

I come to this committee with the utmost of empathy and humility regarding this devastating disease, which has no known cause, and causes such significant morbidity, mortality, and family distress. I also have an element of personal involvement. As a practicing general internist, I have diagnosed this condition twice in my patients, a bit above the odds, and suffered the loss of a close family friend out of state in December.

I want to clearly provide for you a perspective on the proposed legislation, lest it be too optimistically presumed that a registry is the missing ingredient, the pathway to successfully understanding this disease and moving closer to understanding causality. **Well-designed epidemiologic studies need to be conducted to get us closer to understanding the causes of ALS. A well-designed study is one without bias and which accounts for potential confounders.**

Clearly, more research in this area is needed. The Department supports quality epidemiological research into the causes of ALS. We are aware of spatial analysis/ecological studies that look at the association between ALS and cyanotoxin. There are many weaknesses with studies like this so strong conclusions should not be drawn from these.

It is not clear that a registry is the best way to approach that research in Vermont. Let me tell you why.

Registry data does not collect information on risk factors such as occupational, environmental and lifestyle risk factors. For example, in a study Dr Stommel and colleagues published last year, they found an association between pesticide exposure and ALS. Studies have also shown associations with heavy metals, head trauma, smoking, and a small percentage may have a genetic predisposition among other things.

If the goal of a registry is to determine a cause of ALS, the registry will not provide the information needed. Data on risk factors, demographics and other potential exposures would need to be collected as part of a well-designed epidemiologic study. These are not data physicians typically collect and therefore they can't be reported to the Health Department. As an example, the Massachusetts ALS registry collects the following data - patient demographics (age, gender, address), Clinical symptoms and laboratory data, Diagnosis and Treatment. Massachusetts received funding from ATSDR/CDC to start their registry.

Additionally, the number of cases of ALS in Vermont is relatively small which makes deriving meaning from the data challenging due to a lack of statistical power. Now it may be true that collaborative epidemiological studies involving larger populations (for example, combining reports from multiple states) or registries such as the National ALS registry may yield more promising results in a disease as uncommon as ALS. The National ALS Registry is a separate and voluntary (self-report) registry created to identify and gather information about ALS from cases throughout the United States. We could ask HCPs to encourage patients to report here. There is an exposure questionnaire that people can fill out (or they can opt out).

As an example of something I believe would be equally helpful, let me describe the Breast Cancer Surveillance System approach to research. The Vermont Mammography Registry is **part of the Vermont Breast Cancer Surveillance System** and a partner of the nationwide Breast Cancer Surveillance Consortium (BCSC). Leading scientists from across the country and in Vermont join together to study breast cancer screening and diagnosis. The VT Mammography Registry is a partnership of 13 facilities across the state that conducts quality research on breast health and mammograms. Based out of UVM, every time an individual gets a mammogram, a questionnaire collecting risk factors, demographics and other data is completed. These data have contributed to hundreds of quality published studies on breast cancer screening. I could envision a quality epidemiologic research study working with neurologists in Vermont being done in a similar fashion. An approach where researchers reach out to Vermont neurologists to ask their ALS patients to take part in a research study that collects data on demographics, risk factors and exposures with a validated questionnaire.

A disease registry for one disease raises issues of equity as well. Currently the only disease registry in our state is the cancer registry. Even far more common and often similarly devastating conditions. Disease registries are generally developed for surveillance and to track clinical care and outcomes. The cancer registry seeks to reduce the impact of cancer on individuals, families, and communities and examines screening, diagnosis, treatment, and survivorship. It contains physician/medical information. While the financial, logistical, and human resource challenges of establishing a new registry need to be considered, these are by no means insurmountable or large. And to go on record, concerns about the impact on tourism related to cyanotoxin in our lakes has never been a consideration regarding support of an ALS registry. But I do worry that the admirable goals the advocates for this registry have would fail to be realized, in consideration of the uncommon nature of the disease, and the issues of lack of comprehensive data to allow comprehensive hypothesis testing I have described.

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Below please find helpful links.

The Vermont Mammography Registry factsheet -

http://www.med.uvm.edu/docs/about_vbcss/surgery-documents/offical_flyer.pdf?sfvrsn=500ed4fb_2

Vermont Breast Cancer Surveillance System: <http://www.med.uvm.edu/vbcss>

The Breast Cancer Surveillance System and the Principal Investigator of the Registry:

<http://www.med.uvm.edu/vbcss/faculty-staff>

Epidemiology Department at Dartmouth's School of Medicine

<https://geiselmed.dartmouth.edu/epidemiology/>