under way with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

The commission was asked last year to look at the ethical issues raised by genetic engineering by President Carter's science adviser, Dr Frank Press, following a letter to the President from three church groups expressing concern that recent advances in genetic research meant that "those who would play God will be tempted as never before". Since then the churches involved have not demonstrated a particularly close interest, but public concern has been stimulated by various press reports of potential new surgical techniques.

At last week's meeting the members discussed a draft report on the ethical and social aspects of genetic engineering. And although reluctant to raise unnecessary fears, they agreed that the implications were likely to be significant — for example in terms of the potential ability of an individual to alter the genetic characteristics of his or her descendants.

Most commission members agreed that there was a need for a wider public dissemination of information about the potential effects of new clinical techniques. Also that it might be appropriate for some type of advisory body to indicate areas in which caution should be used.

There was less of a consensus on whether it was desirable that such a body should suggest that certain types of experiments — for example the cloning of a human being — should be prohibited. Some, for example, suggested that any attempt at what the draft report described as the "control of evolution" should be proscribed; others pointed out the phrase was so broad as to include many currently-accepted practices, such as the treatment of diabetes with insulin.

The commission also debated whether discussions should take place at an international level. There was general agreement, however, that achieving international consensus on the boundary between acceptable and unacceptable practices would be even more difficult than at a national level. **David Dickson**

New substance regulations

Industry complains

The British Chemical Industries Association is protesting vigorously at the draft on the notification of new chemical substances drawn up by the Health and Safety Executive. The association claims that the draft regulations would mean the end of research and development in the British chemical industry.

The draft regulations were published last February, when comments from interested parties were invited by the end of this month. They are an attempt to bring British practice into line with a directive of the European Commission, whose aim is to protect "man and the environment" from the potential hazards of new substances. Although the directive deals chiefly with the protection of the consumer, the Health and Safety Executive is (given its remit) primarily concerned with the protection of workers' health.

Thus the British regulations would require industry to notify not only all new manufactured substances but also all new intermediates in chemical processes. The Chemical Industries Association complains that the extra costs involved will drive research and development away from Britain. The dilemma is, however, real. The Health and Safety Executive says that intermediates must be tested if existing regulations to protect workers from potential hazards are to be put on a more formal basis than required by the Health and Safety at Work Act.

The consultative document is precise about the tests required for new chemicals. Manufacturers would be required to assess the toxicity of substances by LD_{50} tests, provide data on skin and eye irritability, tests for mutagenicity and possibly carcinogenicity and teratogenicity. They would also have to provide data on biodegradability. The executive estimates that the total cost would be about £45,000 per substance.

The objections of the chemical industry appear to centre more on the range of chemicals covered than the direct cost. As well as chemical intermediates, the draft regulations cover pharmaceuticals, foodstuffs and pesticides, all of which are excluded from the European directive on the grounds that they are covered by other regulations. The Health and Safety Executive's argument is that such assessments relate only to specific uses, and are not necessarily sufficient.

After the July deadline, the chemical industry will also be arguing for a strengthening of the provisions for preserving confidentiality. The association is concerned that valuable data, especially those on intermediates which would provide information on novel process routes, could fall into competitors' hands.

So far, few other bodies have put in comments, but the trade unions and environmentalists will also be having their say. The controversy aroused by the chemical industry's response, however, suggests that further negotiation will be needed before the regulations are in a final form and that the European Commission's 18 September deadline for the implementation of legislation will not now be met.

The European Commission is at the same time going ahead with its plan to compile a catalogue of all chemicals manufactured in Europe. Thereafter, industry will be required to notify the commission of all new chemicals manufactured during the past ten years that are not included, a ruling that will apply even in countries that will not have introduced their own legislation. **Judy Redfearn**

UK pharmaceutical industry

Keeping up

"Britain's medicine makers have brought out an 'unfashionable' annual report — it tells a success story." So says the cheery publicity blurb announcing the 1980–81 report of the Association of the British Pharmaceutical Industry (ABPI). The claimed success is an increase in the value of exports of pharmaceuticals to £745.4 million in 1980, 16.7 per cent up on the sales in 1979, and representing a £523 million surplus of exports over imports.

Evidence of success is rare enough in British industry and the bouncy confidence affected by ABPI is likely to please a government eager for good news. And the industry seems to be getting its views across with some aplomb. Already this year the industry has had a victory in the form of new regulations governing the granting of the clinical trial certificates which must be obtained before new drugs can be tested clinically. From March, the certification process requires simpler documentation and data requirements have been reduced.

In another area of concern to ABPI, Mrs Sally Oppenheim, Minister of State for Consumer Affairs, has said that the government will try to include a "state of the art" defence in the EEC directive on product liability. The objective is that manufacturers should not be held liable for injuries to health caused by a product which could not be termed "defective" in the light of scientific knowledge when the drug was put onto the market.

The supposed main benefits to be gained by the simpler clinical certification rules are a reduction in the 10 to 12 years now needed for a new drug to reach the patient (a debatable improvement, especially after Fisons' withdrawal of Proxicromil when it was all but on the market, see *Nature* 12 March, p.81), and a stimulus to encourage development of drugs to treat less common diseases.

However, the most tangible effect of relaxations in control of drugs in clinical trials is likely to be an increase in the numbers of trials conducted in the United Kingdom rather than in other, less restrictive, countries. This is one factor to be considered by multinational companies when deciding whether to invest in Britain or go elsewhere. At present investment in research in the United Kingdom is holding up well, with £16 million to be invested by Merck, Sharp and Dohme in a neurobiology research centre near Harlow, £5 million by Upjohn in expanding facilities at West Crawley, £10 million by the Wellcome Foundation in a chemical research laboratory in Beckenham, and £3.3 million by Roche in improving research facilities at Welwyn Garden City. But competition between the developed countries for the favours of the research-based companies can only increase. **Charles Wenz**

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