

NEUROLOGY GRAND ROUNDS

Friday, September 23, 2011
8:00 – 9:00 a.m.

LSU Health Sciences Center – Shreveport
Lecture Hall, Room 3-322

“Legal & Ethical Issues in Neurology”

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Learning Objectives:

At the completion of this regularly scheduled activity, participants should be able to:

- Discuss the basic constraints on neurologic practice
- Explicate the constraints by means of specific examples

Disclosure: Dr. Marino has no significant conflict of interest.

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Legal/Ethical Issues in Neurology

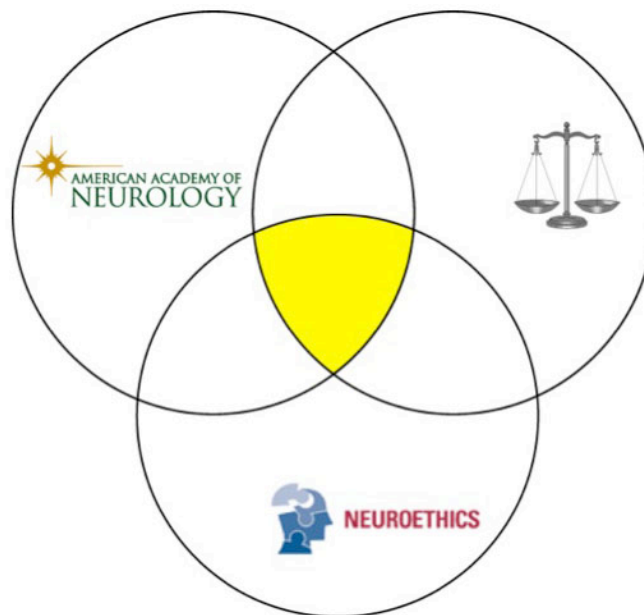
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Summary

- Legal/ethical constraints on neurologic practice
- AAN perspective
- Three specific issues
- Inter-relationship of constraints

I'll discuss the general classes of constraints, the perspective of the American Academy of Neurology, and three specific issues. I'll conclude that legal constraints have the most immediate and practical impact on neurologic practice.

Constraints on Neurologic Practice



Constraints may arise from considerations of professional responsibilities, ethical or moral considerations, or from the demands and requirements of applicable laws. Some issues can be classified and discussed in the context of one or perhaps two of the constraints, but probably the most complex issues faced in practice involve issues that contain elements of all three constraints.

American Academy of Neurology
Ethics, Law and Humanities Committee

ETHICAL DIMENSIONS OF NEUROLOGIC PRACTICE

A Case-Based Curriculum for Neurology Residents

March, 2000

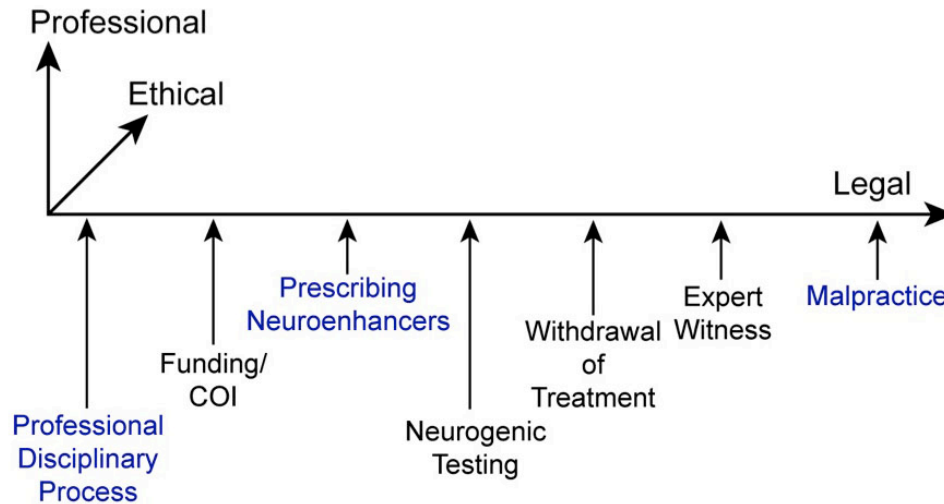
A practicing neurologist is expected to act in a professional manner. We can get an idea of what that means by examining what ethical dimensions the Academy considers necessary for teaching neurologists-in-training.

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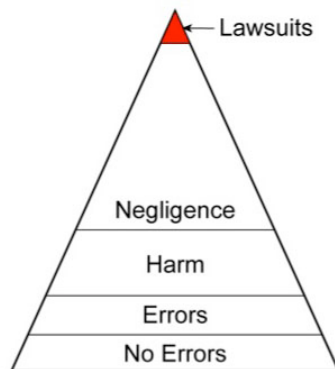
These are the topics in the recommended curriculum for residents. With the exception of neuroenhancers, which I'll discuss shortly, no other major topics have arisen in the last 10 years.

Pick Issues to Emphasize Legal Aspect



All of the specific issues that arise are three-dimensional in the sense that, in varying proportions, they involve all three general constraints. I adopted a legal perspective and ranked some important issues along that axis. In this perspective, and speaking qualitatively, I ranked the legal proportion of the constraint for the indicated specific issues. For discussion purposes I chose issues at the low and high end of the legal scale, and the issue of neuroenhancers which I think is somewhere in the middle but has the potential to move up the scale.

First Issue: The Malpractice Iceberg



- Small fraction of negligence cases → lawsuit.
- Some lawsuits even in absence of negligent care.

J. Am. Med. Inform. Assoc. 11:468–478, 2004.

Positive law has its greatest impact in the issue of malpractice. There are two salient points. First, the number of lawsuits represents only a tiny minority of the possible lawsuits, that is, of cases involving harm to patients brought about by culpable errors by the neurologist. Physicians are human beings, human beings make errors, and errors sometimes result in harm for patients. The number and impact of these errors can be minimized, but not eliminated. Second, some malpractice cases do not involve physician errors. In other words, there are cases where lawsuits could have been brought but weren't, and cases where they were brought but should not have been. Consequently, malpractice claims are uncorrelated with quality of care.

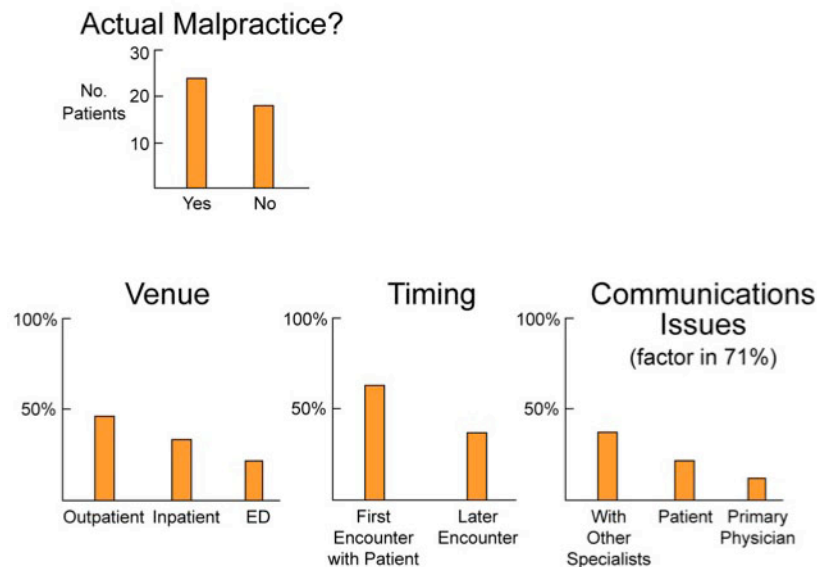
Longitudinal Analysis of Neurologic-Patient Malpractice Claims

- Harvard
- Closed claims 1986–2004
- ≥ 1 neurologist (resident or staff)
- 42 claims

Neurology 65:1284, 2005.

When a lawsuit is brought against a neurologist, what are the typical reasons, and what are the conditions that might generalize and hence merit prospective consideration? I think we can find some useful answers from a study done at the Harvard teaching institutions. The study evaluated all claims that involved a neurologist during a 15-year period, and 42 such claims were identified and analyzed.

Evaluation of 24 Neurologic Claims



- Basis of claim: Failure to diagnose: 63%
- Supervision Issue: 25%

In the judgment of the authors 24 claims were malpractice (physician errors that resulted in patient harm). Although the percentages vary widely from study to study depending on the criterion adopted, about 50% is probably a reasonable average for the number of malpractice suits that actually involved physician malpractice. Only a small percentage of the cases in this study originated in the emergency department. Among the possible explanations is the law's reluctance to recognize liability when a physician is functioning under emergency situations. The Good Samaritan laws, which exist in essentially all the states, exemplify this attitude. Seventeen of the 24 cases of actual malpractice involved some form of miscommunication between the neurologist and either another physician, or the patient. The take-home message is: be especially on guard in a non-ED setting during your first encounter with the patient, and empathize.



Second Issue: Professional Disciplinary Process

CODE OF PROFESSIONAL CONDUCT

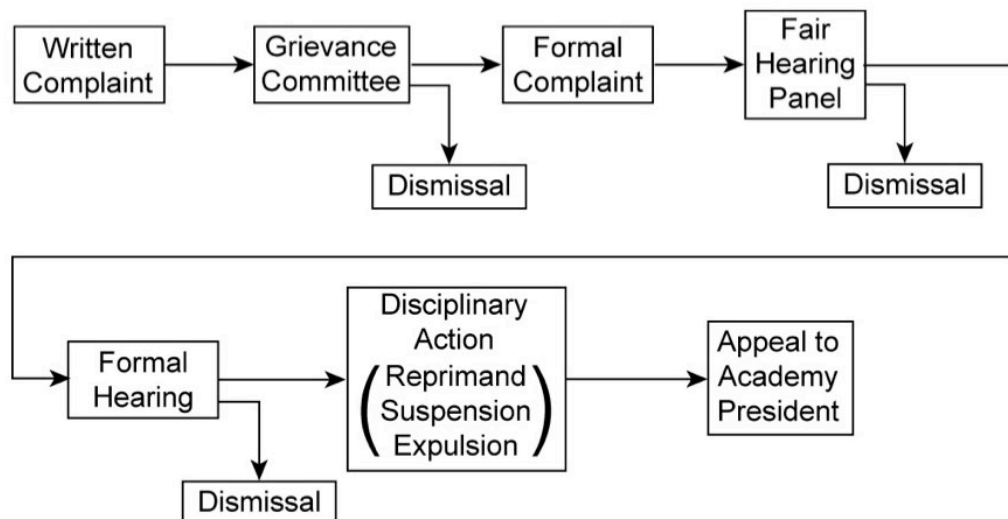
December 2009

1. The Neurologist-Patient Relationship
2. General Principles of Neurologic Care
3. Special Categories of Neurologic Care
4. Personal Conduct
5. Conflicts of Interest
6. Relationships with Other Professionals
7. Relationships with the Public and Community
8. Clinical Research and Scholarly Works

The Academy published a Code of Professional Conduct that explicitly treats eight general areas, and it developed a disciplinary process for handling cases of alleged violation of the Code.



Disciplinary Process



The process is triggered when the Academy receives a written complaint concerning the conduct of a member and involves the indicated procedural steps leading to either dismissal of the complaint or a disciplinary action.

Complaints Received

Year	Number
2004	3
2005	5
2006	12
2007	6
2008	16
2009	16

- 3 Resignations
- 6 Disciplinary Actions

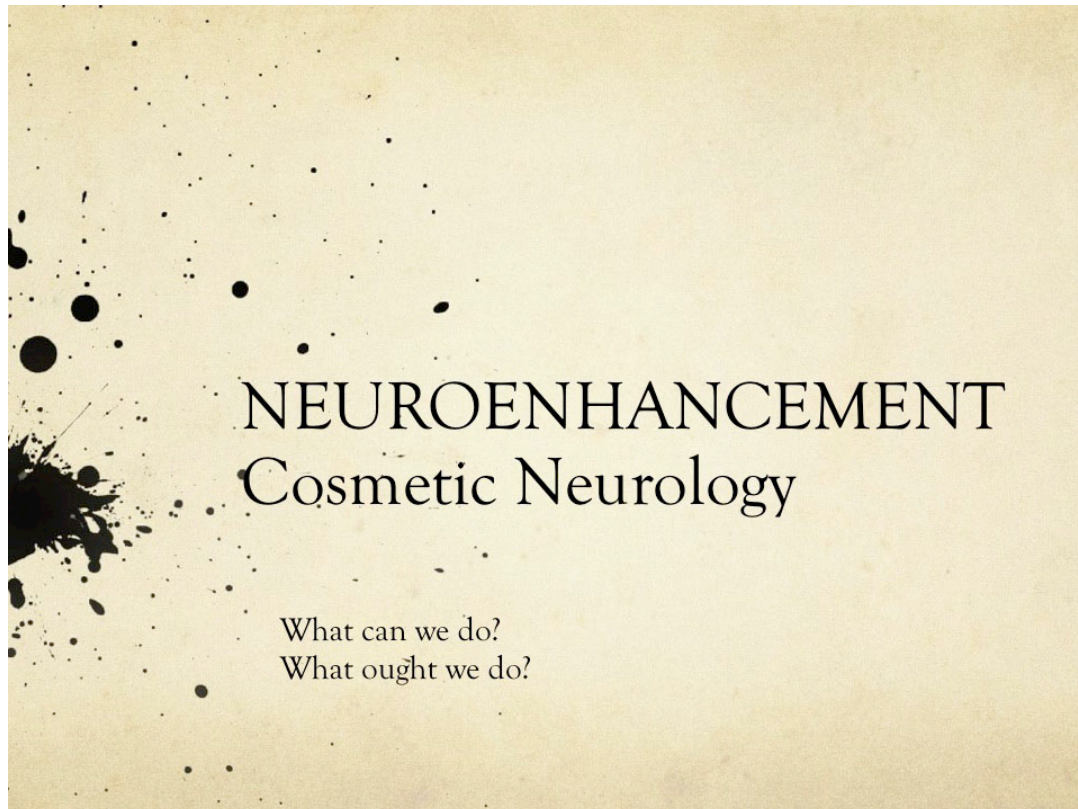
Neurology 75:2198–2203, 2010.

The Academy's disciplinary process has rarely been invoked. Considering that there are about 10,000 members, the data shows that the disciplinary rate is about $10^{-6}\%$ per year. It's clear, therefore, that the Code is not coercive, like positive law, but rather aspirational, like an ethical principle.

Third Issue: Neuroenhancers for Improving Cognitive Function in Clinically Normal Subjects

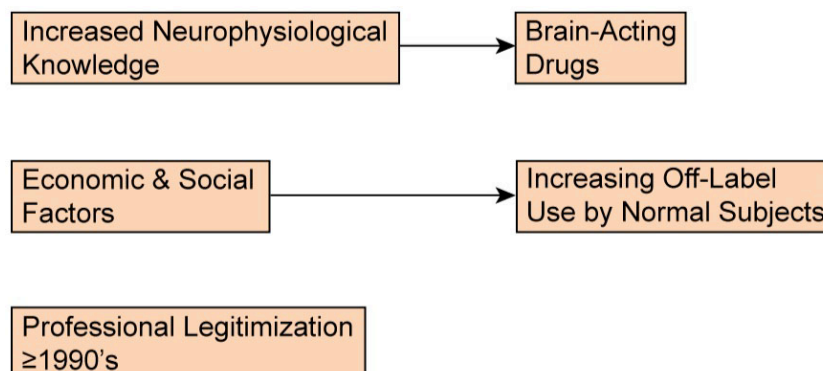


The issue of neuroenhancers has a legal impact on neurologists that is somewhere between the Academy's Code of Conduct and the civil law's tort of negligence.



The use of neuroenhancers raises fundamental questions regarding what it means to be a physician. Historically a physician was conceived of as an individual who diagnosed and treated diseases. But people who take neuroenhancers are clinically normal but take drugs for the purpose of achieving greater-than-normal performance. The fundamental issue regarding whether neurologists ought to prescribe drugs for the purpose of improving normal behavior was discussed in an earlier Grand Rounds. I am revisiting the question from the legal perspective, asking what the liability might be for a neurologist who prescribes neuroenhancers to a patient who requests them.

Historical Developments



The question of the professional legitimization of neuroenhancers has arisen only recently.

Influential Articles in *Nature*

Neurocognitive enhancement: what Can we do and what should we do? (2004)

“The enhancement of normal neurocognitive function by pharmacological means is already a fact of life.”

“The question is not whether we need policies, but rather what kind of policies we need to govern neurocognitive enhancement.”

Towards responsible use of cognitive-enhancing drugs by the healthy (2008)

“We should welcome new methods of improving our brain function.”

“Many kinds of employee may benefit from enhancement.”

“Technological fixes do not offer a path to moral absolution, but to technical resolution.”

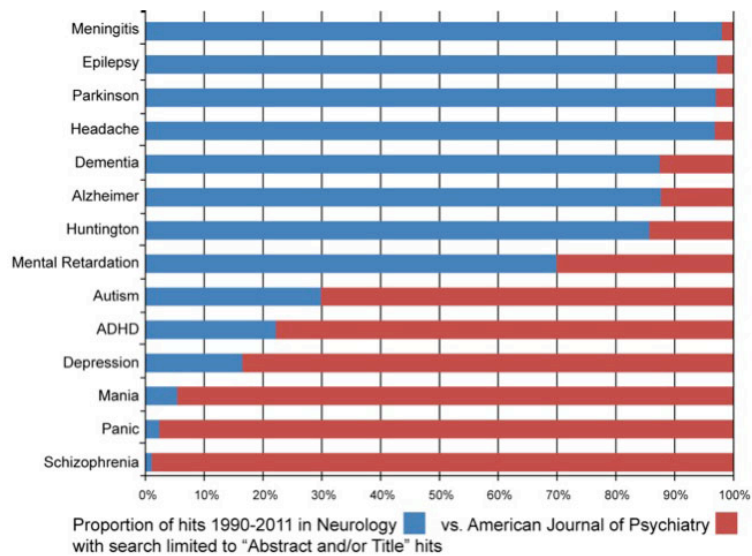
Several influential articles advocating the use of neuroenhancers significantly increased pressure on neurologists to prescribe the drugs. It is noteworthy that the authors of these articles were famous basic scientists and authors of well-known textbooks in neuroscience, and representatives of drug companies. None of the authors were neurologists.

Putative Brain Boosters

Drug	Medical Use
Methylphenidate (Ritalin®, Concerta®)	ADHD Narcolepsy
Amphetamines (Adderall®)	ADHD Narcolepsy
Modafinil (Provigil®)	Excessive daytime sleepiness due to obstructive sleep apnea
Donepezil (Aricept®)	Cognitive deficits of Alzheimer's

This is a list of some representative drugs being used as neuroenhancers. Each of these drugs was approved for use in treating a specific neurological disorder. None were approved by the US FDA as brain boosters, nor have any been studied using randomized controlled studies.

Which Diseases are “Neurological” and “Psychiatric”



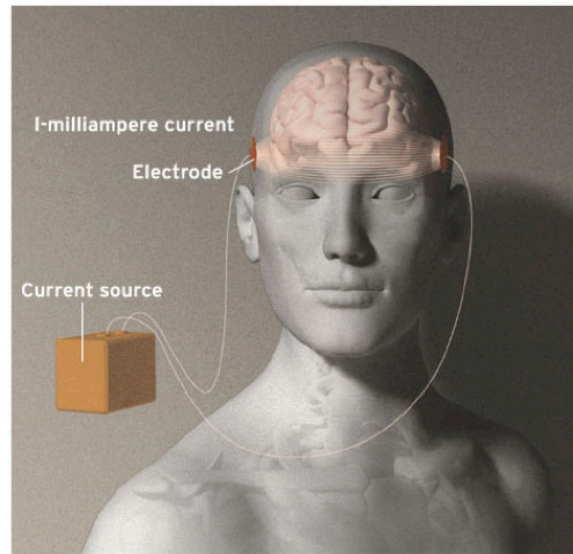
It's not clear why neurology rather than psychiatry has become the focus of considerations involving neuroenhancers. Various disorders are studied to different degrees in both specialties, but thus far only the Academy of Neurology has formally considered the impact of enhancers on neurologic practice.

Prospects in the Pipeline for Neuroenhancers

Drug Class	Developers
Nicotinic acetylcholine receptor activators	Abbot, CoMentis, EnVivo, Targacept/AstraZeneca
Ampakines	Cortex Pharmaceuticals; Eli Lilly, GlaxoSmithKline/Neurosearch, Organon, Pfizer, Servier
Phosphodiesterase inhibitors	Helicon Therapeutics, Hoffmann-La Roche, Merck
Antihistamines	GlaxoSmithKline, Johnson & Johnson, Medivation/Pfizer

The issue of neuroenhancers seems likely to continue and increase in its public profile. Many drug companies are developing different classes of potential neuroenhancers.

Transcranial Electrical Stimulation

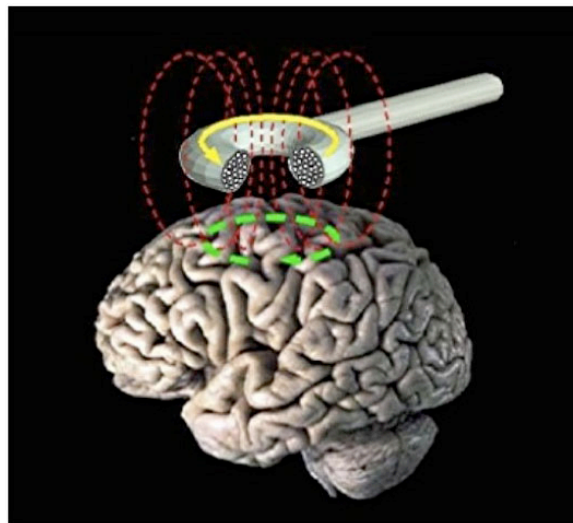


FDA approved for treatment of anxiety, depression, insomnia

Neuroscientist 16:285, 2010.

Not all potential neuroenhancers are drugs. Transcranial electrical stimulation has been suggested as a possible neuroenhancer. The technique is FDA approved for the treatment of anxiety, depression, and insomnia. The initial approvals were given before there was any meaningful device legislation, and all similar devices since then have been grandfathered under the current law.

Transcranial Magnetic Stimulation



Neurology 76:187, 2011.

Transcranial magnetic stimulation which is a fundamentally different electrical stimulation technique has also been suggested as a modality for producing neuroenhancement.


SPECIAL ARTICLE



2009

Responding to requests from adult patients for neuroenhancements

Guidance of the Ethics, Law and Humanities Committee



Dan Larriviere, MD, JD
Michael A. Williams, MD, FAAN
Matt Rizzo, MD, FAAN
Richard J. Bonnie, LL.B.
On behalf of the AAN Ethics, Law and Humanities Committee*

Guidance for responding to requests from adult patients for neuroenhancement medications

The prescription is within the physician-patient relationship.

Neurologists should respond to a request for neuroenhancement as they would respond to a chief complaint.

The prescription of medications for neuroenhancement is 1) not legally obligatory, 2) not legally prohibited, and therefore, 3) is legally permissible in the United States.

The prescription of medications for neuroenhancement is 1) not ethically obligatory, 2) not ethically prohibited, and therefore, 3) is ethically permissible.

Limited evidence exists regarding the efficacy and safety of medications prescribed to normal adults for neuroenhancement.

The liability risks associated with prescribing medications for neuroenhancement are uncertain.

The Academy considered the issue of neuroenhancements and adopted a relatively neutral position, which is probably appropriate, given the extent of its authority and its role in neurologic practice. The Academy committee reached the significant if somewhat understated conclusion that liability risks associated with prescribing neuroenhancers are uncertain.

Neuroenhancers and the Law

- No cases MD's prosecuted/sued in relation to neuroenhancement
- Discussion based on potential legal liability

There are no actual cases involving neurologists being sued in connection with prescribing neuroenhancers to clinically normal patients, but I can discuss the potential legal liability by considering how the law would apply in a hypothetical situation.

Liability Considerations Regarding Prescribing Neuroenhancers

Hypothetical Case

University student tells her neurologist she's having trouble staying focused and retaining information. Her roommate had the same problems and got much better when she used her brother's Ritalin. Mindful of the Academy Committee advice, the neurologist prescribed the drug, which the student took through the school year when facing exams and deadlines for papers. She began experiencing serious psychotic symptoms and had to leave school. She sued the neurologist. What are the legal issues?

Consider this hypothetical case.

Legal Elements in the Case

- Doctor/patient relationship
- **Neurologic standard of care**
- **Violation of standard**
- Harm
- Neurologist defenses
- Patient contributory negligence

These are the legal elements in the case. I want to focus my analysis on the elements where the evidence would be most contentious, namely the elements involving the standard of care.

Does Prescribing Ritalin for Cognitive Enhancement Violate the Standard of Care?

- Unreasonable risk of harm
 - Probability of harm $\begin{matrix} \text{High} \\ \swarrow \\ \text{Low} \end{matrix} ?$
 - Cost of avoiding the risk $\begin{matrix} \text{High} \\ \swarrow \\ \text{Low} \end{matrix} ?$
 - Social utility of prescription $\begin{matrix} \text{High} \\ \swarrow \\ \text{Low} \end{matrix} ?$
 - Accepted by a \geq respected minority of neurologists

As with any negligence action the key issue involves whether there was an unreasonable risk of harm. I've listed several considerations regarding which evidence might be adduced to argue that there was or was not an unreasonable risk.

Violation of Standard: Act of Prescribing

- **“Warning:** Ritalin should not be used for prevention or treatment of normal fatigue states.”
- No peer-reviewed-publication evidence that neurologists prescribe Ritalin for neuroenhancement
- Don’t know the probability for harm
- Possible harms are serious
- Efficacy is unknown
- Social utility is dubious

One argument the plaintiff might make is that the act of prescribing Ritalin was a violation of the applicable standard of care. The plaintiff could then present several lines of evidence which, individually and collectively, could persuade a jury that the standard of care was breached. For example, the Ritalin package label specifically warns against using Ritalin in the manner in which it was prescribed for the plaintiff. There are no peer-reviewed publications supporting the prescription of Ritalin for neuroenhancement. The probability that it might result in harm when prescribed to normal subjects is unknown and unstudied. From studies of the clinical use of Ritalin for ADHD, the possible harms that might result are known, and are recognized as serious. It can be seen that there is considerable evidence that could persuade a jury that prescribing Ritalin for normal subjects is a violation of the standard of care.

Violation of Standard: No Warning or Informed Consent

- Family history of Tourette’s Syndrome?
- Any contra-indicated conditions (long list)?
- Patient warnings given (long list)?
- Lack of evidence of efficacy disclosed?
- Informed consent process not billable (not medically necessary services)

Even if prescribing Ritalin wasn’t a violation, a failure to obtain informed consent could be pleaded and proved by the plaintiff as a violation of the standard of care. The plaintiff would present evidence indicating that she was never explicitly warned about the long list of potential side-effects associated with use of Ritalin. The failure to obtain informed consent, by itself, could constitute a violation of the standard of care.



Given the available evidence concerning the efficacy of neuroenhancers and their risks, and considering basic principles and rules of evidence regarding malpractice, prescribing neuroenhancers to a normal patient for the purpose of enhancing normal behavior is probably among the least wise things a neurologist could do.

Conclusion



The practicing neurologist is subject to ethical and professional constraints, but probably the legal constraints are more immediate, and more likely to have an impact on practice on a day-in and day-out basis. Consequently it is prudent to think about them on a daily basis.