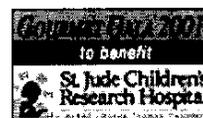


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HHS Office to Monitor Overseas Research Rep. Brown Calls For Hill Hearings

By Deborah Nelson and Mary Pat Flaherty
Washington Post Staff Writers
Wednesday, January 24, 2001; Page A08

A new office in the Department of Health and Human Services will oversee U.S.-funded medical research on foreign patients and address the ethical problems caused by experimenting on Third World populations, a top official said.

E. Greg Koski, director of the Office for Human Research Protections at HHS, said the international program will educate and assist U.S. scientists working offshore, particularly in developing nations, and monitor the effects of research on local populations.

"We want to make sure it is not exploitive, and we want to make sure it benefits them in an appropriate way -- that it leaves something of value behind," he said.

The new Office of International Activities will tackle issues raised in December in The Washington Post's series, "The Body Hunters," Koski said. It documented risky and exploitative medical research that U.S. companies and institutions carried out in poor countries that had scant hope of benefiting from new drugs or medical breakthroughs. Although Koski has no authority over company-sponsored research, he enforces human subject protections in experiments funded with U.S. tax dollars.

The Post series described federally funded experiments on HIV-positive pregnant women in Thailand that withheld known to stop transmission of the disease to the fetus. Fifty-nine babies were born HIV-positive. The series also reported on genetic research in a remote, impoverished region of China, carried out by Harvard University with millions of dollars of private and U.S. tax dollars.

Although Harvard officials say the China experiment was carried out responsibly, participants said government officials used "thought work" to pressure them into participating and promised medical care that never materialized.

Revelations about foreign medical experiments also have sparked concern on

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Capitol Hill.

Rep. Sherrod Brown (Ohio), the senior Democrat on the House health subcommittee, yesterday called for hearings into how to protect foreign test subjects and ensure that questionable results obtained overseas do not allow dangerous drugs to reach American medicine cabinets.

"It sort of shows how the drug companies disregard the ethics of what they do," Brown said of The Post series. "The [Food and Drug Administration] probably needs more authority [to police foreign experiments] and probably needs more money to do this."

At HHS, Koski also has suggested creation of specialized ethics panels to review research proposals for work in developing countries. The panels might include representatives of the international research community and host country, he said.

Under current rules, an institution must conduct its own ethics review before beginning any tax-supported human experiment here or abroad. Koski's proposal would establish an independent body to provide additional review and input, when the research involves vulnerable foreign populations.

For months, the National Bioethics Advisory Commission has been drafting ethical guidelines about appropriate research methods, patient protections and the obligations owed to countries that host clinical research. Last week at a meeting in Tysons Corner, the commission continued to struggle with how best to enhance oversight of foreign test sites.

The commission discussed whether test subjects recruited in developing nations amounted to vulnerable populations that needed special, added protections such as those afforded children or mentally disabled patients.

The panel's recommendations would have no binding effect without further legal or regulatory action.

Sen. Edward M. Kennedy (Mass.), ranking Democrat on the Senate health committee, said yesterday that "new legislation is clearly needed to deal with these problems."

"Rapid growth in the number and complexity of clinical trials in recent years has often strained current procedures for protecting research subjects," Kennedy said. "Clinical trials overseas raise even more serious concerns."

Staff writer Joe Stephens contributed to this report.

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