

SPECIAL SECTION: The Year in Bioethics, 2004

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Institute Establishes Advisory Board



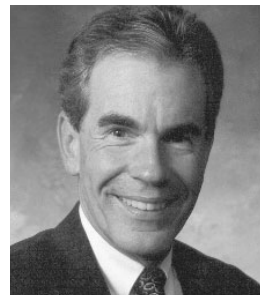
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The newly established Advisory Board of the Institute for Bioethics, Health Policy and Law held its inaugural meeting on October 14, 2004, at the Institute. The eight members of the Board include representatives of public health agencies, private health care providers, and community leaders. The Board, which will meet semi-annually, has three main responsibilities:

(1) helping to facilitate collaborations with other public and private entities with similar and complementary interests and expertise; (2) helping to increase the visibility of the Institute among researchers, clinicians, and other professionals and the public; and (3) helping to secure additional public and private support to maintain and expand the activities of the Institute.

Center for Public Health Law Partnerships to Release First Public Health Law Bench Book

The Center for Public Health Law Partnerships is preparing to release its first public health law bench book in December 2004. The Public Health Law Bench Book for Indiana Courts is intended to serve as a readily-accessible reference tool for Indiana judges confronted with public health cases. The Bench Book includes excerpts of Indiana public health statutes, summaries of relevant caselaw, and model isolation, quarantine, search, and

seizure orders. Because most judges in the U.S. have never confronted public health issues in their courtrooms, the Bench Book includes introductory public health materials and a public health glossary to familiarize judges with the fundamental principles of public health.

The Public Health Law Bench Book integrates the Center's public health law and ethics

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Havasupai Tribe Sues Genetic Researchers

by Lori Andrews, J.D.

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The foundation of genetics research around the world was built on studies of *Drosophila* and lab rats. But with the advent of the Human Genome Project, genetics researchers turned increasingly to humans as research subjects. Now researchers are finding that the human subjects have a characteristic that other species do not: they have lawyers. This allows them to raise concerns about informed consent, privacy, and fair dealing when researchers behave in ways that the human subjects find unacceptable.

Litigation pending before Judge Fredrick J. Martone of the U.S. District Court for Arizona¹ could help clarify the duties of genetics

The complaint alleges that the defendants authored 15 publications dealing with schizophrenia, inbreeding, and theories about ancient human population migrations from Asia to North America—secondary uses of the samples to which the Havasupai would not have consented.

researchers toward their subjects. Members of the Havasupai Tribe allege that researchers of Arizona State University (“ASU”) and the University of Arizona (“U of A”) collected 400 blood samples from them for researching diabetes, but that additional unauthorized research was undertaken on those samples regarding schizophrenia, inbreeding, and population migration.² They assert that the research on schizophrenia and inbreeding was stigmatizing to them and that they would not have authorized the migration research because it conflicts with their religious origin story.

The 650-member Havasupai Tribe are descendents of the Hohokam Indians,³ who migrated north from Mexico around 300 B.C.⁴ The Havasupai settled in an isolated and remote

location in the Grand Canyon, which is still only accessible by horseback, foot, or helicopter. Such isolation is the reason that the Havasupai Tribe poses a restricted gene pool, in which certain genetic diseases are at higher incidence than in, say, a general urban population. In fact, the Havasupai have one of the highest incidences of type 2 diabetes anywhere in the world. In 1991, 55% of Havasupai women and 38% of the Havasupai men were diabetic.⁵

In 1989, two tribe members approached an ASU faculty member, asking for help to stem the tribe’s high incidence of diabetes. They allege that researcher Therese Markow and a colleague originally presented their project to the tribal council as consisting of three elements: (1) “diabetes education,” (2) “collecting and testing blood samples from individual members to identify diabetics or persons susceptible to diabetes,” and (3) “genetic testing to identify an association between certain gene variants and diabetes among Havasupai people.”⁶ They allege that Markow did not inform them that she was in the process of, or had previously submitted, a grant application to study schizophrenia among the Havasupai. Nor were they subsequently told that Markow caused her assistant to surreptitiously examine their medical charts for schizophrenia after operating hours of the local health clinic. The complaint alleges that the defendants authored 15 publications dealing with schizophrenia, inbreeding, and theories about ancient human population migrations from Asia to North America—secondary uses of the samples to which the Havasupai would not have consented.

The faculty member who introduced Markow to the Havasupai complained to ASU officials that the research had strayed away from diabetes research.⁷ Given that ASU was about to launch an ambitious plan to accelerate genetic research, ASU desired to keep the conflict private and paid for an investigation conducted by attorney Stephan Hart. The investigation resulted in a nine-volume report. An article in *Nature* states that Hart’s report provided “no

firm findings of misconduct, but states that there are ‘issues’ on how the project was administered, the keeping of records, and whether the tribe realized the full extent of research that would be undertaken.”⁸

The complaint in the case of *Havasupai Tribe v. Arizona State University* lists six causes of action: (1) breach of fiduciary duty and lack of informed consent (including not having appropriate procedures for vulnerable subjects such as children, people with mental illness, and people whose main language was the tribal language); (2) fraud and misrepresentation/fraudulent concealment; (3) intentional or negligent infliction of emotional distress; (4) conversion; (5) violation of civil rights; and (6) negligence, gross negligence and negligence per se.⁹ In the complaint, the plaintiffs request the court to hold the defendants (including Stanford University, where some of the samples had been sent) jointly and severally liable for \$25,000,000 in compensatory damages and \$25,000,000 in punitive damages. Further, plaintiffs request that the judge enjoin any further research activity or publication involving the blood samples and prohibit the defendants “from committing similar acts in the future.”

In defense of Markow, *Nature* reports that research into interbreeding and migration patterns is “an accepted procedure” for researching the extent to which the studied population is isolated.¹⁰ According to *Nature*, information on the extent to which a studied population is isolated is “important” for the genetic investigation of a disease. However, most research to identify human disease genes has proceeded without inbreeding studies and *Nature* fails to explain how schizophrenia is linked to diabetes research. Moreover, even if such studies were standard procedure, the Havasupai argue that they should have been told of these “accepted procedures” before they were asked whether they were willing to consent to the research.

On the website about her lab, Markow (now a Regents Professor of Ecology and Evolutionary Biology at the U of A¹¹) reports that her work uses *Drosophila* to research speciation, mating system evolution, ecology and population biology, and biological stoichiometry.¹² There is no mention of research on human subjects, despite the fact that she has published

articles about the Havasupai, including an article on inbreeding.

Perhaps her fruit flies didn’t care which studies she undertook, but her human research subjects certainly did. The pending lawsuits will determine whether certain acceptable practices for animal research require a higher level of ethics when applied to the human realm.

Sources

1. See Court Link Docket Information, “Lexis Nexis” Havasupai Tribe et al. v. Arizona State University, et al., civil docket no. 3:04-CV-1494, (D.Ariz. 2004); Tilousi, et al. v. Arizona State University, et al., civil docket no. 3:04-CV-1290 (D.Ariz. 2004); Tilousi, et al. v. Arizona State University, et al., civil docket no. 2:04-CV-1290 (D.Ariz. 2004).
2. John Merz, “More on the Havasupai Tribe lawsuit...,” available at <http://irbforum.com/forum/read/2/54/54> (last visited October 15, 2004).
3. Council of Indian Nations, “Southwest Indian People: The Havasupai,” available at <http://www.cinprograms.org/people/coloradoriver/havasupai.html> (last visited on October 15, 2004).
4. Council of Indian Nations, “Southwest Indian History: Hohokam,” available at <http://www.cinprograms.org/history/hohokam.html> (last visited on October 15, 2004).
5. Rex Dalton, “When Two Tribes Go to War,” 430 *Nature* 500 – 502, 500 (2004).
6. Pls.’ Compl. 23 (June 28, 2004).
7. Rex Dalton, “When Two Tribes Go to War,” 430 *Nature* 500 – 502, 500 – 502 (2004).
8. Rex Dalton, “When Two Tribes Go to War,” 430 *Nature* 500 – 502, 502 (2004).
9. Pls.’ Compl. 38 – 41, 42 – 45, 44 – 56, 57 – 58, and 59 – 62 (June 28, 2004).
10. Rex Dalton, “When Two Tribes Go to War,” 430 *Nature* 500-502, 500 (2004).
11. University of Arizona, “Markow,” available at http://cis.arl.arizona.edu/markow_lab/ (last visited on October 15, 2004).
12. University of Arizona, “Markow,” available at http://cis.arl.arizona.edu/markow_lab/research.htm (last visited on October 15, 2004).