Two million women in 80 countries across the world receive an injection every three months for birth control, a method that has been in use since 1967. Although considered as effective as oral contraceptives (with which it shares the same side effects), the drug used, Depo-Provera, has not yet been approved by the American Food and Drug Administration (FDA).

And with good reason: in still controversial studies, the experimental injection of Depo-Provera in dogs and monkeys caused various types of cancers. The product’s manufacturer, the Upjohn Company, has taken action to appeal the ban imposed in 1978 by the FDA. According to observers, the company, which is seeking to consolidate its Third World markets, needs the approval of the American watchdog agency to be able to expand Depo-Provera’s distribution abroad. Developing countries have few legal barriers to the importation of medication or drugs and must rely on world-recognized organizations, which is why they require official FDA rulings on product safety.

Despite the refusal of the FDA to clear it for use in North America, Depo-Provera continues to be administered in many developing countries. International institutions, including the World Health Organization and many local governments, support its use although not one thorough study has been conducted on the ten million women receiving this contraceptive since 1967. In effect, an experiment involving millions of women is underway in developing countries — one that would not be permitted in the country where the drug originates.

INFORMED CONSENT

It was after the Second World War that people in the developed countries became concerned for the first time with drafting a code of ethics for human experimentation. The abuse of prisoners in concentration camps led to the Nuremberg Code, which set forth the basic principles that researchers were to observe when experimenting on human beings.

First of all, the Code states that researchers must obtain the informed consent of the subject. The latter must be advised of the nature of the research and of its objectives; he or she must also be able to evaluate the risks and the benefits, if any, of his or her participation in the experiment; finally, he or she must give written consent — although retaining the right to withdraw at any moment if he or she sees fit. The Nuremberg Code was largely responsible for the Helsinki Declaration (1964, revised in 1975), the most widely recognized and most recent code. A clinical section was added to deal with relations between patients and health professionals.

The Helsinki Declaration recommended the creation of ethical advisory committees within medical research institutions and hospitals. These watchdog committees would evaluate the implications of and, where necessary, sanction research conducted by institution staff. In practice, ethics committees in the West have not always lived up to their responsibilities. A study conducted in the United States showed clearly that decisions made by ethics committees varied considerably from one institution to the next. Medical acts or research considered morally acceptable in one institution were very often condemned in another.

Informed consent of the individual, the cornerstone of all Western ethical codes, is often difficult or even impossible to transpose, given the circumstances of developing countries.

What is the meaning of “informed consent” of the individual when the advantages are incomprehensible and the risks untranslatable, when the very notion of science is foreign to the individual? How can the researcher go beyond the simple explanatory text, the words of which may be translated, to obtain informed consent when clinical research is a Western reality without indigenous equivalents?

The subject’s consent should also be understood in social and economic terms. Confidence in the doctor sometimes outweighs a rational analysis of the drawbacks or advantages of participation in the experiment. In some cultures, individual informed consent of the subject is not enough, as an entire network of social relations may be involved: the spouse, the patriarch or...
the tribal chieftain may be called upon for their opinion and consent. Some researchers argue that the consent of a tribal chieftain is sufficient to use an entire community in an experiment. Others are categorically opposed to this easy way out which, for the sake of research, disregards the individual's freedom and rights.

Ethical codes, conceived in and for the West, insist that the consent of the individual be obtained in writing. This method is impractical, given the chronic illiteracy of so much of the Third World. As a solution, researchers have proposed that information be given orally in front of a witness and that the consent be recorded on paper by fingerprints. Despite the good intentions behind this proposal, there is still the risk that the oral agreement will not coincide with the written document.

Furthermore, the subjects of experiments are somewhat reluctant to sign papers. It is easy to understand that many do not want their names on file, especially in totalitarian countries. Too often, experiments have been carried out disproportionately on groups hostile to the political power of the day.

CULTURE

Western researchers involved in Third World research face a host of problems for which they are ill-prepared. Dr David Roy of the Bioethics Centre (Montreal, Canada) believes that ethics should be based on living people, not universal principles. "Medicine is not a neutral science, free of values and restricted to the physiological plane of human existence. Health, well-being, disease, illness and deformities result from the importance and priority that society places on them. Human values, individual as well as social, are an integral part of medicine."

When a study is conducted jointly by Third World and Western researchers, the latter tend to defer to their Third World counterparts in ethical matters, overlooking the fact that most Third World researchers were trained in Western countries, where they often adopted the codes and principles of a foreign culture. As a result, Third World researchers are not always the first to defend the traditional moral principles prevalent among the people to which they themselves belong.

Nonetheless, much research conducted in the Third World under the auspices or with the technical and financial aid of Western institutions continues to be based on traditional codes of ethics. Yet researchers should not feel stymied when confronted with the complex problems of ethics in Third World research. Scientists interested in ethical issues agree that it is not enough to translate the information necessary to consent into another language; much more is in fact required. The quest for informed consent is a long and difficult undertaking, fraught with cultural, hence systemic, misunderstanding.

A number of specialists, including S. Oloso-Annah, an African researcher, recommend that Third World countries set up national research councils to evaluate research projects conceived abroad. At the moment, the practice is far from common, although the United Nations Conference on Science and Technology held in Vienna in 1979 recommended such councils and the World Health Organization has proposed that national medical research councils be established. These bodies would constitute national ethics committees responsible for ensuring that research is carried out in a manner respectful of the individuals concerned.

Arthur Kleinman, author of several works on ethics, proposes that rather than concentrating on supposedly universal moral codes, clinical researchers should work with anthropologists studying the same societies. In this view, practical cooperation between these two disciplines is more likely to resolve ethical problems than are philosophical debates on moral and legal codes for universal application. He maintains that international organizations financing research should encourage the preparation of ethical and practical guides to various traditional societies to aid researchers. He also maintains that negotiations with representatives of native groups should be included, to ensure that problems are detected and resolved quickly.

Where appropriate, public debate with researchers present may be a means of obtaining the consent of a community coming to grips with the cultural barriers of native peoples. The media (radio, press, television) may be of help in reaching this objective.

Mistakes due to differences in value systems illustrate the importance of ethical precautions. Researchers must not only find out about the traditions of the people who are the subject of their clinical experiments, they must also be aware of conflicts of interest. Scientists must become attuned to the economic and political context in which their research takes place. Family planning research programs are often poorly understood in developing countries, even by the governments supporting them. Punitive legislation and coercive and oppressive ways of applying family planning policies in developing countries no doubt stem from good motives, but they are difficult to defend from a purely ethical standpoint.

In addition, scientists know full well that the opposition of local leaders can stall research, and those who know the Third World know where to turn to ensure the survival of their programs. But are they aware of the consequences of their wheeling and dealing? Multinational pharmaceutical and medical equipment companies may be tempted to carry out research in the Third World that would not be tolerated in the West because of stricter laws.

Ethical questions are also raised by marketing practices. Medication that is prohibited in the West is sold freely in developing countries, where pharmaceutical companies can find populous markets for their products. Furthermore, they do not hesitate to change the explanatory folders.

"Human values, individual as well as social, are an integral part of medicine."