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Contraceptives and drug regulation

In May 1980 Upjohn Limited, a major international drug company applied to the Government for a licence for the long-term use of its injectible contraceptive Depo-Provera. In April 1982 the Government rejected the application. This, despite being advised to accept by its own advisory body the Committee on the Safety of Medicines (CSM). There has been widespread debate over the drug and it is thought the particular Health Minister concerned had come down on the side of the opposition to the drug. He argued that as compared to the 'limited benefits' of the drug, the medical and social risks were too high.

Depo-Provera is one of two long-acting contraceptives currently in use around the world. The other is Norigest which is used in Britain at the moment on short term prescription by women who cannot use any other method of birth control. The two are broadly similar and work in the same way as oral contraceptives - the Pill - through the prevention of ovulation. While the Pill contains both progestogen and oestrogen, the injections contain only the former. So for a start they eliminate the oestrogenic risks to health associated with the Pill.

There are many other advantages to the injectible contraceptive. It can be taken by women as another alternative to the Pill. Long-acting injections are equally effective in preventing unwanted pregnancies. But in practice it is much easier to forget to take a pill one night than it is to miss the quarterly injection. it has also been found that extended use of the drug leads to a slightly higher level of haemoglobin in the blood which is useful in the prevention of anaemia. This is especially beneficial in regions of the world where health care is fairly rudimentary. Its clinical record is better than the Pill at a comparable stage of development.

The demand has already been shown to exist for its long term use in many countries. Much publicity has been given to the ban on the drug in the USA. But the drug is widely used in such 'advanced' countries as Sweden and New Zealand.

MISSED OPPORTUNITIES

The US has one of the strictest regulatory authorities in the world, the Food and Drug Administration (FDA) . It also turns out to be the costliest in terms of missed opportunities for improved health. As the Friedmans show in *Free to Choose* the FDA has many pressures on it. The US is one of the most open societies in the world with a very powerful public opinion. An official can make two kinds of mistakes. He can approve a drug that turns out to have un-anticipated side effects resulting in death or serious impairment of a sizeable number of individuals. Or he can refuse approval of a drug that is capable of saving or drastically improving many lives and that has no untoward side effects.

If the first mistake is made - a thalidomide is approved - that agency and that individual will be villified across the nation, even across the world. The agency may be disbanded, the individual would at the very least face a more difficult future. Yet if the second mistake is made only a few well-informed doctors, chemists and patients will know and miss the drug. It is not surprising that the authority with a lot of power will refuse a lot of drugs.

But studies of the costs and benefits of such strict drug regulation show up the futility and damage that it causes. Its essential uselessness is illustrated by the losses to a company that introduces a drug later shown to be unsafe. Not only did Hoffman have to pay out tens of millions of pounds in damages to the victims of the Thalidomide disaster but they also lost a reputation that in the long term has probably proved more costly in terms of the suspicion and hence the reluctance to accept and buy new drugs. The risk of this loss acts as a very powerful regulatory mechanism preventing the introduction of unsafe or potentially damaging drugs.

Studies by Peltzman and Grabowski have highlighted the cost in human terms of strict regulation. Comparing the use of drugs in Britain and the US they have both found that many thousands of lives were being lost unnecessarily through the restrictions on drug use imposed by the FDA.

DEPO-PROVERA IN THAILAND

Some objections to the drug have arisen over the way the drug has been developed and 'tested'. Fears were reinforced recently when a television programme about the drug showed lines of innocent-looking Thais baring their arms for their injections. But this was neither an experiment nor an exposé of some sinister state birth control programme.

It should be noted first that attitudes to injections and modern medicine generally are very different in the less developed regions of the world than they are in the trendier regions of the advanced world. Modern medicines are seen to go into the body and are seen to work, so they are favoured. In the particular programme the Doctor at Chiangmai in deepest Thailand had been working for many years and with many thousands of patients giving women the freedom from unwanted pregnancy.

These people were no backward, undifferentiated mass of frightened women herded into the vaccination camps, but tough, suspicious peasant women who often walked scores of miles to be in the right place at the right time for their quarterly dosage. As many birth control advocates can tell you, if the people do not want it they will stay away unless, as in India, they are forced at the point of a gun to submit.

Many opponents of this and other drugs often raise the notion that there should be 'informed consent' before a patient can be said to have agreed to the treatment. However this problem is not limited to the field of drugs. They are just one set of many, many sets of goods and services that are purchased on an understanding that they are safe and will work satisfactorily. In principle there is no difference between a doctor prescribing a drug to clear up some ailment and you being sold a car to drive around in. Unless a person is a motor mechanic (or a chemist), he will have only a rudimentary knowledge, if any, of how the car (the drug) works. The car dealer (the doctor) has a fairly good idea, but still relies chiefly on the car company (the drug company) for a guarantee of safety and reliability.

The Guardian (4th May 1982) in a particularly protective editorial expressed fears that the drug would be pressed by doctors onto "medically handicapped girls; or women who for a variety of reasons, they consider unsuitable for motherhood - the 'feckless' and promiscuous; or poor black women; or Asian women who do not understand English". Apart from the wrongheaded dispatching of the principle of individual responsibility, what is the fear? It is the fear of the drug reaching one of its potential markets. For many poor or ill-

educated women the injectible contraceptive will be especially beneficial as it is effectively the most reliable and the most easy to carry out. They may not be 'fully informed' and be making a "free decision" but then we do not live in a perfectly enlightened and pressure-free world. No one can ever really take such decisions.

DEPO-PROVERA IN PRACTICE

There are one or two minor problems with the drug, some women may experience irregular menstrual bleeding that can cause discomfort and some confusion if it is taken as a sign of being at a certain part of the menstrual cycle. But a London clinical trial with Norigest found that this was a very minor problem. The drug may also cause some delay in a woman's return to fertility when she stops using it. But here it appears to be no more serious a problem than the Pill, and the trials have shown that 92-97 per cent of women become successfully pregnant within two years of ending their course.

There were two pieces of medical evidence that the CSM advised doctors to be aware of before prescribing the drug - should the government allow it. They warned that 'tumours had developed in monkeys given 50 times the normal human dose but the relevance of this to man has not been established'. This is not altogether surprising since monkeys have acted up like this on a number of previous occasions when pumped full of other assorted drugs and foods.

They also stated that 'a few cases of breast cancer have been reported in women taking Depo-Provera but no causal relationship has been established'. The preliminary results of a study into the effects the drug on the 80,000 women in Thailand are showing no extra likelihood that women will get breast cancer if they are on the drug. Whereas it has been shown that oral contraceptives do definitely increase the risks of a woman getting some sort of cancer. In the Pill's case the benefits are thought to outweigh the risks. The same should be thought of injectible contraceptives.

While the drug is prohibited many women will suffer, many women will become unnecessarily pregnant. As with many other drugs, the state prevents their use and so decreases personal and social welfare, and personal and social freedom.

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A DRUG REGULATION READING LIST

Articles

1. Geraldine Howard, "Injectible contraception, *The Listener* 4th March 1982

2. "Rejecting scientific advice", *The British Medical Journal* 15th May 1982.

Books

1 Milton and Rose Friedman, *Free to Choose*, Penguin, 1981.

2. Sam Peltzman, *Regulation of Pharmaceutical Innovation*, American Enterprise Institute, 1974.

3. Henry Grabowski, *Drug Regulation and Innovation*, AEI, 1976.

4. A report by the Campaign against Depo-Provera, *Depo Provera*, 1980.