

## AMA calls on doctors to put patients' well-being before profit

The patenting of medical procedures "poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis," so says the American Medical Association's (AMA's) Council on Ethical and Judicial Affairs. Accordingly, the Council, AMA's



US Representatives Greg Ganske (top) and Ron Wyden, cosponsors of a bill to ban patents on medical procedures.

equivalent of the 'US Supreme Court', believes that it is "unethical to seek, secure or enforce patents on medical procedures," as it conflicts with the Hippocratic Oath taken by doctors, whereby they are obligated to teach and share medical information.

Although possible since the early 1950s, medical procedure patents were rarely issued until recently. More than 80 countries are said to ban the practice. The United States could, however, follow suit if a bipartisan bill now wending its way through Congress, which would prohibit the US Patent and Trademark Office from issuing such patents, becomes law.

The Council argues that it is patients who would lose out if the practice were to become widespread. Knowledge that a procedure is patented, it argues, could influence a doctor's medical judgement on whether to use the procedure. Moreover, the Council warns that any associated costs resulting from licensing fees or infringement litigation would likely drive up health-care costs and would ultimately be passed along to the consumer.

The Council rejects the notion that patenting medical procedures is necessary to stimulate innovation and to attract private investment in this area. "We don't find any evidence — written or empirical — to support this," says M. Roy Schwarz of the AMA. In this regard,

the Council draws a clear distinction between the patenting of drugs and medical devices, on the one hand, (which is generally accepted), and on the patenting of medical procedures, on the other. The latter, "usually relies on intellectual curiosity and creativity rather than the availability of capital for research and development," the Council states in its report.

Although the Council claims that US patent law in this area is open to some interpretation, patents are being applied for and issued by the patent office, and reportedly in increasing numbers. One celebrated case, often cited by the Council as an example of what can happen, is that of Arizona-based ophthalmologist who was granted a patent on a sutureless incision of the eye used in cataract surgery. The patent holder in this case has since sought to enforce his patent by filing an infringement action in the courts.

Patents have also been applied for, or granted, for everything from a method for reconstructing the breast after mastectomy to a way of determining the sex of a fetus by using ultrasound.

AMA is one of 12 professional organizations supporting the bipartisan effort to bar the patent office from issuing patents on surgical procedures and other medical techniques. Entitled the Medical Procedures Innovation and Affordability Act, the bill was introduced in March by US Representatives Ron Wyden (Democrat, Oregon) and Greg Ganske (Republican, Iowa), himself a plastic surgeon before he was elected to Congress last November. The bill currently has 47 cosponsors, including (perhaps most notably) US Representative Henry Hyde (Republican, Illinois), the influential chairman of the House Committee on the Judiciary (the committee that will vote on the bill).

The legislation is drafted narrowly. It would not, for example, affect the issuance or validity of process patents in fields other than medicine, or the patenting of medical procedures if they are applied for in conjunction with a medical device. Nor would the legislation be applied retroactively. Hearings are set for October.

DIANE GERSON

## TB test readies for market in India

A fast and cheap test based on the polymerase chain reaction (PCR) and designed to detect pulmonary and extrapulmonary tuberculosis (TB) at early stages of infection has been developed at the National Institute of Immunology in New Delhi. The test is expected to be a valuable tool in India's TB armamentarium, especially in preventing deaths among children. It is estimated that 500,000 people die annually of TB in India because of delayed diagnosis.

Although drugs to treat TB are available in India, a positive diagnosis can take weeks. The culture tests now in use can take between six and eight weeks, and, in any case, are not suitable for detecting TB in one-third of the cases where organs other than the lungs are involved. The bacillary load in these organs is usually too small to be detected by culturing.

This is where the new test could make a difference, says Pramod Khandekar, head of the team that developed the test. Khandekar says the new PCR-based test requires as few as ten bacteria for a positive result and produces results in 24 hours. For the first time, he says, doctors will have a tool for the early diagnosis of extrapulmonary infections such as tuberculosis meningitis (TBM), the leading cause of death in children in India infected with *Mycobacterium tuberculosis*. Confirmatory tests for TBM are not routinely available in Indian hospitals, and a brain scan, even if the patient could afford it, does not distinguish between TBM and tuberculoma.

Although PCR-based tests for TB are available abroad, Khandekar says their cost is prohibitive. Aside from being developed by Indian researchers, he adds that the new test has been evaluated on a variety of clinical specimens taken from patients with both pulmonary and extrapulmonary TB.

Khandekar now has to convince the health authorities to put the test to good use as part of its national TB control programme. "Using this test, we confirmed 39 cases of TBM and 52 cases of tuberculosis of the pleura," says A.K. Grover of the University College of Medical Sciences, New Delhi. Grover, who collaborates with Khandekar on this government-funded project, says that with current methods he was able to detect only two cases of TBM and five cases of pleural tuberculosis.

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