Ethics of private panels comes under scrutiny

[WASHINGTON] Private ethics boards set up to review experiments carried out mainly by pharmaceutical companies and medical products manufacturers came under vigorous attack at a congressional hearing early this month for allegedly corrupting the US system of human subjects protection. But they are being equally vigorously defended.

A hearing of the House of Representatives Government Reform Committee's human resources subcommittee was told by some witnesses that private Institutional Review Boards (IRBs) were commercially motivated, and therefore unduly likely to approve undeserving experimental protocols.

They were also charged with opening the door to 'IRB shopping', when a researcher turned down by one IRB will take it to another prepared to approve it. (Academically affiliated researchers cannot engage in such 'shopping', as they are required to use their own institution's IRB.)

But others, including an official from the Food and Drug Administration (FDA), which is responsible for monitoring the activities of most private IRBs, challenge these claims. They say that in practice private IRBs differ little from the local, not-for-profit IRBs set up by research hospitals and universities to ensure that research is ethical and protects human subjects.

The private IRBs are not attached to any particular institution. They are used most frequently in late-stage clinical trials by the producers of drugs and medical devices, and the private physicians they employ.

Some of these boards also monitor other research, ranging from the development of *in utero* genetic tests to studies of dose size for drugs at earlier stages of development.

There are fewer than half a dozen studies funded by the National Institutes of Health which employ a private IRB. One of these is developing diagnostic and treatment-monitoring software for psychiatry.

There are thought to be up to 12 large private IRBs operating in the United States, with an unknown number of smaller ones. Their founders range from retired physicians to researchers originally from academic institutions or industry. Their members include nurses, clergy, scientists and doctors.

Critics at the hearing included Benjamin Wilfond, a paediatrician at the University of Arizona. He argues that "in the commercial sector, there is at least a greater potential and incentive for approving protocols that may be questionable, that may have a concern about the risks". Approvals from private IRBs, he says, keep customers satisfied and coming back.

Wilfond said he recently discovered a private doctor in Tucson carrying out a trial financed by a drug company of a new asthma drug in children, with approval from a private, out-of-state IRB. The University of Arizona's IRB had found the trial unethical, because it required stopping children taking effective drugs.

Wilfond believes that "there needs to be more universal regulation of research so that consistent standards apply to both private sector and academic sector". Christopher Shays (Republican, Connecticut), the subcommittee chairman, said he found it "amazing" that private IRBs were not subject to certification. But some argue that such charges are alarmist. Robert J. Levine, for example, a professor at the Yale University School of Medicine who chairs Yale's IRB, called it

"ridiculous" to present IRB shopping as more than an occasional, if unfortunate, event in a system that worked well overall.

Levine said that researchers heard about IRB shopping "about as often as we hear about the birth of Siamese twins". Others argued that private IRBs are no more vulnerable to financial incentives for approving experiments than those at universities, which depend heavily on grants brought in by government-funded researchers.

The FDA — which audits both types of IRBs — says that it also lacks proof of major problems with private IRBs. Paul Goebel, associate director for human subject protection in FDA's Office of Health Affairs, says he is not convinced that private IRBs "as a category" do a worse job than the academic IRBs, with a wide variation in the competence with which each carried out their tasks.

Whatever their quality, the purview of private IRBs is likely to grow with the increasing privatization of research support. "There's a brave new world looming and I'm not sure the regulatory system was constructed with that world in mind," said Arthur Caplan, director of the University of Pennsylvania's Center for Bioethics.

The only private research at present required by law to receive IRB approval is that done by makers of drugs, medical devices and other FDA-regulated products. These companies often employ private physicians to carry out late-stage trials. Those without institutional affiliations therefore have to find private IRBs. By contrast, privately funded researchers at universities are generally required to submit their proposals to their institution's IRBs.

Under a bill introduced by Senator John Glenn (Democrat, Ohio), approval by an IRB would become mandatory for private-sector researchers.

The Human Research Subject Protections Act of 1997 was introduced in the Senate in January, but has just three co-sponsors. The act is opposed by the drug industry, partly because it would impose criminal penalties on violators.

Meredith Wadman

Indifferent performance on privacy protection

[WASHINGTON] Institutional Review Boards (IRBs) vary in willingness and ability to protect the privacy of human subjects in medical research, according to a report commissioned by Donna Shalala, the US Health and Human Services Secretary, which was released last week.

The report, *Privacy and Health Research*, by William Lowrance, a health policy consultant, says there is "no doubt" that IRBs enhance the protection of research

subjects. "But it is less clear that IRBs have been attending as vigorously to privacy risks as they have to physical and emotional risks," it says, suggesting that "whether they are able and willing to do so should be assessed".

The focus of the report is on balancing individual privacy protection with medical research. It concludes that, for much research outside formal clinical trials — such as epidemiological reviews and secondary studies in

databases — "notice is not routinely given nor explicit [informed] consent sought".

Lawrence Gostin, a professor of law and public health at Georgetown University Law Center in Washington DC, and an expert on medical privacy issues, says the rules governing IRBs are vague on "It's commonly thought that government research regulations have a vigorous privacy protection that the IRB has to follow," he says. "They don't."

M.W.