

Consortium on Law and Values in Health, Environment & the Life Sciences 2016-17 Student Proposal Cover Page

Applicant Information

Applicant name(s):	Joshua Panduro Preston	Email:	prest202@umn.edu
Project title:	"The Legal Implications of Detecting Alzheimer's Disease Earlier"		
Department:	Law School/Center for Bioethics	College:	Law School/Graduate School
Degree program:	J.D./M.A.	Faculty advisor name & email:	Francis X. Shen, fxshen@umn.edu <input type="checkbox"/> NA
Dept. Head:	Dept. Head's email:		
Dean:	Garry Jenkins	Dean's email:	gjenkins@umn.edu
How did you hear about this funding opportunity?			
<input checked="" type="checkbox"/> Consortium e-mail <input type="checkbox"/> Graduate & Professional Student Update <input type="checkbox"/> The Brief <input type="checkbox"/> Advisor <input type="checkbox"/> Dept. email/newsletter <input checked="" type="checkbox"/> Consortium website <input type="checkbox"/> Other			

Funding

Total amount of funding requested:	\$ 3,760
Executive summary (maximum 200 words)	

I am requesting \$3,760 to study the legal implications of detecting Alzheimer's Disease (AD) earlier. New neuroimaging technologies and techniques can allow clinicians to detect the biomarkers for AD long before a patient manifests behavioral changes. While beneficial for prevention and treatment, little scholarship exists to guide the legal systems' handling of those with a high, probabilistic risk of AD. As an expansion of a previously published essay, this research project will contribute to the literature by focusing on three key areas. First, it will critically review the current state of early AD neuroimaging technologies. Second, it will synthesize the literature on how the legal system has thus far addressed the issue of accommodating people with AD. (This will include the categorization of ~4,200 court opinions that either "Alzheimer's Disease" or "biomarker/s"). Third, it will adapt existing AD-related policy recommendations to include individuals with early AD biomarkers. The outcome of this research will be a law review article submitted to a top-tier law and biosciences journal and, hopefully, two conference presentations.

Approvals

Check all appropriate approvals required for your proposal. It is not necessary to have all approvals at the time of proposal submission; however, approvals must be obtained prior to receipt of funding. If you have applied for approval but have not yet received it, indicate that below.

IRB	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> NA	<input type="checkbox"/> Application pending	
Other	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> NA	<input type="checkbox"/> Application pending	Specify:

Checklist—for reviewer use

<input type="checkbox"/>	The proposal is 1000 words or less excluding budget, biographies, references and citations.
<input type="checkbox"/>	The proposal includes a work plan with a specific timeline using months or quarters to identify work to be done and completion dates.
<input type="checkbox"/>	The proposal includes a 1-2 paragraph biography of the applicant and all co-investigators.
<input type="checkbox"/>	The budget form is complete including the funds sought for this project, other pending applications for this project, and the amount/source of matching or other funds.
<input type="checkbox"/>	The applicant's faculty advisor is copied on the application email. Professional students w/o advisors check NA.
<input type="checkbox"/>	All necessary approvals are pending or received.

Project Proposal

Title: “The Legal Implications of Detecting Alzheimer’s Disease Earlier”

Author: Joshua Preston

Faculty Advisor: Francis X. Shen (Law School)

Nature and Importance¹

In 2010, an estimated 4.7 million Americans aged 65 and older suffered from Alzheimer’s disease (AD).² By 2050 this number is expected to triple.³ Though there is currently no cure for AD, new neuroimaging techniques are being developed to detect biomarkers for the disease in its earliest stages—long before patients manifest observable behavioral changes.⁴ Such data regarding atrophying neural tissue can, for clinicians, help facilitate prevention or slow down the disease’s progression.⁵ Thus as our understanding of AD grows, the traditional diagnosis of mild-moderate-severe may expand to include new diagnostic categories based upon these biomarkers. Yet for as promising as this research is, little scholarship exists to guide the legal system’s handling of those with a high, probabilistic risk of AD.⁶

Most bodies of law—including torts, contracts, and criminal law—have traditionally required outwardly manifested behavior as a prerequisite for the legal recognition of physical injury.⁷ Outside of these domains, probabilistic risk of AD is likely to raise questions involving insurance coverage, federal disability benefits, etc. In the latter case, many government programs focus on elderly populations and are designed to help individuals and families with costs associated only with *severe* disabilities. Consequently, those who are “at-risk” may, like those with “early onset” AD, be excluded from short- and long-term care benefits.⁸ As they currently exist, neither the legal system nor the social safety net is

¹ Some of the text from this proposal is drawn from a previously co-authored essay. See Joshua Preston & Francis X. Shen et al., *infra* note 6.

² Liesi E. Hebert et al., *Alzheimer’s Disease in the United States (2010-2050) Estimated Using the 2010 Census*, 80 NEUROLOGY 19 (2013).

³ *Id.*

⁴ J. R. Hodges, *Decade in Review—Dementia: A Decade of Discovery and Disappointment in Dementia Research*, 11 NAT. REV. NEUROL. 11 (2015); Kim Henriksen & Blood-Based Biomarker Interest Group et al., *The Future of Blood-Based Biomarkers for Alzheimer’s Disease*, 10 ALZHEIMER’S DEMENT. 1 (2014).

⁵ Shannon L. Risacher & Andrew J. Saykin, *Neuroimaging and Other Biomarkers for Alzheimer’s Disease: The Changing Landscape of Early Detection*, ANNUAL REV. CLIN. PSYCHOL. 9 (2013).

⁶ Joshua Preston & Francis X. Shen et al., *The Legal Implications of Detecting Alzheimer’s Disease Earlier*, 18 AMA J. ETHICS 12 (2016).

⁷ Francis X. Shen, *Mind, Body, and The Criminal Law*, 97 MINN. L. REV. 6 (2013).

⁸ Sarah McDaniel, *Student Work: The Costs of Early-Onset Alzheimer’s Disease and the Federal Benefits Dilemma*, 113 W. VA. L. REV. 133 (2010).

adequately prepared to accommodate this new category of individuals.⁹ Given the aging population and rapidly advancing neuroimaging techniques to detect relevant brain changes earlier, the time is right for careful examination of the legal frameworks.

This proposed research project will examine the legal and ethical issues arising from these scientific advances. In addition to synthesizing current literature, regulatory guidance, and case law, this project will develop policy proposals to meet the needs of those with early biomarkers for AD. Specifically, this project critically review the current state of early AD neuroimaging technologies, categorize court opinions that mention relevant key words (discussed below), and adapt existing AD-related policy recommendations to fit individuals with early AD biomarkers. For example, the standard for negligence liability could be a reasonable person *with AD*,¹⁰ lawyers could encourage the use of Mental Health Advance Directives,¹¹ and state registries could be created for research and policy planning.¹² In the realm of health insurance, new predictive neuroscience could be protected from discrimination.¹³

Innovative Contribution to Law, Health, and the Life Sciences

The study of the legal implications of detecting AD earlier is a new topic within the field of law and neuroscience. The first essay on this topic was published in December 2016,¹⁴ authored by myself, UMN Law Professor Francis X. Shen, and additional members of the Shen Neurolaw Lab. This initial, 1,500-word essay was broad in its scope and raised more questions than it answered. My proposed research project seeks to dig further into this issue and provide guidance for lawyers, courts, and legislators who, very soon, will need to address this problem. Given the breadth of this project and the nature of law school, I am unable to pursue this research without this financial support from the Consortium on Law and Values.

⁹ In fact, some scholars argue they have already failed to serve the most-vulnerable AD population, those with the severe form of the disease. See Vaughn E. James, *No Help for the Helpless: How the Law Has Failed to Serve and Protect Persons Suffering from Alzheimer's Disease*, 7 J. HEALTH & BIOMED. L. 407 (2012). (regarding issues pertaining to tort law, guardianship, and due process protections in court proceedings).

¹⁰ *Id.*

¹¹ Lisa Brodof, *Planning for Alzheimer's Disease with Mental Health Advance Directives*, 17 ELDER L. J. 239 (2010).

¹² Elizabeth Weeks Leonard, *Best Practices for Establishing Georgia's Alzheimer's Disease Registry*, 17 MINN. J. L. SCI. & TECH. 221 (2016).

¹³ Joyce J. Shin, *Comment: Closing The Gap: Protecting Predictive Neuroscience Information from Health Insurance Discrimination*, 64 EMORY L. J. 1433 (2015).

¹⁴ See Joshua Preston & Francis X. Shen et al., *supra* note 6.

Work Plan

As this proposed law review article is an expansion of a previously published essay, much of my time will be spent focusing on three key areas. First, I will critically review the current (and promising) state of early AD neuroimaging technologies and techniques. Second, I will synthesize the literature on how scholars, courts, and administrative agencies have engaged the question of accommodating not only individuals with AD but those who test positive for *other* diseases' biomarkers prior to any other physical manifestation. This will include categorizing the ~4,200 cases available in LexisNexis and Westlaw that mention either "Alzheimer's Disease" or "biomarker/s." Doing so will allow me to identify emerging trends and problems that will be useful in the last key area. Third, I will survey existing policy recommendations that can be adapted to those diagnosed as having a high, probabilistic risk of AD. Throughout this process, I will consult and solicit feedback from my advisor, Francis X. Shen, and colleagues at both the Shen Neurolaw Lab and Center for Science & Law. Additional feedback will come from presenting this research at two law and biosciences conferences.

Timeline

May – June 2017: *total 80 hours*

- Survey relevant literature and categorize court cases involving individuals with AD and/or biomarkers for other diseases. Begin drafting text for law review article.

July 2017: *(As an enlisted in the Minnesota National Guard, I will be in Fort Benning, GA, training during the month of July. Accordingly, I will not be working on this project at this time).*

August 2017 – November 2017: *total 40 hours*

- Continue research and produce first draft of law review article. Submit to faculty advisor, the Shen Neurolaw Lab, and the Center for Science & Law for feedback.

December 2017 – January 2018: *total 30 hours*

- Revise article based on feedback. Pursue additional research as necessary.

January 2018 – June 2018: *total 20 hours*

- Produce second draft of article. Submit to faculty advisor for feedback. Continue to revise article as necessary.

July 2018 onwards:

- Submit narrative and financial report to Consortium. Submit presentation proposals to the 2018 annual conferences of (1) the American Society for Bioethics and Humanities and (2) *The Journal of Law & The Biosciences*. Incorporate conference feedback into the article.
- Because many law journals do not accept submissions from law students, this article will be submitted to top interdisciplinary journals during the first submission cycle following my graduation (2019).

Biography

Joshua Preston is J.D/M.A. joint-degree candidate at the University of Minnesota Law School and Center for Bioethics. He is a graduate of the University of Minnesota, Morris (2013: political theory, history) and from 2012-2016 he was a research fellow at Baylor College of Medicine's Center for Science and Law. There he worked under neuroscientist David Eagleman on several projects related to the intersection of law, technology, and public policy. During that time, he was a contributor to Columbia University's online magazine *Voices in Bioethics*. Currently he is a research assistant for UMN Law Professor Francis X. Shen and the assistant managing editor of the *Journal of Science & Law*.

Budget

[Included with my submission as a separate Excel document]

**Consortium on Law and Values in Health, Environment the Life Sciences
Proposed Budget**

Project Title:

Provide justification along with costs.

			Requested funding	Matching/other funding <i>Provide this information is you have other funding sources for this project.</i>	
	Category& instructions	Justification	Amount	Amount	Source
1	Your stipend <i>Maximum of \$5,000</i>	<i>Research at \$18/hr (Law school research assistant rate). As I note in my timeline, May-Nov. 2017 will include 130 hours of literature review and writing before I submit it to my faculty advisor for feedback. Dec.-Jun. 2018 will include 40 hours of additional revision and research.</i>	\$3,060		
2	Speaker honoraria (for colloquia)	___ speakers x \$ _____ honorarium	\$0		
3	Supplies & Services <i>Identify and explain use here or in the body of your proposal.</i>		\$0		
4	Equipment <i>Identify and explain use. Allowable only if the equipment is necessary for this project. All equipment must be given to your dept. at the completion of your project.</i>		\$0		
5	Travel <i>Indicate the purpose of the travel, estimated dates of travel, transportation, housing and allowable per diem costs (see travel.umn.edu).</i>	<i>My goal is to present this research at the 2018 annual conferences of (1) the American Society for Bioethics and Humanities (ASBH) and (2) the Journal of Law and The Biosciences. These would be two separate flights and one night in a hotel (each). Other costs I will pay out of pocket.</i>	\$700		
Subtotal research expenses (2-5)			\$700	\$0	
TOTAL BUDGET			\$3,760	\$0	