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Bibliography

IDEOLOGICAL ATTACKS ON SCIENCE

The September 2006 issue of *Jurimetrics* contains the Hogan & Hartson Jurimetrics Lecture, presented on March 1, 2006, at Arizona State University Sandra Day O'Connor College of Law by Paul Berg, 1980 Nobel Prize winner in chemistry and a member of the National Academy of Sciences. Dr. Berg ponders what he sees as a growing threat to science arising from the scientifically illiterate public and policymakers and attempted imposition of faith-based and politically motivated restrictions on the work that can be done, sometimes with criminal penalties attached.

"Unlike the debate over the recombinant DNA issue, which turned on a possible threat to human health, the concerns about human embryonic stem-cell research have more to do with values and ideology." He points out that the blastocysts created to establish patient-specific cell lines are significantly different biologically from blastocysts arising from a fertilized ovum, yet they have been said to require the same protection accorded human life.

"When science is attacked on ideological grounds, its integrity is threatened," he says, pointing to the enormous damage done to biological research in the Soviet Union by Stalin and Lysenko's rejection of Mendelian genetics in favor of the doctrine of inheritance of acquired characteristics. Berg also discusses the possible protection of scientific research by the First Amendment. The reference is Berg P. Brilliant science, dark politics, uncertain law. 46 Jurimetrics J 379–389 (2006).

GENETIC TESTING: WHO WILL PAY?

The cover story in a November 2006 supplement to *Managed Care* reviews the value and problems of genetic testing. One big question is who will pay for it. Many insurers believe that unless the results will affect a patient's treatment or the patient is enrolled in a clinical trial, patients who want such testing must pay for it themselves. Still to come: a $1,000 full-genome scan that would become part of a patient's medical record.

Payors are likely to face requests for testing more often. According to Joanne Armstrong, MD, Senior Medical Director at Aetna in Houston, "over the past three years, we've seen a rise in cost trends for genetic testing that is about two times that of overall medical cost trends. In real dollars, it is less than 1 percent of total medical costs, but this is still in its infancy."

The article, by Maureen Glabman, is titled "Genetic Testing: Major Opportunity, Major Problems."

WILL PHARMACOGENOMICS CONTROL PRESCRIPTIONS?

A related article concerns the possible future role of pharmacogenomics as a means of controlling who received particular drugs. Warfarin, the anticoagulant, and clozapine, the antipsychotic, seem likely to be first, but insurance companies are particularly interested in reducing prescriptions for expensive specialty products.

"Drug companies need to fight fire with fire," the author recommends. "Only by incorporating genetics tests during the drug development process can manufacturers prevent managed care from defining their markets for them."

The paper is Rawson K. The next coverage hurdle: pharmacogenomics as formulary control tool. RPM Report 2006;1(11)24–27.

USING GENETIC ANALYSIS IN PROGNOSIS

In a paper that caused considerable excitement and shows the clinical potential of genetic analysis, researchers from Taiwan described a panel of five genes that correlates strongly with tumor behavior and survival in patients with non-small-cell lung cancer. The publication is Chen H-Y, Yu S-L, Chen Ch-H, et al. A five-gene signature and clinical outcome in non-small-cell lung cancer. N Engl J Med 2007; 356:11–20.

WHEN TO BRING SUIT FOR INFRINGEMENT

"Should you be scared off by the high costs of bringing a patent case . . . or should you focus on the potentially enormous awards that can result . . . ? How do you balance the toll on your business from years of litigation against the potential to shut down a competitor with an injunction?"

Those questions are the focus of "Is patent litigation worth the headaches?" by Michael Albert and Ilan Barzilay, published in *Mass High Tech: The Journal of New England Technology* on September 29, 2006. They note that fewer than 20% of patent cases are resolved by courts and fewer than 5% go to trial. "Ironically, the stronger a case you build for trial, the more likely you are to get the results you want without one," the authors note.

STATE REQUIREMENTS FOR CLINICAL TRIALS

John C. Serio and Dorothy L. Puzio of Brown Rudnick (Boston, Mass.) have written the *State-by-State Clinical Trial Requirements Reference Guide 2007*. This manual provides updated profiles of clinical trial standards and breaks down each state's requirements in critical areas, including informed consent, Institutional Review Board activities, and protocol requirements; special rules for cancer research; and requirements for genetic testing. The book is available from Barnett Educational Services for $49.95 per copy. The publisher can be reached by phone at (703) 310-2549, by E-mail at customer.service@parexel.com, or on the Web at www.barnettinternational.com.

IRBs AND CONFLICTS OF INTERESTS

In the November 30 issue of the *New England Journal of Medicine*, researchers from the Institute of Health Policy at Massachusetts General Hospital and the Center for Survey Research at the University of Massachusetts look at conflicts of interest in Institutional Review Boards. They find little evidence of bias, and several respondents to their survey said industry connections were helpful in providing appropriate expertise. However, the authors note that organizations should ensure they have an appropriate means of handling any conflicts that do arise.

The paper is Campbell EG, Weissman JS, Vogeli C, Clarridge BR, Abraham M, Marder JE, Koski G. Financial relationships between institutional review board members and industry. N Engl J Med 2006;355: 2321–2329.

U.N. RESTRICTIONS ON rDNA FOR AGRICULTURE

BLR Board Member and founding Director of the Food and Drug Administration's Office of Biotechnology, Henry I. Miller, M.D., finds the new rules for rDNA-based foods formulated by the U.N. Food and Agriculture Organization and World Health Organization to make no sense. "Having already stifled innovative research on food plants and microorganisms, the commission is now penetrating other areas, such as animals and even animals immunized with high-tech vaccines," he writes, noting that the approach taken by the U.N. "is also incompatible with FDA policies." "The U.N. Menu" was published on WSJ.com on December 4, 2006.

VIEW OF NEW WTO RULING ON GENETICALLY MODIFIED CROPS

The Washington Legal Foundation has released *WTO Ruling on Biotech Foods Addresses "Precautionary Principle"* by Lawrence Kogan of the Institute for Trade, Standards and Sustainable Development, Inc., who argues that the new ruling by the World Trade Organization is a serious blow to European biotechnology regulators. Europeans traditionally have rejected ruling on the basis of science in favor of strict rules intended to eliminate every possible theoretical risk.

The WTO ruling, issued in response to a complaint filed by the United States, Argentina, and Canada, said that the "precautionary principle" approach of European regulators violated the WTO's Sanitary and Phytosanitary Agreement and that the regulators were making decisions based on politics, not science.

Copies of this Legal Backgrounder can be obtained by forwarding a request and a check for $5 per copy to: Publications Department, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, D.C. 20036, or calling (202) 588-0302.

WHITHER MONOCLONALS?

The Business Insight Report "The Future of Monoclonal Antibodies Therapeutics: Key Growth Strategies and Forecasts to 2011: Market Research Reports" is available as a pdf from Datamonitor for $2,875. The report sees a shift in the targets from a focus on cancer and autoimmune disorders to ophthalmology, infectious diseases, and drug delivery.

FIGHTING MICROBES WITH MICROBES

In the October 2006 issue of *Antimicrobial Agents and Chemotherapy*, Liu et al. describe the creation of a stably transformed vaginal strain of *Lactobacillus jensenii* that produces an HIV inhibitor, cyanovirin-N, derived from cyanobacteria (blue-green algae) such as *Nostoc ellipsosporum*. The hope is to establish the organism in women at risk for HIV as a way of preventing infection. The paper is Liu X, Lagenaur LA, Simpson DA, et al. Engineered vaginal lactobacillus strain for mucosal delivery of the human immunodeficiency virus inhibitor cyanovirin-N. Antimicrob Agents Chemother 2006;50:3250–3259. A related U.S. patent is 6,987,096, "Antiviral proteins and peptides, DNA coding sequences therefor, and uses thereof," issued January 17, 2006 and is assigned to the U.S. Department of Health and Human Services

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