Adjournment Debate

being manufactured in the United States because of danger to the employees and the community.

Earlier, during Question Period at that time, the Minister of National Defence had admitted that one ingredient used in the manufacturing of the drug is bis-chloromethyl ether, which is a known carcinogen, that is, it has cancer-causing properties.

The minister for health, in his reply, indicated that tests done in other jurisdictions showed the drug is safe. If one did not specifically test for cancer-causing properties of the drug and one did not have so-called purity data, that is the extent of chemical reactions during manufacturing, one takes the risk the carcinogenic ingredient could transmit its danger.

In fact, allowing such a practice would set a bad precedent for testing of new drugs for cancer in animals before trials in humans. To say that HI-6 could possibly cause cancer without animal data is meaningless and unethical.

On November 8, one of the subjects for the clinical trials was quoted in the press as having agreed to participate mainly because he was "broke" and he stayed in the study because he needed the money.

I therefore asked the minister whether enticing Canadians who are poor with extra dollars to serve as subjects is ethical. Examination of the consent form reveals some inconsistencies with respect to this matter. Page 3 of the form states: "Discontinuation from the study will involve no penalty", yet, page 4 states: "the subject will only receive percentage of the full fee—" unless the subject completes, "all aspects of the study."

Page 2 of the consent form alluded to one clinical study in Yugoslavia to sustain the claim that there were no untoward effects to date yet page 3 of the form alluded to "previous clinical studies", thereby suggesting more than one. My question is, why the discrepancy in numbers?

The form also indicates that the drug "may damage sperm cells which could result in birth defects." While advice was given to subjects "to practice contraception

during the study and for 90 days following the study," no clear information was available as to possible damage that may occur as a consequence of cumulative doses as this particular study would allow.

I further challenged the minister why the clinical testing on humans should proceed before testing for cancer is done on animals. Indeed, Mr. Speaker, I thought the government had the sequence backwards.

The issue before us is indeed most important. I would like to conclude by reading into the record of this debate a brief letter to the editor of *The Globe and Mail*, the issue of last November 11, from Dr. David Roy, Director of the Centre for Bioethics and Clinical Research at the Institute of Montreal. He writes:

Respect for human beings and the protection of their health and lives, dignity and rights have formed the core of the many codes and guidelines governing the ethics of research with human subjects since the Second World War. The Nuremberg code marks a turning point. It crystallized the essential characteristics of consent required to protect the autonomy of human beings in biomedical research.

Consent is not voluntary if people are seduced by money to submit themselves to potentially dangerous tests of new drugs. Consent to such tests is not adequately informed if those seduced to participate are not told about the effects previous tests of a new drug have had on animal and human bodies. Consent cannot be adequately informed if previous testing was insufficient to deliver reliable information about possible toxicity. Consent cannot be comprehending if warnings are couched in terms so vague they blind participants to the possible dangers of testing.

He continued:

It makes no difference whether the sponsor of drug testing is the medical establishment, a drug company, or the military—the ethics of research with human beings remains the same.

He concluded his letter:

We must not now, or ever, abandon the ethical progress we have made with and since Nuremberg.

I submit, Mr. Speaker, the HI-6 drug testing in question has failed to fully comply with the established ethical guidelines that now govern the conduct of biomedical research in human volunteers. Therefore, this particular study must be halted until the required animal studies for the concerns that I have raised have been done.

I trust and hope that this government will respond accordingly.