

HEALTH LAW

The Legal Implications of Detecting Alzheimer's Disease Earlier

Joshua Preston, Jaleh McTeigue, Caitlin Opperman, Jordan Dean Scott Krieg, Mikaela Brandt-Fontaine, Alina Yasis, and Francis X. Shen, JD, PhD

Abstract

Early detection of Alzheimer's disease (AD) raises a number of challenging legal questions. In this essay, we explore some of those questions, such as: Is a neurological indicator of increased risk for AD a legally relevant brain state before there are any outward behavioral manifestations? How should courts address evidentiary challenges to the admissibility of AD-related neuroimaging? How should the government regulate the marketing of neuroimaging diagnostic tools? How should insurance coverage for the use of these new tools be optimized? We suggest that many voices and multidisciplinary perspectives are needed to answer these questions and ensure that legal responses are swift, efficient, and equitable.

Introduction

In 2010, an estimated 4.7 million Americans aged 65 and older suffered from Alzheimer's disease (AD), and by 2050 this number is projected to reach 13.8 million [1]. Although there is currently no cure for AD [2], new neuroimaging techniques are being developed to detect biomarkers for AD in its earliest stages [3-5]. Such biomarkers can identify atrophying neural tissue in people with AD before they manifest observable behavioral changes [6]. For clinicians, this early detection can help facilitate prevention or help slow the disease's progression [4]. Because early detection is seen as so important, in 2004 the Alzheimer's Disease Neuroimaging Initiative (ADNI) was formed to develop a range of biomarkers—including imaging, genetic, and biochemical—for the early detection and monitoring of AD [7, 8]. Research such as this has produced new diagnostic options for clinical use. For example, in 2012, the Food and Drug Administration (FDA) approved an imaging technique that uses positron emission tomography (PET) scanning with the radioactive tracing compound florbetapir F-18 to identify the accumulation of amyloid- β plaques, which are believed to play a central role in AD [9]. The clinical implications of these advances are being actively discussed [3, 4, 10, 11]. Scant attention, however, has been paid to the *legal* implications of what it means to test positive for a biomarker that suggests a higher probabilistic risk for developing AD.

As it is likely that early-detection technology for AD will become more widely used, the Shen NeuroLaw Lab at the University of Minnesota is exploring the ramifications that this technology will have for issues such as legal relevance, courtroom admissibility of evidence, government regulation, privacy, insurance, and employment. Among the questions we seek to answer are these:

1. Is a neurological indicator of increased risk for AD a legally relevant brain state before there are outward behavioral manifestations of AD?
2. How should courts address evidentiary challenges to the admissibility of AD-related neuroimaging?
3. How should the government regulate the commercial use, advertising, and marketing of neuroimaging diagnostic tools?
4. Who should—and should not—have access to a patient’s AD neuroimaging data?
5. Should insurance providers provide coverage for the use of these increasingly informative, but not yet dispositive, tools?

In this essay, we consider these questions, recognizing that they deserve a more extended discussion than we offer here. We present more questions than answers, but we aim to inspire a discussion about what it means to be [at risk](#) for a currently incurable disease like AD and how the legal system ought to respond.

Determining the Legal Relevance of Increased Risk for AD

To the extent that early detection technologies based on biomarkers are sufficiently reliable, practical, and ethical, they will likely have a great impact on how we understand, classify, and treat the multiple stages of AD. What is less clear is whether the presence of biomarkers is a *legally* relevant brain state. Most bodies of law—including tort, contracts, and criminal law—have traditionally demanded outwardly manifested behavior as a prerequisite for legal recognition of physical injury [12]. The advent of Alzheimer’s biomarkers thus poses a conundrum: how should the law treat a person who does not exhibit behavioral symptoms but whose brain is documented to have already altered in such a way as to suggest a higher likelihood of AD?

Consider, for instance, the following hypothetical situation involving a 50-year-old man named John, someone with no significant medical history. Let us assume the FDA approves a neuroimaging technique that allows physicians to diagnose people as being at an elevated risk of developing AD. Although John is well below the average age at which AD symptoms typically appear (age 65), he tests positive for the brain AD biomarker. What happens next?

For social security disability benefits, it is unclear if the positive biomarker result will matter (at least under current law). Currently, the Social Security Administration (SSA) provides disability benefits to applicants who demonstrate early-onset AD. The SSA

regulations state that the “diagnosis of early-onset AD is based on the combination of clinical and family history; neurological, cognitive, or neuropsychological examination; and neuroimaging” [13]. The regulations emphasize that “clinical information documenting a progressive dementia is critical and *required* for disability evaluation of early-onset AD” [13]. In our hypothetical case, John’s clinical record does not include behavioral manifestations of the disease. That is, John’s brain is altered in ways that suggest he will develop AD, but John is not yet consciously aware of experiencing memory loss.

Should disability benefits always require clinical manifestations? If not, what threshold of elevated risk needs to be met before John qualifies? The same question could be asked of insurance coverage. For instance, if John tests positive for an AD biomarker, should his insurer be required to cover the costs of (potentially expensive) treatments? Such questions are specific versions of the fundamental question concerning the use of AD biomarkers in the law: In what particular legal contexts, if any, should the law require behavioral manifestation of AD, and in what contexts should the law rely on predictive neuroimaging data alone? Put another way: How should the law treat a healthy person with a not-so-healthy brain?

The question will arise not only in disability and insurance law, but also in core legal domains such as contracts, torts, and criminal law. In each domain, issues of “capacity,” “competency,” and liability may be affected by AD biomarkers. Returning to our hypothetical case allows us to imagine some possibilities. Imagine that sometime after brain alterations are identified, John is convinced by a co-worker to invest his life savings in a business venture that fails. Does John have legal recourse on the grounds of contractual incapacity to void the contract (as those in the advanced stages of AD can sometimes successfully claim)? Or what if one day John forgets to put his car in park and it crashes into a house? If John is subsequently sued on the grounds of negligence, would he have a viable defense based on his early AD diagnosis? What if John forgets which way to enter a highway and crashes into an oncoming car, killing its passengers? Would he have a criminal defense to charges of vehicular homicide?

Even if John had been diagnosed clinically with AD, resolving many of these questions would be difficult because the law is currently struggling with how, if at all, an AD diagnosis should modify legal doctrine for people with Alzheimer’s [14]. For instance, in tort law, scholars are presently debating whether the standard for negligence liability should be the reasonable person or the reasonable person *with AD* [14]. AD biomarkers raise further novel questions that the law will likely need to address in the years to come.

Admissibility in Court

As legal challenges involving people with AD come before the courts, novel questions of evidentiary admissibility will surface. The 1993 Supreme Court decision in *Daubert v*

Merrell Dow Pharmaceuticals provides guidelines for federal courts to evaluate the admissibility of expert evidence. The factors to be considered include:

1. Whether the theory or technique in question can be (and has been) tested;
2. Whether it has been subject to peer review and publication;
3. Its known or potential error rate and the existence and maintenance of standards controlling its operation; and
4. Whether it has attracted widespread acceptance within a relevant scientific community [15].

Some state courts primarily use *Frye*, a 1923 case which held that in order to be admissible the expert evidence must “have gained general acceptance in the particular field in which it belongs” [16]. Given these standards, should juries be able to hear [testimony from experts](#) about the neuroimaging evidence of early AD diagnosis?

Looking first at *Frye*, the critical question will be whether the AD biomarker is generally accepted for the particular legal purpose for which it is proffered. Under *Daubert*, the court’s inquiry will be broader, focusing on whether there is research connecting the AD biomarker to the legally relevant behavior (e.g., what can be said about the relationship between the AD biomarker and contractual capacity?).

The science is presently clear that neuroimaging techniques utilizing radioactive tracers like florbetapir F-18 are not meant to be stand-alone diagnostic tools. Even the creators of florbetapir F-18 [17] note that it “is an adjunct to other diagnostic evaluations” [18] and a “positive [PET] scan does not establish a diagnosis of AD or other cognitive disorder” [19]. But evidence need not be dispositive to be admissible under either the *Daubert* or *Frye* standard. Indeed, as the Supreme Court noted in its *Daubert* opinion, the traditional methods of challenging admissible but shaky evidence are cross-examination and calling opposing experts to the stand [15].

Should judges exclude these types of diagnostic tools from the courtroom—at least for now? Or should they admit them but also allow for opposing expert witnesses and perhaps place limits on expert testimony? Neuroimaging evidence has been admitted in a host of other contexts [20]. It thus seems likely that attorneys will attempt to introduce neuroimaging biomarkers of AD into the courtroom as well. It would be wise for lawyers, judges, and doctors to develop guidelines for the contexts—if any—in which such evidence should be admitted.

Regulating Early Detection Technology

FDA regulation of neuroimaging technology is, and will continue to be, an important focus of scholars and practitioners [21]. The same can be said of how these technologies are marketed to the public. To be viable, neuroimaging companies require a sizeable market [22], and to build such a market one can easily imagine advertising departments running far ahead of the science, thus potentially creating a need for improved industry

self-regulation or government oversight. To use just one example that gives rise to these concerns, in 2012 a UCLA research lab launched the neuroimaging company MindGenesis™, which claimed on its website to be the “Rocky Mountain region’s first imaging center focused on finding and confirming Alzheimer’s disease and dementia sooner” and touted its PET scan approach to AD detection under the tagline “Life plan imaging begins here” [23]. MindGenesis’s problem was the inability of its technology to definitively distinguish AD from other forms of dementia. The company’s website was eventually taken down without government intervention, but had it stayed up, federal or state action may have been taken for false claims, as was done when a similar company claimed the ability to use PET scans to diagnose chronic traumatic encephalopathy [24, 25].

As our understanding of AD advances and neuroimaging technologies become increasingly available, more companies like MindGenesis will likely emerge. Balancing competing priorities will be important as a regulatory regime takes shape. The recent experience of a personal genomic company, [23andMe](#), might serve as a useful touchstone [26]. 23andMe is a private company that provides consumers with genetic information based on a DNA sample [27]. In 2013, six years after the company began offering genetic testing, the FDA sent a warning letter to 23andMe, stating “we still do not have any assurance that the firm has analytically or clinically validated the PGS [Personal Genome Service] for its intended uses, which have expanded from the uses that the firm identified in its submissions [for marketing approval]” [28]. A central concern is that consumers might experience unwarranted anxiety, or even make important health decisions, based on unreliable analysis of their genetic profile. 23andMe is currently going through the FDA regulatory process for specific disease tests, and the future of [federal regulation](#) in the area of personalized genetic testing remains uncertain [29].

The most important lesson for regulation of AD biomarker technology may be this: 23andMe was created in 2006, and the FDA warning letter did not occur until 2013. Thus for a number of years, the genetic testing marketplace operated without significant federal regulation. Whether the lack of regulation was good (because it promoted innovation and consumer choice) or bad (because it misled consumers about their health) depends upon one’s normative views about the proper role of federal regulation. We do not here posit a specific position on how extensively the FDA, the Federal Trade Commission (FTC), or other state or federal agencies should regulate companies developing and marketing AD biomarkers. But we do hope for improved communication between industry, regulators, and the public as neuroimaging for AD becomes more prominent.

Optimizing Insurance Coverage

Before its website was taken down, MindGenesis (the company discussed earlier that offered neuroimaging for AD) declared on its front page (in bold font), "Only You Need to Know!" [23]. The site told users that "You have total privacy with MindGenesis. No insurance provider, government agency, physician, or hospital has access to your results unless you give signed written permission for your files to be sent to another provider" [23]. MindGenesis was sensitive to the reality that medical privacy, especially about a matter as important as AD, would be at the forefront of consumer concern.

Protecting the privacy of genetic testing results requires several considerations. On the one hand, ensuring legal privacy protections might be straightforward. Since the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), more attention has been paid to how we regulate and protect a patient's medical records [30]. But it is unclear and perhaps doubtful that companies like MindGenesis and 23andMe fall under HIPAA's "covered entities" [31]. Thus, it could be that companies providing AD biomarker services will not be held to the same privacy protection standards as health care and insurance providers. One solution then may be to expand the definition of covered entities to include these direct-to-consumer companies.

HIPAA compliance aside, other vexing problems, overlooked by MindGenesis, are that (1) most consumers would need their insurance company to pay for the brain scan, and (2) if a costly intervention was recommended upon receiving the results, most consumers would need their insurer to pay for that intervention. It thus seems likely that consumers would need to voluntarily disclose the results of their brain scans to their insurers, which could lead to better health outcomes through coverage of AD treatments. But with disclosure comes the risk of discrimination: insurance companies might charge a higher premium based on the brain data.

Novel questions may be raised for employment law litigation as well. The Americans with Disabilities Act (ADA), applicable to businesses with 15 or more employees, defines "disability" as "(A) a physical or mental impairment that substantially limits one or more major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment" [32]. The ADA further notes that "major life activities" include "the operation of a major bodily function, including but not limited to, functions of ... neurological ... [and] brain ... functions" [32]. Let us return to our hypothetical character John for a moment, to see whether he would be considered "disabled" under the ADA. On one hand, John is not yet experiencing any limitations in major life activities. He works as well as he always has. On the other hand, his brain functioning has changed, and continues to change, in such a way that it suggests he may develop AD in the years to come. But this is merely a probabilistic prediction based on neurological function. It is not legally dispositive. Is John "disabled" if it is estimated that he has an 80 percent chance of developing AD? What if the prognosis is a 51 percent

chance? These questions return us to our central issue: Under what circumstances should a brain state, independent of any observable behavioral change, be legally relevant? For instance, should an airline that learns that one of its pilots had tested positive for a biomarker for AD be able to reassign the pilot over the pilot's objection? We suspect that the public might feel differently depending on whether the person's AD diagnosis was likely to have such serious potential negative impacts.

In addition to the ADA, there remain open questions about whether the Genetic Information Nondiscrimination Act of 2008 (GINA) [33] would apply to neuroimaging AD biomarker information in the contexts of disability and health insurance. Congress enacted GINA to address the "potential misuse of genetic information to discriminate in health insurance and employment" [33]. GINA includes provisions stating that insurance companies cannot alter group or individual premiums on the basis of genetic information and cannot mandate individual genetic testing. But GINA's definition of "genetic information" would not necessarily include the brain data we are considering in this essay. GINA defines a person's "genetic information" as "(i) such individual's genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual" [33]. While genetics surely play a role in AD, genetic information is not required to obtain and analyze brain data. An employer could know nothing about our hypothetical character John's genetic profile, yet still know he tested positive for an AD brain biomarker.

While GINA protections may not apply to health insurance coverage, the Patient Protection and Affordable Care Act of 2010 (ACA) prevents insurer discrimination on the basis of "preexisting conditions" [34]. That is, if a person has AD, the insurance company cannot deny coverage or artificially inflate premiums on the basis of the AD diagnosis. Yet, as at least one commentator has observed, predictive neuroscience information, gathered *before* the onset of any symptoms, may not constitute a "preexisting condition" [35]. When the Alzheimer's Association explained the benefits of the ACA, it highlighted provisions concerning insurance for people with "early onset/younger onset Alzheimer's" [36]. It is not yet clear how the ADA would treat the category of "pre-onset" AD people.

Whether or not people in the pre-onset AD category should be given the same or similar legal protections as those with early-onset AD is not clear to us. On the one hand, we are concerned about insurers discriminating on the basis of nongenetic, predictive neuroimaging data. On the other hand, the steep costs of insuring people with AD must be considered as well. One complicating factor is the size of the population of people who would fit in this pre-onset category. Over 4.7 million Americans are currently diagnosed as having AD, a number expected to nearly triple by 2050 [1]. The number of people whose biomarker results suggest an elevated risk would be even greater, and they would be identified decades earlier than current AD detection methods allow. We

have not seen an estimate of the associated costs, but surely they are high. Balancing competing interests, in the face of such market realities, is a topic ripe for ethical and legal debate.

The Need for Continued Dialogue

To date, courts have struggled to incorporate evidence of AD into legal doctrine and practice [14]. The advent of brain-based AD biomarkers suggests that future litigation involving people with an elevated risk for AD will be even more challenging. In this essay we have raised more questions than answers. Continued dialogue is needed to explore in depth these and other legal questions surrounding the early diagnosis of dementia. For instance, in this essay we focused on AD, but it is only one of many forms of dementia, including dementia with Lewy bodies, vascular dementia, and frontotemporal dementia. Moreover, we did not consider the implications of early AD detection for areas such as estate law, end-of-life care, and family law. It is unclear how long it will take for brain biomarkers of AD to develop and how much longer still until we have more effective clinical treatments for AD. But it is not too early for the legal system to begin thinking carefully about how it will respond.

References

1. Hebert LE, Weuve J, Scherr PA, Evans DA. Alzheimer's disease in the United States (2010-2050) estimated using the 2010 census. *Neurology*. 2013;80(19):1778-1783.
2. Hodges JR. Decade in review—dementia: a decade of discovery and disappointment in dementia research. *Nat Rev Neurol*. 2015;11(11):613-614.
3. Pearson SD, Ollendorf DA, Colby JA. Diagnostic tests for Alzheimer's disease: generating and evaluating evidence to inform insurance coverage policy. Institute for Clinical and Economic Review. https://icer-review.org/wp-content/uploads/2016/02/AD_Diagnostics_White_Paper_FINAL-12-10-12.pdf. Published December 10, 2012. Accessed November 2, 2016.
4. Risacher SL, Saykin AJ. Neuroimaging and other biomarkers for Alzheimer's disease: the changing landscape of early detection. *Annu Rev Clin Psychol*. 2013;9:621-648.
5. Fiandaca MS, Mapstone ME, Cheema AK, Federoff HJ. The critical need for defining preclinical biomarkers in Alzheimer's disease. *Alzheimers Dement*. 2014;10(3)(suppl):S196-S212.
6. Henriksen K, O'Bryant SE, Hampel H, et al; Blood-Based Biomarker Interest Group. The future of blood-based biomarkers for Alzheimer's disease. *Alzheimers Dement*. 2014;10(1):115-131.
7. Weiner MW, Veitch DP, Aisen PS, et al; Alzheimer's Disease Neuroimaging Initiative. The Alzheimer's disease neuroimaging initiative: a review of papers published since its inception. *Alzheimers Dement*. 2013;9(5):e111-e194. doi:10.1016/j.jalz.2013.05.1769.

8. Mueller SG, Weiner MW, Thal LJ, et al. Ways toward an early diagnosis in Alzheimer's disease: the Alzheimer's Disease Neuroimaging Initiative (ADNI). *Alzheimers Dement*. 2005;1(1):55-66.
9. Yang L, Rieves D, Ganley C. Brain amyloid imaging—FDA approval of florbetapir F18 injection. *N Engl J Med*. 2012;367(10):885-887.
10. Teipel SJ, Grothe M, Lista S, Toschi N, Garaci FG, Hampel H. Relevance of magnetic resonance imaging for early detection and diagnosis of Alzheimer's disease. *Med Clin North Am*. 2013;97(3):399-424.
11. Baum ML. Patient requests for off-label bioprediction of dementia. *Camb Q Healthc Ethics*. 2016;25(4):686-690.
12. Shen FX. Mind, body, and the criminal law. *Minn Law Rev*. 2013;97(6): 2036-2175.
13. Social Security Administration. Program operations manual system (POMS): DI 23022.385 early-onset Alzheimer's disease. <https://secure.ssa.gov/poms.nsf/lnx/0423022385>. Effective May 12, 2015. Accessed October 17, 2016.
14. James VE. No help for the helpless: how the law has failed to serve and protect persons suffering from Alzheimer's Disease. *J Health Biomedical Law*. 2012;7:407-448.
15. *Daubert v Merrell Dow Pharmaceuticals*, 509 US 579 (1993).
16. *Frye v United States*, 293 F 1013 (DC Cir 1923).
17. Eli Lilly and Company. Amyvid (florbetapir F 18 injection) prescribing information. <https://pi.lilly.com/us/amyvid-uspi.pdf>. Revised December 2013. Accessed August 1, 2016.
18. Eli Lilly and Company, 1.
19. Eli Lilly and Company, 2.
20. Jones OD, Schall JD, Shen FX. *Law and Neuroscience*. New York, NY: Wolters Kluwer; 2014.
21. Giordano J, ed. *Neurotechnology: Premises, Potential, and Problems*. Boca Raton, FL: CRC Press; 2012.
22. Williams SC. Alzheimer's imaging agents struggle to find a market outside trials. *Nat Med*. 2013;19(12):1551.
23. MindGenesis™ website. <https://web.archive.org/web/20120814142743/http://mindgenesis.net/>. Accessed July 1, 2016.
24. Zaremba A. FDA forces UCLA researchers to stop touting experimental dementia scan. *Los Angeles Times*. April 10, 2015. <http://www.latimes.com/science/sciencenow/la-sci-sn-brain-scan-warning-taemark-20150410-story.html>. Accessed August 16, 2016.
25. US Food and Drug Administration. Review of the website entitled "Taemark Better Brain Diagnostics" for the investigational new drug [F-18] FDDNP. Letter to Gary W. Small, Semel Institute for Neuroscience & Human Behavior, February

- 20, 2015.
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLettersToPharmaceuticalCompanies/UCM436520.pdf>. Accessed August 30, 2016.
26. Ghosh S. Decentering the consuming self: personalized medicine, science, and the market for lemons. *Wake Forest J Law Policy*. 2015;5:299-338.
27. 23andMe website. <https://www.23andme.com/>. Accessed October 15, 2016.
28. Gutierrez A. Warning letter. Letter to Ann Wojcicki, CEO, 23andMe, Inc., November 22, 2013. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm>. Accessed November 4, 2016.
29. Ashburn S. Controlling your DNA: privacy concerns in genomic testing and the uncertainty of federal regulation and legislation. *DePaul J Health Care Law*. 2016;18(1):1-30.
30. Tovina SA. *HIPAA Privacy Law: Cases and Materials*. Durham, NC: Carolina Academic Press. In press.
31. Moore L, Sherlock E. Federal privacy regulation and the financially troubled DTC genomics company. *Genomics Law Report*[®]. October 27, 2009. <http://www.genomicslawreport.com/index.php/2009/10/27/federal-privacy-regulation-and-the-financially-troubled-dtc-genomics-company/>. Accessed October 26, 2016.
32. Definition of disability, 42 USC sec 12102 (2016). <https://www.law.cornell.edu/uscode/text/42/12102>. Accessed November 3, 2016.
33. Genetic Information Nondiscrimination Act of 2008, Pub L No. 110-233, 122 Stat 881, 885. <https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/pdf/PLAW-110publ233.pdf>. Accessed November 3, 2016.
34. 42 USC sec 300gg-3(a) (2016).
35. Shin JJ. Closing the gap: protecting predictive neuroscience information from health insurance discrimination. *Emory Law J*. 2015;64:1433-1465.
36. Alzheimer's Association. Health care reform and Alzheimer's disease. http://www.alz.org/living_with_alzheimers_healthcare_reform.asp. Accessed October 15, 2016.

Joshua Preston is in his first year of a joint JD/MA in bioethics at the University of Minnesota Law School in the Twin Cities, where he is also a research assistant in the Shen Neurolaw Lab. He is a research fellow at the Center for Science and Law at Baylor College of Medicine. His work focuses on the intersection of law, neuroscience, and public policy.

Jaleh McTeigue is a third-year undergraduate at Mount Holyoke College in South Hadley, Massachusetts. Previously, she was a research assistant in the Shen Neurolaw Lab,

conducted protein crystallography research at Los Alamos National Laboratory, and worked as a science and technology intern with the office of Congressman Ben Ray Lujan of New Mexico.

Caitlin Opperman is a second-year law student at the University of Minnesota Law School in the Twin Cities, where she is a research assistant in the Shen Neurolaw Lab. Prior to attending law school, she earned her undergraduate degree in psychology and worked as a clinical psychometrist. She is interested in exploring the intersection of law and neuropsychology as well as the connections between science and law more broadly.

Jordan Dean Scott Krieg is a fourth-year undergraduate studying neuroscience at the University of Minnesota in the Twin Cities, where he is also a research assistant in the Shen Neurolaw Lab. He plans to attend medical school.

Mikaela Brandt-Fontaine is a second-year undergraduate studying neuroscience at the University of Minnesota in the Twin Cities, where she is also a research assistant in the Shen Neurolaw Lab. She plans to attend medical school and to continue researching the relationship between medicine and the legal system.

Alina Yasis is a fourth-year undergraduate studying psychology with a minor in neuroscience at the University of Minnesota in the Twin Cities, where she is also a research assistant in the Shen Neurolaw Lab. She plans to pursue graduate studies in neuroscience.

Francis X. Shen, JD, PhD, is an associate professor of law at the University of Minnesota in the Twin Cities, where he also serves as director of the Shen Neurolaw Lab. He is executive director of education and outreach for the MacArthur Foundation Research Network on Law and Neuroscience and a faculty member at the Center for Law, Brain and Behavior at Massachusetts General Hospital.

Related in the *AMA Journal of Ethics*

[Direct-to-Consumer Personal Genome Services: Need for More Oversight](#), September 2009

[Ethical Issues in the Early Diagnosis of Alzheimer Disease](#), December 2011

[The Future of Neuroimaging in Witness Testimony](#), November 2010

[Locating Risk in the Adolescent Brain: Ethical Challenges in the Use of Biomarkers for Adolescent Health and Social Policy](#), December 2016

[Regulation and the Fate of Personalized Medicine](#), August 2012

The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

**Copyright 2016 American Medical Association. All rights reserved.
ISSN 2376-6980**