GENETIC LAW REGULATIONS IN THE USA

Yrd. Doç. Dr. Fatih ÖZTÜRK*

I. HISTORICAL OVERVIEW

- 1964, US Chemical manufacturer undertakes cytogenetic monitoring of employees through pre-employment medical exams, to build thousands of chromosomal profiles of workers
- 1968, The UN adopts a resolution inviting the international community to study…the protection of human integrity in light of advances in biology and medicine
- 1970, A Test is developed to screen for sickle cell carriers
- 1970-75, As part of a major public health initiative, several US states pass mandatory screening legislation for sickle cell anemia for marriage applicants and school children, among others. Many states later amend the laws to encourage voluntary approaches.
- 1988, The Supreme Court of Canada rules that the information contained in one's tissues and cells falls within the protections of the Canadian Charter of Rights and Freedoms.
- 1991, A Dozen states in the US enact laws to restrict genetic testing in job settings
- The American Medical Association issues a formal statement claim that it is inappropriate to exclude workers with genetic risk of disease from the workplace
- 1997, The UNESCO Universal Declaration on the Human Genome and Human Rights calls for informed consent, no discrimination based on genetic characteristics and respect for confidentiality

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* Melikşah Üniversitesi Hukuk Fakültesi Öğretim Üyesi.

- The Council of Europe Convention on Human Rights and Biomedicine proclaims right to respect for private life, genetic tests should be taken only for health or health research purposes
- 1999, The Government of Canada adapts legislation to extend national privacy protection to the private sector.
- In 2000, the US President signs an executive order that generally bans the use of genetic information in hiring or employment actions within the federal government.

II. HUMAN RIGHTS

- Human rights are not simply abstract ideals. They do influence how we think.
- Law of human rights offers principles-standards-and process may meaningfully guide the development of genetic testing policy
- Respect of human dignity-protection and promotion of human health-equality and non-discrimination-privacy and confidentiality-autonomy-justice and-public participation[1]

III. WHAT DOES SAY THE US LAW?

- The President Bush signed Genetic Information Non-Discrimination Act (GINA) in May 2008. It went into effect on November 21, 2009
- GINA: Prohibiting group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future
- Barring employers from using individuals' genetic information when making hiring-firing job placement or promotion decisions or compensating

[1] Health Canada, Health Policy Working Paper Series, Selected Legal Issues in Genetic Testing: Guidance from Human Rights, October 2001.

- Require victims to prove intentional discrimination but allow recovery of punitive and compansatory damages leading to potentially steep fines against employers up to $ 200,000 USD per breach

- Most states already have some regulation-35 states have employment laws banning genetic discrimination and 47 states have laws restricting genetic discrimination in health care-but supporters feel the legislation implements a unified federal standard, sending a strong message that DNA may not be used for commercial advantage by employers or insurers.

IV. REGULATION OF GENETIC TESTING INDUSTRY

- Commercial market for direct-to-consumer genetic testing is largely unregulated lacking a regulatory entity or stnadards that assist people to understand test results or assess the validity of tests available

- Bogus (false) tests can cause needless worry or false reassurance based on their results

- GINA may cause insurers and employers to not provide genetic testing as part of healthcare plans (it increased liability on them)[2]

V. PROTECTING GENETIC PRIVACY

- Need of Federal Genetic Privacy Law

- Primary purpose of law must be individual control over their identifiable DNA samples and the genetic sequence information extracted from them

- Current US state laws at best offer some economic protections…

- State laws have significant gaps and inconsistently regulate those who engage in DNA banking and genetic research[3]…Discussions going on…

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2 "President Bush signs genetic anti-discrimination bill into law", available at: http://www.Bionews.org.uk.

3 Patricia A. Roche, George J. Annas, Law & Genetics in the United States: Protecting Genetic Privacy and Genetic Property.

VI. GENETICALLY MODIFIED FOODS (GMF)

- Food and food additivies under regulatory jurisdiction of FDA (food and drug administration)
- The term GM foods or GMOs (genetically-modified organisms) is most commonly used to refer to crop plants created for human or animal consumption using the latest molecular biology techniques.
- In 1992 FDA policy provided that GMF not be inherently dangerous and except in rare cases , should not require extraordınary premarket testing and regulation-regulated as ordinary foods, not food additivies unless they contaın substances or demonstrate attributes thar are not usual for the product
- FDA regards GM products as generally regarded as safe. No revıewıng food additive
- However, the 1992 policy established voluntary process which producers could consult with the agency about safety and regulatory issues prior to marketing food derived from biotechnology.
- Granted, the industry may have IPR (Intellectual Property Rights) concerns with respect to any disclosure of informatıon concerning GM products.
- manufacturers may place a food product on the market without FDA premarket approval because whole foods are gras (safe).
- Under the Federal Food, Drug and Cosmetıc Act (FFDCA) manufacturer bears responsibility for ensuring that a product is not adulterated or misbranded. If it is shown that the food is adulterated the FDA is authorized to seek sanctions through seizure, injunction, or criminal prosecutıon.
- 45 % corn-85 % soybean- 70-75 % processed foods on supermarket shelves GM.
- Sum: regulatory framework for GM remains the same as for non-GM[4]

[4] GMO Journal, Inroduction to GM Foods by the FDA.

VII. THE CENTER FOR FOOD SAFETY CLAIMS THAT

- GMF (number of studies have revealed) can pose serious risks to humans, domesticated animals, wildlife and the environment.
- Human health effects can include higher risks of toxicity, allergenicity, antibiotic resistance, immune-suppression and cancer
- Enviromental impact: using genetic engineering in agriculture could lead uncontrolled biological pollution, threatening numerous microbial, plant and animal species with extinction, and the potential contamination of non-genetically engineered life forms with novel and possibly hazerdous genetic material
- Unlabeled GMF despite a finding by the FDA scientists that these foods could pose serious risks. Even that they approved by federal agencies[5]

VIII. GENETICALLY ENGINEERED ANIMALS (GMA)

- Creating multi-cellular, transgenic animals: have specific traits from another plant or animal genetically engineered into them
- Better able to resist disease, increased growth performance, better reproductive traits
- Transgenic salmon, that grow larger and at a faster rate than natural varities, created and farmed
- Another common use: dairy cows to increase milk production
- Creating transgenic farm animals-non-sentient, without ability to experience pleasure-no stress-no feel pain
- John Owens "…this technology would leave the modified animals with the 'same status as a rock which earns no protection under the movement's philosophy"
- Cloning endangered species may provide some benefits

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[5] Genetically Engineered Food, Center for Food Safety, Washington D. C.

- The use of patents: protecting and owning GMA and species
- The Animal Welfare Act (AWA) primary legislation regulates animal property in the US
- Considered no providing guidance for the human treatment of non-human animals
- 1985, amendments on the AWA: primate used for research experience a minimized level of suffering, by providing a physical environment adequate to promote their pshyological well-being.
- Still a weak act, no protection for birds, rats, mice..etc.
- On january 15, 2009 FDA issued final guidance on regulating genetically engineered animals(contains non-binding recommendations)
- "The regulation of genetically engineered animals containing hertable rDNA constructs" use of recombinant DNA (rDNA) techniques introducing new characteristics or traits into an organism
- Developers of these animals must demonstrate that the construct and any new products expressed from the inserted construct are safe for health of the GEA and if they are food animals for food consumption.
- Guidance describes manufacturer's responsibility in meeting the requirements for environmental review under the national environmental policy act[6]

CONCLUSIONS

- Genetic testing results can help doctors and their patients anticipate medical conditions that could arise and help them take steps to reduce the risk. However, the benefit of obtaining genetic tests in certain situations (for example, in the case of a woman with a strong family history of breast cancer) could be offset if those same test results are turned against the individual. What happens when genetic testing results are used to determine

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6 FDA Issues Final Guidance on Regulating Genetically Engineered Animals, available at: http://www.fda.gov.

whether someone can obtain insurance or whether an employer will hire that individual? Or when the mere prospect of such misuse of genetic information prevents someone from getting genetic testing in the first place?[7]

- Genetically-modified foods or animals have the potential to solve many of the world's hunger and malnutrition problems, and to help protect and preserve the environment by increasing yield and reducing reliance upon chemical pesticides and herbicides. Yet there are many challenges ahead for governments, especially in the areas of safety testing, regulation, international policy and food labeling.

- Many people feel that genetic engineering is the inevitable wave of the future and that we cannot afford to ignore a technology that has such enormous potential benefits. However, we must proceed with caution to avoid causing unintended harm to human health and the environment as a result of our enthusiasm for this powerful technology.

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[7] The Boston Globe, available at: http://www.boston.com/news/globe/editorial_opinion/oped/articles/2005/11/02/ensuring_privacy_in_genetic_testing/