



# UNIVERSITY OF FLORIDA

Fredric G. Levin College of Law  
Offices of the Faculty

Prof. Lars Noah  
(352) 392-0563  
noah@law.ufl.edu

02N-0209

Spessard L. Holland Law Center  
P.O. Box 117625  
Gainesville, FL 32611-7625  
(352) 392-2211  
Fax (352) 392-3005  
<http://www.law.ufl.edu>

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Dockets Management Branch  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061 (HFA-305)  
Rockville, MD 20852

Re: Docket No. 02N-0209: Notice, "Request for Comments on First Amendment Issues,"  
67 Fed. Reg. 34,942 (May 16, 2002)

Because it may be of some interest to the agency as it considers its regulatory approach in light of the First Amendment, I have enclosed my newly published article, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373-466 (2002). The abstract follows:

*In the last decade, "evidence-based medicine" (EBM) has become all the rage. Just as the Supreme Court instructed the federal judiciary to take a more critical approach to the assessment of expert testimony, proponents of EBM call on health care professionals to apply the best available evidence when making treatment decisions. Instead of relying on what they may remember from medical school or have learned from their personal experiences (or from drug company sales-persons), EBM insists that physicians consult the biomedical literature for the latest clinical research findings. The fact that the medical profession views such an idea as novel—even radical—offers a startling picture of traditional ("opinion-based") medical practice, one quite different from that imagined by courts and regulatory agencies when they blithely assume that physicians can effectively assimilate tremendous quantities of complex information. EBM may, however, embody some naive assumptions about the character of the available scientific evidence, failing to appreciate shortcomings such as the extent to which conflicts of interest have affected the biomedical literature. Nevertheless, the debate surrounding evidence-based medicine offers important insights for various decisionmakers when they address health care quality issues. In turn, legal institutions may help to facilitate EBM by addressing conflicts of interest in biomedical research and by encouraging physicians to rely on rigorous research rather than largely anecdotal information when treating their patients.*

In particular, as elaborated at length in my article, the factual predicate implicit in question #1 of your notice (i.e., that learned intermediaries may be less in need of protection from potentially misleading information about drugs) is open to serious question. I hope that this information is of some use.

02N-0209

CB

Sincerely yours,

Lars Noah