

The Patients' Voice Summer 2001

Informed consent is an admirable ideal, difficult to achieve even under the best conditions. In the current market, informed consent must compete against other values such as scientific progress, market competition, consumer confidence, patent rights, and avoidance of litigation. Vague or misleading informed consent documents leave patients with limited opportunities to get a balance perspective. Cases of medical malpractice are reported – if at all – to agencies which shield them from public access.¹ A few examples from different areas of research and medicine will indicate why vigilance is essential where informed consent is concerned.

Scientific Progress vs Informed Consent

The development of new medicines and treatments is an exciting field for researchers in biotechnology. The high demand for willing human subjects for pre-market testing² can overcome the ideal of informed consent in research hospitals.

Federally mandated Institutional Review Boards (IRBs) need more support to effectively protect the welfare of human research subjects in research hospitals and laboratories.³ Under-reporting of negative outcomes – including death⁴ – to the federal Office of Protection from Research Risks (OPRR) limits the effectiveness of this registry to protect patients' rights. "Tips for Protection from Research Risks," published by the OPRR, includes the following recommendation:

"Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects . . . may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas."⁵

Congress is considering greater oversight for genetic research projects, but "a growing consensus in the biomedical research community (is) that prevention through education is the best way to reduce scientific misconduct."⁶ Education on professional ethics is valuable mainly for keeping honest people honest.

Surviving families of five research subjects are suing the Fred Hutchinson Cancer Research (the Hutch) in Seattle for providing insufficient or misleading information on informed consent forms. Dr. E. Donall Thomas, co-founder of the Hutch, in a letter to Dr. Henry Kaplan of Swedish Hospital, chairman of the Hutch IRB, wrote: "(IRB) Committee members have not only an obligation to review the ethical aspects of this work, but also an obligation to assist us and not impede our research, . . ."⁷ Dr. John Pesando, also of the Hutch IRB, was dissatisfied with the lack of response by Federal and state authorities to his complaints about conflicts of interest and misleading informed consent documents.⁸

Patients who consider experimental treatment need to keep in mind that not all research subjects actually receive treatment. Patient-advocate Abbey Meyers found that many informed consent documents "held out the hope of a cure to terminally ill patients even in trials designed only to test for a safe dose of an experimental drug."⁹

Consumer confidence vs full disclosure Biotechnology is introducing more new drugs and therapies to the US market every year. Although they are subject to more pre-market testing than GE foods, they are not necessarily safer.¹⁰ Viruses are genetically unstable by nature, and genetic manipulation makes them even less stable. Gene therapies inject foreign DNA into patients' bodies, where further mutations are beyond medical intervention. Genetically engineered medicines are produced by human or animal DNA artificially

spliced together using viral and/or bacterial DNA. Gene therapy may trigger auto-immune diseases, because the immune system tends to destroy the body's own cells after they receive the viral DNA used to deliver therapeutic genes.¹¹

research costs, and the shortage of willing subjects for long-term studies make short-term research the norm. Financial concerns, such as patents and liability, also discourage drug companies, if not doctors, from revealing suspected long-term side-effects. According to Dr. Allan Korn, Chief Medical Officer of Blue Cross/Blue Shield, drug companies are not likely to publish information that doesn't fit with their marketing plans.¹² Since most physicians rely on pharmaceutical companies for information, most patients will not have easy access to data on potential risks from new GE medicines or gene therapies.

The FDA approval process is not sufficiently rigorous to guarantee safety. Genetically engineered "human" insulin (approved by the FDA since 1988) is one example. Two manufacturers of GE insulin – Aventis Pharmaceuticals and Nordisk Pharmaceuticals – have both stated publicly that it is associated with increased side effects. Adverse reactions to "human" insulin "have been largely ignored by regulatory bodies, doctors and healthcare professionals."¹² Increased supply and/or decreased cost of GE insulin may only contribute to increased side effects, especially if diabetics are lulled into increasing their intake of both carbohydrates and insulin.

Buyer Beware

Patients need to get a second opinion and gather as much independent information as possible – preferably from a professional with training in alternative medicine – before trying any new or experimental medical treatment. Warnings (in fine print) of side effects for more vulnerable patients do not make advertising a reliable source of unfavorable information on any product. The purpose of the coupons is to induce patients to use more convenient, but more expensive medications.¹³ Government regulations offer insufficient protection, and increased regulations are more likely to decrease patients' alternatives than to increase safety.

Endnotes

1 "Medical errors should be public, forum advises," USAToday.com, Aug. 13, 2001, <http://www.usatoday.com/news/health/2001-05-21-medical-errors.htm> See also: Appleby, Julie; "Medicare oversight found to be ailing," USAToday.com, Aug. 13, 2001, <http://www.usatoday.com/news/health/2001-08-13-medicare-oversight.htm> . See also Davis, Robert; "Hospital mistakes must be disclosed," USA Today, Aug. 13, 2001, <http://www.usatoday.com/news/healthscience/health/2001-06-28-mistakes-usat.htm> See also: Pear, Robert (Associated Press); "HMOs Not Tracking Errors – Thousands die, but few doctor mistakes reported, study shows," Seattle Post-Intelligencer, May 29, 2001, p.1

2 "Safeguarding participants in clinical trials," The Lancet, Vol. 355, No. 9222, June 24, 2000, p. 2177

3 "Improving the safety of patients during clinical trials," The Lancet, volume 357, No. 9274, June 30, 2001 p 2067

4 Friend, Tim; "It's in the genes: Scientists confront issues," USA Today, Feb. 22, 2000, <http://www.usatoday.com/life/health/genetics/therapy/lhgh024.htm>.

5 "Tips on Informed Consent," Office for Protection from Research Risks, <http://ohrp.osophsdhhs.gov/humansubjects/guidelines/ictips.htm>

6 Bagla, Pallava; "Query by Congress Halts New Policy," *Science*, March 2, 2001, vol. 291, p. 1679. See also: Marshall, Elliot; "Bioethics panel urges broader oversight," *Science*, May 2, 2001, vol. 292, p. 1466

7 Wilson, Duff and David Heath; "Uninformed Consent, Part 1: The Blood-Cancer Experiment," *Seattle Times*, March 11, 2001

8 Wilson, Duff and David Heath; "Uninformed Consent, Part 2: The Whistleblower," *Seattle Times*, March 12, 2001

9 Meyers, Abbey, founder of the National Organization for Rare Diseases, as cited by David Heath and Duff Wilson; "Many patients think that joining testing will help them, but often they're mistaken," *Seattle Times*, March, 2001

10 For an example of an FDA approved drug pulled from the market for causing deaths, see: "Bayer Drug Linked to More Deaths," *BBC News online*, Aug 13, 2001, http://news.bbc.co.uk/1/hi/english/business/newsid_1488000/1488486.stm

11 Korn, Dr. Allan, cited by Sherrid, Pamela in "Designer Drugs, What's best for patients isn't always what's best for profits," *usnews.com* 8/13/01, <http://www.usnews.com/usnews/issue0813/biotech/drugs.htm>

12 "Admission of adverse reactions to genetically engineered 'human' insulin by insulin manufacturers," *Insulin Dependent Diabetes Trust, UK, News Release*, July 24, 2000, <http://www.diabetes-ernaehrung.ch/fis/news-e.shtml#admission> or <http://www.gene.ch/genet.html>

13 "Drug makers trying coupons to keep customers," *USA Today*, Aug. 13, 2001, <http://www.usatoday.com/news/healthscience/health/2001-31-drug-coupons.htm>