Japan faces aging population, continued scandals

New concerns about Japan's ability to protect the health care interests of the aged — a rapidly growing segment of its population — are further undermining public confidence in its already beleaguered health care system. During the last three months Japan has been rocked by a seemingly endless series of health-care controversies, including the testing of a new Alzheimer drug on residents at an old age home without proper consent, euthanasia being conducted on elderly patients without clear prior permission or discussion with relatives, and the alleged bribery of senior Ministry of Health officials in exchange for ministry subsidies for the construction of nursing homes of the elderly.

A physician at Nara Medical University in western Japan participating in a clinical trial of a potential new drug for Alzheimer's disease is alleged to have conducted tests on four residents at a nursing home run by his relatives without receiving consent from either

the residents or their families. Under Japan's Good Clinical Practice guidelines (GCP) clinical trials have to be conducted at medical centers with the consent of those participating or their relatives.

Although the GCP guidelines take the form of official administrative guidance and are not legally binding, data based on clinical trials that do not comply with the guidelines will not be accepted by the Ministry of Health and Welfare during new drug approval applications. There are, however, no penalties prescribed for physicians who break the guidelines in clinical trials.

In another incident, doctors at a local hospital in Kochi allegedly allowed as many as twenty elderly patients to die by "passive" euthanasia without informing relatives of potential life-prolonging treatments or receiving clear prior permission. The patients, ranging in age from 74 to 93, died between November, 1995, and December, 1996. Guidelines

for passive euthanasia (that is, removing life-prolonging treatment to allow a patient to die "naturally"), were issued at a landmark 'active' euthanasia court ruling in 1995 (*Nature Medicine* 1, 393), in which a doctor was found guilty of unlawfully killing a 58-year-old man with multiple myeloma. At the trial, the judge issued a list of criteria for legal use of both active and passive euthanasia. Under these criteria, relatives may give permission for treatment to be withheld if it is presumed that it is also the patients wish.

Both the euthanasia and the clinical trial incidents demonstrate a lack of informed consent and, despite the GCP guidelines, there is still little understanding in Japan of patients' rights, according to Masanori Fukushima, a long term advocate for reform of the current clinical trials system.

An estimated 100,000 individuals, the majority of them elderly, who need care but not medical treatment currently stay in the hospital because of the low cost compared to nursing homes. One of the ways the government is trying to cut costs and promote and improve health and welfare for the elderly is by offering large subsidies to private companies to construct new nursing homes. Currently, the average length of stay in hospitals in Japan for an elderly person is 46.4 days the longest in the world. Japan has 50 per cent more hospital beds per capita than France and Germany and nearly four times the number in the United States. Government efforts to reduce these numbers have turned the construction of new care facilities for the aged into big business. The generous government subsidies available have also caused a corruption scandal involving alleged bribery of senior ministry of health and welfare officials in exchange for subsidies (*Nature Medicine* 3, 12).

These incidents highlight the need for reform of Japan's health-care system. The GCP guidelines are under review, but penalties for physicians are not expected to be included in the revision. Advocates for reform argue that guidelines need to be legally binding, and should include penalties for physicians who break them. However, reformers admit that, in itself, this will not be sufficient to improve the situation, as physicians need to be educated about the practical terms of informed consent. They also say that a thorough independent review of the ministry's policy making and practice is long over due.

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Japanese pharmaceutical giant shares the wealth

In an effort to stimulate new drug development, Takeda Chemical Industries Limited, Japan's largest pharmaceutical company, will start paying its researchers results-based bonuses worth up to an estimated 50 million yen (US\$410,000), starting this April. Although similar schemes are quite common amongst Japan's internationally competitive electronics and game software manufacturing companies, they are unheard-of in its pharmaceutical industry; Takeda is the first major Japanese pharmaceutical company to introduce performance-related bonuses for researchers.

Under the proposed scheme, researchers who develop profitable new drugs will receive annual bonuses three years after the launch of a new product. A researcher who develops a drug with annual sales of 10 to 15 billion yen (US \$83 to 125 million) will be entitled to a bonus of 1.5 million yen per year for a five year period, if sales are sustained at this level. If turnover reaches 80 billion yen a year, the researcher could receive a bonus worth 10 million yen per year for five years. Up to four researchers will be entitled to receive bonuses per each drug, to be divided among them based on how much they contributed to the research effort.

The new program comes partly in response to new government cost-cutting initiatives. More than a quarter of Japan's public medical insurers expenditure is spent on drugs and injections, higher than any other major industrial nation. As a result, Japan's escalating medical costs have led to mandatory government price cuts for drugs purchased through the public insurance system. In 1996, the government aimed to reduce the average price it paid for drugs purchased through the public insurance system by 2.6 percent, reducing the proportion of total medical expenditure by 6.8 percent, according to ministry of health officials. It plans to reduce this by a further 1.32 percent and 4.4 percent respectively this year. The government will, however, pay premiums for innovative drugs purchased through its public health insurance system. This is increasing the pressure on domestic companies to become more creative and come up with novel products.

Takeda hopes its new scheme will add vigor to its drug development efforts. "The future development of the company in the twenty-first century depends on developing new drugs that can compete on an international level," a company spokesman says. A promising new anti-high blood pressure drug that Takeda plans to launch next year, known now only as TCV-116, could become the first drug to enrich its researchers under the new corporate plan.

-R.N.