



Dr. Henry

Silverman, a professor of Medicine at the University of Maryland. (Photo by Mahmoud Kheir, The Daily Star)

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## Bioethics conference: Drug trial guidelines needed

By Hannah Ellis-Petersen

BEIRUT: The second annual bioethics conference met Friday to discuss the pressing need for clearer and more assertive ethical guidelines for drug trials, which are on the rise in the region.

With countries in the Middle East working under considerably less strict and regulated ethical guidelines than their European and North American counterparts, drug companies are increasingly moving trials on new and untested drugs to Arab countries.

Between 2006 and 2010, there was a 4 percent rise in the global number of drug trials conducted in the Middle East, the largest increase out of any region in the world. Conversely, the number of drug trials in North America dropped by 11 percent in the same period.

Dr. Henry Silverman, a professor of Medicine at the University of Maryland, spoke at length about the problem of “ethics being left behind as drug trials soar in developing countries.”

“The lack of regulation and easy access to willing participants who are often not aware of the side effects gives drug companies a large incentive to carry out their trials in areas such as the Eastern Mediterranean region,” he told the conference.

“Recent data shows that only 53 percent of the subjects of clinical trials in the Eastern Mediterranean region were made known of the risks.”

In the United States, in order to gain FDA approval for a new medication, a researcher or a pharmaceutical company must first prove that its product is safe and effective. This involves a lengthy and expensive process of highly regulated drug trials; red tape that can be avoided by relocating the trial to the less restrictive grounds of the Middle East and India.

While there is a Lebanese Code of Medical Ethics, it does not directly address the complex issues of bioethics and was deemed as far from fully comprehensive by many at the conference.

“We need to fill the gap of bioethics and catch up with the rest of the world,” said Fadwa Attiga, a scientific officer at the King Hussein Cancer Center.

“We have to move away from just talking about issues in a clinical setting and properly address the need for laws of bioethics.”

Silverman spoke about the need to ensure “informed consent” to prevent drug companies from taking advantage of subjects from poorer or even illiterate backgrounds who do not have the complex medical forms explained to them before signing. With local ethical committee boards lacking authority, Silverman urged the need for “stronger national regulation across the Arab world to ensure the application of ethical practice across the board.”

“The prospect of free access to new and expensive drugs is an incentive for many in the poorer countries to take part in such drug trials, without being fully informed of the risks,” he said. “They do not have the same luxury of choice as those in Europe or North America. The biggest issue with clinical trials in the international community is the issue of justice.

Ghaiath Hussein, of King Fahd University in Saudi Arabia, was similarly critical of ethical accountability across the Middle East.

“Global research is not a threat, unless you don’t have the system in place to regulate it,” he said. “We just do not have enough policies and guidelines to monitor all the ethical issues.”

The lack of post-trial care and accountability for the patients in poorer regions, should the drug

trial have a negative effect, was raised as an additional ethical issue of the outsourcing the clinical to the poorer Arab regions.

Unlike medical trials enacted in Europe and America, many of the subjects in the Middle East lack access to free and available health care once the trial is completed.

Taner Hifnawy, an associate professor at the Beni Suef University in Egypt, who has also acted as a consultant for Egypt's Health Ministry on ethics and ethical codes, took a similar stance.

"We are in need of capacity building in clinical research, especially in human trials" he told The Daily Star.

"We are here to help unify the code of ethics and create a network of bioethicists across the Arab world so we can build on it collectively, and tackle the ethical issues of clinical trials and research.