

Memo To: FIELD SALES COLLEAGUES
From: Neurontin Marketing Team
Subject: JAMA NEURONTIN ARTICLES
Copies PDMT

Date: November 30, 1998

Enclosed are some slides that are designed to explain why the Neurontin articles are able to be distributed. The comments below are meant to clarify and expand on the slides.

- Washington Legal Foundation (WLF)

Five years ago the WLF, a nonprofit public interest law group, filed a citizen's petition with the FDA protesting its policy on continuing medical education (CME). They based their objections on the theory that restrictions in the dissemination of information on off-label product uses in the form of journal article reprints, reference texts and CME seminars violate the First Amendment. On July 30th, the court granted the WLF's motion for summary judgment and ordered the FDA to refrain from enforcing certain of their guidelines.

In summary, the court ultimately recognized the FDA's "substantial interest" in getting companies to seek approval for new uses, but protected the industry's commercial speech rights within the framework of the Constitution. So the dissemination of certain educational materials is allowed, but promotion of off-label uses is NOT allowed.

- Parke-Davis position on the issue

The Advertising Review Committee (ARC) must review ALL material prior to dissemination and central marketing will be responsible for submitting articles to the ARC. All information we disseminate will be scientifically and medically sound and placed in a fair, balanced context, and is NOT to be promoted.

Parke-Davis takes no position as to the safety or efficacy of the drugs discussed for the unapproved uses described in the articles.

- Guidelines

Territory managers can distribute, one time only, the approved off-label articles on an unsolicited basis, but they must tell the physician the use noted in the article is not approved by FDA and that the article is being disseminated by Parke-Davis for educational purposes only. There CANNOT be any discussion between the TM and healthcare professional regarding the content of the article or any other off-label use of the product.

Here is an example of an appropriate interaction with a physician:

"Doctor, you may be interested in reading this article, which appeared in the *Journal of the American Medical Association*. The article is titled, 'Gabapentin Monotherapy for the Symptomatic Treatment of Painful Neuropathy in Patients with Diabetes Mellitus: A Randomized Controlled Trial.' This use of NEURONTIN has not been approved by the FDA. Parke-Davis is distributing this article for educational purposes only."

END OF DISCUSSION!

If the healthcare professional has any questions, these should be referred to Medical Affairs.

- Future

It is important to strictly follow these guidelines while Parke-Davis monitors developments. Any change in company position will be communicated to field force colleagues as appropriate.

It is reasonable to believe there will continue to be some strong debate among all parties concerning the court ruling and it is quite possible guidelines may change at some future date. However, for now, the attached information reflects our position. Since this is a highly visible and changing situation, it is VERY IMPORTANT that no one deviate from the guidelines provided.

If you have any questions, please talk with your CBU management team.

Washington Legal Foundation Ruling

- What is WLF? A nonprofit public interest law group
- Position- Free speech, public interest in information protected by First Amendment
- Federal court ruling July 30, 1998
- Summary of ruling
 - *dissemination* of certain materials allowed
 - *promotion* of off-label uses not allowed

Parke-Davis Position

- PD intends to utilize these new opportunities to provide appropriate information for healthcare providers
- All information we disseminate will be scientifically and medically sound and placed in a fair, balanced context
- Information will be disseminated and not promoted
- ARC will review all material

PD Interaction Guidelines

- Central marketing will submit these articles for ARC review
- TMs can distribute one time only the approved off-label articles on an unsolicited basis
- Tell physician the use noted in the article is not approved by FDA

PD Interaction Guidelines (cont.)

- **No discussion** can take place with healthcare professionals regarding article content or any other off-label use
- Refer questions to Medical Affairs
- The company takes no position concerning the scientific or clinical relevance of the data for unapproved uses
- **Again, do not discuss the article**

FUTURE

- Continue to follow the guidelines just noted
- Parke-Davis will monitor developments through our Legal and Regulatory groups
- Any change in the company's position will be communicated to field force colleagues, as appropriate