

OPINION

THE NATIONAL
LAW JOURNAL

WWW.NLJ.COM

EDITOR-IN-CHIEF

Rex Bossert

PUBLISHER

Stephen P. Lincoln

MANAGING EDITOR

Steve Fromm

ASSOCIATE EDITORS

Carla Main, Ruth Singleton

DESIGN DIRECTOR

Doug Hunt

WEB SITE EDITOR

Laura Noueibed

WASHINGTON BUREAU CHIEF

Marcia Coyle

STAFF REPORTERS

Tresa Baldas, Gail Diane Cox, David Hechler,
Leigh Jones, Leonard Post, Gary Young

ASSISTANT ART DIRECTOR

Roberto Jimenez

RESEARCH EDITOR

Cleo Cacoulidis

EDITORIAL ADMINISTRATOR

Dee McAree

CHIEF COPY EDITOR

Peter Dolack

COPY EDITORS

Roger Adler, George Szamuely

CONTRIBUTING WRITERS

Mark Ballard, June D. Bell, Emily Heller,
Steve Seidenberg, William C. Smith,
Lisa Stansky, Joe Slobodzian

DIRECTOR OF BUSINESS OPERATIONS

■ THE 'TAP' ACQUITTALS

Stop creative prosecutions

By Harvey A. Silverglate & Andrew Good SPECIAL TO THE NATIONAL LAW JOURNAL

ELEVEN CURRENT and former employees of TAP Pharmaceutical Products Inc. recently took the unusual step of risking huge sentences by going to trial on felony charges that, among other things, they attempted to illegally induce medical providers to prescribe TAP products. After three months of jury trial, all were acquitted on July 14. In contrast, under threat of Medicaid debarment, the company, not showing similar resolve, had earlier pleaded guilty and paid an \$885 million settlement. [NLJ, July 26, Page 6.]

The result of the criminal trial sent a message that should be heeded by federal regulators and prosecutors: "Creative prosecution" theories are being challenged more successfully. Neither the public interest, nor the credibility of government agencies, nor the advancement of law benefits when prosecutions rely on strained interpretations of complex legal obligations.

tionally paying kickbacks to prescribe TAP's prostate cancer drug Lupron and heartburn remedy Prevacid. Such practices are hardly surprising in an industry in which billions of research dollars are spent before a drug is marketed. To be sure, kickbacks are illegal, but there is considerable debate over what expenditures meet the definition of a kickback. The regulations are not models of clarity.

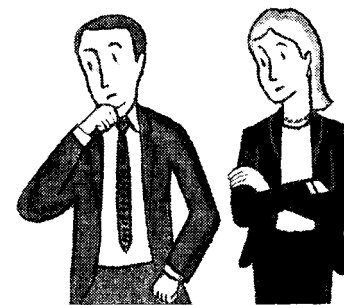
Why prosecute at all?

The TAP verdict calls into question why, when industrywide promotional practices raise regulatory concerns, prosecutors make them the centerpiece of criminal prosecutions rather than civil or administrative litigation or rule-making to clarify the industry's legal obligations not to influence unduly a customer's medical judgment.

Such prosecutions do little to clarify the law. The threat of debarment, directed against a corporation, usually assures

payments made "as part of a routine cultivation of a business relationship rather than with the intent to induce specific purchases" were legal.

Given the law's recognition, by the inclusion of "safe harbors," that certain payments by drug companies to customers are medically valuable—such as sponsoring research and educational programs and distributing free samples—care must be taken in basing criminal prosecutions on after-the-fact



Hal Cohen

DIRECTORS OF ADVERTISING

Brian Corrigan (Law Firm),
Martha Sturgeon (Classified and Directories)

MARKETING CONSULTANTS

Alicia Brown, Peter Hano, Gary Hartry,
Patty Martin, Mitch Prager, Sarah Tunland

LAW FIRM ACCOUNT MANAGERS

Christopher Rockaway, Jennifer Shearer

CIRCULATION MARKETING MANAGER

Michael Bennett

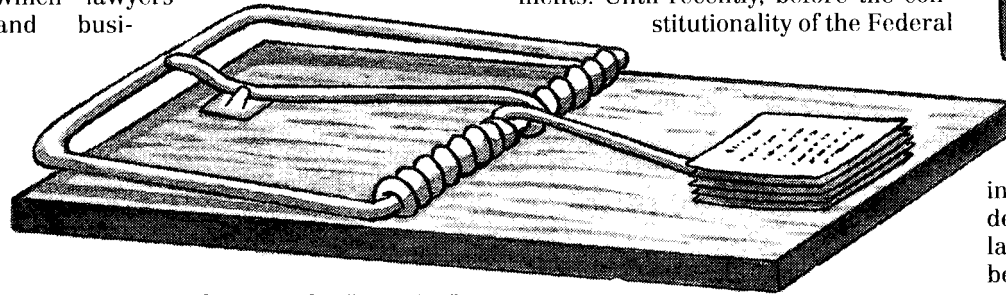
VICE PRESIDENT/MANUFACTURING

Glenn Filippone

PRODUCTION COORDINATORS

Samuel Wong, Evelyn Fernandez

It is unclear that the message will be heard, however, by aggressive prosecutors who increasingly allege that certain practices—which lawyers and busi-



nesspeople consider merely “creative” and about which the law is vague—are crimes. For example, the current spate of prosecutions for revenue-recognition practices is being challenged by some defendants on the ground that they involve generally accepted accounting procedures. Another example would be the most serious count against Martha Stewart—an attenuated securities fraud count based on her public statements proclaiming innocence—which was dismissed by the trial judge.

The TAP trial centered around common pharmaceutical-industry product promotions: payment for educational programs and medical and scientific consulting, as well as free meals and entertainment, and drug samples to physicians, hospitals and group medical organizations.

The government claimed that the company’s marketing staffers were inten-

Harvey A. Silverglate (has@harveysilverglate.com) and Andrew Good (agood@goodcormier.com) are criminal defense lawyers with Boston’s Good & Cormier. The firm represented a defendant in two of the cases cited in this article, Prigmore and Lachman.

a corporate guilty plea. The debarment threat enables a creative prosecution, which might fail if contested, to reap massive but unfair monetary settlements. Until recently, before the constitutionality of the Federal

Sentencing Guidelines were called into question, most individuals pleaded guilty rather than risk the huge sentences attendant upon conviction at trial in federal cases. There was, therefore, precious little appellate case law to clarify the regulations.

The TAP investigation was commenced when whistleblowers—former TAP Vice President Douglas Durand and Dr. Joseph Gerstein, medical director of Tufts Health Plan, a provider of health care services—complained to the government that they felt the company’s salesmen were trying to bribe them. Gerstein allowed prosecutors to bug his office while negotiating a contract with salespeople. Both Durand, who received \$77 million as whistleblower compensation from TAP’s \$885 million settlement in 2001, and Gerstein, who split a \$17 million bounty with Tufts, testified at the criminal trial. The jurors apparently did not agree that the tapes represented a “smoking gun.”

The judge, trying to make the thicket of anti-kickback standards intelligible to jurors, instructed them that the statute and regulations outlaw payments and freebies when they are given “to induce orders” for the company’s drugs, but that



FELIPE GALINDO

feggo

interpretations of what may be, at worst, debatable conduct. Any time complex laws are loaded with exceptions, they become traps for the unwary rather than a useful guide for an industry.

Regulations often unclear

In recent years, courts have begun to recognize that prosecutions alleging regulatory violations often do not involve conduct that is intrinsically or obviously criminal. In response, the courts have enhanced the government’s burden to provide proof that businesspeople did not act on the basis of honest, even if mistaken, understandings of the law. We see examples in various complex regulatory areas including *Cheek v. United States* (1994), concerning tax; *Ratzlaf v. United States* (1994), involving money laundering; *United States v. Lachman* (1995), involving export controls; and *United States v. Prigmore* (2001), concerning medical devices.

The government has awesome powers to impose huge disgorgement, restitution and civil monetary penalties in civil and administrative proceedings geared to remedy wrongdoing, while helping to clarify the obligations of those in regulated industries. But when the government has to rely on creative legal interpretations in order to secure indictments and convictions, it’s likely abusing process while heedlessly wrecking lives. **NW**

HOW TO REACH US

EDITORIAL (212) 313-9000

ADVERTISING (212) 545-6275

CIRCULATION (800) 274-2893

REPRINTS (212) 545-6111

AMERICAN LAWYER MEDIA INC.

WWW.AMLAW.COM

CHAIRMAN

Bruce Wasserstein

PRESIDENT/CHIEF EXECUTIVE OFFICER

William L. Pollak

SENIOR VICE PRESIDENT

Jack Berkowitz

SENIOR VICE PRESIDENT

George M. Dillehay

VICE PRESIDENT/CHIEF FINANCIAL OFFICER

Eric Lundberg

VICE PRESIDENT/ONLINE PUBLISHING

Stacey Artandi

VICE PRESIDENT/BOOKS AND DIRECTORY PUBLISHING

Sara Diamond

VICE PRESIDENT/GENERAL COUNSEL

Allison C. Hoffman

VICE PRESIDENT/INFORMATION SYSTEMS

Iain Murray

VICE PRESIDENT/GROUP PUBLISHER,

NATIONAL PUBLICATIONS

Kevin J. Vermeulen

SEND YOUR OPINIONS AND COMMENTS TO MAILBOX@NLJ.COM