





## **Legal and Ethical Advertising of Compounded Medications** *International Academy of Compounding Pharmacists*

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In September 1999, a U.S. District Court found that the advertising provision of FDAMA violates the First Amendment of the Constitution and is therefore unenforceable. The section stated that a drug may be compounded only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. Thus, pharmacists are no longer restrained from advertising and promoting compounded products. However, pharmacists should be aware of the following points when promoting compounded medications:

1. Pharmacists should not make claims as to safety and effectiveness of compounded medications. Avoid statements, including performance claims that would be false or misleading.
2. Avoid referring to manufacturer's products, or trade names in promotional materials.
  - a) Such references, or claims that a compounded product is similar to a manufactured product, could be viewed as misleading, suggesting that the compounded product is as safe and effective as the commercially available product. Such a drug may be considered "misbranded" under the FD&C Act and subject to FDA enforcement action.
  - b) You could also be subject to FDA's enforcement under other circumstances if your compounded drug is "essentially a copy" of the commercially available product. FDAMA provides that a pharmacist may not compound "regularly" or in "inordinate amounts" drugs, which are "essentially copies of a commercially available drug product." A compounded drug is not considered "essentially a copy" of a commercially available product if it includes a change, made for an identified patient, which produces for that patient a significant difference, (as determined by the prescribing practitioner) between the compounded drug and the comparable commercially available drug product.
  - c) Manufacturers are watching advertisements of compounded products with increased scrutiny and could pressure FDA and/or Congress to take action if the compounding appears to be inconsistent with the intent of the legislation. Moreover, a manufacturer could elect to bring its own legal action if it is believed that its rights on a product, such as a trademark, have been infringed upon. Using another company's brand name may well be viewed as trademark infringement.

IACP is solely dedicated to the promotion, preservation, and protection of pharmaceutical compounding. The ethical and professional practice of pharmaceutical compounding acknowledges the service provided by the compounding pharmacist and recognizes the relationship of the patient, the physician and the pharmacist in the performance of that service.

Therefore, the following marketing or promotion practices mislead patients, physicians and others in the marketplace, and are considered unethical and unprofessional:

1. utilizing manufacturers names or the names of patented products;
2. creating misinformation with claims of therapeutic equivalence;
3. creating misinformation by perception that compounded products are generic products, and
4. basing such promotion and advertising solely on price.