Off-Label Neuroimaging

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Off-label pharmaceuticals are widely used in medicine, where clinicians prescribe a drug or biologic agent for treatment regimens not specified in the approved labeling or package insert. The use of off-label medication may be as high as 40% in adults and even higher in children. Medications may be used for a different purpose, for a different age range, or with a different dosing regimen. While off-label use may be common and often effective, there are ample concerns about the lack of scientific proof of efficacy and the safety of such practices. However, working groups have developed consensus recommendations to help distinguish between off-label use that is justified by high-quality evidence and when it should be limited to a research context. Professional consensus recommendations might translate well to the courtroom for what I term "off-label neuroimaging."

Off-label neuroimaging (OLN) includes the use of imaging technologies for non-clinically accepted purposes or the use of research imaging technologies that do not yet have clinical adoption. Yet courts often admit such OLN evidence, seemingly unaware of these concerns.

In deciding whether to admit the testimony, courts may rely on the *Daubert* factors alone, without recognizing the serious concerns about the current state of research or the misuse of a given technology for a stated purpose. Sometimes, there still is a wide gap between preliminary data in small groups and its use in an individual subject. Might consensus recommendations be useful for the court?

OLN evidence highlights multiple, foundational problems: (1) error rate and replication concerns in neuroscience research; (2) the complicated division between research and medicine in neuroscience and neuroimaging; (3) the proper qualifications of the witness to testify about a given neuroimaging modality; (4) the often wide gap between preliminary, small-group data and its use in an individual subject; and (5) the absence of clinical acceptance for some neuroimaging technologies.

At root, all these concerns rest on deeper, theoretical evidentiary problems that plague science-based expert testimony: when is evidence sufficiently reliable for the courtroom? Should law lead or follow science? Do we treat neuroscience in an exceptional fashion when evaluating its reliability? Have we really made progress since *Frye* on evaluating the reliability of developing science for courtroom use?

Using the example of Diffusion Tensor Imaging (DTI) to image TBI, this presentation will highlight many of the concerns present with OLN and presents an argument in favor of a consensus-based approach to neuroimaging evidence.