reassure patients about future conception, as there is no association between the calculated internal

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radiation dose and risk of genetic abnormalities observed in subsequent pregnancies.^{6 7}

Patients with young children at home should be advised to avoid prolonged daily close contact (within less than 1 metre) with them for a time dependent on the dose of radioiodine to be administered. The inconvenience or impracticality of this requirement often deters many patients from having treatment.

Long term follow-up data show no increased risk of cancer after radioiodine therapy and, contrary to some patients' misconception, there is no overall excess mortality from cancer.^{8 9} Some studies have highlighted a small increased risk of thyroid cancer, but the increased absolute risk is very small—in about 7500 patients treated with radioiodine nine cases of thyroid cancer were observed compared with 2.8 expected.^{8 10}

The only recognised long term adverse effect of radioiodine therapy is hypothyroidism, so all patients are warned that they might need lifelong thyroxine replacement. The rate at which hypothyroidism develops depends on the dose of radioiodine. Current evidence says that best practice is to give higher doses of ¹³¹I to render patients hypothyroid more quickly, given the observed increased all cause mortality in hyperthyroid patients treated with radioiodine (in about 105 000 person years of follow-up, 3611 deaths were observed compared with 3186 expected).¹¹ This increased mortality is no longer seen, however, once patients are hypothyroid and receiving replacement therapy.¹²

Patients are advised to avoid public transport for two weeks so that they do not expose nearby passengers to radioactivity but, to date, advice regarding air travel and radiation detectors has been overlooked in many centres. It is not possible to devise prescriptive guidelines to clearly define the period during which patients may activate security alarms at airports. Despite the constant biological half life of ¹³¹I (eight days), its effective half life varies widely with the patient's renal function. Furthermore, anecdotes of patients who have travelled to eastern Europe without incident after radioiodine therapy, only to activate a security alarm on entering the United States two weeks later, suggest that different detectors are set at different radioactive thresholds. Not surprisingly, the British

Airports Authority was unwilling to give any information regarding the sensitivity of their detectors when we approached it for clarification.

The only practical solution must be to adequately counsel anyone receiving radioiodine (or indeed any radioisotope) about travelling overseas and advise them to carry their radiation certificates. To prevent the alarm bells ringing, this practical advice should be incorporated into the new guidelines on the use of radioiodine for thyroid disease that are to be published later this year by the Royal College of Physicians.

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Classification of illegal and harmful drugs

The UK's confusing and inadequate ABC system is ready for an urgent overhaul

This week the House of Commons Select Committee on Science and Technology published the report of its inquiry on the classification of illegal drugs in the United Kingdom.¹ The report highlighted glaring anomalies in the classification of illegal drugs into classes A, B, and C and reflected a broad agreement that the current system is not fit for purpose. The committee also reported considerable confusion over the remit of the Advisory Council on the Misuse of Drugs and serious flaws in the way that the council conducts its business.

The select committee's report criticises the government for failing to meet its commitments to evidence

based policy making. Indeed, the inquiry on illegal drugs was part of a wider investigation into how the UK government handles scientific advice, risk, and evidence. Launching the whole inquiry last November, the committee chairman, Phil Willis MP, said "We keep hearing from government ministers that policy is based on evidence. We want to... (know what that) means in practice."

The classification system (based on the United Nations Single Convention, 1971, and the Misuse of Drugs Act, 1971) was designed as a way to control the use of illegal drugs according to their relative harmfulness (table).² The Misuse of Drugs Act created the

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