



# **Enforcement and Litigation Conference: Actions against Competitors**

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⌘ Washington, D.C.

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# No Private Cause of Action under FDCA



Buckman Co. v. Plaintiffs' Legal Committee, 531  
U.S. 341, 353 (2001)

BUT

“false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA.” Summit Technology, Inc. v. High-Line Medical Instruments, 933 F. Supp. 918, 933 (C.D. Cal. 1996)

# No Private Cause of Action under FDCA



Affirmative factual misrepresentations made “in commercial advertising or promotion” which misrepresent the “nature, characteristics, [or] qualities” of an FDA-regulated product will support a Lanham Act violation.

Healthpoint Ltd. v. Stratus Pharms., Inc., 2001 WL 1682949, at \*11 (W.D. Tex. June 1, 2001)

# Lanham Act



## 15 U.S.C. § 1125(a)(1):

Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

# State Laws on Unfair Practices



Unlawful business practice under Cal. Bus. & Prof. Code

Cal. Bus. & Prof. Code § 17203:

Any person who engages, has engaged, or proposes to engage in unfair competition may be enjoined . . . .

Cal. Bus. & Prof. Code § 17200:

Unfair competition shall mean and include any unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising . . .

# State Laws on Unfair Practices



Unfair competition can be based upon conduct that has been determined to be a violation of FDA regulations – even though the FDCA itself does not provide for “private civil enforcement.” Watson Labs., Inc. v. Rhone-Poulenc Rorer, Inc., 178 F. Supp. 2d 1099 (C.D. Cal. 2001)

# Other Options:



## Complain to State governments:

Attorney General's Offices

District Attorney's Offices

Consumer Protection Offices

## Complaints about:

False or misleading promotion, advertising, labeling

Marketing of unauthorized drugs, devices

# Qui tam lawsuits

Usually brought by former/present employee, but can be brought by anyone

Illegal promotion may provide basis (see Parke-Davis)

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
<u>ex rel.</u> DAVID FRANKLIN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CIVIL ACTION NO. 96-11651-PBS
	)	
PARKE-DAVIS, DIVISION OF	)	
WARNER-LAMBERT COMPANY and	)	
PFIZER, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

August 22, 2003

SARIS, U.S.D.J.

**I. INTRODUCTION**

In this qui tam action, Relator Dr. David Franklin brings a claim under the False Claims Act, 31 U.S.C. §§ 3729 et seq., alleging that Defendant Parke-Davis (Franklin's former employer) promoted the drug Neurontin for uses not approved by the Food and Drug Administration, resulting in federal reimbursement payments for Neurontin prescriptions that were ineligible under Medicaid. Parke-Davis moves for summary judgment. The government, which has not intervened, has filed a Statement of Interest. After hearing, Parke-Davis's motion is **DENIED**.

# Contacting Other Federal Officials

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OMB

HHS

SBA

DOJ

Congress



# Third Party Complaints



# How Can FDA Help Besides Suing?



Testimony

Documents

Affidavits

Pleadings