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SCIENTIFIC EXPERTS AND THE COURTS

By Jason Borenstein

Our legal system has struggled with the vast assortment of scientific claims presented in the courtroom. Separating well-warranted claims from dubious ones is not easily accomplished. One looming problem is that there are individuals seeking to testify in court from fields whose claims have not been studied thoroughly enough. Further, even if it is shown that the alleged expert is a member of a credible field, he/she still might not be trustworthy. There are scientists testifying in court who, for example, have been accused of having shoddy intellectual habits and significant conflicts of interest.[1] The courts and the federal government, mainly through the Federal Rules of Evidence and several crucial Supreme Court decisions, have set forth guidelines for determining the admissibility of scientific expert testimony. Their hope is to ensure that only reliable expert testimony is admitted into the courtroom, but their efforts have met with mixed results.

Over the years, experts have come to the courts from a variety of scientific and related fields, including psychology, psychiatry, chemistry, toxicology, dentistry, mechanical engineering, toolmarks, voiceprint analysis, geology, bioethics, computer programming, epidemiology, ophthalmology, and cardiology.[2] These experts claim to have specialized abilities and skills, ranging from the mundane to the astounding. As witnesses, these experts have offered testimony on topics from polygraphs, hypnosis, cause of death, medical malpractice, medical products, ballistics, microanalysis, DNA testing, dental identification, fingerprinting, footprints to sexual abuse, a psychological condition known as "closure,"[3] and "future dangerousness."[4]

Already in the 1800's experts had a reputation for selling opinions that conformed to a litigant's agenda.[5] Cynics still believe that if a lawyer searches long enough, an expert opinion can be found to support any side of an issue. In the early 1900's, Judge Learned Hand questioned whether jurors are able to evaluate specialized matters unfamiliar to them.[6] When a battle of opposing experts ensues, the jury is supposed to resolve the dispute. But Hand asks, "how can the jury judge between two statements each founded upon an experience confessedly foreign in kind to their own? It is just because they are incompetent for such a task that the expert is necessary at all."[7] Hand's insight throws the entire practice of having experts testify into doubt, especially in scientific cases where lay judges and juries typically lack familiarity with the specialized scientific vocabulary, methods, and instruments.

Complaints about the courts' handling of scientific evidence surfaced recurrently in the 1980's and 90's. Best known among the critics is Peter Huber, who alleges that "junk science" continues to infiltrate our legal system because scientific evidence is admitted too liberally.[8] His allegations raise questions about whether the legal system's admissibility guidelines are adequate to prevent unreliable testimony from being heard. Succinctly put, Huber fears that claims which would not be accepted by respectable scientists are given legitimacy by the courts.

In recent years, the Supreme Court has grappled with questions relating to scientific expert testimony. *Daubert v. Merrell Dow Pharmaceuticals* (1993) is one crucial case where the Court had the opportunity to clarify how future courts should handle scientific testimony.[9] The importance and impact of this case cannot be overstated (there were over twenty amicus briefs filed). The Court had to determine whether the anti-nausea drug Bendectin produced by Merrell Dow Pharmaceuticals is a teratogen, meaning a substance that can cause birth defects.[10]

The Supreme Court reviewed the *Daubert* case at the request of the petitioners "in light of sharp divisions among courts regarding the proper standard for the admission of expert testimony."[11] The Court believed that the "general acceptance" standard stemming from *Frye v. United States* (1923)[12] encumbered the "liberal thrust" of the Federal Rules of Evidence.[13] Accordingly, the Court held that the *Frye* standard should no longer be considered a necessary precondition for admitting scientific expert testimony. In principle, juries should be allowed to hear and evaluate a wider range of testimony under the federal rules. Novel testimony should not be categorically dismissed even if it is not generally accepted in the relevant scientific community. However, if complaints about junk science are legitimate, then letting in more scientific evidence may just worsen already existing problems.

Because of the support that it gave to judicial gatekeeping, courts and legal scholars could not even agree whether *Daubert* is more permissive or more rigid than the "conservative" *Frye* test that it was supposed to replace.[14] During its history, *Frye* was cited rather infrequently and almost always in criminal cases (although it was cited in the earlier stages of *Daubert*). In practice, *Daubert*, a civil case, probably conflicts with the "liberal thrust" of the federal rules by taking evidence away from juries that would not have been challenged under *Frye*.[15]

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The philosophical underpinnings of the *Daubert* decision are problematic.[16] The majority opinion in *Daubert* distinguishes scientific evidence from other types of evidence, which seems to indicate that the Supreme Court thought it was important to separate the two. According to the Court, "scientific" knowledge "implies grounding in methods and procedures of science."[17] Yet determining whether claims should be characterized as "scientific" has proven to be a difficult and ill-advised task. Moreover, the Court's insistence that the focus of a judge's inquiry "must be solely on principles and methodology, not on conclusions that they generate"[18] is troubling; it interferes with a judge's ability to evaluate testimony properly. Further, it is not clear whether a precise separation between conclusions and methodology can be made, as the opinion in *General Electric Co. v. Joiner* (1997) seemed to recognize.[19]

Chief Justice Rehnquist, joined by Justice Stevens concurring in part and dissenting in part from *Daubert*'s majority opinion, astutely recognized flaws with the ruling. The Court's ruling extends well beyond the issue that it was supposed to address to "matters far afield from the expertise of judges,"[20] he argued, and suggested that the Court's list of factors would inevitably lead to confusion when "district judges try to apply its teaching to particular offers of expert testimony."[21] Decisions since *Daubert* suggest that Rehnquist's dissent was well founded.[22]

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There was vigorous and diverse argument by courts and legal scholars about how *Daubert* should be interpreted. It was hotly debated whether *Daubert* mandated a reliability inquiry for nonscientific expert testimony. At times, *Daubert* put scientific expert testimony under a more rigorous and exacting review than nonscientific expert testimony.[23] As John Conley and David Peterson point out, "arguably scientific research that seemed likely to fail the *Daubert* test could then be repackaged...and admitted under the more lenient non-science standard."[24] Thus, holding scientific and nonscientific expert testimony to different standards sometimes "rewards the expert who avoids science and creates an unwarranted exception to vigorous *Daubert* screening."[25] Further, beyond the jumble of interpretations and rulings that *Daubert* created, it did not resolve the question of the standard for appellate review of a trial court's decision regarding expert testimony, an issue that was subsequently resolved in *Joiner*.[26]

Joiner settled that the appropriate standard of review for scientific expert testimony is abuse of discretion but did not quell the debate over what types of expert testimony are within the domain of *Daubert*. Inconsistent rulings continued because the requirements of judicial gatekeeping when evaluating nonscientific expert testimony remained unclear. *Daubert* caused district courts to distinguish "scientific" expert testimony from other types when making admissibility decisions (a trend that has thankfully lessened). Recognizing the problems resulting from *Daubert*, the Supreme Court overtly and conclusively addressed the domain of its prior ruling in the case of *Kumho Tire Company v. Carmichael* (1999).[27]

In *Kumho*, the Supreme Court had to decide whether the expert testimony of a tire failure analyst falls within the domain of *Daubert*. The Court held that a judge's gatekeeping role as described in *Daubert* was not intended to apply only to scientific expert testimony. *Kumho* reminds the courts that the admissibility factors outlined in *Daubert* were not intended to be a definitive checklist.[28] When a *Daubert* inquiry is performed, the judge is supposed to have broad discretion in weighing the merits of expert testimony. The Supreme Court recognized in *Kumho* that "there is no logical basis for applying a lower standard of trustworthiness to expert testimony in fields outside the scientific arena."[29] Similar standards of reliability should be applied to all expert testimony, including the testimony of engineers and other specialized experts, because "there is no clear line that divides the one from the others."[30] *Kumho* thus alleviated the worry about demarcating scientific from nonscientific testimony. The primary task of a judge, following *Kumho*, should be to discern whether testimony is reliable, not whether it is scientific or otherwise.

Critics of gatekeeping were less than pleased with *Kumho*, because of its insistence on upholding and expanding judicial gatekeeping. For instance, the Association of Trial Lawyers of America cautions that expanding the judge's role may be unwise because "there is no inherent reason to believe that the lay person on the bench is more capable at dealing with scientific issues than the lay person in the jury box."[31] The Trial Lawyers of America rightly point out that judicial expertise does not necessarily bestow upon judges the wisdom to evaluate scientific and other specialized claims. As Chief Justice Rehnquist cautioned years before in his dissent from the *Daubert* majority opinion, it may be misguided to encourage judges to become "amateur scientists."[32] However, presiding over similar cases may give a judge greater insight into scientific testimony than the average lay juror.

The *Kumho* ruling does place an enormous responsibility and burden upon judges to evaluate the merits of all sorts of testimony. The *Kumho* Court suggests that judges should have "broad latitude" when performing their inquiries to decide whether testimony should be admitted.[33] With this in mind, the recently revised Federal Rule of Evidence 702, which took effect December 2000, is supposed to aid judges in their inquiries by clarifying the considerations that judges should take into account.[34] The revised Rule offers several conditions that should be met before an expert's testimony is considered reliable. Neither *Kumho* nor Rule 702 require judges to apply a *Daubert*-style checklist rigidly. However, it is an open question whether judges can undertake all of the complex and sophisticated assessments required by the revised Rule 702.[35]

Over the last century, our legal system has tried to institute a multitude of guidelines regulating scientific expert witness testimony. In sum, the history of how the courts have handled scientific claims indicates that finding a suitable solution for evaluating the opinions of experts is a profoundly difficult task. At times, suggested

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guidelines have led ensuing courts to render inconsistent decisions on comparable testimony. Both *Frye* and *Daubert*, two of the most significant cases addressing expert testimony, created many problems when they were applied in practice, some of which were resolved by *Kumho*. With ramifications of *Kumho* and the revised federal rules still being sorted out, we shall see whether the way in which the courts handle scientific expert witness testimony is promising or otherwise.

References

[1] One scientist currently being investigated is Joyce Gilchrist, a forensic chemist who worked for the Oklahoma City police department. Gilchrist allegedly provided misleading courtroom testimony in numerous criminal cases in order to secure convictions. See Jim Yardley, "Inquiry Focuses on Scientist Employed by Prosecutors," *New York Times*, 2 May 2001.

[2] See Stephan Landsman, *Of Witches, Madmen, and Products Liability: A Historical Survey of the Use of Expert Testimony*, 13 *BEHAVIORAL SCIENCE & LAW* 131 (1995) (describing the types of experts who have provided testimony).

[3] See *Farley v. Commonwealth*, 458 S.E.2d 310 (Va. App. Ct. 1995).

[4] See *Barefoot v. Estelle*, 463 U.S. 880; 103 S. Ct. 3383 (1983).

[5] See Landsman at 145 (see note 2).

[6] See Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 *HARVARD LAW REVIEW* 40 (1901) (discussing problems with expert testimony).

[7] *Id*. at 54.

[8] Huber discusses "junk science" at great length in his book *Galileo's Revenge: Junk Science in the Courtroom* (USA: Basic Books, 1991); for a response to Huber's allegations see Kenneth J Chesebro, *Galileo's Retort: Peter Huber's Junk Scholarship*, 42 AMERICAN UNIVERSITY LAW REVIEW 1637 (1993).

[9] 509 U.S. 579, 113 S. Ct. 2786 (1993).

[10] For a synopsis of Bendectin research see Kenneth R. Foster and Peter W. Huber, *Judging Science: Scientific Knowledge and the Federal Courts* (Cambridge, MA: The MIT Press, 1999), pages 8-10, Box 1.4.

[11] *Daubert* at 585 (see note 9).

[12] 293 F. 1013 (D.C. Cir. 1923).

[13] See *Daubert* at 579 (see note 9).

[14] See Daniel J. Capra, *The Daubert Puzzle*, 32 *GEORGIA LAW REVIEW* 699, 704 (1998).

[15] See Michael Graham, *The* Daubert *Dilemma: At Last A Viable Solution?* 179 FEDERAL RULES DECISION 1, 7 (1998).

[16] See Susan Haack, *An Epistemologist in the Bramble-Bush: At the Supreme Court with Mr. Joiner*, 26 JOURNAL OF HEALTH, POLITICS, POLICY & LAW 217 (2001); for a different perspective, see Marc S. Klein, Daubert: *Worldwide Judicial Management of Humanity's Specialized Knowledge*, 30 UNIVERSITY OF CALIFORNIA AT DAVIS LAW REVIEW 1229, 1237 (1997) (claiming that *Daubert* is "an important victory for all who are committed to the rational adjudication of disputes").

[17] *Daubert* at 579 (see note 9).

[18] *Id*. at 581.

[19] 118 S.Ct. 512 (1997).

[20] *Id*. at 524 (Rehnquist, C.J. concurring in part and dissenting in part).

[21] *Id*. at 524 (Rehnquist, C.J. concurring in part and dissenting in part).

[22] For example, see Jennifer Laser, Note, *Inconsistent Gatekeeping in Federal Courts: Application of* Daubert v. Merrell Dow Pharmaceuticals, Inc. *to Nonscientific Expert Testimony*, 30 *LOYOLA OF LOS ANGELES LAW REVIEW* 1379 (1997); see also Jonathan R. Schofield, Note, *A Misapplication of* Daubert: Compton v. Subaru of America *Opens the Gate for Unreliable and Irrelevant Expert Testimony*, 1997 *BRIGHAM YOUNG UNIVERSITY LAW REVIEW* 489 (1997).

[23] Not only did *Daubert* generate controversy about its application to nonscientific expert testimony, it also has stirred up debate about the types of scientific expert testimony it applies to. For instance, in *Moore v. Ashland Chemical, Inc.* (1998), 151 F.3d 269 (5th Cir. 1998), the Fifth Circuit examined whether "soft" sciences should be held to the same evidentiary standards as "hard" sciences.

[24] John M. Conley and David W. Peterson, *The Science of Gatekeeping: The Federal Judicial Center's New Reference Manual on Scientific Evidence*, 74 *NORTH CAROLINA LAW REVIEW* 1183, 1204 (1996).

[25] Brief of the American Automobile Manufacturers Association, the Association of International Automobile Manufacturers, Inc., and Society of Automobile Engineers, Inc. as Amicus Curiae in Support of Petitioners at 3, *Kumho Tire Co. v. Carmichael*, 119 S. Ct. 1167 (1999) (No. 97-1709).

[26] See note 19.

[27] 119 S.Ct. 1167 (1999).

[28] See *id*. at 1175.

[29] Brief of the National Academy of Engineering as Amicus Curiae in Support of Petitioners at 3, *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167 (1999) (No. 97-1709).

[30] *Kumho* at 1172 (see note 27).

[31] Brief of the Association of Trial Lawyers of America as Amicus Curiae in Support of Respondents at 13, *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167 (1999) (No. 97-1709).

[32] See *Daubert* at 591 (Rehnquist, C.J. concurring in part and dissenting in part) (see note 9).

[33] See *Kumho* at 1170 (see note 27).

[34] Revised FED. R. EVID. 702 (enacted December 1, 2000) states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case."

[35] For instance, it is unclear how judges are supposed to determine whether principles and methods are "reliable" when the criteria for determining reliability have not been clearly delineated.

IN THE NEWS

SURVEY REPORTS AMERICANS' ATTITUDES TOWARD THE INTERNET

A July 10th report found that Americans have a positive view of the Internet, but concerns about on-line accountability have influenced many to support increased regulation. The report presents the results of a study funded by the Markle Foundation. The Foundation stressed the need for a well-informed dialogue at a time when enacted policy will serve as precedent for the future of Internet regulation.

The study found that most Americans who use the Internet have a strongly favorable attitude towards it, but have concerns regarding privacy, security, accuracy of information, and objectionable content. In a finding that does not bode well for on-line retailers, the study reports that Americans tend to regard the internet as an information resource, rather than as a venue for commerce or as a financial tool. This being the case, 70% of Internet users say that it is important to question the accuracy of the information that one reads on-line. While almost 80% of Internet users agree that the Internet makes life easier, close to half consider the net to be a "source of worry." The study found that pornographic and violent content on-line was the greatest cause of worry, followed by the safety of children, privacy, fraud, and cyber crime.

These concerns all stem from what the public views as a general lack of accountability on-line. Most internet users are con-

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fused as to what rights and protections they have while using the Internet, and most of those surveyed say that they would not know whom to turn to if they experienced problems while on-line. Experts and the public disagree over what should be done about the issue. A clear majority of the public favor government regulation of the Internet, while experts remain evenly divided. Both groups feel non-profit organizations and the private sector have a significant role to play in shaping Internet policy. While there is a strong sentiment that the Internet requires some form of governance, half of those surveyed agree with the statement that "the Internet is impossible to govern."

Some have questioned the relevance of public opinion on a highly technical topic that most Americans fail to fully comprehend. While 55% of those surveyed say that the views of the public should play an important role in shaping Internet policy, a 53% majority also says that the public does not know enough about the internet to have a meaningful say about its governance. The Markle Foundation explains that the Foundation intentionally conducted the study at a time in which most people's views regarding the Internet are still in their "formative stage." The Foundation believes that reporting on the "values, preconceptions, and initial reactions" of the public stands to make a valuable contribution to the developing debate over Internet policy.

The report can be viewed at: http://www.markle.org/news/_news_pressreport_index.stm *BJK

MD COURT CRITICIZES STUDY

On August 16, the Maryland Court of Appeals issued a caustic opinion in a case between two Maryland families and the Kennedy Krieger Institute, an affiliate of The Johns Hopkins University. (Grimes v. Kennedy Krieger, Institute, Inc.; Higgins, et al. v. Kennedy Krieger Institute, Inc.)

In 1993-1994, researchers at The Kennedy Krieger Institute conducted a study, funded by the Environmental Protection Agency and the Maryland Department of Housing and Community Development, to examine the impact varying degrees of home-repair have on lead-paint ingestion by children and to determine less expensive ways landlords can reach adequate lead abatement. In his 98-page opinion, Judge Dale Cathell likened the experiment to the infamous Tuskeegee syphilis experiments saying that "otherwise healthy children . . . should not be enticed into living in, or remaining in, potentially lead-tainted housing." Cathell said that the Johns Hopkins Institutional Review Board (IRB) overseeing the research encouraged researchers to rewrite consent forms to avoid some of the more stringent federal regulations concerning the protection of human subjects, thereby intentionally misleading the subjects as to the nature and risks of the experiment. He then asserted the courts' jurisdiction over informed-consent agreements as contracts and ruled that parental consent alone is not enough in studies that have no therapeutic benefit for the children involved or are otherwise ethically questionable. Cathell also questioned the ability of IRBs in general to evaluate objectively the research conducted by institutional researchers, saying review boards have as much interest in the success of the research as in the ethics of it.
For the study, Kennedy Krieger encouraged landlords to rent to families with small children, the group most susceptible to lead poisoning. The resulting 108 families were separated into five groups. One group lived in lead-free homes while the other four groups were in homes that received or had already received varying degrees of lead-removing renovations. Researchers regularly tested the homes and children for lead throughout the experiment, offering parents compensation for participating in testing and interviews. The two families in the suit charge that they were not adequately informed by researchers of the continued lead risk in their partially-renovated homes nor of their children's rising blood-lead levels that allegedly resulted in permanent cognitive impairment in at least one of the children.

Just after the opinion was issued, Johns Hopkins received notification of an investigation into the project by the U.S. Office on Human Research Protection (OHRP). In July of this year, OHRP placed a moratorium on all federally-funded human subjects research at The Johns Hopkins University, including research at Kennedy Krieger. That action followed from the June death of a healthy volunteer in an asthma study at the University. The ban was eased after five days, although many projects are still on hold, pending further review. At that time, the OHRP expressed concern that the Johns Hopkins IRB was not adequately reviewing research project proposals prior to approval nor thoroughly monitoring research already in progress. An external review committee appointed by the University's president echoed that concern in an August 29 report on the asthma study saying that "interviews suggest that many people at Hopkins believe that oversight and regulatory processes are a barrier to research and are to be reduced to a minimum rather than . . . serving as an important safeguard." IRBs nationwide are analyzing how these events could impact their policies and procedures.

The Kennedy Krieger case reached the Appeals Court after two Baltimore judges each dismissed one of the lawsuits without trials, granting summary judgment for Kennedy Krieger. The Appeals Court vacated both grants of summary judgment and remanded the cases for trial. Meanwhile two other Kennedy Krieger studies into the effects of different treatments on blood-lead levels are still ongoing. The full text of the opinion is available at http://www.courts.state.md. us/opinions/coa/2001/128a00.pdf. *KS

COUNCIL FOR RESPONSIBLE GENETICS SUGGESTS BAN ON EMBRYONIC MANIPULATION

On June 6, the Council for Responsible Genetics (CRG) released a statement supporting a ban on embryonic manipulation and commercialization.

The CRG statement opposes "the utilization of human eggs and embryos for experimental manipulations and as items of commerce." The CRG endorses a ban on manipulations of eggs or embryos via the transfer of cellular components including nuclei, cytoplasm, mitochondria, chromosomes, or isolated DNA or RNA molecules. The statement applies regardless of whether or not the embryos are to be implanted and gestated.

The CRG acknowledged that such a ban is important to set an example against the commercialization of life. The statement also declares that, "No human embryo is to be produced solely for purposes of research."

A full statement from the CRG and more information can be found online at http://www.gene-watch.org. *JAR

RESEARCHERS CALL FOR REVIEW OF PLACEBO-CONTROLLED GUIDELINES IN REVISED DECLARATION OF HELSINKI

A workgroup has been assembled by the World Medical Association (WMA) to study implications of the nine month-old revisions to the Declaration of Helsinki. Particular controversy surrounds the di-

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rectives concerning the use of placebo control subjects in clinical research studies. October 2000 revisions to the 1996 version of the Declaration further restrict placebo use in human research trials. Some researchers are calling for changes that might alleviate the restrictions imposed in the 2000 revision.

While most changes done in October were embraced by the research community, extensive controversy still surrounds Article 29. This section declares, "the benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists." In other words, contrary to many national research protocols, which allow the more liberal use of placebo controls, the new international directive restricts the use of placebos in cases where a current treatment might otherwise improve the health condition of a study patient.

The Council for International Organizations of Medical Sciences (CIOMS) represents the views of researchers in opposition to the current version of the Declaration of Helsinki. CIOMS is a non-governmental, international organization established by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949 to serve the scientific interests of the international biomedical community. They argue that withholding the best current treatment from placebo control groups results in no serious adverse consequences. Patients are likely to experience only temporary discomfort. It is therefore implied that the benefits of withholding short-term treatment far outweigh the long-term risks to the patient.

They go on to insist that the scientific and ethical suitability of placebo-controlled studies is expanded when patients are switched to active treatments under circumstances where intolerable symptoms continue. Further, researchers argue that lack of a negative control, provided by an untreated placebo group, will compromise the scientific results of the trial. No reliable data will be yielded in a comparison of two treatments without such a control group.

The Declaration of Helsinki is a widely held international code of ethics, establishing principles for medical research involving human subjects. It has been revised only five times since its initial adoption in 1964. The current version can be found at http://www.wma.net/. If the workgroup appointed by the WMA agrees on the need for further modifications, the issue will be addressed at the WMA assembly this fall. **MD*

GENETIC SCREENING FOR ABNORMAL EMBRYOS

The Human Fertilisation and Embryology Authority (HFEA), the body that *regulates in vitro* fertilization (IVF) in the UK, has agreed in principle to allow embryos to be screened for an abnormal number of chromosomes. The technique called aneuploidy can screen out embryos that are aneuploid (contain more or less than 46 chromosomes). Embryos that contain an abnormal number of chromosomes usually result in a failure to implant in the womb that can lead to miscarriage. For such reasons, HFEA contends that aneuploidy screening would be of particular benefit to women who have suffered repeated miscarriages or unsuccessful IVF. Additionally, the screening would also likely increase the success rate of IVF by eliminating embryos that have little chance of implanting in the womb.

A fertilization clinic in London and another in Nottingham have applied for licenses to conduct aneuploidy screening. A spokesman for HFEA stated that "any such license would be subject to satisfactory inspection of the intended laboratories; approval of clinic staff; the provision of detailed technical and patient information; and ongoing monitoring." HFEA recognizes that although the technique is used in a number of fertilization clinics around the world, it is still in its early stages of utilization and needs to be overseen.

Paul Scriven, a principal scientist at Guy's and St. Thomas's Hospitals NHS Trust in London, said that with present aneuploidy testing methods, "it is too easy to misdiagnose a normal embryo as abnormal and therefore not attempt to transfer it into the womb." Other opponents of the screening are concerned that it is another step toward designing a "perfect" baby. Richard Nicholson, editor of the *Bulletin of Medical Ethics*, said that, "it is important to realize that the same technique has be used to screen out other abnormalities like Down's and Turner's syndrome." Until now, fertility specialists in the UK have only been permitted to screen for specific genetic disorders. However, aneuploidy screening can detect a whole range of genetic abnormalities, leading some to worry about indiscriminate screening that could "eliminate" an embryo for what most would now consider a minor genetic flaw.

No licenses for aneuploidy screening have been issued yet. Further information on HFEA can be found on the WWW at: http://www.hfea.gov.uk/. **RJG*

NORD ISSUES GENE PATENTING STATEMENT

In May 2001, the National Organization for Rare Disorders (NORD) issued a statement condemning the U.S. Patent and Trademark Office's (PTO) policy of allowing scientists and corporations to patent genes and gene sequences even before any applications of this knowledge are known.

NORD's policy position regarding the patenting of genes states that the practice restricts scientific research, thereby limiting the development of therapies and pharmaceuticals that could benefit millions of people. It argues that preventing research on any illness, particularly those with a genetic basis, is "unethical." The organization calls on PTO and the federal government to disallow future patenting of genes or gene sequences. According to the statement, Congress should enact a "compulsory licensing law" that requires free access to genes by researchers without having to pay fees or sign confidentiality agreements. Claiming that genes are not *inventions* (and thus protected by PTO as such), NORD calls for the federal government to monitor current gene patent holders so that the latter could not require royalty payments or secrecy agreements unless the gene or gene sequence has been changed or engineered in order to create a product for commercial use. According to NORD, until such time, free access to genes should be mandated in order to foster research. The full statement can be found at http://www.rarediseases.org **VG*

IN THE SOCIETIES

AMA ADOPTS NEW PRINCIPLES OF MEDICAL ETHICS

For the first time in twenty-one years, the American Medical Association (AMA) adopted two new principles and revised existing principles as a part of its Medical Ethics. On June 17, 2001, the *Revised Principles of Medical Ethics* were adopted. The action represents a change toward emphasizing patient care and providing access to medical care for all people.

The most notable change to the document is the addition of Principles VIII and IX.

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Principle VIII reads, "A physician shall, while caring for a patient, regard responsibility to the patient as a paramount." Principle IX reads, "A physician shall support access to medical care for all people."

Privacy was added to Principle IV's list of patient rights. In Principle V, the words "maintain a commitment to medical education" were added to the list of physician duties. Under Principle VII, in addition to recognizing community activities, a physician should also recognize activities contributing to the "betterment of public health."

The Preamble to the *Revised Principles of Medical Ethics* now emphasizes that "a physician must recognize responsibility to patients first and foremost…" The introduction stresses that the principles are standards of conduct, not laws, that "define the essentials of honorable behavior for the physician."

For a copy of *Principles of Medical Ethics* or more information, see http://www.ama-assn.org/ama/pub/printcat/4256.htm. **JAR*

ESA URGES MORE PEER REVIEWED RESEARCH ON ENVIRONMENTAL EFFECTS OF GMOS

Genetically modified organisms (GMOs) may or may not pose undue threat to global ecological health. In light of the current paucity of conclusive data, the Ecological Society of America (ESA) adopted a statement in May 2001 urging the continued need for peer-reviewed research to address this concern.

"It's important to recognize that some GMOs can possess genuinely new characteristics that may require much greater scrutiny, in terms of scientific research, than organisms produced by traditional techniques of plant and animal breeding," says Diana Wall, ESA committee chair and Director of the Natural Resource Ecology Laboratory at Colorado State University. A copy of the statement can be obtained at http://esa.sdsc.edu/statement 0601.htm.

Specific points of interest include formal possibilities for potential risk associated with the release of genetically modified crops or insects into the natural environment. Potential negative effects include the unintentional creation of new or heartier pests, loss or alteration of natural genetic diversity, or detriment to "non-target" species. Specific fears include the potential for genetically modified salmon, for example, to out-compete native fish populations. In addition, viruses, genetically altered and released to control unwanted insect populations, may have unanticipated effects on other populations of insects, birds or soil organisms.

The society acknowledges the positive potential for GMOs "to play a role in sustainable agriculture, forestry, aquaculture, and bioremediation." However, due to the novelty of GMOs in these instances, "both deliberate and inadvertent releases of GMOs into the environment could also have negative ecological impacts under certain circumstances." ESA, therefore, recommends a cautious approach to the environmental release of GMOs. Long-term, scientifically based risk assessment will prove the safest remedy for environmental concerns associated with the release of genetically modified plants and animals. **MD*

AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE ADDRESSES PRECONCEPTION GENDER SELECTION

According to a May 2001 statement by the American Society for Reproductive Medicine (ASRM), preconception gender selection for nonmedical reasons should not be indiscriminately prohibited or condemned. The practice, ASRM argues, is unlikely to increase the risk to children, women, or society. The technique, unlike preimplantation or prenatal sex selection, does not destroy embryos or fetuses or intrude on a woman's body. The ASRM statement provides an in-depth ethical analysis of preconception gender selection after describing selection techniques.

Although ASRM maintains that preconception sex selection would unlikely have any dire consequences for individuals or society as a whole, it cautions against the practice's widespread use. Recognizing the significant ethical concerns related to preimplantation genetic diagnosis for sex selection, the Committee attempted to balance competing concerns for if and when safe and effective techniques become available.

In its arguments for preconception gender selection, of particular importance is procreative liberty, or allowing couples discretion in reproductive matters. Supporters of this argument acknowledge that respect for personal liberty does not make the practice of preconception gender selection inherently good, but maintain that disagreement with a choice is not, independently, reason enough to prohibit it.

On the other hand, many worry that such techniques could serve to strengthen gender discrimination or cause psychological harm to sex-selected offspring due to unattainable parental expectations. On the societal level, some are concerned that preconception selection could lead to sex ratio imbalances or the commodification of offspring. ASRM claims that of the arguments against preconception gender selection, the most compelling is that of increased gender discrimination. However, ASRM contends that sex ratio imbalances are highly unlikely and that the technique could even bring the two genders into an improved balance due to gender preferences.

ASRM advises that the most appropriate use of preconception gender selection techniques would be to use them only to increase the gender variety of the individual family. However, it recommends that four conditions for parents be followed. Potential parents should be advised of the risk of failure in preconception gender selection techniques. They must affirm that they will fully accept children of the opposite gender if the technique fails. Additionally, parents must be counseled not to have unrealistic expectations about their children's behavior due to their gender. Finally, they must be offered the opportunity to participate in research regarding the safety and efficacy of preconception selection. The full statement can be found in *Fertility and Sterility*, Volume 75, No.5, May 2001, 861-864)
**VG*

ENDOCRINE SOCIETY APPROVES CODE OF ETHICS

In January, the Endocrine Society approved a code of ethics drafted by its Ethics Advisory Committee. In two sections, the Code outlines the responsibilities of the society as an organization and those of its members, while establishing official positions on controversial issues such as embryonic stem cell research.

The stated purpose of the Code is to identify the highest standards of professional behavior, to delineate expectations for the conduct of individual members, and to support adherence to those expectations through the issuing of sanctions for violations. The sanctions outlined in the Code include expulsion from the society and prohibition from publishing in any of the Society's journals. However, Joan Zaro,

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the Society's director of Governance and Policy, states that for liability reasons the Endocrine Society has no mechanism in place for the issuing of sanctions.

Among the standards that the Society outlines for itself in the Code is the complete disclosure of industry ties to avoid conflicts of interest. In the section delineating standards of conduct for Society members, the Code emphasizes such issues as the need for respectful treatment of human research subjects and patients, and the importance of the sharing of intellectual property and research tools.

Taking the opportunity to address a controversial issue faced by its members, the Endocrine Society's Code of Ethics endorses the National Bioethics Advisory Committee's recommendations on stem cell research (http://www.bioethics.gov/pubs.html) and the guidelines on embryo research developed by the American Society for Reproductive Medicine (http://www.asrm.com/Media/Ethics/informedc.html). The Code reiterates the Endocrine Society's stance on embryonic stem cell research that it issued in a 1999 letter to the National Institutes of Health, stating that "research utilizing human pluripotent stem cells for both basic knowledge and clinical applications is encouraged." Diabetes, one of the most costly endocrine disorders, is among the diseases that stem cell therapy could eventually treat or cure.

To view the Endocrine Society's Code of Ethics, see: http://www.endo-society.org/pubrelations/ethics.cfm *BJK

ETHICS, LAW AND PUBLIC POLICY

The following article is reprinted in part with author's permission from *The Scientist* 15[11]:35, May. 28, 2001. Since its original publication, the Bush Administration issued a revision on August 9 of the embryonic stem cell policy set by its predecessor. The new policy allows federal funding of ES cell research to proceed, but only on existing cell lines.

CYNICAL SCIENCE AND STEM CELLS

By Arlene Judith Klotzko

So powerful has the language of science become that it has in effect been hijacked by those who seek to discredit or even derail it. Two cases in point: Creationists are repackaging their message as the pseudoscience of "intelligent design theory." And pro-life groups are misusing real science, remarkable advances with adult stem cells, to argue that there is no need for embryonic stem cell research—research that carries with it virtually limitless potential for the alleviation of human suffering.

The real scientists seem to be losing the argument. The National Institutes of Health canceled the first meeting of the committee set up to review applications seeking federal funds for human embryonic stem cell research. For some time, there have been ominous signs. Shortly after taking office, President George W. Bush asked Tommy Thompson, his Secretary of Health and Human Services, to review the legal basis for the NIH stem cell guidelines. With this latest development, the future of stem cell research—and with it the prospect of finding treatments for hitherto intractable chronic disease and disability—is clearly at grave risk.

Embryonic stem cells have the potential to develop into all basic tissue types—but not into a human being. They could provide a virtually limitless source of tissue for transplantation. Adult stem cells are more problematic. While their destinies are not as limited as we had once believed, they tend to occur in low numbers and to be hard to access and isolate.

There have been promising advances in redirecting adult stem cells to become something Mother Nature never intended—blood into nerve, for example. Recently, scientists working with fat sucked out of patients during liposuction were able to isolate stem cells that, in a laboratory dish, gave rise to cells that make muscle, bone, and cartilage and also to cells that made more of themselves.[1]

However, some remarkable feats of adult stem cells seem more like party tricks than the predictable, controllable metamorphoses that would be required before actual human therapies could be undertaken. It would be very convenient if the spare tire around our waists could be sucked out and turned into replacement patches for failing hearts, but we are not there yet. Not even close.

Debating Tactics

Tactically, resorting to science or pseudo science is a pretty good strategy. When one runs up against the stone wall of opposition in a morally fraught political cause or line of argument, there are only two choices. We can make a moral argument for a somewhat limited audience: those who already agree or at least are disposed to be brought around. Or we can search about for some alternative scientific theory and find a much wider number of potential adherents. If we throw a sufficient number of scientific terms into the mix, it will seem that a stem cell is a stem cell is a stem cell.

Letters to the Editor: The editors welcome comments from our readers. We reserve the right to edit and abridge letter as space permits. Please address all correspondence to the deputy editor.

The overwhelming consensus among real scientists about the state of real science is that no avenue of stem cell research can be safely ignored. We simply don't know what types of cells would work best for particular diseases. Those seeking to exploit exciting and potentially life-saving adult stem cell breakthroughs to advance their religious views and political goals are not just misusing science; they are perverting it.

And if all goes as the opponents hope—and federal funding for embryonic stem cell research is stopped in its tracks—science's most unlikely cheerleaders may well be responsible for ceding leadership of this major area of research to Great Britain. In January, after a surprisingly contentious debate lasting more than eight hours, the British House of Lords voted overwhelmingly to allow research on embryonic stem cells, this following an equally lopsided victory in the House of Commons one month before.

Differences Across the Atlantic

In Britain, creation of embryos specifically for research was made legal by the Human Fertilisation and Embryology Act of 1990. However, the permissible purposes of such research had been circumscribed. Embryo research could be conducted only to increase understanding of infertility and to improve techniques of in vitro fertiliza-

Arlene Judith Klotzko, a lawyer and bioethicist, is writer in residence at the Science Museum, London, and visiting scholar in bioethics, The Windeyer Institute of Medical Science, University College, London. Her anthology, *The Cloning Sourcebook* [See *PER* RESOURCES] was published this month by Oxford University Press.

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tion.
Under the new legislation, drafted as an amendment, embryo research related to cell and tissue therapies would also be allowed. This includes so-called therapeutic cloning or—as it has been termed by the policymakers keen to avoid any association with reproductive cloning—cell nuclear replacement. What they have made legal is something akin to a Woody Allen script run backward. In Allen's 1973 film Sleeper, attempts are made to clone Hitler from his preserved nose. Instead of cloning people from spare parts—or spare cells, as is the case with the animal and human reproductive cloning—British scientists hope to grow those parts by cloning people.

This procedure is the same as the one used to create Dolly the sheep.[2] Up to a point. The nucleus from a human cell is inserted into an egg that had its own nucleus removed. An embryo is formed. But the embryo will not be implanted in a uterus. Instead, embryonic stem cells will be derived from its inner cell mass. Because cloning is done first, there will be no problem with immunological compatibility.

Because of pervasive disquiet about any form of cloning—and a very real threat that the amendment would be scuttled by a behind-the-scenes move to refer the entire question to a House of Lords Select Committee, thereby killing this research for at least two years—a compromise was cobbled together at the last minute: The legislation would be passed immediately and the Select Committee review would start later. The Select Committee was then formed, and it has recently held its first meeting.

As further reassurance for anxious peers, the health minister, Lord Hunt, promised that the government would introduce primary legislation to ban reproductive cloning, the legal status of which is somewhat ambiguous. It probably is technically legal, at least for the moment. To add to the legal murkiness, a court challenge to the new regulations was filed at the end of January, less than a week after the Lords' vote. The crux of the legal argument is that the Human Fertilisation and Embryology Act (including the amendment to it just passed) is not applicable at all to therapeutic cloning because the act defines the word embryo as the product of fertilization. Not somatic cell nuclear transfer.

Meanwhile, back on our side of the Atlantic, the...use of federal funds for embryonic stem cell research... is far more modest in scope than the British scheme. Two of the steps described above would be left out. There is no plan to use federal funds to support therapeutic cloning, and the embryo will not be created specifically for cell therapies.

Of course,... even without federal government involvement, embryonic stem cell research will go forward in the United States. But it won't be the full-scale effort that we all deserve—an effort that could exploit the vast intellectual potential of U.S. science. Federal funding is imperative because of the resources it would provide and the ethical and scientific oversight it would mandate.

No one is exempt from the scourge of the chronic diseases for which stem cell-derived therapies hold the promise of cure. Patients, future patients, and loved ones of patients—we all have a stake in the president's decision.

References

1. P.A. Zuk et al., "Multilineage cells from human adipose tissue: Implications for cell-based therapies," Tissue Engineering, 7:211-8, April 2001.
2. I. Wilmut et al., "Viable offspring derived from fetal and adult mammalian cells," *Nature*, 385:810-3, 1997.

RESOURCES

BOOK REVIEW
The Cloning Sourcebook, Edited by Arlene Judith Klotzko (Oxford University Press, 2001, $34.95, 328 pp.)

Are humans next on the list of organisms to be cloned? And if so, is it ethical to go about doing this? After announcing the success of Dolly, many people have asked these questions of scientists. Understandably, even these experts may not have all the answers.

In *The Cloning Sourcebook*, Editor Klotzko compiles interviews and papers from scientists and bioethicists alike to address the many opinions and implications of cloning technology. The book includes worldwide resources and perspectives that offer insight to the reader regarding the many challenges that cloning opportunities present.

The volume is divided into four sections that address the scientific, contextual, ethical, and policy issues of cloning. In many instances, human and animal cloning comparisons are made. Almost every article refers to the cloning of Dolly and what it means to humans to have access to such technology. Pursuant to this, questions of technological regulation, privacy, and genetic rights are discussed. The underlying theme of the book is, "Where should we draw the line when it comes to human cloning decisions?"

International perspectives on the issues that surround human cloning are included. Legislation from the UK allowing human cloning for therapeutic purposes is discussed. Media, theology, and family issues are all included within ethical discussions. Both pro and anti-cloning perspectives are included. Klotzko opens the book with an interview with Ian Wilmut, the leader of the team that cloned Dolly, and his colleagues at the Roslin Institute and PPL Therapeutics. From here, the reader is introduced to the scientific steps required in cloning.

Cloning advocates such as Lee Silver provide perspectives on the safety, professional opinions, and misunderstandings of human cloning. He offers his opinions on the effects of cloning on children, society, and religion. Soren Holm, on the other hand, provides a chapter on "One Reason We Should Not Clone Humans," discussing genetic essentialism as a common cultural belief.

Anyone with an interest in cloning will find this book a valuable resource for a wide range of views on the topic. *JAR

ANNOUNCEMENTS

Conference- The conference **"Beyond Cloning: Protecting Humanity from Species-Altering Experiments,"**will be held September 21-22, 2001, at Boston University. This conference addresses the need for policies to prevent the alteration of the human species through genetic engineering. It will discuss where lines should be drawn, lessons learned from existing policies and procedures, and new national and international approaches and mechanisms for proscribing species-altering experiments. Program and registration information is available online at http://www.bumc.bu.edu/www/sph/lw/website/index.htm.

Research Grants- **The Office of Research Integrity (ORI, DHHS), the National In-**

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stitute of Neurological Disorders and Stroke and the National Institute of Nursing Research invite applications to support research on research integrity. "Integrity" in this context is understood as "adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms." The proposed grant program is intended to foster empirical research on the institutions, processes and values that influence integrity in research. The letter of intent deadline is October 15, 2001, and the grant application must be received by November 19, 2001. The ORI intends to commit approximately $500,000 in FY 2002 to fund three to five new grants with project periods of up to two years and a direct cost budget up to $100,000 per year. See http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-02-005.html.

Conference- A **Round Table of Ministers of Science** from around the world will convene at UNESCO Headquarters in Paris on October 22-23, 2001. The subject of the event will be "Bioethics, International Implications." The round table is intended to promote flexible dialogue on the topic, which could shape UNESCO's future actions in the realm of bioethics, and more broadly in how UNESCO approaches its goal of promoting ethical norms to guide scientific progress. The round table will include four sessions that will focus on "concepts and founding principles of bioethics," "current challenges of bioethics," "awareness raising, information, education and public debate," and "institutional and regulatory norms and systems: the case for a universal text on bioethics." Contact Mr. G. Kutukdjian, the UNESCO director of the Division of Human Sciences, Philosophy and Ethics of Science and Technology, for additional information at g.kutukdjian@unesco.org.

Meeting- PRIM&R and ARENA are pleased to announce their **2001 annual IRB meetings**, to be held December 1-4, 2001 in Boston, Massachusetts. December 1: IRB 101 - Educational Training Program for IRB Newcomers and Investigators & RCR 101 - Teaching Responsible Conduct of Research: Tools and Methods. December 2: The 15th Annual Meeting of The Applied Research Ethics National Association. December 3-4: IRBs and New Approaches: Assessing, Evaluating, Discarding and Moving Forward. Complete program information and online registration is available through the PRIM&R Web site at http://www.primr.org.

Conference- The **2001 Jerome B. Wiesner Symposium**, entitled "Braving the New World, Benefits and Challenges of Genetic Knowledge," will be held December 7-8, 2001, at the University of Michigan. Discussion will focus on the effects of genomics on social life, the expanding horizon of what is humanly possible, and perceptions of life itself. Plenary sessions will be held on "race, ethnicity, and the human genome," "genes and human nature," and "designing life." Attendance will be free but registration is required, and is available on-line at http://www.wiesner.research.umich.edu/2001/index.html. For updates and more information, send a message to wiesner2001@umich.edu.

Call for Papers/Conference- The conference **"Research in Ethics and Engineering,"** hosted by the Department of Philosophy of Delft University of Technology, will be held April 25-26, 2002, in the Netherlands. The conference will bring together those working in the broad fields of ethics and engineering to exchange ideas, and will focus on the themes of "autonomy and professional context," "risk," and "ethics and engineering and other applied ethics." Paper submissions on these themes are invited for half-hour presentations and subsequent publication. The deadline for abstract submissions is December 15, 2001, and the deadline for papers is March 1, 2002. For more information, see the conference Web site at http://www.ethiek.tudelft.nl/conference2002/.

Call for Papers- Submissions are being requested for **The Journal of Philosophy, Science & Law**, a new online journal. The journal is an interdisciplinary forum that seeks to stimulate research and publish articles in areas including philosophical issues associated with science policy and the growth of technology, philosophy, the legal system, and scientific evidence, the effect of legal and ethical guidelines on scientific research, and educational issues relating to how legal and ethical guidelines are taught within scientific fields. Submissions of scholarly articles, book reviews, profiles of legal cases, conference reports, and policy proposals will be considered for publication. Accepted articles will be available online following the journal's peer review process. Submissions, preferably via e-mail, should be sent to Jason Borenstein, Editor, Georgia Tech School of Public Policy, 685 Cherry Street, Atlanta, GA 30332 Email editor@psljournal.com

New Publication - **Geneforum.org**: Building an Informed Citizenry for the Gene Age is introducing a newsletter dealing with geonomic breakthroughs. The Internet represents a tremendous tool with great potential for educating and engaging the electorate in the development of policies guiding biotechnology research.

Toward this end, geneforum.org, a nonprofit, nonpartisan organization headquartered in Portland, Oregon, was created in 1999 to promote dialogue and educate people about genome science and its impact on their lives.(http://www.geneforum.org)

Reflecting this mission, geneforum.org's electronic newsletter, *The DNA Dispatch*, is designed to keep subscribers abreast of the latest breakthroughs in genome science and biotechnology. Recently, there have been calls for "A national and international dialogue on the acceptability of IGM (inheritable genetic modification) techniques" (Frankel & Chapman, *Science* 292:1303, May 18, 2001). Inheritable genetic modification refers to any genetic alteration that can be passed on to descendents.

To help facilitate a public dialogue on the social, legal and ethical issues raised by IGM techniques, the October, 2001 issue of the *DNA Dispatch* will feature an interview with Eric Juengst--Case Western Reserve bioethicist and first Chief of the Ethical, Legal, and Social Implications Branch of the National Human Genome Research Institute at NIH-on genetic enhancement and IGM techniques.

For those visitors to the Geneforum.org website interested in learning more about the topic, the same issue of the Dispatch will also feature a link to a new interactive scenario on IGM techniques created by Amber Roche, a second-year student in the Institute for Public Health Genetics Program at the University of Washington, Seattle. Contact G. Fowler, Geneforum.org; (503) 675-0772;Email gfowler@geneforum.org

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Professional Ethics Report
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American Association for the Advancement of Science
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