

October 24, 2002

0310 12 31 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852

Re: Docket Number ^{02N-0209}~~02N-0292~~
Response to Comments on First Amendment Issues

I am a graduate student in the Quality Assurance/Regulatory Affairs program at Temple University. I am working on a project on the First Amendment and Docket No. 02N-0292 under Professor Roseanne Termini, Esq. in a class called Food and Drug Law I.

My project team has done a review of the comments submitted in response to the nine questions posed by FDA published in the Federal Register Notice of May 16, 2002. I am pleased to have the opportunity to respond to the comments that have been submitted.

I am quite impressed by the tremendous public response to FDA's request for comment on the Agency's regulations, guidances, policies and practices and their compliance with governing First Amendment case law. The wide ranging variety of comments received provides insight into the daunting task that faces FDA in ensuring that their decision in these matters are in accordance with this seminal Amendment to the United States Constitution. The First Amendment may well be what most defines our American freedom. As members of the industry overseen by FDA, we also have a vested interest in the outcome.

As a student of Food and Drug Law, I read with great interest many of the comments submitted in response to Docket No. 02N-0292. These comments consistently speak to case law precedence and the impact it has on current FDA policies and practices regarding speech restrictions in off-label use of approved drugs, unapproved drugs, CME sponsorship and direct-to-consumer advertising.

Therefore, I would recommend that FDA give serious consideration to the comments submitted by:

AdvaMed
Federal Trade Commission
Johnson & Johnson
Media Institute
National Consumers League
PhRMA
Schering Plough

02N0209

C101

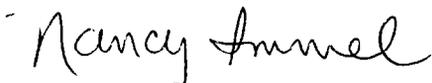
These responses are consistent on several important points:

- *Central Hudson, Thompson v. Western States Medical Center, Pearson v. Shalala* and *Washington Legal Foundation v. Friedman*, among others, provide important case law precedence in these matters.
- Truthful speech about lawful commercial activity is protected by the First Amendment.
- FDA should permit manufacturers to disseminate truthful and non-misleading information about off-label use and unapproved drugs. As long as this information is targeted to professionals, includes statements about FDA approval status of the content and financial interest of the parties involved, relies on peer reviewed information and contains no claims of safety and effectiveness, I feel that FDA's goals of preserving the new drug approval process and curbing false or misleading claims would not be compromised. Open scientific exchange between manufacturers and physicians is in the best interest of scientific advance and solutions for patients.
- While comments from individual patients and physicians indicate that direct-to-consumer advertising of prescription drugs is a questionable practice at best, major surveys conducted by FDA, *Prevention*, and the Henry J. Kaiser Family Foundation suggest that DTC advertising has stimulated discussions between doctors and patients, encouraged consumers to learn more about previously undiagnosed conditions, and not prevented doctors from recommending non-drug therapies. FDA's current policies on DTC advertising are adequate and should not become more restrictive out of fear that disseminated information might be misused.

Empirical research findings suggest that maximizing the free flow of commercial speech promotes consumer welfare. First Amendment commercial speech doctrine embodies a "preference for disclosure over outright suppression." Therefore, there should be an emphasis on remedies that favor disclosures and qualifications of claims over outright suppression.

The professional organizations referenced above have my full support in their pursuit of the FDA reforms they seek on First Amendment issues. And I have the utmost respect for FDA in seeking comment on this important issue. It would be in line with FDA's mission to protect and promote the public health to undertake reforms with a minimum of delay.

Sincerely,



Nancy Immel