



The Public Eye Swiss Award 2010 for irresponsible corporate behavior goes to:

ROCHE

Speech by Patrick Durisch, Health Program Coordinator, Déclaration de Berne

Ladies and gentlemen

The Swiss pharmaceutical giant Roche conducts clinical studies in China of its immunosuppressive drug CellCept without being able to state the origin of donated organs. This is despite the fact that even Chinese authorities have admitted that more than 90 percent of transplanted organs come from prisoners sentenced to death. Since Roche cannot rule out that some organs come from prisoners, the pharma company violates the ethical principles of the world's most prominent health organizations. For this reason, both the Public Eye Swiss Award as well as the People's Award (chosen by the public via Internet voting) this year go to Roche. On this occasion we also call on Roche to put an immediate end to these studies.

With this nomination, the Berne Declaration wishes to remind multinational pharma companies that they must accept socially-responsible practices, even in developing and emerging countries where guidelines and ethical principles – provided they exist at all – are easier to get around.

The trade in organs from prisoners in China is nothing new; it has already been the topic of several parliamentary motions and political statements in Switzerland. A news segment from Britain's BBC News, filmed with a hidden camera in a leading hospital for organ transplants in northern China, illustrates this organ trading very clearly.

Video: *Organ sales "thriving" in China* (www.youtube.com/watch?v=0wtSV_BEf14)

This report was filmed in late 2006, but the problem still exists today. Since the report was filmed, the Chinese government has passed laws that partially curb transplant tourism. It has also more clearly defined the regulations for hospitals that perform transplants, including regulations for organ donation and selection of a recipient. However organ removal from prisoners is still officially allowed and practiced.

Furthermore, an independent investigation and several U.N. reports have confirmed statements that some organs have even been removed from living prisoners of conscience.

The most pessimistic projections of the number of executed prisoners – which remains a state secret in China – do not by themselves explain the rise in organ transplants. According to official figures, during the past 10 years an average of more than 10,000 transplants were performed each year, whereby the waiting times for the recipients often turned out to be conspicuously short. At the same time, voluntary organ donors are still a rarity in China, due both to cultural beliefs as well as to the non-recognition of the concept of brain death in the Chinese legal system.

It is therefore irresponsible to carry out clinical studies with a drug like CellCept, which inhibits the rejection of transplanted organs, without looking into the question of where the trans-

planted organs came from. The Basel-based company has nonetheless been carrying out two studies across multiple clinics on roughly 300 patients that have received a transplanted liver or kidney. In 2006 alone, Roche conducted a clinical study in three Chinese clinics on approximately 36 heart transplant patients to test the effectiveness of CellCept. Other multinational pharma firms have conducted similar studies of immunosuppressive drugs in the past, but to our knowledge Roche is the only one that is still doing so today.

In response to its nomination for the Public Eye Swiss Award, Roche stressed that not only is it not responsible for the origin of the organs, but also that it does not have the right to such information. The corporation also claims to do all that is necessary to respect the applicable Chinese legal regulations as well as the ethical principles of international reference institutions such as the Transplantation Society and the World Health Organization (WHO). However the Transplantation Society is against organ removal from prisoners, since a prison is not an environment where a truly free choice about organ donation can be made. Therefore the Transplantation Society does not recognize research results from medical studies in China conducted on transplant patients where the donated organs came from prisoners. For its part, the WHO's guidelines for organ transplants call for a transparent organization of organ donations and traceability of the origin of transplanted organs. It also calls for this traceability to be guaranteed beyond the operation, which according to the WHO is compatible with the protection of anonymity and the privacy of organ donor and recipient. Roche can therefore not use the safeguarding of confidentiality as an excuse to avoid examining its own procedures and the origin of transplanted organs. This is particularly the case for clinical studies where it has even more direct responsibility. In our opinion, it's not only about moral obligations and due diligence. More importantly, the pharma company carries the burden of proof that the acquisition of new organs for study participants complies with ethical principles.

We also question the significance of the two clinical studies from a medical perspective. CellCept is already known to be effective and safe; it has been officially approved for some time now, not only by the governments of Europe and the U.S. but also in China. Roche claims that the two current Phase IV studies (or post-marketing studies) are necessary to adjust the dosage of the drug for the specific characteristics of the Chinese people. But CellCept is administered in identical dosages to the participants of both studies. It is therefore suspected that these studies serve primarily to better market the drug to Chinese transplant specialists, since it is already being produced in China and its sale in China and other countries could help make up for the expiration of patent protection in the U.S.

Since it cannot prove that the transplanted organs of the 300 study participants – with whose help it has tested its drug since 2008 – do not originate from prisoners, Roche must refrain from such studies in the future and immediately halt the studies now in progress. Furthermore, it is now time for international transplant medicine organizations to seize this opportunity: They must expand their guidelines to prevent pharma companies from profiting from practices that violate medical ethics principles. For the Berne Declaration, the disregard for human rights in favor of commercial interests is simply unacceptable.