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WLF Washington Legal Foundation
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2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

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Paper Assesses Legal, Regulatory Environment for Pharmaceutical Advertising

Federal and state regulators, members of Congress, prosecutors, and legal activists have all targeted 2007 as the year that they bring pharmaceutical advertising and promotion to heel. As a new Washington Legal Foundation WORKING PAPER discusses, activity aimed at direct-to-consumer advertising is on the rise, but much of it seems to be at cross-purposes, and will, according to the paper's author, ultimately undermine public health.

The publication, **PHARMACEUTICAL ADVERTISING: "MAY YOU LIVE IN INTERESTING TIMES**," was authored by **Arnold I. Friede**, a former attorney in the Chief Counsel's office of the Food and Drug Administration who is currently a Senior Corporate Counsel with Pfizer, Inc. He is a frequent writer on commercial speech matters, recently authoring a WLF COUNSEL'S ADVISORY, **Fresh Bagels And A Schmear: A Sign Of The Times Ruling On Commercial Free Speech**.

Mr. Friede begins by examining the federal regulatory and enforcement activity drug advertisers face. He notes the uncertain and regularly shifting approach that the Food & Drug Administration takes towards enforcing its ad regulations, as well as the HHS Office of Inspector General's scrutiny of off-label communications, as being key in this area. He also mentions industry self-regulatory measures and how, in many ways, they go beyond government rules in imposing limits on promotional practices.

The paper then turns to legislation and public policy, where Mr. Friede focuses on proposed legislation in Congress that is expected to be heavily debated this year. He also discusses state laws seemingly designed to chill drug company promotion, such as limits on doctor-drug marketing representative interaction and requirements that companies report on advertising expenditures.

In the paper's final section, Mr. Friede examines what he calls the "most potent 'regulators' in this area:" class action plaintiffs' lawyers and state attorneys general wielding lawsuits. Many of the suits against producers of allegedly harmful drugs, such as Vioxx, are based not on personal injury, he writes, but on "improper" promotion of the drug. Consumer fraud and allegations that promotion caused doctors to overprescribe Medicaid-covered drugs are two highly novel, popular theories that plaintiffs and attorneys general have pursued.

Mr. Friede begins his conclusion by stating, "In reflecting on this tsunami of activity, one would suppose that a unifying theme would be readily discernible." But, as he explains, much of the activity seems to be random and at cross-purposes, in the sense that FDA has long advanced a philosophy that adding information and warnings to drug labels and promotion undermines the clear message that doctors and patients need to make health care choices. Mr. Friede sees this heightened scrutiny as intruding upon

doctor's ability to act as the "learned intermediary," and injects federal regulators, lawyers, and legislators into the doctor-patient decision making scheme. Such a state of affairs, the paper concludes, contradicts policymakers' stated goal in regulating pharmaceutical advertising – protection of public health.

Copies of this educational paper, WLF WORKING PAPER, Number 144 (February 2007), can be obtained by forwarding a request to: Publications Department, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, D.C. 20036, or calling (202) 588-0302.