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HHS Committee Opens Public Comment on Gene Patents

GenomeWeb Daily News
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NEW YORK — A National Institutes of Health task force has released a draft report on its findings about the effects of gene patenting on medicine, research, and business, and has issued a set of potential policy options for public consideration as part of the report.

The Secretary's Advisory Committee on Genetics, Health, and Society, which meets this week to discuss a number of other genomics-related issues, will seek public comments until May 15, 2009, on the findings and policy options drafted by its task force.

The SACGHS task force worked with Duke University's Center for Genome Ethics to draft policy options based on a variety of findings from case studies of certain tests, companies, illnesses, and research areas.

The group reviewed a number of these case studies to draw conclusions about how gene patents affect pricing, access to and availability of genetic tests, new innovations and research related to genes, and other areas.

The case studies did not show "widespread overpricing" of genetic diagnostic tests that were patented and exclusively licensed relative to those that are unpatented or non-exclusively licensed.

So far, the panel found, patents covering genetic tests and related licensing practices do not appear to be impeding patient or clinical access to the tests. Although several cases were found in which patient access to genetic tests may have been impeded, these cases were mostly resolved and access to the tests is not an issue now.

The committee also found that patents may not serve as powerful incentives, but rather a minor stimulus, for either genetics research in the diagnostic arena or development of genetic tests. Most academic scientists are driven to conduct research "by a mix of motives," the committee suggested, including advancing their careers, adding to knowledge, and developing treatments.

While the case studies showed patented discoveries that were developed into tests, unpatented genetic discoveries also were "routinely developed into clinical genetic tests," suggesting that "patents are not needed for development of these tests."

If regulatory oversight of genetic testing evolves to require "some type of costly independent review before marketing, patent protection may be needed for companies" to feel the risk and expense is worthwhile, according to the committee. In addition, "Concerns about the quality and validity of genetic tests may be best addressed by enhancing the oversight system for laboratory developed tests," the group proposed.

These and other findings outlined in the draft report led the committee to propose a number of potential options. But it has not developed these into final conclusions and will await completion of the public comment phase before it makes recommendations to the Secretary of Health, which it expects to do in October.

SACGHS said that a set of principles and guidance documents should be developed that engage stakeholders over issues regarding patenting and licensing strategies for genetic diagnostic tests.

In order to optimize patient access for genetic tests, "stakeholders should work together to develop a code of conduct to encourage broad access to such technologies," the group found.

In cases where multiple stakeholders have collaborated to identify genetic mutations and to develop a diagnostic test, they should determine whether to seek patent protection and how to disseminate, utilize, and license such technology in a manner that balances their proportional contributions.

A forum could be used to discuss technology development strategies among research collaborators, the committee suggested. In addition, they said strategies should be pursued that balance protecting IP rights associated with discoveries such as diagnostic tests with appropriate patient and physician access.

Transparency in patents and licensing could be enhanced, and federal agencies should adopt policies to increase that transparency by encouraging patent holders to make license information available, it said. The National Institutes of Health also should change its best practices for genomic licensing to encourage licensors and licensees to include in their contracts a provision allowing each party to disclose some information about the license.

The Food and Drug Administration and the Centers for Medicare and Medicaid Services could require DNA-based tests to display on its packaging or on websites any issued patent and published numbers that the company believes covers their patents.

More information is needed about the gene patenting and licensing arrangements that are used to commercialize genetic tests, according to SACGHS. To remedy that, the Secretary of HHS should establish an advisory board that provides ongoing advice about the public health impact of gene patenting and licensing practices. To assess whether gene patents or licensing arrangements may be

negatively affecting patient access to genetic tests, HHS and other agencies should develop a reporting system to encourage researchers and medical practitioners who order, use, or perform genetic tests to report those effects, the committee recommended.

The data that the committee believes might be most useful include whether or not the licensor of the invention granted the licensee the rights to make and sell a test or to provide a service, the nature of that agreement, the patent number and licensing timelines, date of the first sale of a genetic test on the market, and some measure of the volume of sales.

SACGHS also is considering if there should be federal efforts to promote broad licensing and patient access, and proposes that licensing policies governing federally funded research facilitate access to gene tests.

It also said that there should be studies of the federal implementation of intellectual property laws, and that the US Patent and Trademark Office's policies covering genetic tests should be clarified and improved.

When It Isn't Really Senility

By Robin Marantz Henig
The New York Times
March 11, 2009

When Jane Simpson's mother, then 91, started showing signs of memory loss in December 2007, Ms. Simpson thought age had finally caught up with her. "As this had been a gradual process, and considering her age, we were not unduly alarmed — just saddened that it seemed we were losing my mother mentally," she wrote in an e-mail to this blog.

But on a visit six months later, Ms. Simpson, a 61-year-old advertising copywriter in North Carolina, was struck by how much worse her mother's memory loss had become and by her confusion about everything happening around her.

Just typical 91-year-old behavior? Just the first signs of the inevitable slide toward dementia we all may face if we live long enough? Not at all.

Since the '70s, geriatric specialists have been aware of many unusual causes of memory loss, confusion and disorientation in older people. These include not just medical conditions ranging from urinary tract infection to hydrocephalus to the flu, but also side effects from many commonly used medications.

Often, doctors and family members disregard these symptoms, thinking that they are just signs of an inevitable age-related decline. But many cases of pseudo-senility, as it's called, are reversible — if they are caught early enough.

By coincidence, Ms. Simpson had recently read a short article in her local newspaper about the side effects in the elderly of a bladder control drug called Ditropan, which include severe memory loss. Her mother was taking Ditropan.

Ms. Simpson and her sister got their mother switched to an alternative bladder control drug, Enablex. Sure enough, her mental symptoms eased. "Within three months," Ms. Simpson recalled in her e-mail, "we felt that we had our mother back."

You'd think that with the constant attention being paid to Alzheimer's disease and other causes of memory loss in aging, doctors would have learned by now that severe memory loss in healthy aging is a problem to be diagnosed, not an inevitability to be lived with and accepted.

But according to the National Institute on Aging, missed diagnoses of reversible dementia still occur too often. "Some physical and mental changes occur with age in healthy people," the agency writes in a publication called "Forgetfulness." "However, much pain and suffering can be avoided if older people, their families, and their doctors recognize dementia as a disease, not part of normal aging."

Reversible causes of dementia include the side effects of many medications. Ditropan is only the most recent addition to the list, occasioned in part by a study by U.S. Navy neurologist Dr. Jack Tsao involving 870 men and women with an average age of 75. The subjects, who were all Catholic priests, nuns and brothers, were followed for almost eight years. At a 2008 meeting of the American Academy of Neurology, Dr. Tsao reported that those who were taking anticholinergic drugs — a class that includes not only Detrol but also drugs to treat hypertension, asthma and Parkinson's disease — had a 50 percent higher rate of cognitive decline than those who were not.

According to Dr. Samuel Gandy, a neurologist at Mt. Sinai School of Medicine in Manhattan, drugs with antihistamines often cause mental confusion and sedation in the elderly — especially those containing the antihistamine doxylamine, such as the sleep aid Unisom. In addition, confusion and forgetfulness in the elderly can be caused by malnutrition, chronic alcoholism and metabolic disturbances such as thyroid, kidney or liver disorders — and even on occasion by something as common as dehydration or a high fever.

Doctors are better than they used to be at diagnosing pseudosenility, according to Dr. Gandy. "Most physicians are taught in medical schools to evaluate a patient for dementia by first excluding the reversible causes," he said.

But one kind remains a particular problem, he added: depression masquerading as dementia. Doctors can't simply order a test to rule it out; the best they can do is recommend a trial run of antidepressant therapy, he said, "to see if the person will perk up and come back."

First, though, the physician must think of something other than aging as a possible cause of the symptoms.

Less Salt Will Cut Heart Disease Rate; Study Shows Small Cutback in Salt Intake Will Reduce Heart Disease Cases

By Caroline Wilbert
WebMD
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You'd better start reading the sodium amounts on food packages.

If Americans reduced their salt intake by just 1 gram per day, there would be 250,000 fewer new cases of heart disease and 200,000 fewer deaths in a decade. These new statistics, announced at the American Heart Association's Annual Conference on Cardiovascular Disease Epidemiology and Prevention, were calculated through a computer simulation of heart disease among adults in the U.S.

"A very modest decrease in the amount of salt -- hardly detectable in the taste of food -- can have dramatic health benefits for the U.S.," study researcher Kirsten Bibbins-Domingo, MD, PhD, an assistant professor of medicine and epidemiology at the University of California, San Francisco, says in a news release. "It was a surprise to see the magnitude of the impact on the population, given the very small reductions in salt we were modeling."

The health improvements could be particularly meaningful for African-Americans, who are more likely to have high blood pressure and whose blood pressure may be more sensitive to salt. The study found that a 3-gram per day reduction in salt among all Americans would result in 6% fewer new cases of heart disease and 3% fewer deaths. Among African-Americans, there would be a 10% reduction in new cases of heart disease and a 6% reduction in deaths. Three grams per day is equivalent to 1,200 milligrams of sodium.

Despite evidence that salt intake is linked to high blood pressure and heart disease, Americans have continued to increase their salt intake during the last few decades, according to the researchers. Salt consumption is up about 50% since the 1970s.

Americans on average eat 9 to 12 grams of salt per day, or 3,600 to 4,800 milligrams of sodium. Most health organizations recommend 5 to 6 grams of salt per day, which is 2,000 to 2,400 milligrams of sodium.

Researchers called for changes in the food industry. "It's clear that we need to lower salt intake, but individuals find it hard to make substantial cuts because most salt comes from processed foods, not from the salt shaker," says Bibbins-Domingo. "Our study suggests that the food industry and those who regulate it could contribute substantially to the health of the nation by achieving even small reductions in the amount of salt in these processed foods."

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