

BIOTECHNOLOGY AND THE BAR: A RESPONSE TO THE GROWING DIVIDE BETWEEN SCIENCE AND THE LEGAL ENVIRONMENT

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The future is now with respect to biotechnology; we now have the tools to shape succeeding generations of human nature. The question facing legislatures is not “can we?” but “should we?” To find a durable answer to this question as it arises in the judicial system requires a sophisticated blend of scientific information and adjudication techniques that can be applied to cases raising novel biotechnology issues.

This Article is based on a lecture delivered by the Honorable Thomas J. Moyer, Chief Justice of the Supreme Court of Ohio, in the Republic of Chile during March 2004 as part of the United States Speaker/Specialist Program sponsored by the United States Department of State. The lecture focused on the reality that every judicial system in the world will soon face legal issues that arise from advancements in biotechnology. To assist these judicial systems in the management of such cases, the Chief Justice discussed the manner in which the United States has addressed the increasingly difficult relationship between biotechnology and law.

Yet, however embedded in descriptive terms, Chief Justice Moyer’s lecture had a more forward-looking objective: the creation of an institution that would mediate between science and the legal environment. To that end, Chief Justice Moyer, together with Dr. Franklin Zweig, president of the Einstein Institute for Science, Health, and the Courts in Washington D.C., has endorsed a national program designed to prepare

judges to preside over cases involving complex scientific issues. That program is known as “ASTAR”—the Advanced Science and Technology Adjudication Resource Center. Now moving from concept to reality, ASTAR will soon affect the manner in which biotechnology cases are adjudicated in state and federal courts around the nation. This Article explores that program and, in so doing, examines many of the legal issues that biotechnology inspires.

I. INTRODUCTION

During the past two decades, our nation has experienced an explosive growth of scientific and technological knowledge. That knowledge has given rise to an increasing number of legal disputes involving science- and technology-related issues.¹ Although legislative parliaments are better suited to resolve legal issues presented by advancements in science and technology, courts often render legal decisions first about emerging technologies because parliaments are slower to act.

State and federal courts have thus been forced to react, often without the requisite scientific training or education to make an informed decision regarding whether scientific evidence is a cutting-edge breakthrough or what has been called “junk science.”² Key cases from the United States Supreme Court and state supreme courts further complicate this issue by affording trial courts discretion to evaluate not only the methodology behind the science but also the reasoning process to reach the scientific conclusion. Increases in the complexity of technology, particularly in areas of biotechnology such as DNA forensics, genetic engineering, and genetic privacy, only aggravate the problem.

This Article explores a ground-breaking institution, known as the Advanced Science and Technology Adjudication Resource Center (“ASTAR”), which offers standardized training to judges around the nation to handle the increasing volume of complex, high-tech cases on court dockets. With the participation of over thirty-five states, ASTAR aims to provide a response to the problem facing every jurisdiction in the nation: that, in the words of U.S. Supreme Court Justice Stephen Breyer, “a judge is not a scientist and a courtroom is not a scientific laboratory,” but that “to

1. *See* *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 149 (1997) (Breyer, J., concurring) (citing Judicial Conference of the United States, Report of the Federal Courts Study Committee 97 (Apr. 2, 1990) (“Economic, statistical, technological, and natural and social scientific data are becoming increasingly important in both routine and complex litigation.”)).

2. *See also* C. WRIGHT & V. GOLD, *FEDERAL PRACTICE AND PROCEDURES* § 6266, at 265 (1996).

do our legal job properly we [need] to develop an informed, though necessarily approximate, understanding of the state of . . . scientific art.”³

To better understand the need for an institution such as ASTAR, Part II of this Article begins with a brief background on the evolution of the admissibility of scientific evidence in federal and state courts and focuses on the evolving role of judges as “gatekeepers” to determine the admissibility of scientific evidence. This Article then examines three areas of biotechnology that will soon challenge (or have already begun challenging) the scientific literacy of courts. Part III discusses the use of DNA forensics in criminal trials. Part IV examines the practice of genetic engineering and relates the ongoing and future legal issues inspired by genetically modified organisms. Part V explores genetic privacy and the ability of insurance companies and employers to discriminate on the basis of genetic information. Finally, Part VI argues that ASTAR is an institution well on its way to assisting courts in resolving both these biotechnology issues and those beyond the scope of this Article.

II. ADMISSIBILITY OF SCIENTIFIC EVIDENCE

In understanding the evolving relationship between biotechnology and the legal environment, it is useful to first appreciate the evolution of the rules governing the admissibility of scientific evidence. Scientific evidence is “any demonstrative and testamentary information that uses the techniques of science to assist the trier of fact in deciding which of two or more theories explain what, why, who, and when something happened which is the object of contention in a trial.”⁴ Scientific techniques, however, can often be manipulated to reach a desired result.⁵ The primary

3. Shirley S. Abrahamson, *Forward*, 83 JUDICATURE 102, 102 (1999). Justice Breyer has noted that “law itself increasingly needs access to sound science” and that scientific technology “increasingly underlies legal issues of importance to us all.” *Id.* As a result, Justice Breyer has exhorted judges to “build legal foundations that are sound in science, as well as in law . . . to resolve many of the most important human problems of our time.” *Id.*

4. Anna M. Michalak, *Environmental Contamination with Multiple Potential Sources and the Common Law: Current Approaches and Emerging Opportunities*, 14 FORDHAM ENVTL. L. REV. 147, 195 (2002) (citing William G. Eckert & Ronald K. Wright, *Scientific Evidence in Court*, in INTRODUCTION TO FORENSIC SCIENCES 69 (William G. Eckert ed., 1997)).

5. The Supreme Court expressed its dissatisfaction with adversarial expert testimony nearly a century-and-a-half ago, noting that “[e]xperience has shown that opposite opinions of persons professing to be experts may be obtained to any amount . . . wearying the patience of both court and jury, and perplexing, instead of elucidating, the questions involved.” *Winans v. N.Y. & Erie R.R.*, 62 U.S. 88, 101 (1858). Courts impose a differ-

charge of American courts as technology pervaded society, therefore, was to consider—or, more precisely, to reconsider—the standard that should govern the admissibility of expert testimony relating to scientific evidence.⁶ This Part reviews the evolution of this standard and traces the growing importance of the trial court as the “gatekeeper” to the admissibility of scientific evidence.

A. Pre-*Daubert* — The *Frye* Test

Prior to 1993, many courts had adopted the rule that scientific evidence was admissible if the scientific technique from which the evidence was derived was sufficiently established to have gained “general acceptance” in the relevant scientific community.⁷ The D.C. Circuit Court of Appeals first enunciated this “general acceptability” standard in *Frye v. United States*⁸—a 1923 decision involving a primitive form of the modern polygraph.⁹ Although *Frye* received little immediate attention, judges began to invoke the “general acceptability” test as litigants increasingly offered novel and dubious forms of scientific evidence in court.¹⁰ In time, the *Frye* test became the prevailing analytic framework by which to de-

ent admissibility standard for expert witnesses in part because, unlike lay witnesses, expert witnesses need not have knowledge of the facts relevant to the case. As a result, the pool of available expert witnesses is significantly larger than the pool of lay witnesses, which “enables parties to shop for expert testimony—especially with the growth of the expert witness business.” Tim Cram, Arthur J. Hartz & Michael D. Green, *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 719 (2002). In addition, “the psychology of adversarial litigation and subtle pressure on adversarial experts contribute to greater disagreement by experts.” *Id.*

6. For a discussion of the various evidentiary approaches courts employed during the technology era, see John D. Borders, Jr., Note, *Fit to Be Fryed: Frye v. United States and the Admissibility of Novel Scientific Evidence*, 77 KY. L.J. 849, 864-73 (1989).

7. See *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923); see also Richard L. Marcus, *The Agenda-Setter for Complex Litigation*, 149 U. PA. L. REV. 1257, 1264 (2001) (noting that this test “had been roundly attacked by commentators but still prevailed in most courts”).

8. 293 F. at 1014.

9. *Id.* Prior to the widespread adoption of the *Frye* standard, “most courts only asked whether the expert was ‘qualified’ before admitting the expert’s testimony and, in some jurisdictions, whether the subject matter in issue was beyond the range of knowledge of the average juror.” Joseph Sanders, *The Merits of the Paternalistic Justification for Restrictions on the Admissibility of Expert Evidence*, 33 SETON HALL L. REV. 881, 885 (2003).

10. Heather G. Hamilton, *The Movement from Frye to Daubert: Where Do the States Stand?*, 38 JURIMETRICS J. 201, 203 (1998).

termine the admissibility of scientific evidence—a distinction that it would hold for more than half a century.¹¹

The “general acceptability” standard, however, came under attack in the 1960s and 1970s.¹² This attack was partially attributable to the consumer and environmental movements of the time.¹³ Critics argued, for example, that the *Frye* test was too conservative because it imposed a waiting period before a scientific technique was “generally acceptable.”¹⁴ Thus, “an alleged victim of chemical poisoning or some other toxic tort [would be] denied compensation just because his offer of proof could not meet the exacting standards of ‘acceptance’ in a broader scientific community.”¹⁵ This fact—coupled with the view that *Frye* was “elitist and unhelpful” in an era in which the prevailing intellectual mood was anti-establishment¹⁶—set the stage for a reevaluation of the *Frye* test when the legal community drafted the Federal Rules of Evidence in 1974.

When the drafters of the Federal Rules of Evidence codified the principles governing the admissibility of “expert testimony” in Rule 702, they made no mention of “general acceptability.”¹⁷ That rule provided that “[i]f 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 educa-

11. Paul C. Giannelli, *The Admission of Novel Scientific Evidence: Frye v. United States, a Half-Century Later*, 80 COLUM. L. REV. 1197, 1205 n.41 (1980).

12. Peter Huber, *Junk Science in the Courtroom*, 26 VAL. U. L. REV. 723, 732 (1992).

13. *Id.* Huber has described the impetus behind the departure from *Frye* thus: For half a century, *Frye* served reasonably to exclude exotic, unreliable evidence from the courtroom. The rule came under attack, however, in the 1960s and ‘70s. The consumer and environmental movements were gathering momentum at this time. The prevailing intellectual mood was anti-establishment, and *Frye* was seen as elitist and unhelpful, particularly in cases involving new pollutants, and unfamiliar hazards. In the legal world, meanwhile, theories of liability were evolving to give plaintiffs the advantage at trial. *Frye* critics felt that an alleged victim of chemical poisoning or some other toxic tort should not be denied compensation just because his offer of proof could not meet the exacting standards of “acceptance” in a broader scientific community.

Id. at 732.

14. Sanders, *supra* note 9, at 886.

15. Huber, *supra* note 12, at 732.

16. *Id.*; see also Joseph T. Walsh, *Keeping the Gate: The Evolving Role of the Judiciary in Admitting Scientific Evidence*, 83 JUDICATURE 140, 141 (1999).

17. Fed. R. Evid. 702.

tion, may testify thereto in the form of an opinion or otherwise.”¹⁸ Given that Rule 702 did not contemplate the “general acceptance” of a scientific technique as a criterion of admissibility, several federal courts interpreted the rule to supersede *Frye*.¹⁹ Other circuits, by contrast, concluded that *Frye* survived the adoption of Rule 702.²⁰ The United States Supreme Court ended this debate in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*²¹

B. *Daubert*—The Trial Court as a “Gatekeeper”

Daubert addressed whether scientific evidence was admissible in a lawsuit brought by infants and their guardians ad litem against a pharmaceutical company to recover for birth defects. The infants allegedly sustained these defects as a result of their mothers’ ingestion of the anti-nausea drug Bendectin.²² The court of appeals affirmed the decision of the trial court to disallow the evidence because the scientific technique from

18. *Id.* With its emphasis on the reliability of the expert, the rule thus “appear[ed] almost at cross-purposes to *Frye*’s focus on the subject matter of the expert’s opinion.” Walsh, *supra* note 16, at 141. Nonetheless, Rule 703 permitted an expert to rely upon inadmissible scientific information to formulate an opinion provided that such information is “of a type” that experts would reasonably rely upon “in [a] particular field.” *Id.* Rule 703 thus “seem[ed] to suggest a *Frye*-like test without the general acceptance requirement.” *Id.*

19. In support of this view, courts emphasized that the notes accompanying the Federal Rules of Evidence did not mention the vitality of the *Frye* standard in its discussion of the rules governing expert testimony. *See, e.g.*, *United States v. Downing*, 753 F.2d 1224, 1234 (3d Cir. 1985). In *Downing*, Judge Becker noted that, to be admissible, expert testimony on eyewitness identification must survive the preliminary inquiry of the trial court. *Id.* at 1226. The Third Circuit held that a trial judge should conduct an in limine proceeding in which it should consider: (1) the reliability of the scientific principles the expert employed against (2) the likelihood that the evidence may overwhelm or mislead the jury. *Id.* The Fifth Circuit set forth a similar test for determining the admissibility of scientific evidence in *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1110 (5th Cir. 1991) (en banc), *cert. denied*, 503 U.S. 912 (1992).

20. *See, e.g.*, *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985). The Honorable Joseph Walsh, a justice of the Delaware Supreme Court, has noted:

Courts seeking to reconcile *Frye*’s general acceptance test with the more specific criteria imparted by Rules 702 and 703 struggled to provide a consistent practical guide for practitioners. To the extent that *Frye* was viewed as unduly conservative, courts sought to relax its application to avoid the exclusion of evidence, particularly in criminal cases. Also, as more scientific studies and methodology were brought to bear in toxic and pharmaceutical based tort actions, courts struggled to permit the use of innovative science to establish causation.

Walsh, *supra* note 16, at 141.

21. 509 U.S. 579 (1993).

22. *Id.* at 582.

which the evidence was derived was not “generally accepted” as reliable in the relevant scientific community.²³ The United States Supreme Court reversed, holding that Rule 702 displaced the *Frye* test and that the principle of scientific soundness applied to novel as well as conventional techniques.²⁴ That Rule 702 superseded the *Frye* test did not mean, however, that the Federal Rules placed no limitations on the admissibility of scientific evidence.²⁵ To the contrary, the Court concluded that “under the rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”²⁶

To assess whether scientific evidence is reliable, the Court listed four non-exclusive factors that the trial court should consider: first, whether the theory or technique at issue is susceptible to testing and has been subjected to such testing;²⁷ second, whether the theory or technique has been subjected to peer review and publication;²⁸ third, whether there is a known or potential rate of error associated with the theory or technology;²⁹ and

23. *Daubert v. Merrell Dow Pharmaceuticals*, 951 F.2d 1128, 1129-31 (1991).

24. *Daubert*, 509 U.S. at 589; David W. Barnes, *General Acceptance Versus Scientific Soundness: Mad Scientists in the Courtroom*, 31 FLA. ST. U. L. REV. 303, 309-10 (2004) (citing *Daubert*, 509 U.S. 579, 592 n.11 (1993)).

25. *Daubert*, 509 U.S. at 589.

26. *Id.*

27. *Id.* at 593. The rationale supporting such an inquiry, the Court reasoned, derived from the fact that:

Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. “Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.”

Id. (quoting Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of Agent Orange and Bendectin Litigation*, 86 NW. U. L. REV. 643, 645 (1992)).

28. *Id.* The Court noted, however, that:

Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability . . . and in some instances well-grounded but innovative theories will not have been published. . . . The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94.

29. *Id.* at 594. To provide examples of judicial decisions that have examined the error rate and the existence and maintenance of standards controlling the operation of the scientific technique, the Court cited *United States v. Smith*, 869 F.2d 348, 353-54 (7th Cir. 1989) (surveying rate-of-error studies concerning spectrographic voice identification

fourth, whether the theory has been generally accepted in the relevant scientific community.³⁰

The effect of *Daubert*, therefore, was to take “the decision-making process out of the hands of the scientific community, and [to] place[] it in the hands of the trial judge.”³¹ In so doing, the Court described the role of the trial judge as a “gatekeeper”—one that requires judges to admit reliable science and to screen out “junk science.”³² *Daubert* thus converted trial courts from “passive recipients of scientific and technical data” into engaged evaluators of scientific techniques.³³

C. Post-*Daubert*—*Joiner* and *Kumho Tire*

In recent years, the Supreme Court has revisited the doctrinal basis underlying *Daubert* and provided further guidance on the role of the trial judge as a gatekeeper.³⁴ In *General Electric Co. v. Joiner*,³⁵ the Court re-examined its prior assertion in *Daubert* that a judge’s inquiry “must be solely on principles and methodology, not on the conclusions that they generate.”³⁶ Specifically, the Court in *Joiner* addressed the question of whether the judge may examine the reasoning process that linked the methodology (which the judge could consider under *Daubert*) with the con-

technique) and *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978) (reviewing the standard of one organization that governs spectrographic analysis), respectively.

30. *Daubert*, 509 U.S. at 594 (noting that “general acceptance” can yet have a bearing on the inquiry). In analyzing this “general acceptance” factor against the backdrop of *Frye*, the United States Court of Appeals for the Sixth Circuit has noted that:

[G]eneral acceptance is no longer *the* test for admissibility of scientific evidence but now is only one factor to consider. Therefore, it is now less compelling to argue that we should take judicial notice of a report by scientists in the field in order to gauge the “general acceptance” of DNA matching by those in the field.

United States v. Bonds, 12 F.3d 540, 553 n.10 (6th Cir. 1993). Justice Blackmun, writing for the majority in *Daubert*, further noted that the four factors do not constitute “a definitive checklist or test.” 509 U.S. at 593; *see also* David S. Caudill & Lewis H. LaRue, *Why Judges Applying the Daubert Trilogy Need to Know About the Social, Institutional, and Rhetorical—and Not Just the Methodological—Aspects of Science*, 45 B.C. L. REV. 1, 14 (2003).

31. Thomas L. Cooper, *Expert Witness Testimony—Frye Revealed—The Impact of Trach-Fellin II*, 75 PA. B.A. Q. 10, 11 (2004).

32. Walsh, *supra* note 16, at 141, 143.

33. Timothy Zick, *Constitutional Empiricism: Quasi-Neutral Principles and Constitutional Truths*, 82 N.C. L. REV. 115, 181-82 (2003).

34. Walsh, *supra* note 16, at 141.

35. 522 U.S. 136 (1997).

36. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993).

clusion (which the judge could not).³⁷ Answering that question in the affirmative, the Court “affirmed the discretionary authority of a federal judge to reject an expert’s rationale, even where the methods and principles which formed the expert’s opinion are recognized as valid.”³⁸

More recently, the Supreme Court elaborated on the role of the trial judge as a “gatekeeper” in *Kumho Tire Co. Ltd. v. Carmichael*.³⁹ The issue in *Kumho Tire* was whether the subject of an expert’s testimony—tire technology—fell outside the scope of *Daubert* because it was not based on “scientific knowledge.”⁴⁰ Reasoning that Rule 702 makes no distinction between “technical” and “scientific” knowledge, the Court concluded that *Daubert* applies to all expert witnesses, scientific and non-scientific experts alike, who rely on skill or experience to formulate opinions.⁴¹ The Court emphasized that the trial court’s decision with respect to the admissibility of expert testimony is afforded considerable discretion “not only in the acceptance or rejection of the expert’s opinion, but also in the evaluation of the factors leading to that conclusion.”⁴²

Although *Daubert* and its progeny significantly affected the Federal Rules governing the admissibility of scientific evidence, these decisions do not bind state courts.⁴³ Nevertheless, the majority of states have adopted a counterpart to Rule 702, which now codifies similar principles to those of *Daubert*.⁴⁴ Several states—most notably Florida—have rejected the *Daubert* standard and continue to employ the *Frye* test.⁴⁵ Other

37. Gerald J. Todaro, *The Admissibility of Medical Testimony in Ohio: Daubert, Joiner, and Ohio’s Relevance-Reliability Standard*, 46 CLEV. ST. L. REV. 319, 321 (1999).

38. *Id.* at 321-22.

39. 526 U.S. 137 (1999).

40. Walsh, *supra* note 16, at 142.

41. *Kumho Tire*, 526 U.S. at 147.

42. Walsh, *supra* note 16, at 142.

43. *Daubert*, *Joiner*, and *Kumho Tire* do not bind state courts because they were predicated on a federal rule—Federal Rule of Evidence 702—and not on the United States Constitution or federal statute.

44. See J. Eric Smithburn, *The Trial Court’s Gatekeeper Role Under Frye, Daubert, and Kumho: A Special Look at Children’s Cases*, 4 WHITTIER J. CHILD & FAM. ADVOC. 3, 9-34 (2004) (reviewing the standards that have been developed to determine the admissibility of expert testimony). *But see* *Turner v. State*, 746 So. 2d 355 (Ala. 1998) (applying the *Daubert* standard solely in DNA cases because only the DNA statute, § 36-18-30 of the Alabama Code, has superseded *Frye*).

45. *Flanagan v. State*, 625 So. 2d 827, 829 (Fla. 1993). In declining to adopt the standard later announced in *Daubert*, the Supreme Court of Florida offered the following explanation:

While the balancing approach solves the primary concern with the *per se* rule of exclusion, namely that it is too inflexible, the balancing ap-

states have applied *Daubert* only in DNA cases⁴⁶ or have “found *Daubert* [to be] ‘instructive,’ but not necessarily required, of trial courts.”⁴⁷

Despite its widespread acceptance, however, commentators continue to question the merits of *Daubert* and its progeny.⁴⁸ One critic, for example, has noted a “paradoxical assumption” in *Daubert* that “trial judges, as gatekeepers, can effectively and competently apply their level of scientific knowledge to determine the reliability of all sciences . . . as well or conceivably better than each individual well-credentialed scientist who proffers their [sic] evidence.”⁴⁹ Other critics have suggested that despite “their general enthusiasm and diligence,” judges “tend to be highly resistant to the sort of learning that *Daubert* demands.”⁵⁰ Still others contend that judges “tend to be scientifically ignorant, which means that they are not acquainted, let alone conversant, with scientific practice or language.”⁵¹

Whatever the merit of these arguments, judges will face ever-increasing difficulties in their roles as gatekeepers as advancements in biotechnology continue to outstrip the scientific knowledge of courts. The purpose of this Article, therefore, is to explore alternatives that neither defer exclusively to the scientific community regarding the admissibility of scientific evidence (*Frye*) nor endorse the gatekeeping function of trial courts without the impartial aid of the scientific community (*Daubert*). To underscore the need for institutions that provide such an alternative, the

proach may well take the concept of flexibility too far. . . . We acknowledge that the *Frye* rule has come under some criticism since its inception in 1923 as too harsh and inflexible, *see* McCormick on Evidence § 203 (2d ed. 1972); however, we believe that the problems associated with the other recognized judicial approaches foreclose their use.

Stokes v. State, 548 So. 2d 188, 194-95 (Fla. 1989).

46. *See, e.g.*, Turner, 746 So. 2d at 355.

47. Walsh, *supra* note 16, at 142.

48. Mary Elliott Rollé, *Unraveling Accountability: Contesting Legal and Procedural Barriers in International Toxic Tort Cases*, 15 GEO. INT'L ENVTL. L. REV. 135, 143-44 (2003) (noting that some scholars “have argued that the [sic] there is an inherent unfairness in allowing judges to decide the question of causation before the trial even begins, particularly given the lack of scientific knowledge many judges have.”).

49. Craig Lee Montz, *Trial Judges as Scientific Gatekeepers After Daubert*, Joiner, Kumho Tire, and Amended Rule 702: *Is Anyone Still Seriously Buying This?*, 33 UWLA L. REV. 87, 106 (2001).

50. Walsh, *supra* note 16, at 141 (quoting John M. Conley & David W. Peterson, *The Science of Gatekeeping: The Federal Judicial Center's New Reference Manual on Scientific Evidence*, 74 N.C. L. REV. 1183, 1205 (1996)).

51. Alan G. Gless, *Some Post-Daubert Trial Tribulations of a Simple Country Judge: Behavioral Science Evidence in Trial Courts*, 13 BEHAV. SCI. & L. 261, 263 (1995).

following Parts III, IV, and V examine three areas of biotechnology that will soon challenge—or have already begun challenging—the scientific literacy of courts: (1) the use of DNA forensics in criminal trials; (2) genetic engineering and genetically modified organisms; and (3) genetic privacy and the ability of insurance companies and employers to discriminate on the basis of genetic information.

III. DNA FORENSICS

As science has become increasingly integrated into our judicial system, American courts have embraced modern technologies, such as DNA testing, to provide a universal means for criminal identification. Embracing these modern technologies was born of sound policy; for the advent of genetic fingerprinting in the mid-1980s led to convictions that previously would have been impossible, exonerated criminal suspects before prosecutors filed charges, and freed mistakenly convicted defendants.⁵² With the advent of DNA forensics, however, came new issues that challenged our

52. As of April 2007, 198 defendants had been exonerated by DNA evidence. *See, e.g.*, Raymond Bonner, *Death Row Inmate Is Freed After DNA Test Clears Him*, N.Y. TIMES, Aug. 24, 2001, at A11; Adam Liptak, *DNA Will Let a Montana Man Put Prison Behind Him, but Questions Linger*, N.Y. TIMES, Oct. 1, 2002, at A22; The Innocence Project, <http://www.innocenceproject.org> (last visited Apr. 15, 2007). The first death row prisoner exonerated by DNA evidence was Kirk Bloodsworth in 1994. *See* Center on Wrongful Convictions, Northwestern University School of Law, Illinois Death Penalty Exonerations, <http://www.law.northwestern.edu/depts/clinic/wrongful/Chronology2.htm> (last visited Mar. 16, 2007). Since the exoneration of Bloodsworth, DNA has played a substantial role in exonerating eleven other death row prisoners. *See* Steven J. Mulroy, *The Safety Net: Applying Coram Nobis Law To Prevent the Execution of the Innocent*, 11 VA. J. SOC. POL'Y & L. 1, 7 (2003). The most recent exonerated defendant—and the most unusual—is William Walters, who was convicted for kidnapping in 1914. Allen G. Breed, *DNA Clears Man of 1914 Kidnapping Conviction*, USATODAY.COM, http://www.usatoday.com/tech/news/2004-05-05-1914-dna_x.htm (last visited Mar. 16, 2007). Nine decades after Walters was convicted, a DNA test indicated that the boy with whom Walters was found was not a missing boy, but rather, the illegitimate son of his brother. *Id.*

Further, the use of DNA evidence to exonerate defendants has provided insight into other aspects of criminal investigation. According to the Cardozo Innocence Project, for example, twenty-three percent of cases in which DNA was used to reverse the defendant's conviction involved a false confession. *Crime, False Confessions and Videotape*, N.Y. TIMES, Jan. 10, 2003, at A22. In addition, “[i]n sixty of the first eighty-two DNA exonerations, mistaken eyewitness identification played a major part in the wrongful conviction.” Richard A. Rosen, *Innocence and Death*, 82 N.C. L. REV. 61, 70 n.32 (2003). Cases in which defendants were convicted and later exonerated also included “suspicious behavior, and physical and other circumstantial evidence supporting guilt.” *Id.* at 71-72.

existing legal framework, such as genetic privacy in DNA databanks and genetic determinism. This Part examines the manner in which American courts have addressed these issues. To provide the necessary background on DNA forensics, this Part begins with a brief overview of the genetic principles behind DNA. The Part then reviews the history of courts admitting DNA evidence and concludes with a discussion of the future legal issues involving DNA forensics.

A. Scientific Overview

Deoxyribonucleic acid, more simply referred to as DNA, is an organic polymer found within every cell of every organism.⁵³ The monomeric units comprising the polymer contain three parts: a phosphate portion, a ribose sugar portion, and a structure called a nitrogenous base.⁵⁴ Although the first two components are the same in every monomeric unit, the third—the nitrogenous base—differs.⁵⁵ Four nitrogenous bases are found in DNA: adenine, cytosine, guanine, and thymine.⁵⁶ It is the sequence of these bases in DNA that determines genetic identity; the sequence differs somewhat between individual members of a species and much more between members of distinct species.⁵⁷

Held together by hydrogen bonds, these components form a DNA molecule that resembles a ladder twisted to form a helix.⁵⁸ The two outer strands, or the “backbone,” of the ladder are made of the sugar and phosphate portions.⁵⁹ The rungs of the ladder, by contrast, are composed of complementary base pairs—adenine pairing with thymine; cytosine with

53. Micah A. Luftig & Stephen Richey, *DNA and Forensic Science*, 35 NEW ENG. L. REV. 609, 609 (2001).

54. *Id.* The nitrogenous base is selected from one of four chemically distinct bases, see *infra* note 56, each of which—along with its accompanying share of deoxyribose-phosphate backbone—is called a “nucleotide.” Allen C. Nunnally, Note, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, 311 (2002).

55. Luftig & Richey, *supra* note 53, at 609.

56. *Id.* The four nitrogenous bases are often represented by their first letters; thus, “A” (adenine), “G” (guanine), “C” (cytosine), and “T” (thymine). See M. Scott McBride, *Bioinformatics and Intellectual Property Protection*, 17 BERKELEY TECH. L.J. 1331, 1335 (2002).

57. See Luftig & Richey, *supra* note 53, at 609. With the single-letter designations of nitrogenous bases, see *supra* note 56, scientists can concisely describe a sequence of a particular DNA (e.g., “ATTGGCATGGA”). McBride, *supra* note 56, at 1135-36.

58. WAYNE BECKER ET AL., *THE WORLD OF THE CELL* 58 (Catherine Pusateri ed., The Benjamin/Cummings Publishing Company 1996) (1986).

59. *Id.* at 60-61.

guanine.⁶⁰ This complementary pairing is essential for various DNA testing methods and for the basic principles of DNA chemistry.⁶¹

Because the DNA in each human cell is composed of a string of bases approximately three billion bases long, it provides for variations that allow scientists to distinguish between DNA samples.⁶² Given that DNA is uniform throughout all cells of an individual but distinct from the DNA of every other individual, scientists can detect small variations in DNA to differentiate among individuals.⁶³ As a result, scientists can match the genetic profile of an individual to a DNA sample found at a crime scene or on a crime victim.⁶⁴ In 1986, this observation led to the first use of DNA testing in a United States court.⁶⁵

B. The Admissibility of DNA as Scientific Evidence

Though accepted as a means of criminal investigation, the use of DNA forensics to establish guilt or innocence at trial—where the rules of evidence apply—was an unsettled issue of law during the late 1980s. The reluctance of courts to admit into evidence the results of DNA testing “resulted mainly from the lack of reliability in the early form of tests.”⁶⁶ As a result, some scholars have suggested that DNA forensics paved the way for the Supreme Court’s decision in *Daubert* because early courts focused on the reliability of the scientific techniques of DNA testing rather than on whether the techniques were “generally accepted” in the relevant scientific

60. *Id.*

61. *Id.* Certain combinations of bases, termed codons, “specify the production of particular amino acids, which then link to form proteins. Thus, the DNA sequence of the gene of interest will determine which amino acids and, ultimately, which proteins its host cell produces.” John M. Conley & Robert Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADE-MARK OFF. SOC’Y 371, 381 (2003).

62. See Human Genome Project Information, DNA Forensics, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/forensics.shtml (last visited Mar. 16, 2007).

63. Luftig & Richey, *supra* note 53, at 609.

64. The chance that a positive DNA match does not belong to the same person may be less than one in 500 million. SIMSON GARFINKEL, DATABASE NATION 49 (2000).

65. See NAT’L INST. OF JUSTICE NATIONAL COMMISSION ON THE FUTURE OF DNA EVIDENCE, POSTCONVICTION DNA TESTING: RECOMMENDATIONS FOR HANDLING REQUESTS 1 (1999).

66. Jennifer Boemer, Note, *In The Interest of Justice: Granting Post-Conviction Deoxyribonucleic Acid (DNA) Testing to Inmates*, 27 WM. MITCHELL L. REV. 1971, 1974 (2001).

community (although the fact that such procedures were not generally accepted did, to be sure, contribute to that reluctance).⁶⁷

It was against this backdrop that the first appellate court in the United States addressed the issue of DNA forensics in 1988 in *State v. Andrews*.⁶⁸ In *Andrews*, police officers obtained DNA from a semen sample found on a rape victim and matched it to the DNA taken from a blood sample that was drawn from the alleged rapist.⁶⁹ The trial court was thus faced with deciding whether to admit the results of a DNA test at trial.⁷⁰ Consistent with the national doubt regarding the continued viability of *Frye*, the Florida appellate court “confess[ed] some uncertainty as to the standard applicable in this state governing admissibility into evidence of a new scientific technique.”⁷¹ Rather than apply the *Frye* test, however, the court concluded that the “relevancy approach set out in the evidence code is the appropriate standard for determining the admissibility of expert testimony” and that “without some indicia of reliability, opinion evidence on a particular subject could hardly be helpful to a jury.”⁷²

Applying this standard (which the United States Supreme Court effectively adopted five years later in *Daubert*), the *Andrews* court held that the DNA evidence was admissible.⁷³ The court observed that several expert witnesses, including a prominent molecular biologist from the Massachusetts Institute of Technology (MIT), testified that the DNA techniques used to identify the defendant as a rapist were relevant and reliable, notwithstanding the novelty of applying them to establish human identity.⁷⁴

67. See generally David L. Faigman, *The Tipping Point in the Law's Use of Science: The Epidemic of Scientific Sophistication that Began with DNA Profiling and Toxic Torts*, 67 BROOK. L. REV. 111 (2001).

68. 533 So. 2d 841 (Fla. Dist. Ct. App. 1988).

69. *Id.* at 842-43.

70. *Id.* at 843.

71. *Id.*

72. *Id.*

73. *Id.* at 850.

74. *Id.* at 847-49. The professor from MIT was Dr. David E. Housman, who, at the time of trial, specialized in molecular genetics and had published approximately 120 papers on that topic. *Id.* at 847. In addition to serving on advisory boards involving genetics for the National Institute of Health, the Heredity Disease Foundation, and the Tourette's Syndrome Foundation, Dr. Housman visited Lifecodes, Inc.—the company which performed the instant test—to examine the company's testing procedures. The state additionally called two esteemed scientists, Allen Guisti and Dr. Michael Baird, who worked for Lifecodes and had published numerous articles on DNA technology. *Id.* The credibility of these witnesses no doubt played a substantial role in the trial court's decision to admit DNA evidence in *Andrews*.

Given that the DNA print results were “helpful to the jury”⁷⁵ and that “evidence derived from DNA print identification appears based on proven scientific principles,”⁷⁶ the court determined that the DNA evidence satisfied the relevancy and reliability tests. In so doing, the court affirmed the first DNA-based conviction in the United States.⁷⁷

Change was thus afoot. In the decade that followed, every state and Federal Circuit recognized the admissibility of DNA evidence in one form or another.⁷⁸ As a result, courts now readily accept DNA forensic evidence for identification purposes in criminal trials,⁷⁹ postconviction relief proceedings,⁸⁰ and civil litigation (to establish paternity and other family ties in adoption, child support, and immigration cases).⁸¹ Indeed, “the scientific basis for this evidence is now so well established that its admissibility is sanctioned by statute in many jurisdictions”⁸² Consequently, American courts have generally accepted the basis for DNA identification.⁸³ Most recently, a series of federal courts have sustained state laws requiring DNA samples from convicted offenders to be stored in DNA databases.⁸⁴

75. *Id.* at 849.

76. *Id.* at 850.

77. The first court of last resort to address the admissibility of DNA evidence was the West Virginia Supreme Court of Appeals in *State v. Woodall*, 385 S.E.2d 253 (W.Va. 1989).

78. Paul C. Giannelli, *The DNA Story: An Alternative View*, 88 J. CRIM. L. & CRIMINOLOGY 380, 381 (1997).

79. Walsh, *supra* note 16, at 140.

80. See Brooke A. Masters, *DNA Testing in Old Cases Is Disputed: Lack of National Policy Raises Fairness Issue*, WASH. POST, Sept. 10, 2000, at A1, A5 (discussing the practices of different jurisdictions regarding postconviction DNA testing).

81. Denise K. Casey, *Genes, Dreams, and Reality: The Promises and Risks of the New Genetics*, 83 JUDICATURE 105, 109 (1999).

82. Walsh, *supra* note 16, at 142. On January 11, 2006, the U.S. Supreme Court heard arguments to determine whether prisoners have a right to use DNA evidence to seek new trials. In 2004, on a hearing en banc, the Sixth Circuit held, 8-7, that a man sentenced to death for a 1985 murder was not entitled to a new trial, despite recent DNA evidence that allegedly cast doubt on his guilt. *House v. Bell*, 386 F.3d 668 (6th Cir. 2004), *rev'd*, 126 S. Ct. 2064 (2006). The case is reportedly the first time a death row inmate has brought DNA evidence before the U.S. Supreme Court to prove his innocence. Duncan Mansfield, *High Court to Weigh DNA in Death Row Case*, THE BOSTON GLOBE, Jan. 10, 2006, http://www.boston.com/news/nation/articles/2006/01/10/high_court_to_weigh_dna_in_death_row_case.

83. *Id.* Given the widespread admissibility of DNA evidence, the Bush Administration has devoted nearly \$800 million “to perform DNA analysis over the next five years in unsolved rapes and other old cases and to make improvements in the nation’s computerized DNA crime-fighting system.” Richard Willing, *More Funding Directed to DNA Crime Fighting*, USATODAY.COM, http://www.usatoday.com/news/washington/2004-03-07-dna-funds_x.htm (last visited Mar. 16, 2007).

C. Future Legal Issues Involving DNA Forensics

Although the reliability of DNA technology for identification purposes is well settled, the use of such technology to predict or explain behavior will inevitably give rise to new and challenging legal issues.⁸⁵ Many state legislatures, for example, have required DNA samples from convicted sex offenders⁸⁶ and authorized the creation of DNA databanks.⁸⁷ Beyond the questions regarding ownership, access, and genetic privacy, such databases raise concerns about the propriety of using genetic information to discriminate against individuals for insurance or employment purposes.⁸⁸ Genetic information will also raise legal issues about “what constitutes ‘having’ a particular disease as compared with being ‘predisposed’ to contracting a disease”—a distinction that “may have a significant impact on insurance, medical malpractice, product liability, and other health and employment issues that come before the courts.”⁸⁹

84. See, e.g., *Nicholas v. Goord*, 430 F.3d 652, 671 (2d Cir. 2005); *United States v. Kincade*, 379 F.3d 813 (9th Cir. 2004) (en banc), *cert. denied*, 544 U.S. 924 (2005); *Green v. Berge*, 354 F.3d 675, 679 (7th Cir. 2004). See generally Sasha Polonsky, Note, “Banking” on Law Enforcement: Advocating a New Balancing Test for DNA Storage After *United States v. Kincade*, 83 WASH. U. L.Q. 1331 (2005).

85. See generally Mark A. Rothstein, *The Impact of Behavioral Genetics on the Law and the Courts*, 83 JUDICATURE 116, 117 (1999).

86. Jennifer Graddy, *The Ethical Protocol for Collecting DNA Samples in the Criminal Justice System*, 59 J. MO. B. 226, 226-27 (2003). Although every state requires the collection of DNA samples from convicted sex offenders, “beyond th[at] . . . the states differ significantly.” Many states, for example, “require DNA samples from only a narrow group of felons, such as those convicted of homicide and sexual assault.” *Id.* at 227-28. Nevertheless, Alabama, New Mexico, Virginia, and Wyoming require DNA samples from all convicted felons. *Id.* (citing ALA. CODE § 36-18-24 (2001); N.M. STAT. ANN. §§ 29-16-1 to -13 (Michie 2003); VA. CODE ANN. § 19.2-310.2 (Cum. Supp. 2002); WYO. STAT. ANN. §§ 7-19-401 to -405 (Michie 2003)). Several states, such as Arizona, Arkansas, and Delaware, even require DNA samples for certain misdemeanors. *Id.* (citing ARIZ. REV. STAT. ANN. § 31-281 (A) (West 2002); ARK. CODE ANN. § 12-12-1109 (LexisNexis Supp. 2003); DEL. CODE ANN. tit. 29 § 4713 (LexisNexis 1997)).

87. Giannelli, *supra* note 78, at 392-93.

88. For a detailed discussion of these issues, see *infra* Part V.

89. Abrahamson, *supra* note 3. Additionally, as DNA research progresses, legal arguments predicated on genetic determinism may reappear. Rothstein, *supra* note 85, at 119. As one scholar has observed, “behavior genetic arguments are particularly appealing in criminal cases because they can be used to prove that the defendant was compelled to act by uncontrollable genetic factors. *Id.* Justice Joseph T. Walsh of the Delaware Supreme Court has asserted that “the emergence of DNA evidence as a forensic tool for identification purposes and as a prediction of physical and emotional abnormality is a good example of how knowledge [of courts] outstrips the ability of courts to accommodate its implications.” Walsh, *supra* note 16, at 142.

One novel issue of DNA forensics currently facing courts is the admissibility of a new form of DNA, known as “Y-STR DNA.” Y-STR DNA testing can identify male DNA (the Y chromosome) in male/female DNA mixtures, even where the female DNA is present in an overwhelming proportion to the male DNA. As a result, many scientists and lawyers believe that Y-STR DNA will be increasingly helpful in cases of sexual assault between a male perpetrator and a female victim.⁹⁰ Although few published decisions address the admissibility of Y-STR DNA evidence, courts that have confronted the issue have generally concluded that Y-STR DNA is reliable and, therefore, admissible.⁹¹

Another novel issue currently facing courts is the practice of indicting genetic material when law enforcement officers are unable to match DNA found at a crime scene with a named individual.⁹² In an attempt to indict the unknown suspect within the applicable statute of limitations, prosecu-

90. See Cassie Johnson, *Validation and Uses of a Y-Chromosome STR 10-Plex for Forensic and Paternity Laboratories*, 48 J. FORENSIC SCI. 6, 1-9 (Nov. 2003).

91. See, e.g., *Shabazz v. State*, 592 S.E.2d 876, 879 (Ga. Ct. App. 2004). Squire, Sanders & Dempsey L.L.P. (where one of the authors, Stephen Anway, practices law) recently represented a criminal defendant on a pro bono basis in a post-conviction proceeding that involved Y-STR DNA. See *State v. Elkins*, Summit C.P. No. CR 1998-06-1415 (Ohio Ct. Com. Pl. Dec. 9, 2002). The defendant, Clarence Elkins, had been convicted in 1999 for the rape and murder of his fifty-eight-year-old mother-in-law and the rape of her six-year-old granddaughter. The court sentenced Mr. Elkins to life in prison.

Three years later, Mr. Elkins sought a new trial and an order requiring the state to pay for DNA testing. After these requests were denied, Mr. Elkin’s wife raised funds from internet contributors to pay for DNA testing on pieces of evidence admitted at trial. This new testing used Y-STR DNA technology, which had been unavailable six years earlier at his trial. The Y-STR DNA testing revealed another individual’s DNA on both the child’s panties and on the grandmother’s vaginal swab.

Mr. Elkins filed a notice of appeal in 2005. While the appeal was pending, Mr. Elkins reportedly discovered that the DNA found on the two victims appeared to match the DNA of an individual who is currently incarcerated for sexual offenses against minors and who happened to live two doors down from the grandmother. Mr. Elkins—with the support of the Ohio Attorney General—sought to remand the matter to allow the trial court an opportunity to consider the evidence. The request was denied.

On December 15, 2005, Mr. Elkins received another DNA report on outstanding hair strands taken from the victims’ clothing that appeared to closely match the individual who is currently incarcerated for sexual offenses against minors. The prosecutor thereafter filed a motion to dismiss all charges against Mr. Elkins and secure his immediate release. Mr. Elkins was home for Christmas—the first with his wife and children in over seven years.

92. Andrew C. Bernasconi, *Beyond Fingerprinting: Indicting DNA Threatens Criminal Defendants’ Constitutional and Statutory Rights*, 50 AM. U. L. REV. 979, 981-82 (2001).

tors have brought charges against the DNA of the suspect.⁹³ For example, California police, unable to match the DNA found at the crime scene to a named individual, recently indicted the suspect's genetic profile—one day before the statute of limitations would have barred his prosecution.⁹⁴ Although this case marks the first time the police have arrested a suspect after his DNA was indicted, prosecutors in at least nine states have filed charges against or indicted “John Doe” suspects by relying exclusively on the DNA of the suspect.⁹⁵

Notwithstanding questions about the propriety of indicting genetic material (which are beyond the scope of this Article), DNA evidence will continue to present new and challenging issues to every judicial system. Indeed, the assimilation of DNA technology into criminal trials comes just as the role of judges as “gatekeepers” to assess scientific evidence is expanding.⁹⁶ The reality for every judicial system, therefore, is that other novel, more complex issues concerning DNA evidence will require an intricate knowledge of biotechnology. With this concern in mind, the next Part examines another issue of biotechnology that will challenge the scientific knowledge of trial courts—genetic engineering.

IV. GENETIC ENGINEERING

Advancements in biotechnology have empowered scientists to manipulate a variety of factors in our environment, including the food that we

93. *Id.* at 983.

94. *Id.* at 980. Because the police could not determine the identity of the suspect at the time of the indictment, they sought a “John Doe” warrant. *Id.* California police eventually arrested Paul Eugene Robinson and charged him with committing a series of sexual assaults. *Id.* (citing Erin Hallissy & Charlie Goodyear, *Databank Match Brings Arrest on DNA Warrant*, S.F. CHRON., Oct. 25, 2000, at A3).

95. *Id.* at 981-82. The other states in which a genetic material has been indicted include Texas, Wisconsin, North Dakota, Pennsylvania, Oklahoma, New York, Utah, Missouri, and Kansas. See Julian E. Barnes, *East Side Rapist, Known Solely by DNA, Is Indicted*, N.Y. TIMES, Mar. 16, 2000, at B1; Greg Kennedy, *Prosecutors File Charges Against DNA Profile in OU Student's Murder*, THE DAILY OKLAHOMAN, Mar. 21, 2000, at 1A; Lisa Sink & Linda Spice, *Use of DNA Evidence Expands; State Lab Testing Saliva on Envelope*, MILWAUKEE J. SENTINEL, Oct. 26, 2000, at 1B; Brady Snyder & Amy Joi Bryson, *Charge Filed Against DNA*, DESERET NEWS (Utah), Mar. 3, 2000, at A01; *DNA Profile is Used as Basis for Arrest Warrant in Sexual Assault Case*, ST. LOUIS POST-DISPATCH, Dec. 5, 1999, at C2; *Unknown Man Indicted in Austin Rape Case*, HOUS. CHRON., Nov. 5, 2000, at A45.

96. Abrahamson, *supra* note 3; see *supra* Section II.C (discussing the Supreme Court's decisions in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), and the resultant expansion of the trial court's role as gatekeeper).

consume.⁹⁷ One such advancement is genetic engineering, which has enabled scientists to alter the genetic composition of both plant and animal organisms.⁹⁸ For example, scientists have “mix[ed] genes on the cellular and molecular level in order to create new breeds of plants for human and animal consumption.”⁹⁹ Although genetically engineered breeds provide benefits unavailable with organic breeds, genetic engineering has been fraught with controversy—particularly in the production, sale, and trade of genetically modified foods. This Part examines the current and future legal issues of genetic engineering that courts are facing and will continue to face in coming years. It begins with a scientific overview before turning to two genetic engineering legal issues: intellectual property rights and safety. This Part further illustrates the challenges that courts face when hearing and deciding biotechnology cases: these cases raise highly technical issues that often precede legislation on key issues and require judges to apply a level of scientific knowledge with which most judges are not armed.

A. Scientific Overview

Genetic engineering—also referred to as “bioengineering” or “genetic modification”—is the process of modifying the DNA of an organism by uniting it with another organism’s genes.¹⁰⁰ To render the desired modifications, scientists employ a technology, called recombinant DNA (rDNA), whereby they identify specific genes, make copies of those genes, and introduce the gene copies into recipient organisms.¹⁰¹ The transfer of the

97. See *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 169 (D.D.C. 2000) (discussing, in one of the first reported opinions to address the safety concerns associated with GMOs, that biotechnology allows scientists to manipulate a variety of factors in our environment through genetic engineering).

98. *Id.*

99. Alicia T. Simpson, *Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 TEMP. ENVTL. L. & TECH. J. 225, 228 (2001) (citing *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 169).

100. Heather N. Ellison, *Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?*, 10 PENN ST. ENVTL. L. REV. 345, 347 (2002).

101. *Id.* One commentator has described the various methods of gene-splicing in the following manner:

Modern gene-splicing techniques allow scientists to introduce genes from a living organism (called the “donor”) into a plant (called a “host”) in several ways, including: (1) direct DNA uptake by the plant cells mediated by chemical or electrical treatments; (2) microinjection of DNA directly into plant cells; (3) biolistics, or firing tiny metal particles coated with the DNA of interest into plant cells; and (4) infecting the plant with a bacterium that scientists have modified to carry the

DNA segments from the donor organism to the host organism occurs when a host cell incorporates the fragment of the donor DNA. The cell then expresses the new gene by producing the protein for which the new gene “codes.”¹⁰² The protein (or its byproduct) alters a characteristic or trait of the host organism, which the host reproduces in succeeding generations.¹⁰³ As a result, “genetic engineers can in a generation or two design plants to produce different types and quantities of proteins, carbohydrates, fats and oils, the primary building blocks of human food.”¹⁰⁴

The benefits associated with genetic engineering have caused a proliferation of “GMOs”—an acronym for “genetically modified organisms,” which we use as shorthand for all bioengineered foods throughout this Part.¹⁰⁵ The benefits of GMOs include improved quality and abundance, longer freshness, enhanced flavor and nutritional value, and enhanced resistance to insect pests (which reduces the cost and health risks associated with insecticide use). Nevertheless, some critics have voiced concerns over the health, consumer choice, and environmental harms of GMOs.¹⁰⁶

DNA into plant cells. In each of these techniques, scientists insert DNA segments from the “donor” organism into the chromosome of the “host” plant cells in a semi-random fashion.

Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 406-07 (2002) (footnotes omitted).

102. McGarity, *supra* note 101, at 407.

103. *Id.* Professor McGarity further explains that “[t]o distinguish those cells that have successfully taken up the donor gene from those that have not, scientists typically attach an additional DNA segment containing a gene that is capable of rendering the host cell resistant to a particular antibiotic, herbicide, or other toxic agent.” *Id.*

104. *Id.* at 408. The first GMO food—a genetically modified tomato—was sold in the U.S. market in 1995. Debra Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD DRUG L.J. 167 (2006).

105. Frank J. Miskiel, *Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy*, 38 CAL. W. L. REV. 223, 223 (2001). Indeed, “the acreage planted with genetically modified crops has exploded: a third of the country’s corn by 2002 and three-quarters of its soybeans.” *Keeping Seeds Safe*, N.Y. TIMES, Mar. 1, 2004, at A1.

106. Rebecca M. Bratspies, *Bridging the Genetic Divide: Confidence-Building Measures for Genetically Modified Crops*, 44 JURIMETRICS J. 63, 71 (2003). These safety concerns stem from both known and unknown allergenic, toxic, pathogenic, and immunological effects of GMOs and are discussed *infra* Section IV.B.2.a.

B. Legal Issues Associated with GMOs

As GMOs proliferate, so too will the legal issues that surround them. The following Sections examine two legal issues associated with GMOs: ownership and safety.¹⁰⁷

1. Intellectual Property Rights and GMOs

Genetic engineering transformed the agriculture industry.¹⁰⁸ An essential part of this transformation was the ability of start-up biotech companies to “own” genetic innovations—preventing others from capitalizing on the labor and money used to develop genetic inventions.¹⁰⁹ Having the ability to protect such inventions was necessary to provide incentive to start-up biotech companies “whose seed capital depended upon their ability to develop patent portfolios and thereby attract investors.”¹¹⁰

The focus of the scientific community thus turned to patent law.¹¹¹ Given that Congress had not yet addressed whether patents could be granted for genetically modified living organisms, courts were forced to address the issue within the preexisting statutory framework.¹¹² The Patent Act defines a patentable invention as a “process, machine, manufacture, or composition of matter” that is new, useful, and non-obvious.¹¹³

In its 1972 landmark decision *Diamond v. Chakrabarty*,¹¹⁴ the United States Supreme Court interpreted the Patent Act to provide that living organisms—in that case, a man-made bacterium with properties unlike any known naturally-occurring organism—comprised patent-eligible subject

107. Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 87 (2001).

108. See David R. Nicholson, *Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?*, 8 VA. J.L. & TECH. 7, ¶ 12 (2003). This transformation is perhaps best illustrated by the fact that the agriculture-biotech industry is expected to reach \$20 billion by 2010. *Id.*

109. *Id.* As Nicholson observed, “[t]o produce these results, obviously, substantial investment in research and development is necessary, which can only be undertaken if there is the opportunity to gain a return on the investment.” *Id.*

110. *See id.*

111. *See id.*

112. 35 U.S.C. §§ 100-103 (2000). Thus, rather than address the proprietary rights of genetic engineers under a statutory law that is specifically tailored to agricultural innovations, courts were forced to address such issues under the general patent law. That law, however, presents unique problems in the context of agricultural innovations because, although the purpose of intellectual property law is to control access to certain property, plants are self-perpetuating.

113. *Id.* §§ 101, 103.

114. 447 U.S. 303 (1980).

matter.¹¹⁵ The Court thus affirmed the judgment of the United States Court of Customs and Patent Appeals, which had concluded that the United States Patent and Trademark Office erred in denying a patent because the subject matter was a “live organism[.]”¹¹⁶ In awarding the patent, the Court declared that patentable subject matter includes “anything under the sun that is made by man.”¹¹⁷ This declaration became “the mantra for the unprecedented expansion in patent-eligible subject matter over the past twenty-plus years.”¹¹⁸

Nevertheless, plants that reproduce through seed have presented “a particularly vexing intellectual property problem because these plants can reproduce through natural processes, in effect providing a free, renewable supply to the farmer.”¹¹⁹ As one scholar has noted, “intellectual property protection is about controlling access to or use of a particular invention, and a self-propagating invention obviously presents unique problems in this context.”¹²⁰ In response to the unique characteristics of such inventions, Congress enacted the Plant Patent Act of 1930 (PPA),¹²¹ which confers patent protection on specified asexually-reproduced plants, and the Plant Variety Protection Act (PVPA),¹²² which Congress originally enacted in 1970 and provides some protection concerning sexually-reproduced or tuber-propagated plants. These Acts, together with trade secret law and utility patents, provide inventors with a variety of legal means to protect plant innovations.¹²³

115. *Id.* at 318.

116. *In re Chakrabarty*, 571 F.2d 40, 41 (C.C.P.A. 1978).

117. *Diamond*, 477 U.S. at 309 (quoting S. REP. NO. 1979, at 5 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399).

118. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 485 (2003).

119. Nicholson, *supra* note 108, ¶ 14.

120. *Id.*

121. 35 U.S.C. §§ 161-64 (2000). The PPA provides *sui generis* protection to an individual who “invents or discovers and asexually reproduces any distinct and new variety of plant.” § 161. The Act excludes from protection, however, plants that sexually reproduce (through seeds) because “it was believed that they would not breed true, thus rendering them incapable of satisfying the ‘written description’ portion of the patent law.” Cullen N. Pendleton, *The Peculiar Case of “Terminator” Technology: Agricultural Biotechnology and Intellectual Property Protection at the Crossroads of the Third Green Revolution*, 23 BIOTECHNOLOGY L. REP. 1, 8 (2004) (citing *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int’l*, 534 U.S. 124, 134 (2001)).

122. 7 U.S.C. §§ 2321-2582 (2000).

123. *Id.* Sexually propagated plants, although not protected under the PPA, see *supra* note 121, became protected by the PPVA in 1970. See *id.* Under the PPVA, a plant is afforded protection if it is novel, distinct, uniform, and stable. 7 U.S.C. § 2402(a) (2000).

Most recently, the United States Supreme Court in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*¹²⁴ addressed whether utility patents could protect plant inventions or whether only the PPA and PVPA protect such inventions.¹²⁵ The Court held that novel plant breeds were eligible for utility patent protection under the Patent Act and that neither the PPA nor the PVPA limited the scope of such coverage.¹²⁶ Consistent with its earlier pronouncement in *Chakrabarty*, the Court reiterated that courts should construe the Patent Act liberally to evolve with developments in science and technology.¹²⁷

Consequently, the manner in which American courts have shaped intellectual property law has been vital to the rise of biotechnology. And just as early patent decisions fostered the proliferation of genetic innovations, the courts' early decisions with respect to GMO safety will shape the future of biotechnology.

2. Safety Issues Associated with GMOs

Public concern about the safety of GMOs can be generally classified into two categories: (1) human health and consumer choice concerns and (2) environmental concerns.¹²⁸ The former set of concerns relates to whether GMOs are safe to consume; the latter to the possible ecological hazards that GMOs present when cultivated.¹²⁹ This section analyzes each concern separately and then draws them together in an examination of *Alliance for Bio-Integrity v. Shalala*¹³⁰—a case in which a judge was called upon to address the cutting edge issue of GMO safety.

a) Human Health and Consumer Choice Concerns with GMOs

With the recent increase of GMOs, the human health and consumer choice issues associated with such foods pose potential safety risks to every nation in the world. To combat these risks, the European Commission in the World Trade Organization blocked the import of bioengineered

124. 534 U.S. 124 (2001).

125. *Id.* at 125-27.

126. *Id.* at 137. The Court concluded that “[i]n short, there is simply no evidence, let alone the overwhelming evidence needed to establish repeal by implication, . . . that Congress, by specifically protecting asexually reproduced plants through the PPA, intended to preclude utility patent protection for sexually reproduced plants.” *Id.* (citing *Matsushita Elec. Indus. Co. v. Epstein*, 516 U.S. 367, 381 (1996)).

127. *J.E.M. AG Supply*, 534 U.S. at 137 n.9 (“[T]hese subject matter terms have been interpreted broadly to evolve with developments in science and technology.”).

128. Bratspies, *supra* note 106, at 70.

129. *Id.*

130. 116 F. Supp. 2d 166 (D.D.C. 2000).

seeds¹³¹—a move that, in addition to costing U.S. corn farmers more than \$200 million a year, prompted a U.S. official to state that he had “strongly considered” filing a lawsuit against the European Commission.¹³²

Through such legal action, the U.S. government might hope to prevent other nations from promulgating unnecessary regulations related to GMOs.¹³³ These initiatives reflect the position that restrictive regulations are not based on verifiable “scientific risk.”¹³⁴ The U.S. policy, in contradistinction to that of the European Commission, is that the GMOs should be permitted to flourish in the absence of proven hazards.¹³⁵

In 1992, the FDA published a “Statement of Policy: Foods Derived from New Plant Varieties” (FDA Statement of Policy).¹³⁶ The FDA Statement of Policy announced that the FDA would presume that foods produced through the rDNA process were “generally recognized as safe” under the Federal Food, Drug and Cosmetic Act¹³⁷ and indicated that labeling for rDNA-developed foods was not necessarily required.¹³⁸ This led to widespread consumer demand for the labeling of GMOs in the late

131. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734 (2003). GMOs have been banned in Europe since April 1998. See Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Support Tort Reform*, 36 IND. L. REV. 645, 685 n.195 (2003). Further, “the European Union is also pushing for strict controls over the importation of GM foods.” *Id.* (citing *EU to Fight for GM Food Ban*, BBC NEWS, Dec. 13, 1999, available at <http://news.bbc.co.uk/2/hi/business/563579.stm>).

132. When asked about the trade conflict with the Europeans, the U.S. officer—Trade Representative Robert Zoellick—stated, “I personally am of the view that we now need to bring a case.” *Zoellick Calls For WTO Case Against EU Biotechnology Moratorium*, INSIDE U.S. TRADE, Jan. 10, 2003, at 1. The purpose of the lawsuit would purportedly be to enjoin the WTO from blocking the import of U.S. bioengineering seeds. Marden, *supra* note 131, at 734. For a more recent discussion of European views regarding GMOs, see *Biotech Food Tears Rifts in Europe*, N.Y. TIMES, June 6, 2006.

133. Marden, *supra* note 131, at 734 *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734 (2003).

134. *Id.*; see Ellison, *supra* note 100, at 348.

135. The U.S. Trade Representative’s fact sheet on Agricultural Biotechnology states in its first bulleted point: “The United States government has a coordinated, risk-based system to ensure new biotechnology products are safe for the environment and human and animal health.” U.S. Trade Representative, *Agricultural Biotechnology: The U.S. Regulatory System*, Sept. 2006, http://www.ustr.gov/assets/Trade_Sectors/Agriculture/Biotechnology/asset_upload_file312_8907.pdf; see also Ellison, *supra* note 100, at 348. For a more comprehensive discussion of U.S. policy on GMOs, see generally Ellison, *supra* note 100, at 348.

136. 57 Fed. Reg. 22,984 (May 19, 1992).

137. 21 U.S.C. § 321(s).

138. 57 Fed. Reg. 22,991 (May 29, 1992).

1990s.¹³⁹ The issue promptly reached the Federal Circuit in *Alliance for Bio-Integrity v. Shalala*.¹⁴⁰

b) Environmental Concerns with GMOs

In addition to challenging the decision of the FDA to not require labeling of GMOs, the plaintiffs in *Alliance for Bio-Integrity* alleged that the potential environmental harms of such foods rendered the FDA policy invalid.¹⁴¹ This allegation was based on the three potential environmental harms of GMOs. First, the cross-pollination of wild plants with genetically modified pollen may transfer herbicide resistance to¹⁴² and reduce biodiversity of¹⁴³ such plants.¹⁴⁴ Second, the use of GMOs may kill beneficial insects¹⁴⁵ or cause harmful insects to develop a tolerance to insecticides.¹⁴⁶

139. According to one survey in 1997, “ninety-three percent of Americans wanted the FDA to require labeling of genetically engineered foods. In addition, a *Time Magazine* poll conducted in 1999 found that eighty-one percent of those polled wanted bioengineered foods to be labeled.” Marden, *supra* note 131, at 760.

140. 116 F. Supp. 2d 166 (2000).

141. Ellison, *supra* note 100, at 347.

142. Ke Geng, *Should China Provide Intellectual Property Protection for Genetically Modified Animals?*, 23 NW. J. INT’L L. & BUS. 467, 470 (2003) (explaining that “crops with herbicide resistance genes may transfer these genes to weeds, thus creating a major threat to the environment”). This resistance may in turn “encourage farmers to use more chemicals, with accompanying risks to the environment and pesticide applicators.” Margaret Rosso Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 220 (2002).

143. Kim JoDene Donat, *Engineering Akerlof Lemons: Information Asymmetry, Externalities, and Market Intervention in the Genetically Modified Food Market*, 12 MINN. J. GLOBAL TRADE 417, 456 (2003) (noting that “[e]nvironmentalists argue that GMOs will destroy biodiversity”).

144. The Union of Concerned Scientists has confirmed that genes from modified plants “somehow drift into unmodified ones.” *Keeping Seeds Safe*, *supra* note 105 (noting that two independent labs examined samples of corn, soybean, and canola and “found contamination in half the corn, half the soybean and more than 80 percent of the canola varieties”). These scientists have thus concluded that “[t]o contaminate traditional varieties of crops is to contaminate the genetic reservoir of plants on which humanity has depended for most of its history.” *Id.*

145. Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461, 476 (2002) (“There is also evidence that beneficial insects, ‘unintended targets,’ are killed as a result of GMOs containing pesticides.”).

146. Donat, *supra* note 143 (noting that “[e]nvironmentalists argue that GMOs will . . . create super-insects and weeds that will cause environmental degradation and contamination”).

Finally, the widespread use of GMOs could result in an increased generation rate of new viruses unaffected by current control measures.¹⁴⁷

Similar to the position of the FDA regarding the health concerns of GMOs, the EPA concluded that the existing statutory and regulatory framework adequately addressed the environmental concerns posed by genetic engineering.¹⁴⁸ And, to date, the EPA has not determined that GMOs pose a verifiable “scientific risk” to the environment under this framework.¹⁴⁹ As a result, the legal theory upon which the plaintiffs relied in *Alliance for Bio-Integrity* was not that the FDA Statement of Policy violated an EPA or USDA regulation, but rather that the FDA did not comply with the existing procedures before issuing the policy.¹⁵⁰

c) *Alliance for Bio-Integrity v. Shalala*

In *Alliance for Bio-Integrity*,¹⁵¹ a coalition of groups and individuals brought suit in federal court to invalidate the FDA policy on GMOs.¹⁵² The plaintiffs had two concerns: first, that new breeds of GMOs contained unexpected allergens and toxins; and second, that the religion of some plaintiffs forbade consumption of foods produced by rDNA technology.¹⁵³ In fashioning legal arguments to address these concerns, the plaintiffs challenged the policy on four grounds: (1) the policy was not subjected to notice-and-comment procedures as required by section 553 of the Administrative Procedure Act; (2) the FDA violated the National Environmental Protection Act (NEPA) by not performing an Environmental Assessment or an Environmental Impact Statement in conjunction with the policy; (3) the presumption that GMOs are “generally accepted as safe” was arbitrary.

147. Some scientists, for example, “are concerned that the use of a common gene promoter from the Cauliflower mosaic virus ‘may result in a major source of new viruses arising from recombination.’” Emily Robertson, *Finding a Compromise in the Debate over Genetically Modified Food: An Introduction to a Model State Consumer Right-to-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 169 (2003) (quoting Richard Caplan & Ellen Hickey, *Weird Science: A Brave New World of Genetic Engineering*, Oct. 31, 2001, <http://www.uspirg.org/home/reports/report-archives/food-safety/food-safety-reports/weird-science-the-brave-new-world-of-genetic-engineering>).

148. Marden, *supra* note 131, at 743-45, 767-77, 776. In contrast to the FDA and the EPA, however, the USDA “initially chose to take a precautionary approach under this existing statutory regime. Instead of presuming that existing regulations were adequate to apply also to GM products, USDA proposed and promulgated regulations specific to GM products.” *Id.* at 768.

149. *Id.* at 778.

150. *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000).

151. *Id.* at 166.

152. *Id.* The coalition was comprised of scientists and religious leaders who were “concerned about genetically altered foods.” *Id.* at 170.

153. *Id.*

trary and capricious; and (4) the policy failed to require labeling of GMOs in violation of the FDCA, the Free Exercise Clause of the United States Constitution, and the Religious Freedom Restoration Act.¹⁵⁴

The district court rejected each of the plaintiffs' arguments and granted a motion for summary judgment in favor of the FDA.¹⁵⁵ The court disagreed that the FDA was required to conduct notice-and-comment procedures because the policy merely created a presumption rather than a substantive rule.¹⁵⁶ The court additionally concluded that the FDA did not violate the NEPA because the FDA Statement of Policy was not a "major federal action" and, therefore, was neither subject to an Environmental Assessment nor an Environmental Impact Statement.¹⁵⁷ Finally, the court determined that scientific applications of statutory law were within the expertise of the FDA and that principles of administrative law prevented the court from second-guessing the decision of the FDA to issue the policy.¹⁵⁸

The court similarly deferred to the FDA's decision not to require the labeling of GMOs.¹⁵⁹ The relevant provision in the FDCA provides that the FDA shall take action for the misbranding of a food if the labeling "fails to reveal facts . . . material with respect to consequences which may result from use of the article."¹⁶⁰ In analyzing this provision, the court de-

154. *Id.*

155. *Id.* at 172-81. In upholding the FDA decision, the court relied on the well-settled proposition that "[t]he rationale for deference is particularly strong when the [FDA] is evaluating scientific data within its technical expertise." *Id.* at 177 (quoting *Int'l Fabricare Inst. v. U.S. Env't'l. Prot. Agency*, 972 F.2d 384, 389 (D.C. Cir. 1992)). On this point, the court elaborated that "[i]n an area characterized by scientific and technological uncertainty . . . [it should avoid] all temptation to direct the agency in a choice between rational alternatives." *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177 (quoting *Env't'l. Def. Fund, Inc. v. Costle*, 578 F.2d 337, 339 (D.C. Cir. 1978)).

156. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 172-73. Unanimity among scientists, the court observed, was not required to preclude a finding that GMOs are "generally accepted as safe"; rather, a plaintiff must show a "severe conflict among experts" to support such a conclusion. *Id.* at 177 (quoting 62 Fed. Reg. at 18,939 (Apr. 17, 1997)).

157. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 173-75.

158. *Id.* at 175-78; Marden, *supra* note 131, at 756.

159. Marden, *supra* note 131, at 756.

160. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178 (quoting 21 U.S.C. § 321(n) (2000)). In its entirety, section 321(n) of Title 21 provides:

If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which

terminated that the FDA may only consider consumer demand for such labeling if the FDA first determined that genetically modified food differed “materially” from unmodified food.¹⁶¹ Because the FDA had concluded that genetic modification of a food was not a “material” change in the food, the court deferred to that conclusion, holding that the policy did not violate the FDCA.¹⁶² The court concluded its analysis by noting that the failure of the policy to require such labeling violated neither the Free Exercise Clause nor the Religious Freedom Restoration Act.¹⁶³ In support of the former conclusion, the court reasoned that the policy was neutral and generally applicable; in support of the latter, the court determined that the policy did not substantially burden a religious practice.¹⁶⁴

may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C. § 321(n) (emphasis added).

161. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

162. *Id.* In response to the plaintiff’s argument that consumer demand requires the FDA to require labeling of GMOs, the court cited a district court opinion for the proposition that, if consumer demand was the sole justification for such labeling, the agency would not even have authority to require it. *Id.* (citing *Stauber v. Shalala*, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995) (“In the absence of evidence of a material difference between [milk from cows treated with a synthetic hormone] and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act.”)).

163. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-81.

164. *Id.* The historical backdrop of these competing tests—whether government action is “neutral and generally applicable” or whether it “substantially burdens” a religious practice—is worth observing. The Free Exercise Clause of the First Amendment provides that “Congress shall make no law . . . prohibiting the free exercise [of religion].” U.S. CONST. amend. I. The United States Supreme Court has established two tests by which to determine whether the government has violated the Free Exercise Clause. The Court enunciated the first test in *Sherbert v. Verner*, 374 U.S. 398, 402-03 (1963). The *Sherbert* test “ask[s] whether [the government action] *substantially burdened* a religious practice, and [if it did], whether the burden was justified by a compelling governmental interest.” *City of Boerne v. Flores*, 521 U.S. 507, 507 (1997) (emphasis added).

Although *Sherbert* provided the Supreme Court with the analytic framework to address free exercise challenges, the Court has been reluctant to apply it in cases involving across-the-board prohibitions of religious conduct. *See, e.g.*, *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520 (1993) (striking down a statute that prohibited animal sacrifices); *Employment Div., Dep’t of Human Res. of Or. v. Smith*, 494 U.S. 872 (1990) (upholding a statute that prohibited the ingestion of peyote). The distinction between such prohibitions and other government action is born of good reason; indeed, virtually *any* criminal prohibition of a religious conduct would “substantially burden” that conduct and, consequently, render the statute presumptively unconstitutional.

To eschew “deeming presumptively invalid . . . every regulation of conduct that does not protect an interest of the highest order,” the Court set forth a new test for determining violations of the Free Exercise Clause in *Employment Division, Department of Human Resources of Oregon v. Smith*, 494 U.S. at 888 (italics omitted). That test stands for the proposition that “[a] law *burdening* religious practice that is *not neutral* or *not of general application* must undergo the most rigorous of scrutiny.” *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993) (emphasis added). Significantly, the *Smith* test still requires some “burden” on a religious practice before the Court considers whether the law is neutral or generally applicable, but that burden is typically obvious (and thus not expressly analyzed) where the government action at issue is an across-the-board prohibition.

In response to *Smith*, Congress enacted the Religious Freedom Restoration Act (RFRA), codified at 42 U.S.C. § 2000bb (1992), in an attempt to reinstate the *Sherbert* test. *Id.* § 2000bb(a)-(b). The United States Supreme Court, however, held that Congress had surpassed its enforcement authority under section 5 of the Fourteenth Amendment in enacting the RFRA. *City of Boerne v. Flores*, 521 U.S. 507, 507 (1997). Although the Court recognized the authority of Congress to render “its own informed judgment on the meaning and force of the Constitution,” it concluded that “this Court’s precedent . . . must control.” *Id.* at 535-36. Until recently, however, it was unclear whether *Smith* entirely displaced *Sherbert* or whether *Smith* merely provided an alternative test that the Court would apply in cases involving the blanket prohibition of religious conduct. *Compare Smith*, 494 U.S. at 876 (“We held that distinction [between prohibition cases and non-prohibition cases] to be critical”), *with id.* at 883 (noting that the Court had recently “abstained from applying the *Sherbert* test . . . at all”).

In *Locke v. Davey*, 540 U.S. 712, 713 (2004), the Supreme Court appeared to endorse the latter position by strongly implying that the *Smith* test does not apply where the government action “imposes neither criminal nor civil sanctions on . . . [a] religious service or rite.” *Id.* The plaintiff in *Locke* challenged a state program that provided scholarships to qualified college students, but exempted any student who majored in theology. Reasoning that the scholarship program only imposed a “minor burden” on the ability of the student to freely exercise his religion, the Court rejected the argument that the program violated the Free Exercise Clause. *Id.* The Court thus abandoned the *Smith* test for the same reason that it had previously departed from the *Sherbert* test: because to apply the prevailing test in the context of that case would lead to “presumptive unconstitutionality.” *Id.* That is to say, government action that does not impose a blanket prohibition may fail the neutrality or general applicability requirements of *Smith* even though it imposes only a minor burden under *Sherbert*; thus, were the *Smith* test to apply to such a case, the government action would be subject to strict scrutiny and, therefore, would be presumptively unconstitutional.

The relevance of this historical backdrop is to demonstrate that the government action in *Alliance for Bio-Integrity*—the failure of the FDA to require labeling of GMOs—did not impose “criminal [] or civil sanctions on any type of religious service or rite.” *Id.* Consequently, the district court arguably applied the incorrect test to determine whether the FDA policy violated the Free Exercise Clause by inquiring whether the policy was neutral and of general applicability. Nevertheless, the court applied the equivalent of the *Sherbert* test in its “substantial burden” analysis under the Religious Freedom Restoration Act (portions of which the district court concluded were nonetheless constitutional after *Flores*). *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 180-81.

Alliance for Bio-Integrity remains one of the few reported judicial opinions to directly address the growing safety concerns associated with GMOs.¹⁶⁵ Nevertheless, the district court in *Alliance* had the benefit of deferring to an administrative agency with much greater institutional expertise than the Court possessed on the issue of genetic engineering. Courts interpreting subsequent genetic engineering disputes, however, may not have such a benefit. And, indeed, it is useful to reflect on the manner in which courts will approach genetic engineering before “the tidal wave of genetics-related litigation hits.”¹⁶⁶ Mindful of this theme, we turn to the issue of genetic privacy—the final area of biotechnology addressed in this Article and one that has similarly received little judicial attention.

V. GENETIC PRIVACY

The increased use of DNA forensics in criminal and civil cases has raised legal issues surrounding the collection of and access to DNA information. Because genetic information can serve as an important predictor of health, it “has led to concerns that employers and insurers may use this information as a means for limiting [an individual’s] employment opportunities or insurance coverage”—a concern not only of the particular individual but also of his or her family members.¹⁶⁷ To address these concerns, this Part examines (1) privacy issues that arise from the collection and storage of genetic information, (2) current state and federal regulations pertaining to conditions under which researchers and other entities may properly access genetic information, and (3) the manner in which American courts have addressed the issue of genetic discrimination in the workplace.

A. Collection and Storage of Genetic Information

In the area of genetic privacy,¹⁶⁸ the collection and storage of genetic information has received the most judicial and legislative attention.¹⁶⁹ As

165. See Grossman, *supra* note 142, at 239 (suggesting that courts have not had “the opportunity to decide cases involving damages from GMOs”).

166. E. Richard Gold, *Hope, Fear, and Genetics: Judicial Responses to Biotechnology*, 83 JUDICATURE 132, 135 (1999).

167. Mary J. Hildebrand et al., *Toward a United Approach to Protection of Genetic Information*, 22 BIOTECHNOLOGY L. REP. 602, 602 (2003).

168. For a discussion of the manner in which genetic privacy will become a concern to the public at large, see Berrie Rebecca Goldman, *Pharmacogenomics: Privacy in the Era of Personalized Medicine*, 4 NW. J. TECH. & INTELL. PROP. 83 (2005).

169. Some states, such as Illinois, have even passed legislation that allows prosecutors to bring Class A misdemeanor charges against any person who deliberately delays or impedes the collection of DNA from a required offender. See 730 ILL. COMP. STAT. ANN. 5/5-4-3(h)(i)(1) (West Supp. 2006). Similarly, the federal government has criminalized

previously discussed,¹⁷⁰ every state legislature has required convicted sex offenders to provide DNA samples and has authorized the creation of DNA databanks.¹⁷¹ In addition to these efforts at the state level, the federal government recently enacted a statute that provides for mandatory DNA testing of all federal inmates and for the compilation of the DNA samples in a federal database—the Combined DNA Index System (CODIS).¹⁷² These databases serve as “repositor[ies] of genetic records, which law enforcement officials can use for criminal identification purposes.”¹⁷³

Nevertheless, the methods for obtaining DNA samples have been subject to constitutional challenges in virtually every jurisdiction.¹⁷⁴ Litigants have predicated the most common challenges to the involuntary extraction of blood for DNA testing on the right against unlawful searches and seizures under the Fourth Amendment¹⁷⁵ and the right against self-

the failure to cooperate with the statutory collection procedure. 42 U.S.C. § 14135a(a)(5) (2000).

170. See *supra* Section II.B.2.

171. Giannelli, *supra* note 78, at 391-92.

172. Jean Coleman Blackerby, *Life After Death Row: Preventing Wrongful Capital Convictions and Restoring Innocence After Exoneration*, 56 VAND. L. REV. 1179, 1213 (2003).

173. Warren R. Webster, Jr., *DNA Database Statutes & Privacy in the Information Age*, 10 HEALTH MATRIX 119, 125 (2000) (citing Michael J. Markett, *Genetic Diaries: An Analysis of Privacy Protection in DNA Data Banks*, 30 SUFFOLK U. L. REV. 185, 189 (1996)).

174. The notion that advancements in biotechnology can raise constitutional concerns brings to the forefront the ongoing debate—and one of utmost importance—over the proper method of constitutional interpretation. Some originalists—those individuals who interpret the Constitution by its original meaning—contend that the document cannot afford protection against uses of modern technologies because the document was not originally intended or understood to do so. See ANTONIN SCALIA, *A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW* 38 (1997). Other scholars and jurists, including those who believe that the Constitution is a “living” document—one that grows and changes over time to meet the needs of a changing society—believe that the document may indeed provide protection against the use of emerging technologies. *Id.*; see, e.g., *Kyllo v. United States*, 533 U.S. 27, 40-41 (2001) (holding that the use of thermal imaging to measure heat emanating from home was a “search” for purposes of the Fourth Amendment). Still others—preeminently the late John Hart Ely—might, based on Professor Ely’s so-called “middle-ground” theory of constitutional interpretation, assert that the use of such technologies may implicate constitutional rights, but only when that use limits access to the democratic process or denies a minority the protection afforded other groups by representation. See JOHN HART ELY, *DEMOCRACY AND DISTRUST: A THEORY OF JUDICIAL REVIEW* 103 (1980).

175. See, e.g., *Roe v. Marcotte*, 193 F.3d 72, 76-77 (2d Cir. 1999); *Boling v. Romer*, 101 F.3d 1336, 1340 (10th Cir. 1996); *Jones v. Murray*, 962 F.2d 302, 308 (4th Cir. 1992); *People v. Wealer*, 636 N.E.2d 1129, 1136 (Ill. App. Ct. 1994); *Landry v. Attorney*

incrimination under the Fifth Amendment.¹⁷⁶ Appellate courts have generally rejected the former challenge on the basis that, although the extraction of blood implicates privacy interests,¹⁷⁷ the government's interest in preventing future crimes through DNA analysis outweighs a prisoner's lessened expectation of privacy.¹⁷⁸ The United States Supreme Court has all but rejected the latter challenge because the extraction of a blood sample and its chemical analysis do not amount to "testimonial or communicative" evidence and, therefore, are not prohibited by the Fifth Amendment.¹⁷⁹

In addition to these challenges, defendants have asserted that the forcible extraction of genetic information violates the constitutional right to privacy.¹⁸⁰ The Supreme Court has recognized the right to privacy as "created by several fundamental constitutional guarantees."¹⁸¹ Nevertheless, the Court in *Whalen v. Roe*¹⁸² held that a government database containing the names and addresses of people obtaining prescription drugs did not violate the United States Constitution.¹⁸³ That case perhaps presents the most analogous situation to the issue of DNA databank privacy.

Gen., 709 N.E.2d 1085, 1092 (Mass. 1999); *State v. Olivas*, 856 P.2d 1076, 1086 (Wash. 1993).

176. See, e.g., *Schmerber v. California*, 384 U.S. 757, 767 (1966); *In re Cooper v. Gammon*, 943 S.W.2d 699, 705 (Mo. Ct. App. 1997). One court has also rejected the theory that the extraction of DNA was cruel and unusual punishment. See *Kruger v. Erickson*, 875 F. Supp. 583 (D. Minn. 1994).

177. In *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 617 (1989), the Supreme Court recognized that the chemical analysis of blood and urine for medical information about the donor implicates privacy interests. Moreover, "[t]he ensuing chemical analysis of the sample to obtain physiological data is a *further* invasion of the tested employee's privacy interests." *Id.* at 616 (emphasis added).

178. See, e.g., *Patterson v. State*, 742 N.E.2d 4, 11 (Ind. Ct. App. 2000) (holding that the government has a compelling Fourth Amendment interest in promoting DNA testing and creating DNA databases). For a general discussion of constitutional challenges to the involuntary collection of DNA, see Graddy, *supra* note 86, at 228-30.

179. *Schmerber v. California*, 384 U.S. 760 (1966).

180. See, e.g., *Alfaro v. Terhune*, 120 Cal. Rptr. 2d 197 (Ct. App. 2002). See generally Robert S. Peck, *Extending the Constitutional Right to Privacy in the New Technological Age*, 12 HOFSTRA L. REV. 893, 895 (1984).

181. *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965). The Court in *Griswold* held that a state law forbidding the use of contraceptives unconstitutionally infringed upon the right of marital privacy. In so holding, the court recognized that various constitutional guarantees create "zones of privacy." *Id.* at 484. Specifically, the Court declared—in oft-quoted language (although not always favorably)—that "specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance." *Id.*

182. 429 U.S. 589 (1977).

183. *Id.* at 602.

Because courts have rejected these constitutional challenges,¹⁸⁴ the involuntary collection of genetic information from convicted inmates is generally permitted in the United States.¹⁸⁵ The unique nature of DNA evidence, however, raises several novel issues that pertain to the collection and storage of genetic information. First, although prisoners have a diminished right to privacy under the Fourth Amendment, their family members—who have a similar DNA composition—should not be affected by that diminished expectation and, therefore, may challenge the retention of such information after the criminal investigation has concluded.¹⁸⁶

Second, a prisoner's lowered expectation of privacy has traditionally permitted the government to conduct a "search" for only a limited period of time—specifically, when the defendant is in prison.¹⁸⁷ DNA information, however, is timeless. Thus, once a sample is collected, it will forever provide information otherwise protected by the Fourth Amendment.¹⁸⁸ One novel issue of genetic privacy, therefore, is whether "an individual who apparently has lost the right to privacy by virtue of having committed a crime, nevertheless [may] be able to regain it after the proverbial debt to society has been paid."¹⁸⁹

184. Notwithstanding the challenges to DNA database laws discussed in this Part, "no court has yet struck down a statute compelling the DNA testing of convicts." Assembly Committee on Public Safety, Committee Analysis of Assembly Bill 673, at 4 (Apr. 3, 2001) (discussing a California bill that would add four new categories of felonious crimes that would require a convicted individual to submit to DNA testing).

185. See Robin Cheryl Miller, *Validity, Construction, and Operation of State DNA Database Statutes*, 76 A.L.R. 5th 239, 239 (2000) (noting that, although statutes that created DNA databases "have frequently been challenged, the challenges usually have been unsuccessful").

186. See Marika R. Athens & Alyssa A. Rower, *Alaska's DNA Database: The Statute, Its Problems, and Proposed Solutions*, 20 ALASKA L. REV. 389, 395 (2003) (noting that although DNA reveals information about every person who shares in that individual's bloodline, a prisoner's reduced expectation of privacy does not extend to the prisoner's family members).

187. See *New Jersey v. T.L.O.*, 469 U.S. 325, 338 (1985) (explaining that the primary rationale behind the notion that prisoners retain no legitimate expectation of privacy is because of "the need to maintain order in a prison").

188. See *Skinner v. Ry. Labor Executives' Ass'n*, 489 U.S. 602, 617 (1989).

189. Mark D. Fox & Chris E. Forte, *Privacy Issues from the Judicial Perspective: Requirements for Protective Orders*, 70 DEF. COUNS. J. 89, 98 (2003). Indeed, genetic databases, biobanks, and population collections are currently available and pose concerns for privacy and discrimination. See Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH L.J. 1 (2006).

B. Legislation Governing Discrimination Based On Genetic Data

Once a genetic sample has been collected and catalogued in a DNA database, it serves as an archive of information that may be of interest to a variety of entities—such as insurers, employers, schools, personal physicians, and medical researchers.¹⁹⁰ The increasing collection and use of genetic samples “has many worried about discrimination resulting from inappropriate access to, and use of, private genetic information.”¹⁹¹ To provide adequate safeguards against the systematic misuse of genetic information—which, as some scholars suggest, could lead to the creation of a new underclass of citizens¹⁹²—state and federal legislatures have enacted laws designed to place limitations on the access to such information.¹⁹³

Much of the current debate regarding genetic privacy centers on whether genetic information “should be protected generally, as another component of health data, or by special privacy laws.”¹⁹⁴ Proponents of the former assert that such information is fundamentally no different from other health data.¹⁹⁵ Advocates of the latter contend that the unchanging nature and predictive qualities of genetic information warrant special protection.¹⁹⁶ To fully understand these two schools of thought, the following Section examines the existing laws that govern the use of genetic information.

1. Federal Legislation

“No current federal statute explicitly addresses genetic discrimination in the workplace.”¹⁹⁷ “Although Congress considered fourteen bills protecting genetic privacy in 1996, and an additional seven bills by May of the following year, federal legislation precluding improper use of this sen-

190. Hildebrand et al., *supra* note 167, at 602.

191. *Id.*

192. As other authors have suggested, “[w]ithout adequate safeguards, genetic information could be misused, and, if the practice carried out systematically, such misused genetic information could lead to the creation a new underclass of genetically less-fortunate individuals.” *Id.*

193. *Id.*

194. *Id.* at 603.

195. *Id.*; see, e.g., Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 JURIMETRICS J. 21, 24 (1999). Gostin and Hodge examine the approaches that such legislation has taken and argue for a more unified approach to addressing concerns about the use of genetic information.

196. Hildebrand et al., *supra* note 167, at 603.

197. Paul Steven Miller, *Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace*, 3 J. HEALTH CARE L. & POL’Y 225, 237 (2000).

sitive information has consistently failed.”¹⁹⁸ Other federal laws, such as the Americans with Disabilities Act of 1990 (ADA),¹⁹⁹ may provide protection against genetic discrimination.²⁰⁰ The purpose of the ADA is “to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities.”²⁰¹ The ADA defines a disability as “(A) a physical or mental impairment that substantially limits one or more of the major life activities . . . ; (B) a record of such an impairment; or (C) being regarded as having such an impairment.”²⁰² In 1995, the Equal Employment Opportunity Commission (EEOC) issued a statement that subsection (C) “applies to individuals who are subjected to discrimination on the basis of genetic information relating to illness, disease, or other disorders.”²⁰³

In view of the EEOC statement, the ADA arguably provides some protection against employer-based genetic discrimination. The ADA is not clear, however, about “whether this coverage will extend to asymptomatic individuals who are carriers of recessive disorders.”²⁰⁴ Moreover, although the ADA prevents employers from obtaining pre-employment genetic information, employers can require a pre-placement genetic examination after a conditional offer of employment. Thus, “although the ADA prohibits an employer from discriminating because of a disability, the individual will find it hard to prove that he or she did not get a job or promotion because of assumed ‘negative’ genetic information.”²⁰⁵

From the perspective of the individual relying on the ADA, new legislation was needed. In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA). Among other things, the Act safeguarded against health insurers who offer group coverage from discriminating based on private health information.²⁰⁶ This legislation for-

198. Sheri Mezoff, Note, *Forcing a Square Peg into a Round Hole: The Negative Ramifications of Misaligned Protections for Predisposed Individuals Under the ADA*, 85 B.U. L. REV. 323, 324-35 (2005).

199. *Id.* at 237-38; see also 42 U.S.C. §§ 12101-12213 (2000).

200. See Nathalie Smith, *The Right to Genetic Privacy? Are We Unlocking the Secrets of the Human Genome Only to Risk Insurance and Employment Discrimination?*, 2000 UTAH L. REV. 705, 738-39 (2000) (analyzing potential discrimination from health insurers and employers based on genetic information).

201. § 12101(b)(1) (2000).

202. § 12102(2)(A)-(C).

203. U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM’N, 2 EEOC COMPLIANCE MANUAL I § 902.8(a) (2000). To clarify this position, the statement provides an example of an asymptomatic individual who genetically tested positive for colon cancer. *Id.*

204. Smith, *supra* note 200, at 739.

205. *Id.*

206. See 29 U.S.C. §§ 1181-83.

bade health insurers offering group coverage from using genetic information to identify a preexisting condition²⁰⁷ in the absence of a diagnosis of the condition related to such information.²⁰⁸ Further, HIPAA prohibited health insurers offering group health insurance coverage from discriminating against individual participants based on genetic information.²⁰⁹

Although HIPAA provides comprehensive protection in the group health insurance market, it does not extend the same coverage to the individual health insurance market.²¹⁰ Hence, the provisions that prohibit health insurers from using genetic information to identify a preexisting condition and from discriminating based on genetic information do not apply to individuals who seek insurance in the individual or self-employment market. Further, HIPAA applies to insurance discrimination rather than employment discrimination. Thus, HIPAA does not serve as an ADA gap filler.²¹¹ In response to these shortcomings, several state legislatures have enacted laws that provide for greater protection of genetic information.²¹²

One recent development in federal legislation is the Genetic Information Nondiscrimination Act (“GINA”).²¹³ GINA is a bill that, if enacted into law, would prohibit discrimination on the basis of genetic information regarding employment and health insurance. Specifically, GINA would prevent employers from discriminating on the basis of predictive genetic information. On January 31, 2007, the Senate Health, Education, Labor,

207. Under HIPAA, “preexisting condition exclusion” is defined as “a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.” 29 U.S.C. § 1181(b)(1)(A) (2000).

208. § 1181(b)(1)(B).

209. § 1182(a)(1)(F).

210. Ashley M. Ellis, Comment, *Genetic Justice: Discrimination by Employers and Insurance Companies Based on Predictive Genetic Information*, 34 TEX. TECH L. REV. 1071, 1072-73, 1078-79 (2003).

211. See Jennifer Chorpening, Comment, *Genetic Disability: A Modest Proposal to Modify the ADA to Protect Against Some Forms of Genetic Discrimination*, 82 N.C. L. REV. 1441, 1467 (2004).

212. Hildebrand et al., *supra* note 167, at 603. For example, several states require a subject to consent before a third party may perform a genetic test or obtain genetic information. See, e.g., ARIZ. REV. STAT. § 20-448.02 (LexisNexis 2006). Other states require written authorization from the subject before a third party may obtain such information. See, e.g., S.C. CODE ANN. § 38-93-30 (West 2006) (“All genetic information . . . must be confidential and must not be disclosed to a third party in a manner that allows identification of the individual tested without first obtaining the written informed consent of that individual.”).

213. For more information on GINA, see Chorpening, *supra* note 211, at 1467.

and Pensions Committee approved GINA by a vote of 19 to 2. The House Committee on Education and Labor later approve the bill by a unanimous vote on February 14, 2007.²¹⁴

2. State Legislation

Despite the scant federal legislation regarding access to and use of genetic information, states have enacted an abundance of legislation on the topic.²¹⁵ The legislation has generally taken two approaches. One approach prohibits all uses of genetic information except for therapy, research, and investigation.²¹⁶ Colorado, for example, broadly declares that genetic information is confidential and then carefully defines exceptions for criminal investigations, research, court proceedings, paternity, and public health.²¹⁷ The other approach narrowly enumerates the uses of genetic information that are prohibited and, to the extent that a practice is not enumerated, makes lawful any other use of such information.²¹⁸ Texas, for instance, specifically prohibits small employers from treating genetic information as evidence of a pre-existing condition absent a diagnosis.²¹⁹

Several states, such as Arizona, Maryland, and Montana, generally forbid insurance companies from refusing to consider applicants on the basis of a genetic condition.²²⁰ Further, Arizona and Montana have stated that basing an applicant's rejection or rates on a genetic condition consti-

214. See Nancy King et al., *Workplace Privacy and Discrimination Issues Related to Genetic Data: A Comparative Law Study of the European Union and the United States*, 43 AM. BUS. L.J. 79 (2006).

215. Smith, *supra* note 200, at 732.

216. William F. Mulholland, II & Ami S. Jaeger, *Genetic Privacy and Discrimination: A Survey of State Legislation*, 39 JURIMETRICS J. 317, 318 (1999).

217. *Id.* (discussing COLO. REV. STAT. ANN. § 10-3-1104.7(3) (West 2006)).

218. Mulholland & Jaeger, *supra* note 216, at 318. One commentator has opined that statutes that fall into the second category "leave open the possibility of various forms of discriminatory practices by insurers." *Id.*

219. *Id.* (citing TEX. REV. CIV. STAT. ANN. art. 26.49(c) (Vernon Supp. 1999)). Several states, however, permit insurers to use genetic information to identify a preexisting condition:

For example, Connecticut allows preexisting condition limitations where the condition is substantiated by "medical information other than a genetic test." Arizona allows insurers to engage in such practices if there is "actuarial justification" based on actual or anticipated loss. Arkansas, on the other hand, is more restrictive, allowing preexisting conditions identified through genetic information only where the individual actually exhibits symptoms of the disease.

Mulholland & Jaeger, *supra* note 216, at 319.

220. ARIZ. REV. STAT. § 20-448(D) (LexisNexis 2006); MD. CODE ANN., INS. § 27-909(c)(1) (West 2006); MONT. CODE ANN. § 33-18-206(3) (2005).

tutes unfair discrimination unless the applicant's medical condition and history, and either claims experience or actuarial projections, establish that substantial differences in claims are likely to result from the genetic condition.²²¹ Florida law provides that genetic tests "may be performed only with the informed consent of the person to be tested, and the results . . . are the exclusive property of the person tested, are confidential, and may not be disclosed without the consent of the person tested." Indiana and Illinois, by contrast, authorize insurance companies to consider "favorable" genetic information that an applicant voluntarily submits.²²² As one scholar has noted, however, these statutes "do not prohibit insurers from inflating insurance premiums for everyone, then reducing these rates for individuals who submit favorable genetic data."²²³

C. Judicial Approaches to Genetic Privacy

Thus, courts will face substantial challenges in dealing with emerging technology issues relating to genetic privacy. Today, case law on the issue of genetic privacy is incipient. Early decisions on this issue will thus be crucial in setting the precedent that shapes how future cases will address issues of genetic privacy. One such case is *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*.²²⁴

1. Genetic Privacy Protection Under the ADA—*Norman-Bloodsaw v. Lawrence Berkeley Laboratory*

In *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, the Ninth Circuit Court of Appeals addressed whether genetic discrimination in the workplace falls under the protection of the ADA. The employees of Lawrence Berkeley Laboratory (LBL), a government-funded research institution, alleged that LBL tested their blood and urine for certain medical conditions—namely, syphilis, sickle cell anemia, and pregnancy—without their knowledge.²²⁵ The testing occurred in the course of mandatory employment entrance exams and on subsequent occasions.²²⁶ The employees

221. ARIZ. REV. STAT. § 20-448(E) (LexisNexis 2006); MONT. CODE ANN. § 33-18-206(4) (2005).

222. Mulholland & Jaeger, *supra* note 216, at 319 (citing 410 ILL. COMP. STAT. ANN. 513/20(6) (West 1993); IND. CODE ANN. § 27-8-26-9 (West Supp. 1998)).

223. Mulholland & Jaeger, *supra* note 216, at 319.

224. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

225. 135 F.3d at 1264.

226. *Id.* With the exception of one plaintiff, who was hired in 1968 and had been subject to an examination thereafter, the employment of each plaintiff was expressly conditioned upon a "medical examination," "medical approval," or "health evaluation." *Id.* at 1264-65.

challenged the testing in federal court under the ADA, Title VII of the Civil Rights Act of 1964, and the right to privacy guaranteed by the constitutions of California and the United States.²²⁷

The employees alleged that LBL violated the ADA by requiring, encouraging, and assisting in medical testing that was “neither job-related nor consistent with business necessity.”²²⁸ The employees further asserted that LBL violated Title VII because it tested only African Americans for the sickle cell trait and tested women for pregnancy.²²⁹ Finally, the employees argued that LBL violated their constitutional right to privacy by conducting the tests, collecting and maintaining the results of the tests, and failing to provide adequate safeguards against disclosure of the results.²³⁰ The district court rejected these challenges primarily on the basis that they were time-barred.²³¹

On appeal, the Ninth Circuit concluded that the claims were not time-barred because the statute of limitations did not commence when the tests

227. *Id.* at 1264.

228. *Id.* at 1265. The relevant portion of the ADA provides:

A covered entity shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be *job-related and consistent with business necessity*.

42 U.S.C. § 12112(d)(4)(A) (2006)(emphasis added).

229. *Norman-Bloodsaw*, 135 F.3d at 1265. Section 703(a) of Title VII of the Civil Rights Act of 1964 makes it unlawful for any employer:

(1) to fail or refuse to hire or to discharge any individual, or *otherwise to discriminate* against any individual with respect to his compensation, *terms, conditions*, or privileges of employment, because of such individual’s race, color, religion, sex, or national origin; *or*

(2) to limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual’s race, color, religion, sex, or national origin.

42 U.S.C. § 2000e-2(a) (2001) (emphasis added). The Pregnancy Discrimination Act further clarifies that discrimination on the basis of “sex” includes discrimination “on the basis of pregnancy, childbirth, or related medical conditions.” *Id.* § 2000e(k).

230. In addition to relying on the federal constitutional right to privacy, the plaintiffs relied upon the privacy protection in Article I, section 1 of the California Constitution. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1265 (9th Cir. 1998). That section provides that “[a]ll people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy.” CAL. CONST., art. I § 1.

231. *Norman-Bloodsaw*, 135 F.3d at 1266.

were administered.²³² Rather, the court observed that “a limitations period begins to run when the plaintiff knows or has reason to know of the injury which is the basis of the action.”²³³ The court further held that the district court erred in dismissing the claims based on Title VII and on the constitutional right to privacy.²³⁴ Writing for a majority of the court, Judge Reinhart noted that “[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one’s health or genetic make up.”²³⁵

Having concluded that the testing implicated privacy rights, the Ninth Circuit held that LBL violated the employees’ constitutional right to privacy and the Fourth Amendment right against unlawful searches and seizures.²³⁶ The court additionally held that the plaintiff’s assertion that LBL singled out black and female employees for additional non-consensual testing fell “neatly into the Title VII framework.”²³⁷ Nevertheless, the court upheld the district court’s dismissal of the ADA claim because “[t]he ADA imposes no restriction on the scope of the entrance examinations; it only guarantees the confidentiality of the information gathered, and restricts the use to which an employer may put the information.”²³⁸

Some scholars have suggested that the holding in *Norman-Bloodsaw* is limited to its facts because “the decision only applied to entrance examina-

232. *Id.*

233. *Id.* (quoting *Trotter v. Int’l Longshoremen’s & Warehousemen’s Union*, 704 F.2d 1141, 1143 (9th Cir. 1983)).

234. *Id.* at 1269.

235. *Id.* at 1269 (citing *Doe v. City of New York*, 15 F.3d 264, 267 (2d Cir. 1994) (“Extension of the right to confidentiality to personal medical information recognizes there are few matters that are quite so personal as the status of one’s health.”). Significantly, the United States Supreme Court has held that, although certain drug testing of high school students is constitutional, “it is significant that [such tests] look only for drugs, and not for whether the student is, for example, epileptic, pregnant, or diabetic.” *Vernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 58 (1995).

236. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1270-71 (9th Cir. 1998). The Ninth Circuit predicated its constitutional analysis on the proposition that “[t]he constitutionally protected privacy interest in avoiding disclosure of personal matters clearly encompasses medical information and its confidentiality.” *Id.* at 1269 (citing *Roe v. Sherry*, 91 F.3d 1270, 1274 (9th Cir. 1996); *Doe v. City of New York*, 15 F.3d 264, 267-69 (2d Cir. 1994)); *United States v. Westinghouse Elec. Corp.*, 638 F.2d 570, 577 (3d Cir. 1980).

237. *Norman-Bloodsaw*, 135 F.3d at 1272. In support of its conclusion that LBL violated Title VII, the Ninth Circuit observed that “[p]laintiffs allege that black and female employees were singled out for additional nonconsensual testing and that defendants thus selectively invaded the privacy of certain employees on the basis of race, sex, and pregnancy.” *Id.*

238. *Id.* (quoting 42 U.S.C. §§ 12112(d)(3)(B)-(C) (2000)) (citations omitted).

tions which include only exams conducted after an offer of employment has been made but prior to the employee's start date."²³⁹ Indeed, the ADA provides that non-entrance employment exams must be based on the ability to perform job-related functions or be consistent with business necessity.²⁴⁰ Nevertheless, the holding in *Norman-Bloodsaw* demonstrates that the ADA does not adequately protect employees against certain forms of genetic discrimination.²⁴¹

2. *The Scope of ADA Coverage and its Impact on Genetic Discrimination—Bragdon v. Abbott*

Also in 1998, the United States Supreme Court addressed to whom ADA coverage extends in the case of *Bragdon v. Abbott*.²⁴² The plaintiff, Sidney Abbott, disclosed to her dentist that she was HIV positive.²⁴³ During the course of the dental examination, the dentist discovered a cavity and informed Abbott of his policy against filling cavities of HIV-infected patients in his office.²⁴⁴ Abbott brought suit in federal court under section 302 of the ADA, which provides that "[n]o individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who . . . operates a place of public accommodation."²⁴⁵ Section 302 is limited, however, by a later subsection, which provides that "[n]othing in this subchapter shall require an entity to permit an individual to participate in or benefit from the goods, services, facilities, privileges, advantages and accommodations of such entity where such individual poses a direct threat to the health or safety of others."²⁴⁶

The Court held that an HIV infection is a "disability" under the ADA because it is a "physical or mental impairment that substantially limits one

239. Ellis, *supra* note 210.

240. *Id.* ("According to the ADA, unlike other employment exams, entrance exams do not have to be based on the ability to perform job-related functions or be consistent with business necessity.").

241. *Id.*

242. 524 U.S. 624 (1998).

243. *Id.* at 628-29. The record reflected that, although the patient was HIV-positive, the condition "had not manifested its most serious symptoms" when the incidents in question occurred. *Id.* at 628. The Court concluded the asymptomatic nature of the condition was immaterial to the legal issue of whether she was disabled under the ADA. *See id.*

244. *Id.* at 629. Nevertheless, the dentist offered to perform the work at a hospital. *Id.* Although the patient would have to pay for use of the hospital's facilities, the service itself would have been at no extra charge. *Id.*

245. *Id.* (quoting 42 U.S.C. § 12182(a) (1997)).

246. *Id.* (quoting 42 U.S.C. § 12182(b)(3)).

or more of the major life activities of such individual.”²⁴⁷ The Court based this conclusion on the fact that Abbott was “substantially limited” in her ability to procreate, which the Court considered a “major life activity” within the meaning of the statute.²⁴⁸ In so doing, the Court determined that a person can be disabled under the ADA even though the patient’s infection had not yet progressed to the symptomatic phase.²⁴⁹ The Court remanded the case to the court of appeals to determine if accommodation of Abbott would have posed a direct threat to the health or safety of others.²⁵⁰

Although Abbott’s HIV positive condition fell within the scope of coverage under the ADA, the narrow language of the statute only permits coverage of individuals with conditions that substantially limit a major life activity.²⁵¹ Genetic disorders generally do not fall within this definition for two reasons: first, genetic disorders typically do not substantially limit a “major life activity” before the symptomatic phase;²⁵² and second, genetic information that suggests an individual is “at risk” is not covered under the ADA—rather, an individual must actually have the disorder to receive coverage.²⁵³ As a result, “companies are still conducting genetic tests because there is no clear federal law prohibiting them from doing so.”²⁵⁴

247. *Id.* at 630. The ADA definition of “disability,” at 42 U.S.C. § 12102(2) (2006), is virtually identical to the definition of “disability” (formerly “handicapped individual”) in the Rehabilitation Act of 1973, 29 U.S.C. § 705(9)(B) (2006), and the definition of “handicap” in the Fair Housing Amendments Act of 1988, 42 U.S.C. § 3602(h)(1) (2000). Further, the ADA provides that “nothing [herein] shall be construed to apply a lesser standard than . . . under . . . the Rehabilitation Act . . . or the regulations issued . . . pursuant to [it].” 42 U.S.C. § 12201(a) (1994) Thus, the Court is required to construe ADA to grant at least as much protection as that which is afforded by the Rehabilitation Act. *Bragdon v. Abbott*, 524 U.S. at 632. To determine whether an activity is a “major life activity,” the Rehabilitation Act provides a non-exhaustive list of major life activities, such as “caring for one’s self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.” 45 CFR § 84.3(j)(2)(ii) (2006); 28 CFR § 41.31(b)(2) (1997). Given that reproduction “could not be regarded as any less important than working and learning,” the court held that “the Rehabilitation Act regulations support the inclusion of reproduction as a major life activity. *Bragdon v. Abbott*, 524 U.S. at 639.

248. *Bragdon v. Abbott*, 524 U.S. at 639.

249. *See id.* at 628 (“We granted certiorari to review . . . whether HIV infection is a disability under the ADA when the infection has not yet progressed to the so-called symptomatic phase . . .”).

250. *Id.* at 655.

251. Ellis, *supra* note 210, at 1086.

252. *Id.*; *see, e.g.*, *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260 (9th Cir. 1998).

253. Ellis, *supra* note 210, at 1086.

254. *Id.* at 1087.

3. *Conclusions*

Notwithstanding the questions that the ADA, HIPAA, and similar state legislation have raised on the issue of genetic privacy, “there has been virtually no case law regarding genetic discrimination in the workplace.”²⁵⁵ The topic of genetic privacy thus stands in marked contrast to DNA forensics—an area of biotechnology that courts have scrutinized for nearly two decades.²⁵⁶ This disparity illustrates two important themes. The first theme is the infancy of legal developments in genetic privacy²⁵⁷—and, as discussed in Part IV, in genetic engineering. As a result, courts are sailing on uncharted waters when attempting to assess the legal issues that these topics inspire.

And this first theme, in turn, makes clear the second: as early judicial decisions shaped the future of DNA forensics, so too will early decisions shape the future of genetic engineering and genetic privacy. Indeed, courts must “fill in the law” when bioethics issues paralyze legislation (the stem cell debate in recent years is but one example). The gravity of this responsibility thus calls for an intricate knowledge of biotechnology and its future implications—one that, at present, the vast majority of courts do not have the resources to acquire. The remainder of this Article is devoted to exploring a response to that problem.

VI. A RESPONSE TO THE GROWING DIVIDE BETWEEN LAW AND BIOTECHNOLOGY

The response of our judicial systems to the legal issues adumbrated in the foregoing Sections will play a significant role in determining whether we are about to enter the promised “enlightened era of genetic marvels” or whether these advancements will go largely unrealized.²⁵⁸ Despite the

255. Miller, *supra* note 197, at 238.

256. *See supra* Parts II and III.

257. Despite the dearth of case law addressing genetic discrimination, “parties have [recently] settled cases involving genetic testing and the ADA outside the courtroom.” Ellis, *supra* note 210, at 1086. In 2001, for example, the Burlington Northern Santa Fe Railway Company and the Equal Employment Opportunity Commission (EEOC) settled a case involving the genetic testing of employees who had developed carpal tunnel syndrome. *Id.* The employees alleged that Burlington Northern threatened to discharge them if they refused to submit to the testing. In the settlement agreement, “Burlington Northern agreed to pay \$2.2 million to the employees who were tested or asked to take genetic tests.” *Id.* Burlington Northern further agreed to refrain from genetic testing in the future and to provide enhanced ADA training to personnel. *Id.*

258. Rothstein, *supra* note 85, at 123. That the resolution of biotechnology disputes will be determined largely by the judge’s decision regarding the admissibility of scientific

weight of this charge, the influx of biotechnology disputes in the *Daubert* era—where trial judges must apply their scientific knowledge to determine the reliability of scientific evidence—has shaped the legal environment into one in which trial judges, who are often not conversant with science, must effectively become “amateur scientists.”²⁵⁹ As one federal judge has observed:

[m]any federal judges believe *Daubert* made their lives more difficult. They are going to have to give a more reasoned statement about why they are letting in evidence. They can't do it on a rubberstamp basis the way some of them did it in the past. . . . After all, we're not scientists. We're in strange territory and we want to do the best we can.²⁶⁰

Federal judges are not alone in this regard. Most state courts have adopted the *Daubert* standard to determine the admissibility of scientific evidence and, consequently, confront the same need for, and suffer from the same lack of, scientific literacy in biotechnology cases. According to one jurist, state judges “tend to have no particular training in statistical analysis as it relates to scientific research, unless they worked through doctoral programs in science before making the career switch to law.”²⁶¹ Indeed, one recent survey indicates that seventy percent of state judges have “limited, and potentially outdated, education or experience with the evaluation of scientific methodology.”²⁶²

evidence—particularly after *Daubert*—is supported by at least some empirical evidence. One survey indicated that judges were “more likely to exclude questionable expert testimony today than they were pre-*Daubert*.” Peter J. Goss et al., *Clearing Away the Junk: Court-Appointed Experts, Scientifically Marginal Evidence, and the Silicone Gel Breast Implant Litigation*, 56 FOOD & DRUG L.J. 227, 231 (2001).

259. One dissenter in *Daubert*, Chief Justice Rehnquist, questioned an interpretation of the Federal Rules of Evidence that required judges to become “amateur scientists.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 600-01 (1993) (Rehnquist, C.J., dissenting).

260. Rorie Sherman, *Judges Learning Daubert: “Junk Science” Rule Used Broadly*, NAT'L L.J., Oct. 4, 1993, at 28 (quoting United States District Judge Jack Weinstein).

261. Alan G. Gless, *Some Post-Daubert Trial Tribulations of a Simple Country Judge: Behavioral Science Evidence in Trial Courts*, 13 BEHAV. SCI. & L. 261, 263 (1995).

262. Cynthia Stevens Kent, *Daubert Readiness of Texas Judiciary: A Study of the Qualifications, Experience, and Capacity of the Members of the Texas Judiciary to Determine the Admissibility of Expert Testimony Under the Daubert, Kelly, Robinson, and Havner Tests*, 6 TEX. WESLEYAN L. REV. 1, 15 (1999). The study revealed that thirteen percent of the state judges received no scientific instruction in high school. *Id.* at 13. Significantly, eighty-nine percent of the judges who reported a science education in high school received that instruction over twenty years ago. *Id.* at 14. The numbers were similar—both in terms of the number of judges that received instruction on the scientific me-

The problem, however, runs deeper than the scientific knowledge of trial judges. Recognizing the multi-faceted impact of *Daubert*, Justice Joseph Walsh of the Delaware Supreme Court has asserted that “[t]here are two factors that hinder the effort to formulate a consistent framework for testing the admissibility of scientific evidence.”²⁶³ The first is that judges’ initial lack of scientific education and training “presents the risk that practitioners of junk science will seek to enter the courtroom to take advantage of the lack of a formalized body of knowledge.”²⁶⁴ The second factor, by contrast (and one not hitherto addressed), is the “highly subjective judgment brought to bear under a gatekeeper construct.”²⁶⁵ Because this latter factor significantly exacerbates the problem at which our response is aimed, we explore it further in the following section.

A. The Problem of Biotechnology Cases After *Daubert*— Subjective Judgment by the Gatekeeper

In addition to the reality that trial judges often fail to possess the scientific acumen necessary to serve as responsible gatekeepers in biotechnology cases,²⁶⁶ two other generalities render the gatekeeper construct problematic: first, the manner in which trial judges apply the construct is highly subjective; and second, that subjective application is afforded considerable deference on appeal.²⁶⁷ The confluence of these two factors has provided the legal community with little ability to predict,²⁶⁸ and appellate judges with little control over, the admission of novel scientific evidence in a particular case.²⁶⁹ As a result, “evidence which achieved admissibility

thod and the number of years ago that such instruction occurred—with reference to the judges’ undergraduate education. *Id.* Only an extremely small number of the surveyed judges received a masters, doctoral, or educational degree in a field related to the scientific method. *Id.* Finally, eighty-three percent of the judges did not report any instruction or educational background in the scientific method received during law school. *Id.*

263. Walsh, *supra* note 16, at 142.

264. *Id.* at 143.

265. *Id.* at 142.

266. *See supra* notes 258-264.

267. *See generally* Walsh, *supra* note 16, at 143.

268. On this point, one scholar has noted that, “[a]lthough [*Daubert*] was intended to improve how courts use science, recent empirical evidence reveals that judges continue to struggle with scientific evidence and that *Daubert* has failed to yield accurate or consistent decisions.” Joëlle Anne Moreno, *Einstein on the Bench?: Exposing What Judges Do Not Know About Science and Using Child Abuse Cases to Improve How Courts Evaluate Scientific Evidence*, 64 OHIO ST. L.J. 531, 531 (2003).

269. *See* Lee Richard Goebes, *The Equality Principle Revisited: The Relationship of Daubert v. Merrell Dow Pharmaceuticals to Ake v. Oklahoma*, 15 CAP. DEF. J. 1, 32 (2002) (noting that “not only do the district courts possess wide discretion in determining whether proffered testimony qualifies as ‘scientific knowledge,’ the appellate courts may

in one court may not be as fortuitous in another court,²⁷⁰ and the decision of the trial judge in that regard is rarely reversed on appeal.

The first factor that renders the gatekeeper construct problematic—the highly subjective nature of an admissibility determination under *Daubert*—comes as no surprise to legal scholars and jurists. To be sure, the majority in *Daubert* recognized this concern when it declared with confidence that “federal judges possess the capacity to undertake this review.”²⁷¹ Nevertheless, “[a]lthough the Court gave the district judges some guidance [by enumerating factors that the trial judge should consider when applying *Daubert*], the ultimate test remained quite subjective.”²⁷² As one scholar notes, “with the subjective nature of the reliability analysis, a judge’s idiosyncrasies or predisposition may affect the admissibility of expert testimony.”²⁷³ Three justices of the Supreme Court (Antonin Scalia,

not reverse the trial courts’ resolution of admissibility issues unless a ruling is ‘manifestly erroneous.’”).

270. Leslie Morsek, *Get on Board for the Ride of Your Life! The Ups, the Downs, the Twists, and the Turns of the Applicability of the “Gatekeeper Function to Scientific and Non-Scientific Expert Evidence: Kumho’s Expansion of Daubert*, 34 AKRON L. REV. 689, 730 n.135 (2001).

271. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993). Indeed, the reason the Supreme Court enumerated the factors that trial judges should consider when determining the admissibility of scientific evidence was precisely to *limit* the discretion of such judges. See Thomas R. Freeman, *Guardians at the Gate*, 24 L.A. LAWYER MAGAZINE, Jul./Aug. 2001, 26, 30 (“[I]n an effort to limit that discretion and provide guidance, the U.S. Supreme Court in *Daubert* and *Kumho* has enumerated several factors that trial courts should consider in making admissibility determinations.”); see also Hyongsoon Him, *Adversarialism Defended: Daubert and the Judge’s Role in Evaluating Expert Evidence*, 34 COLUM. J.L. & SOC. PROBS. 223 (2003) (suggesting that *Daubert* should be interpreted to limit judicial discretion to exclude evidence).

272. Thomas O. McGarity, *Proposal for Linking Culpability and Causation to Ensure Corporate Accountability for Toxic Risks*, 26 WM. & MARY ENVTL. L. & POL’Y REV. 1, 9 (2001). As one scholar has noted:

The *Kumho* Court thus reemphasized the wide latitude granted to the district courts in *Daubert*. A district court, in determining whether proffered testimony qualifies as “scientific knowledge,” can consider any and all factors it deems relevant. This wide latitude was also broadened in *General Electric Co. v. Joiner*, in which the Court held that appellate courts must apply the “abuse of discretion” standard when reviewing a district court’s application of *Daubert*. Thus, not only do the district courts possess wide discretion in determining whether proffered testimony qualifies as “scientific knowledge,” the appellate courts may not reverse the trial courts’ resolution of admissibility issues unless a ruling is “manifestly erroneous.”

Goebes, *supra* note 269, at 32 (citations omitted).

273. Morsek, *supra* note 270, at 739 (noting that it is “unlikely that reversal of these highly subjective decisions . . . would be commonplace with this standard of appellate

Sandra Day O'Connor, and Clarence Thomas) shared this view several years later in *Kumho Tire*.²⁷⁴ The justices observed that the *Daubert* factors “are not holy writ” but rather a proper basis for reversal if the trial court abuses its discretion in applying “one or another of them.”²⁷⁵

Where these justices found solace however, others found trepidation. The second factor that besets the gatekeeper construct—the wide latitude afforded admissibility decisions under *Daubert* on appeal—stems directly from the abuse of discretion standard of review.²⁷⁶ Under this deferential standard of review (applicable to all admissibility determinations under *Daubert*),²⁷⁷ an appellate court may not substitute its judgment for that of the trial court.²⁷⁸ Rather, the appellate court must defer substantially to the judgment of the trial court and reverse that judgment only when it constitutes an “abuse of discretion” as defined by the lenient standards of various federal circuits²⁷⁹ and state courts.²⁸⁰ As a result, the decision of a trial

review”). Other scholars have similarly observed that “whenever a court analyzes admissibility by examining reasonability, reliability, or *Daubert*-type criteria, the court can always exclude the testimony if it chooses. No absolute (that is, non-subjective) constraints seem to exist to prevent a judge from, whether intentionally or unintentionally, determining the result of a case by excluding an expert’s testimony as having been based upon ‘unreasonable’ inductive methodologies.” David M. Malone & Paul J. Zwier, *Epistemology After Daubert, Kumho Tire, and the New Federal Rule of Evidence* 702, 74 TEMP. L. REV. 103, 117-18 (2001).

274. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 158-59 (1999) (Scalia, J., concurring, with whom Justice O’Connor and Justice Thomas joined).

275. *Id.* at 159.

276. See Walsh, *supra* note 16, at 142-43; see also Jean Macchiaroli Eggen, *Clinical Medical Evidence of Causation in Toxic Tort Cases: Into the Crucible of Daubert*, 38 HOUS. L. REV. 369, 429 n.14 (2001). Professor Macchiaroli notes that “[b]etween *Daubert* and *Kumho Tire*, the Supreme Court decided *General Electric Co. v. Joiner*, 522 U.S. 136, 139 (1997), which held that the abuse of discretion standard applied to appellate review of district court admissibility decisions under *Daubert*. *Joiner* thus made it more difficult for appellate courts to reverse exclusion decisions.” 522 U.S. at 139.

277. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141-42 (1997) (concluding that “abuse of discretion is the proper standard of review of a district court’s evidentiary rulings” and that *Daubert* did not change that fact).

278. See, e.g., *Barona Group of the Capitan Grande Band of Mission Indians v. Am. Mgmt. & Amusement, Inc.*, 840 F.2d 1394, 1408 (9th Cir. 1987) (noting that an “appellate court cannot simply substitute its judgment for that of the lower court” under an abuse of discretion standard of review).

279. By way of example, the United States Court of Appeals for the Second Circuit has held that “[a] decision to admit or exclude expert scientific testimony is not an abuse of discretion unless it is ‘manifestly erroneous.’” *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (citing *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1042 (2d Cir. 1995)). The Tenth Circuit, by contrast, will disturb the decision of a lower court under an abuse of discretion standard only when it has “a definite and firm

court in admitting scientific evidence is, in addition to being highly subjective, “fairly well insulated against reversal.”²⁸¹

B. Conventional Efforts to Educate Judges

Given the concomitant rise of biotechnology in legal disputes and the broad deference accorded the highly subjective decisions of trial courts under the *Daubert* standard, the need for scientific acumen in the judiciary is greater now than at any time in our nation’s history.²⁸² To address this need, non-profit organizations, academic institutions, and state bar associations have generally offered two resources: judicial seminars and educational publications.²⁸³ This Section examines each resource and con-

conviction that the lower court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances.” *United States v. Ortiz*, 804 F.2d 1161, 1164 n.2 (10th Cir. 1986).

280. The Supreme Court of Ohio, for example, has defined the term “abuse of discretion” as “more than an error of law or of judgment; it implies that the court’s attitude is unreasonable, arbitrary, or unconscionable.” *State v. Adams*, 404 N.E.2d 144 (Ohio 1980).

281. Walsh, *supra* note 16, at 143.

282. See generally Gilbert S. Merritt, *From the Scopes Trial to the Human Genome Project: Where is Biology Taking the Law?*, 67 U. CIN. L. REV. 365, 367 (1999) (“Even a cursory understanding of Anglo-American legal history leads to the conclusion that science—physics, astronomy, chemistry, and biology—has played little role in the law and in the disputes courts have had to resolve prior to the middle of the twentieth century.”).

283. See Adam J. Siegel, *Setting Limits on Judicial, Scientific, Technical, and Other Specialized Fact-Finding in the New Millennium*, 86 CORNELL L. REV. 167, 202-03 (2000) (discussing the variety of approaches by which jurists can educate themselves on scientific matters); see also Judith A. Hasko, *Daubert v. Merrell Dow Pharmaceuticals, Inc.: Flexible Judicial Screening of Scientific Expert Evidence Under Federal Rule of Evidence 702*, WIS. L. REV. 479, 505 (1995) (noting that “judges can depend on a variety of educational and informational resources to facilitate their adjustment to th[e] responsibility” of applying *Daubert*).

A third educational resource available to judges is a court-appointed technical expert. See Fed. R. Evid. 706(a). Federal Rule of Evidence 706 grants a trial court the authority to appoint such experts, but requires the experts to advise the parties of their findings and subject themselves to cross-examination. *Id.* Many commentators have suggested that judges avail themselves of Rule 706. Justice Breyer has recommended that courts rely on court-appointed experts who are “recommended to courts by established scientific organizations, such as the National Academy of Sciences or the American Association for the Advancement of Science.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 150 (1997) (Breyer, J., concurring) (quoting Brief of Amici Curiae The New England Journal of Medicine and Marcia Angell at 18-19, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997)). However, “researchers at the Federal Judicial Center discovered that an overwhelming majority of federal district judges responding to a survey reported that they had never appointed a Rule 706 expert.” Siegel, *supra*, at 207 (citing Joe S. Cecil & Thomas E. Willging, *Court-Appointed Experts*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE

cludes that these efforts alone are insufficient to arm judges with the knowledge required to responsibly confront novel issues of biotechnology.

1. *Judicial Seminars on Scientific Matters*

One method by which judges acquire scientific knowledge is through their attendance at judicial seminars.²⁸⁴ Non-profit organizations, such as

535 (Fed. Judicial Ctr. ed., 1994)). This infrequent use of court-appointed experts is at least partially attributable to the fact that “more guidance on appointment procedures and communications with the expert [is needed to] help minimize the risks entailed in this departure from adversary procedures.” Ellen E. Deason, *Court-Appointed Expert Witnesses: Scientific Positivism Meets Bias and Deference*, 77 OR. L. REV. 59, 155 (1998). As one critic has noted, “[t]he potential for abuse under Rule 706 is great, and private communications between judges and technical advisors may have a devastating effect on the adversarial system.” Siegel, *supra*, at 208. Siegel argues that “Congress and the Supreme Court should modify the Code of Conduct, 28 U.S.C. § 455 [the judicial disqualification statute], and Federal Rule of Evidence 104(a) in a way that will restrict the discretion Rule 706 currently affords judges.” *Id.*

According to the Federal Judicial Center, however, “the judges who appointed experts have been ‘almost unanimous in expressing their satisfaction with the expert.’” *Id.* at 208 (quoting Cecil & Willging, *Court-Appointed Experts*, *supra*, at 537). Indeed, all but two of the sixty-five judges [surveyed] indicated that they were pleased with the services provided,” Joe S. Cecil & Thomas E. Willging, *Accepting Daubert’s Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1008 (1994), and “the two judges who did not indicate that they were satisfied remain open to appointing an expert in the future.” *Id.* Such a finding, coupled with the fact that court-appointed experts serve an advisory, case-specific function similar to that of ASTAR resource judges, provides an important clue as to the manner in which the judiciary will receive these institutions’ services.

There are other resources to which judges may refer for scientific education. Two less formal resources include “[v]enturing into cyberspace . . . [and] consult[ing] colleagues off the record.” Adam J. Siegel, *Setting Limits on Judicial, Scientific, Technical, and Other Specialized Fact-Finding in the New Millennium*, 86 CORNELL L. REV. 167, 168 (2000). Yet “the extent to which judges can properly engage in such practices has become a matter of great debate and uncertainty due to the divergent teachings of *Kumho*, the Code of Conduct for United States Judges, 28 U.S.C. §§ 144, 455 (the federal judicial disqualification statutes), and the Federal Rules of Evidence.” *Id.* Because the propriety of such practices remains uncertain, this Section will not address them.

In addition, Justice Breyer noted that the Court has received assistance from amicus briefs written by a variety of health-care professionals and experts in related fields. See Stephen Breyer, *The Interdependence of Science and Law*, 280 SCI., Apr. 24, 1998, at 537. “Such briefs,” he extolled, “help to educate the judges on potentially relevant technical matters, helping to make us, not experts, but moderately educated laypersons, and that education improves the quality of our decisions.” *Id.* at 538. Given that such briefs are typically filed by organizations that have a bias in a case (and that their filings are somewhat unpredictable), they too will not be addressed in this Section.

284. Siegel, *supra* note 283, at 203 (“Of the various educational resources available today, judicial seminars have become a popular means by which judges may acquire

the Federal Judicial Center, sponsor these programs to provide judges with an opportunity to learn fundamental scientific principles.²⁸⁵ One such institution is the Law and Economics Center at the George Mason University School of Law, which provides a series of judicial education programs that focus on science and the law (and, as its name indicates, on law and economics).²⁸⁶ Esteemed scholars from a wide range of academic institutions throughout the nation teach these programs.²⁸⁷ As of 1992, “398 federal judges had attended at least one course sponsored by the Law and Economics Center.”²⁸⁸ Since then, that number has significantly grown.

Another non-profit organization that provides science education to jurists—and one that we more closely examine *infra*—is the Einstein Institute for Science, Health, and the Courts (EINSHAC).²⁸⁹ EINSHAC is a voluntary education and research organization affiliated with the judicial branch of government.²⁹⁰ Organized in the District of Columbia in 1993, EINSHAC’s mission is “to provide judges, courts and court-related personnel with knowledge tools related to criminal and civil justice proceed-

knowledge on timely scientific, technical, or other specialized matters pending in courtrooms nationwide.”). Despite their growing popularity however, judicial seminars are grossly underused. One survey indicates that “only 29 percent of state trial judges in Texas reported having received some type of continuing legal, judicial, or other professional continuing education which provided instruction on the use or analysis of the scientific method.” Kent, *supra* note 262, at 14-15.

285. Jack B. Weinstein, *Limits on Judges Learning, Speaking and Acting—Part I—Tentative First Thoughts: How Many Judges Learn?*, 36 ARIZ. L. REV. 539, 543 (1994). Duke Law School offers a similar program, entitled “Judging Science,” which is a week-long seminar geared toward teaching the scientific method and its various applications to trial and appellate judges. John M. Conley, Forward, 64 LAW & CONTEMP. PROBS. 1, 1 (2001).

286. Weinstein, *supra* note 285, at 546. Judge Weinstein describes the seminars: [T]he three courses offered by the Center were “Basic Economic Institute,” a basic course in economics and on the applicability of economic theory to legal issues; “Basic Course on Science and Public Health,” a course designed to provide judges with a better understanding of scientific evidence; and “Advanced Course on the Economics of Risk, Injury, and Liability,” a course on the economics of the judicial allocation of risks through tort law.

Id. (citation omitted).

287. *Id.* at 546-47 (citation omitted).

288. *Id.* at 547 (citation omitted).

289. See *infra* Part V.C.

290. EINSHAC INFORMATION BOOKLET 1 (2004) (on file with author). Since the issuance of *Daubert* in 1993, EINSHAC has provided scientific courses for judges in the United States, Europe, and Asia. Nicola Nosengo, *Science and Law: Biotechnology at the Bar*, NATURE, Sept. 11, 2003, at 117.

ings involving evidence from the genetic sciences”²⁹¹ Led by its president, Dr. Franklin Zweig, the organization has offered genetic education to more than 3,000 judges and court-related personnel since 1996.²⁹²

Although many non-profit organizations sponsor judicial seminars, “others receive funding directly or indirectly from private corporate interests.”²⁹³ This foray of corporate interests into judicial education has led one non-profit organization, the Alliance for Justice, to suggest that “sponsorship of law and economics seminars by powerful business interests has created a legal system in which justice can be bought and sold just like any other commodity.”²⁹⁴ Other critics similarly cautioned that “seminar sponsors with hidden agendas may successfully bias unwary judges.”²⁹⁵

These allegations have not been taken lightly. In 2000, members of the Senate proposed the Judicial Education Reform Act to regulate the attendance of judges at privately-funded educational seminars.²⁹⁶ Despite such efforts, however, not all agree that the seminars are cause for concern. James Pierson, executive director of an organization that has funded judicial seminars at the Law and Economics Center, has remarked that “judges are perfectly capable of assessing law and economics on their own without being told what to think.”²⁹⁷

The veracity of these charges “remains a matter of great debate.”²⁹⁸ Nevertheless, the mere perception of improper influence on judicial education illustrates the first of two general limitations associated with judicial seminars: the wide variety of seminars offered, coupled with the varying (and often inconspicuous) sponsors upon which such seminars depend for support, often raise misgivings about their objectivity, irrespective of

291. EINSHAC INFORMATION BOOKLET, *supra* note 290.

292. *Id.* Specifically, EINSHAC operates five programs: (1) the Genetics Adjudication Resource Project (GARP); (2) the Law and Science Academy (LSA); (3) Courts and Bioterrorism; (4) Courts International Working Conversations; and (5) the Working Party on Conflict Resolution and Legal System Capacity Enhancement of the United Nations Industrial Development Organization’s Global Biotechnology Forum. It is the first of these programs—GARP—that offers the genetic education courses to judges.

293. Siegel, *supra* note 283, at 205.

294. *Id.* at 204-05. One commentator has likewise argued that judicial integrity may be sacrificed “when private interests are allowed to wine and dine judges at fancy resorts under the pretext of ‘educating’ them.” Abner Mikva, *The Wooing of Our Judges*, N.Y. TIMES, Aug. 28, 2000, at A17.

295. Siegel, *supra* note 283, at 204.

296. Judicial Education Reform Act of 2000, S. 2990, 106th Cong. (2000) (prohibiting judges from accepting “anything of value in connection with a seminar”).

297. Siegel, *supra* note 283, at 205 (citing Henry J. Reske, *Expense-Paid Judicial Seminars Hit*, 79 A.B.A. J., Aug. 1993, at 36).

298. *Id.* at 205-06.

whether as a normative matter one reasonably should question that objectivity.

The second limitation associated with judicial seminars flows from the necessarily abstract nature of the forum.²⁹⁹ That is, judicial seminars are often not intended to, and are perhaps largely incapable of, “speak[ing] to the issues that will come up in any particular case.”³⁰⁰ As a result, one judge has observed that “the real value of these seminars is to encourage the judges to feel comfortable in these types of cases” rather than to educate them on specific points of a pending scientific matter.³⁰¹ Thus, although judicial seminars serve as a valuable and arguably objective resource for educating judges on scientific developments,³⁰² these programs alone fail to adequately prepare judges for the case-by-case demands that novel issues of biotechnology impose upon the legal system.³⁰³

2. *Scientific Publications for Judges*

Publication of scientific manuals and periodicals serves as an additional resource with which to educate judges on scientific matters.³⁰⁴ In 1994, the Federal Judicial Center published the Reference Manual on Scientific Evidence to assist federal judges “in managing expert evidence, primarily in cases involving issues of science or technology.”³⁰⁵ The Judicial Center prepared the Reference Manual to provide judges with “quick access to information on specific areas of science in a form that will be useful in dealing with disputes among experts.”³⁰⁶

299. Roderick R. McKelvie, *Problems of Complex Litigation*, 9 FED. CIR. B.J. 529, 531 (2000) (discussing the “formal and informal methods for getting the judge up to speed on the technology . . . cases”).

300. *Id.*

301. *Id.* Judge McKelvie has noted, “I do not expect that many district court judges have undergraduate degrees in science Very few, if any, trial judges have graduate degrees in science (I do not know of any who do).” *Id.*

302. *See supra* notes 281-292.

303. *Id.*

304. *See* Paul S. Miller et al., *Daubert and the Need for Judicial Scientific Literacy*, 77 JUDICATURE 254, 260 (1994) (discussing science information bench books for judges).

305. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 1 (Fed. Judicial Ctr. ed., 1994) [hereinafter REFERENCE MANUAL]. The purpose of the manual is to “provide[] judges with a valuable educational resource that poses little threat to the maintenance of an impartial and independent federal judiciary.” Siegel, *supra* note 283, at 203.

306. REFERENCE MANUAL, *supra* note 305, at 3. One scholar has noted that: [t]he bulk of the Reference Manual, Part II, and the novel part in jurisprudential terms, consists of “reference guides” to areas often the subject of scientific expert testimony. . . . These reference guides consist of seven topics: epidemiology, toxicology, survey research, forensic analysis of DNA, statistical inference, multiple regression analysis, and es-

The Reference Manual is not the only such publication. To assist state court judges, the Einstein Program for Law and Judicial Policy Studies at George Washington University's Center for Health Policy Research has developed a series of bench books for state judges, entitled *Science in the Court: Finding Your Way*.³⁰⁷ Perhaps more common—although much less comprehensive—are legal periodicals that devote one or more volumes to the topic of adjudicating biotechnology disputes.³⁰⁸ One example is the November/December 1999 publication of *Judicature*, entitled “Genes and Justice,” which provides scholarly articles for judges about the effects of biotechnology on our legal system.³⁰⁹

Notwithstanding the undeniable value of these publications to the judiciary, legal manuals and periodicals are fraught with a limitation similar to that which afflicts judicial seminars.³¹⁰ Judge William Schwarzer, director of the Federal Judicial Center, emphasized this point best when he noted that the focus of the Reference Manual is not on evidentiary questions of admissibility, but rather on the epistemology of science.³¹¹ As a result, the Reference Manual does not educate judges on the admissibility of specific types of expert evidence or conclusions of specific scientific studies. In-

timization of economic loss. The collection of topics is obviously eclectic, including specific fields of research (epidemiology and toxicology), subjects of study (DNA and economic loss), and particular methodologies (surveys, regression analysis, and statistics).

Laurens Walker & John Monahan, Essay, *Daubert and the Reference Manual: An Essay on the Future of Science in Law*, 82 VA. L. REV. 837, 846-47 (1996) (citing REFERENCE MANUAL, *supra* note 305, at 119).

307. Walker & Monahan, *supra* note 306, at 845 n.36. The project was supported by the State Justice Institute, the National Institute of Justice, the Federal Bureau of Investigation, and the Human Genome Project of the U.S. Department of Energy. *See also* Miller, *supra* note 304, at 260.

308. *See, e.g., Genes and Justice: The Growing Impact of the New Genetics on Courts*, 83 JUDICATURE 1, 97 (1999).

309. *Id.*

310. *See* Daniel W. Shuman & Bruce D. Sales, *The Impact of Daubert and Its Progeny on the Admissibility of Behavioral and Social Science Evidence*, 5 PSYCHOL. PUB. POL'Y & L. 3, 8 (1999) (“Neither legal education nor judicial selection criteria address education and training in scientific methods necessary to provide the expertise to make sophisticated judgments about the reliability or validity of proffered testimony.”); Walker & Monahan, *supra* note 306, at 845.

311. Walker & Monahan, *supra* note 306, at 845 (citing REFERENCE MANUAL, *supra* note 305, at 3). Consistent with the notion that the academic literature is disconnected from the problems faced by judges, one scholar has observed that “although the alleged disjuncture between science and law continues to be fertile scholarly terrain, the academic discourse often ignores practical problems faced by judges, lawyers, and jurors.” Moreno, *supra* note 268, at 532 (citation omitted).

stead, the manual “presents a primer on the methods and reasoning of selected areas of scientific evidence.”³¹² Similar to judicial seminars, therefore, many educational publications fail to educate judges on specific questions of admissibility that may arise in a particular case.

Our point is thus: given the limitations of judicial seminars and educational publications, the legal community must establish new forums that will more effectively mediate between science and the legal environment. To serve their purposes, these forums must improve upon conventional judicial education and at the same time ease the demand on trial judges to serve as gatekeepers. The forums must, in other words, overcome the problematic features of judicial seminars and scientific publications, yet serve their same instructive purpose. The forums must refrain from deferring exclusively to the scientific community on matters of the admissibility of scientific evidence (as the judiciary did under the *Frye* test), yet modify the current practice of exercising the gatekeeper construct without the impartial advice of the scientific community (as the judiciary has done under *Daubert*). The following Section explores one such forum.

C. A Forum to Mediate Between Science and the Legal Environment

At the 150th annual meeting of the American Association for the Advancement of Science in 1998, U.S. Supreme Court Justice Stephen Breyer remarked that scientific advisors may be of great assistance to the judicial community in the twenty-first century.³¹³ Justice Breyer, whose comments echoed those of his concurring opinion in *General Electric Co. v. Joiner*,³¹⁴ observed that, as judges play an increasingly important role in screening scientific experts, advice from neutral parties in the scientific community can be of enormous value to courts.³¹⁵ Justice Breyer suggested that “in this age of science we must build legal foundations that are sound in science as well as in law. Scientists have offered their help. We in the legal community should accept that offer”³¹⁶

One organization in particular has heeded Justice Breyer’s call. EIN-SHAC, the voluntary education and research organization mentioned in

312. Walker & Monahan, *supra* note 306, at 845 (citing REFERENCE MANUAL, *supra* note 305, at 3).

313. *Justice Breyer Calls for Experts to Aid Courts in Complex Cases*, N.Y. TIMES, Feb. 17, 1998, at A17 [hereinafter *Justice Breyer*].

314. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147-48 (1997).

315. See Stephen Breyer, *The Interdependence of Science and Law*, 280 SCI., Apr. 24, 1998, at 538.

316. *Id.*

the previous Section,³¹⁷ has aided in the recent creation of an institution, ASTAR, that will soon serve as a reference to courts on novel issues of biotechnology and, in so doing, help bridge the gap between the courts and mainstream, independent, and neutral scientific enterprise.

ASTAR is a non-profit agency comprised of the judicial branches of thirty-five states around the nation (the "ASTAR consortium"). Maryland, Ohio, and Washington are serving as the core states that will provide programs for states in their regions. Established in 2003, ASTAR is dedicated to the recruitment, training, evaluation, and certification of judges of state and federal courts who have undertaken specialization in cases involving complex science and technology evidence and issues.³¹⁸ ASTAR's objective is to promote more efficient, public confidence-inspiring adjudication of complex cases involving novel scientific evidence. In 2006, ASTAR received a \$1 million congressional appropriation, administered through the Department of Justice.

1. *The ASTAR Resource Judges*

The ASTAR Consortium endeavors to identify and train judges in the United States and foreign jurisdictions who are conversant in biotechnology to be "resource judges" for their respective jurisdictions. Resource judges are specialized in scientific and technical evidence relevant to novel cases involving evidence of human genetics, agricultural biotechnology, environmental biotechnology, and applied neurobiology. The resource judges share an identified, enumerated group of knowledge foundations expected to be mastered and retained by each resource judge in the course of his or her training. These judges will understand the underlying scientific methodology and technology tests.

The term "resource" refers to reserve skills (a set of performance tasks and knowledge bases that the Consortium has initially defined and described) that each judge will be able to provide his or her respective jurisdiction. Performance tasks include direct adjudication, collegial consultation on procedural matters and novel-evidence gatekeeping, judicial education leadership, and an online case and comment journal.

2. *Training and Certification of the Resource Judges*

The ASTAR Consortium has established an independent non-profit organization, known as the Advanced Science and Technology Adjudication Standards, Credentials, and Accreditation Board ("ASTAboard"), to

317. See Section V.B.1.

318. ASTA News, Volume 1, Issue 2, at 1 (Spring 2005). ASTAR was created by EINSHAC in 2003 and became independent in 2004.

promulgate the standards by which resource judges will be certified. ASTAboard's Chair, the Honorable Eric T. Washington, Judge of the D.C. Court of Appeals, recently presided over the adoption of "The Manual," the principal standards-setting and accreditation instrument to guide ASTAR resource judge preparation.³¹⁹

To qualify as a resource judge, a selected judge must train in three national programs and five state-based workshops. The ASTAboard certifies the judge's completion of basic science and technology training, known as "Platform A." This Platform focuses on the so-called "Four B's"—bioscience, biotechnology, biomedicine, and bioforensics. Upon completion of Platform A, the judge is eligible to be elected as a Fellow of ASTAboard.

Once a resource judge has attained ASTAR Fellow status, the judge may enlist in Platform B. This Platform is an educational workshop that allows resource judges who are interested in one of five more specialized science and technology subjects to obtain more advanced background training. These five subjects are: (1) neuroscience and bio-behavior technologies; (2) environmental biotechnology and bioremediation; (3) health care adjudication and human research subjects disputes; (4) food security and agricultural biotechnology; and (5) synthetic biology, nanoscience, and national security bioforensics. Judges who complete Platform B will earn ASTAR diploma status.³²⁰

Thus, unlike traditional judicial seminars programs, judges certified by ASTAR have completed at least 120 hours of education provided by outstanding faculties at The Ohio State University, the University of North Carolina, and Johns Hopkins. ASTAR has assembled an outstanding group of scientists who are able to impart their knowledge in terms that judges appreciate and can understand. The ASTAR forum therefore provides more intensive training than the traditional one- or two-day judicial

319. ASTA News, Volume 1, Issue 2, at 3 (Spring 2005). The Manual provides a content template that must be met to qualify ASTAR resource judges' eligibility for election as ASTAR Fellows. *Id.*

320. The Honorable Christine M. Durham, Chief Justice of the Supreme Court of Utah, has agreed to Chair ASTAR's Platform B program. *Id.* at 1. Further, the University of Utah President has invited the ASTAR Platform B program in neuroscience and bio-behavioral technologies. *Id.* The Indiana University/Purdue University Health Law Center in Indianapolis will design the Platform B program in Health Care Adjudication. *Id.* These programs are slated to begin in June 2007. *Id.* The Ohio State University will assist with the project.

seminar, which is valuable but does not expose the judges to the intense training ASTAR provides.³²¹

3. *Implementation of the ASTAR Resource Judge Program*

The highest courts of the Consortium states have recently taken measures to implement the ASTAR resource judge program. In Ohio, for example, the trustees of the Judicial College of the Supreme Court of Ohio convened on January 28, 2005 to discuss ASTAR.³²² At that meeting, the trustees accepted responsibility for overseeing the design and implementation of Ohio's ASTAR resource judge program.³²³ The trustees' meeting was a prelude to action on several fronts taken by the Ohio judiciary. On March 2, 2005, letters were sent to each judge in Ohio's jurisdiction inviting application for one of twenty places authorized for the resource judge project's first cycle.³²⁴ By the April 1 deadline, the Judicial College received more than four times that number in applications from Ohio judges.³²⁵

Among the nearly ninety applications ultimately received, the trustees of the Ohio Judicial College selected twenty judges based on diversity of geographical location and geographical jurisdictional status of the court.³²⁶ These resource judges thus represent courts in all major geographic areas in Ohio and at all levels—including the probate courts, the juvenile courts, the courts of common pleas, the courts of appeals, and the Supreme Court of Ohio. The twenty Ohio judges have made a five-year commitment to receive advanced training and to assist other judges presiding over cases that involve scientific matters.

The training and education that Ohio judges received in 2006 included an agricultural science seminar at The Ohio State University in January, a program on the biogenic and environmental causes and treatment of cancer at the University of North Carolina in March, a colloquium on reproductive medicine at The Ohio State University in April, a seminar on computer and internet technologies at the Supreme Court of Ohio in May,

321. This does nothing to prevent a judge from applying Federal Rule of Evidence 706, which permits judges to appoint experts. Because of the ASTAR judge's intense training, he or she will be better able to understand the information provided by the technical expert.

322. *Id.* at 2.

323. *Id.*

324. *See id.*

325. *See id.*

326. The applicants who were not selected will join Ohio's second cycle that begins in January 2007 and have the opportunity to attend the Judges' Science and Medical Schools.

and a case conference on evidence, expert witnesses, and causation at the John Marshall Law School in Chicago, Illinois in October.

Ohio is also in the process of analyzing whether state and local court rules need to be amended to facilitate the use of the ASTAR resource judge. Any necessary changes to the applicable rules are expected to be in place at the beginning of 2008, thus allowing for the first group of ASTAR Fellows to immediately begin serving their respective jurisdictions within Ohio. Several of Ohio's twenty ASTAR judges have already applied their advanced training to cases that have been routinely assigned to them.

Maryland has similarly identified its first group of resource judges. The Honorable Robert M. Bell, Chief Judge of the Maryland Court of Appeals, designated twenty-four Business and Technology Court Judges as ASTAR resource judges. With a strong biotechnology research community, Maryland is one of sixteen states with business and technology specialized courts or judges.³²⁷ The resource judge program thus interfaces well with Maryland's civil and criminal judge priorities.³²⁸ Chief Justice Bell has circulated Judges' Science and Medical School initiations widely among Maryland courts.³²⁹

Maryland recently produced two in-state ASTAR programs, which were attended not only by its ASTAR resource judges, but also by state judges from outside of Maryland, federal judges, and professors from the two accredited law schools in Maryland. The first program, conducted in January 2006 at Johns Hopkins University School of Medicine in Baltimore, was devoted to molecular biology and genetics, stem cell research, and neuro-imaging. The second program was held in April 2006. The first day of the program, conducted at the U.S. Department of Agriculture's Research Service facility in Beltsville, Maryland, was devoted to genetic modification and manipulation of agriculturally important crops and animals. The second and third days were held at Johns Hopkins and addressed the clinical applications of neuro-imaging in assessing competency, evaluating organic brain diseases, cell and gene therapy applications of stem cell research, scientific fraud, scientific peer publications, scientific expert witness qualification assessment, and an exploration of the judicial ethics implications of performing the roles of an ASTAR judge.

327. ASTA News, Volume 1, Issue 2, at 3 (Spring 2005).

328. *Id.* Judges in the Business and Technology Courts have powers to expedite complex cases in each of the State's twenty-four judicial circuits.

329. *Id.*

4. *The Future of ASTAR*

The ASTAR resource judge program is rapidly moving from concept to reality. The initial group of judges identified by Ohio and Maryland commenced their Platform A training,³³⁰ and in October 2006, in Chicago, Illinois, the ASTAboard elected and inducted the group as ASTAR Fellows.³³¹ Approximately forty-five ASTAR resource judges have completed their certified training as of the publication of this Article.³³² In March 2007, ASTAR offered the Advanced Judicial Institute on Nanotechnology, Synthetic Biology, and Environmental Biotechnology to over 200 judges at the Lawrence Berkeley National Laboratory. Numerous regional programs will continue throughout 2007 and beyond.

Resource judges from each state originally in the ASTAR Consortium will provide technical assistance and train resource judges for jurisdictions within the region (the Eastern Region for Maryland and the Central Region for Ohio). Federal courts will be invited to participate in accordance with the plans of the Regional Centers. ASTAR's goal is to train 700 resource judges in the United States and foreign jurisdictions by the end of this decade.

VII. CONCLUSION

The Supreme Court's landmark decision in *Daubert* dramatically changed the role of trial judges in determining the admissibility of scientific evidence. Once passive recipients of scientific data, trial judges must now act as "gatekeepers" to admit reliable science and to screen out "junk science."³³³ U.S. Supreme Court Justice Stephen Breyer emphasized the point further, declaring that judges must do much more than simply reject specious science; they must "aim for decisions that, roughly speaking, approximately reflect the scientific 'state of the art.'"³³⁴

The increased responsibility of trial courts to determine the admissibility of scientific evidence comes as issues of biotechnology are beginning to find their way into the courtroom.³³⁵ This Article has attempted to dem-

330. *Id.* at 1.

331. *Id.*

332. *Id.*

333. Walsh, *supra* note 16, at 141.

334. STEPHEN BREYER, THE INTERDEPENDENCE OF SCIENCE AND LAW, ADDRESS FOR THE ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE ANNUAL MEETING AND SCIENCE INNOVATION EXPOSITION (Feb. 16, 1998), available at <http://aaas.org/spp/yearbook/chap9.htm>.

335. Abrahamson, *supra* note 3 at 102.

onstrate that three areas of biotechnology in particular—DNA forensics, genetic engineering, and genetic privacy—will soon challenge the scientific knowledge of every judicial system in the world. As one scholar predicts, “it will not be long before judges confront issues involving genetics on a regular basis within their courts.”³³⁶

To prepare judges for biotechnology issues in the *Daubert* era, various organizations offer judicial seminars and educational publications. These judicial resources, however, are limited in two respects: first, private corporate sponsors for these resources create an appearance of improper influence; and second, such resources are often not intended to, and are largely incapable of, addressing the specific biotechnology issues that will arise in a particular case.

It is not surprising, therefore, that discussions among jurists and scientists have reached a common conclusion: a new institution is necessary to ease the transition between science and the legal environment as the world adjusts biotechnology to the rule of law. ASTAR, thus realized, will be instrumental to that transition; for biotechnology, in the words of Dr. Franklin Zweig, “push[es] society into a new area where the letter of the law is grey, not black.”³³⁷

336. Gold, *supra* note 166, at 135.

337. Nosengo, *supra* note 290, at 117.