October 22, 2015

Pharmaceutical Compliance Forum

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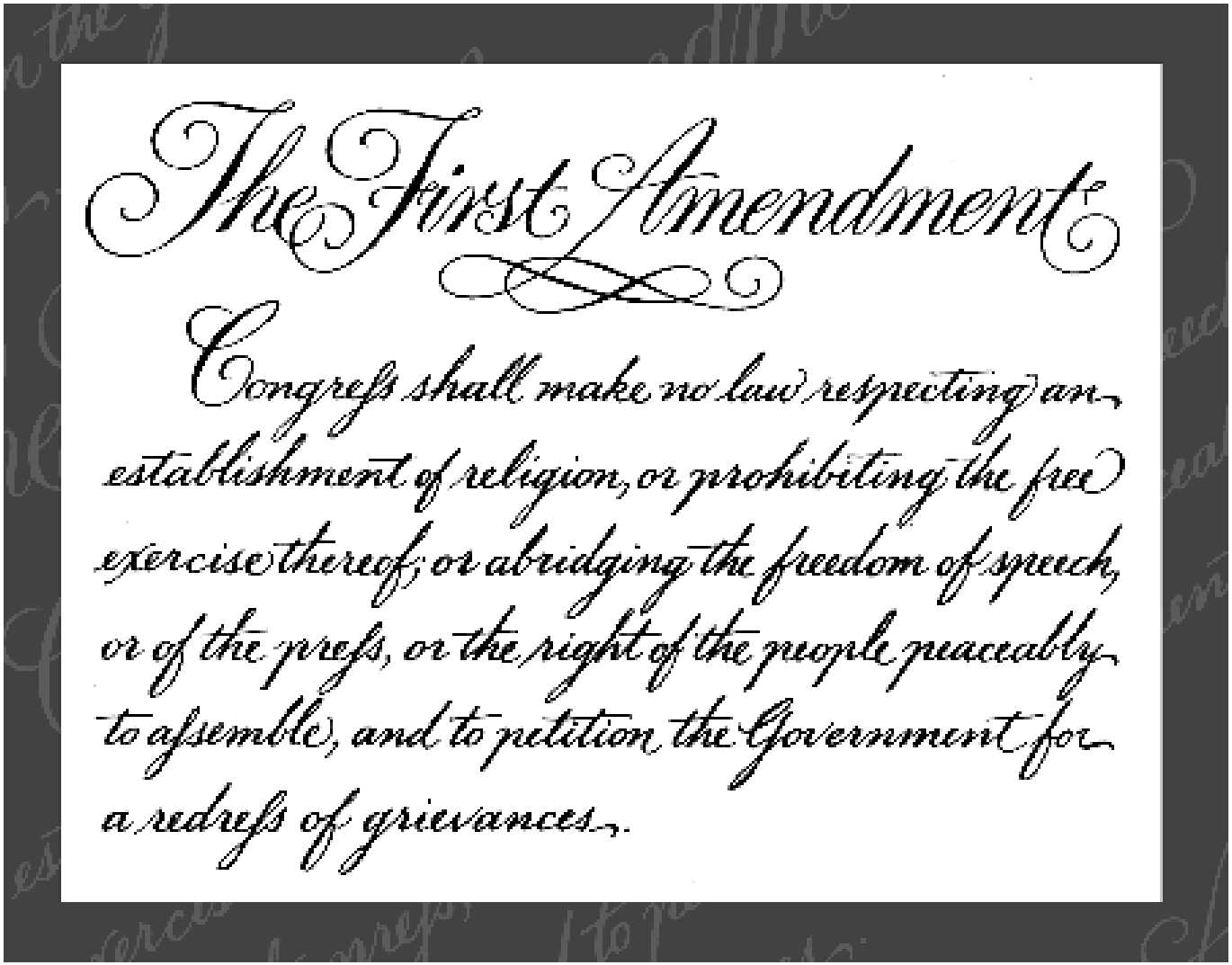
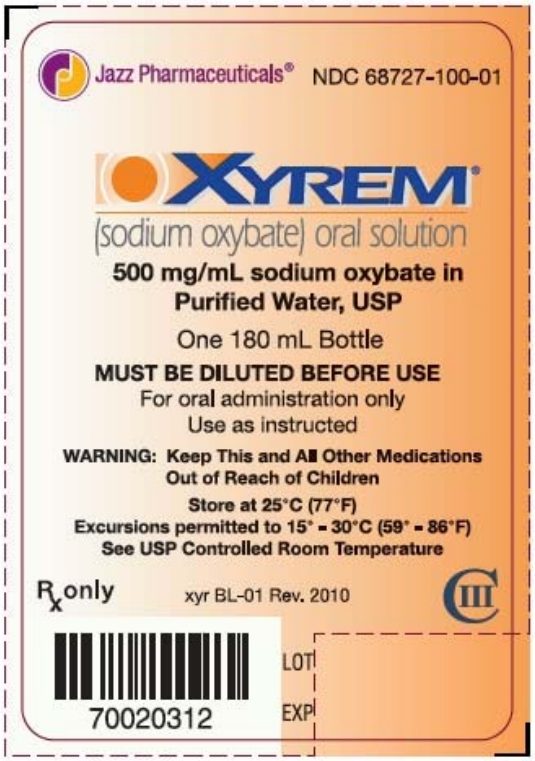
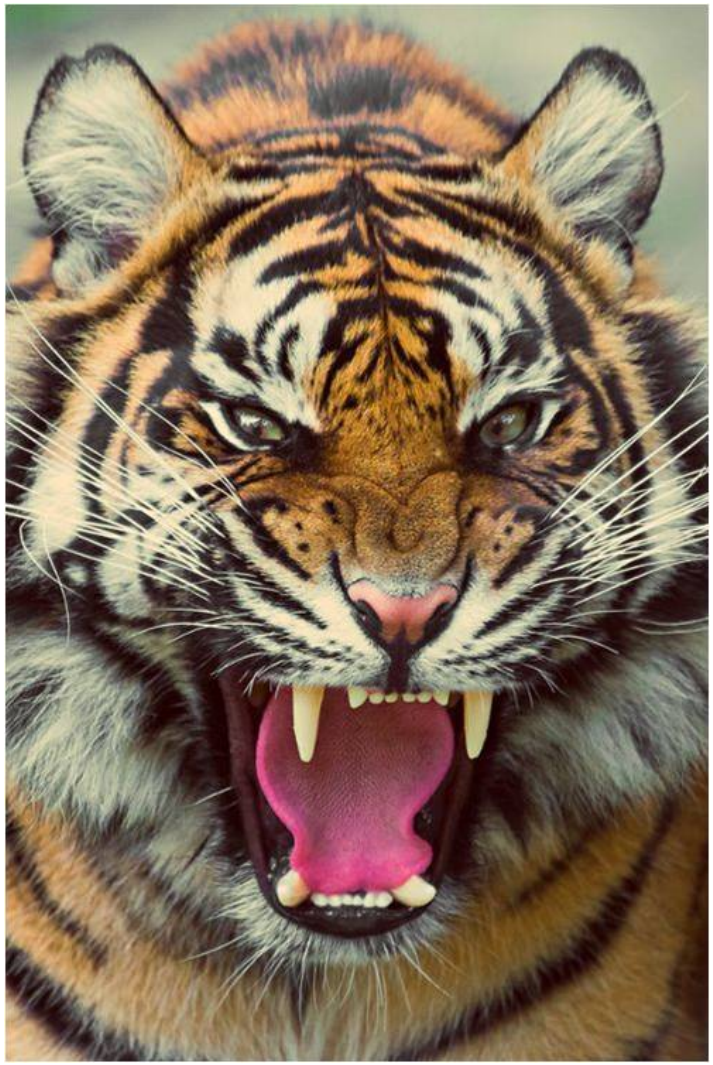

The First Amendment
Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press, or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

“Speech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment.” *Sorrell v. IMS Health,* 131 S. Ct. 2653 (2011)

“We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs.” *United States v. Caronia,* 703 F.3d 149 (2d Cir. 2012)





Dr. Robert Temple, CDER
December 2012:

"What is worth talking about is what the consequences would be…I'm horrified by that"

" Having people promote those uses is frankly terrifying"

Allowing off-label promotion could "kill vast numbers of people"

Tom Abrams, OPDP, January 2013:

"FDA does not believe that the *Caronia* decision will significantly affect the agency's enforcement"

"The decision does not…find a conflict between the Act's misbranding provisions and the First Amendment or call into question the validity of the Act's drug approval framework"

ROPES &GRAY

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SIDLEY AUSTIN LLP
SIDLEY

September 3, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

This petition is submitted under 21 C.F.R. § 10.30 on behalf of members of the Medical Information Working Group (MIWG). The MIWG is an informal working group of major

(1) Respond fully and in a constitutionally permissible manner to the four specific requests set forth in the July 2011 Citizen Petition. In particular, as discussed in further detail in Part II.D, infra, we request that FDA: (a) complete the policy development

from FDA on proposed activities involving the dissemination of off-label information. On July 5, 2011, a subset of MIWG members submitted a Citizen Petition to FDA, asking the Agency to clarify its regulations and policies for four types of manufacturer communications about off-label

(2) Comprehensively review, and modify as necessary in view of constitutional and statutory limitations, the regulatory regime governing manufacturer communications to protect and promote the public health. We have suggested in Part II.E, infra, changes to FDA policies relating to: (1) the definition of "labeling" in Section 201(m) of the

the FDA-approved or "cleared labeling for a drug or medical device, many such variations may lawfully be discussed by manufacturers in promotional communications, and a manufacturer's promotion is not limited to statements in the approved or cleared labeling. In this document, "off-label use" and "new use" are used interchangeably. 59 Fed. Reg. 59,820, 59,820 (Nov. 18, 1994) ("Uses that do not appear in the labeling and are not approved by the agency are referred to as 'unapproved,' 'unlabeled,' 'off-label,' or 'extra-label' uses."), and "approved" also includes FDA clearance of medical devices under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360(k). Moreover, where we ask FDA to provide clarity in the regulatory framework respecting off-label use, we intend for that clarity to apply to all potential departures from approved labeling that, in FDA's view, constitute off-label uses.

FDA-2013-P-1079

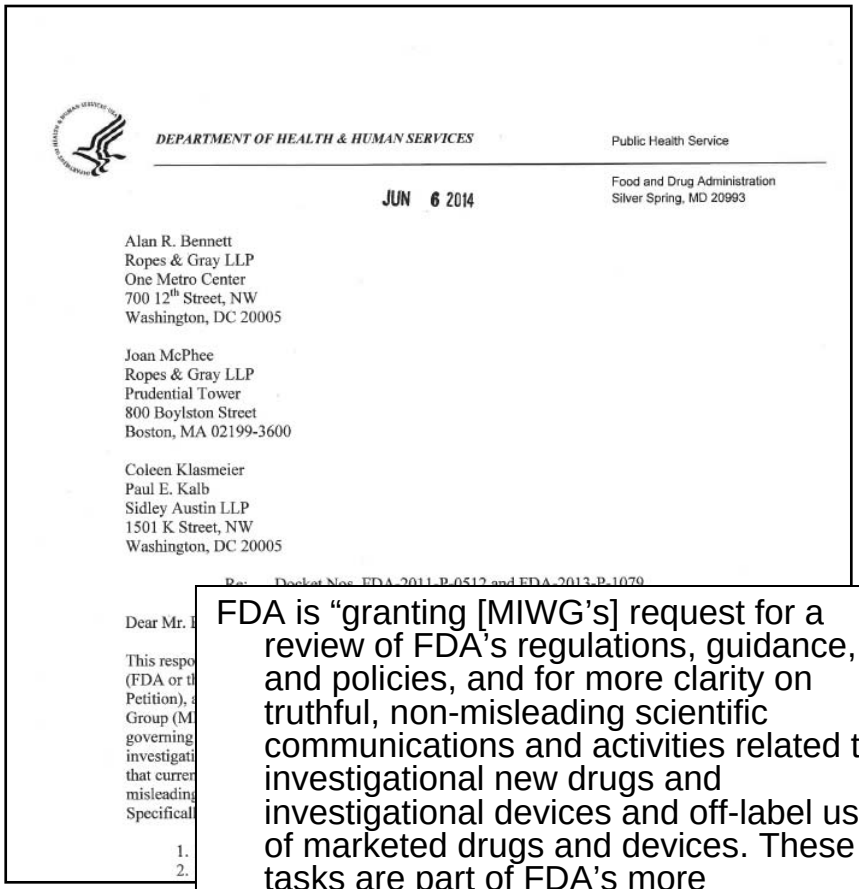
2013-7316
CP

Janet Woodcock, M.D. Director,
Center for Drug Evaluation and Research
April 23, 2014

Regulation of Drug Advertising and Promotion

- FDA has issued 3 draft guidances in past year:
  - Reprints on unapproved new uses
  - Interactive promotional media
  - Product name placement
- We are currently carefully evaluating our policies in light of court decisions on 1st Amendment issues

FDLI



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

JUN 6 2014

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Re: Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079

Dear Mr.

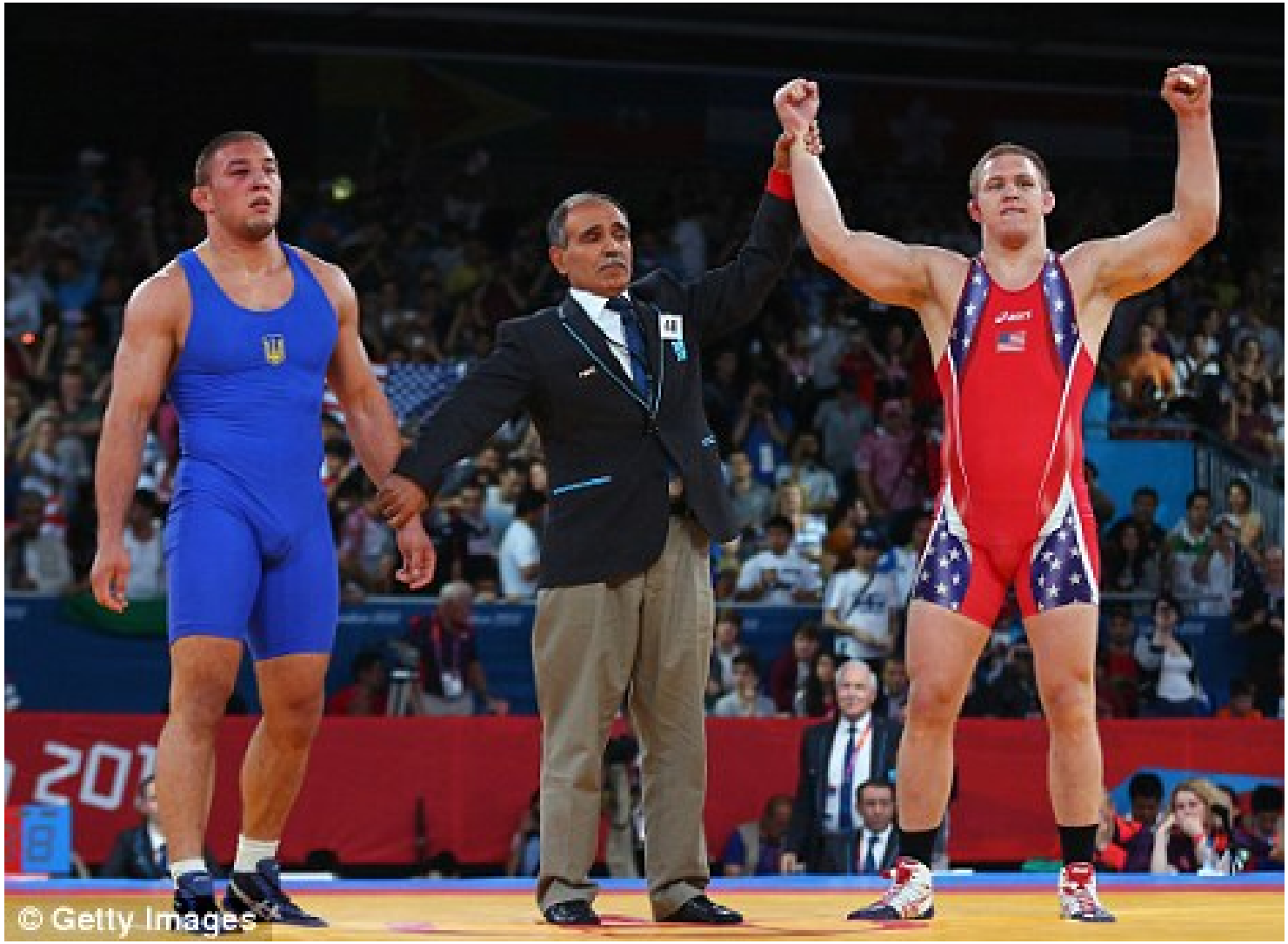
This respo
(FDA or th
Petition),
Group (M
governing
investigati
that currer
misleading
Specifical

1.
2.

FDA is "granting [MIWG's] request for a review of FDA's regulations, guidance, and policies, and for more clarity on truthful, non-misleading scientific communications and activities related to investigational new drugs and investigational devices and off-label uses of marketed drugs and devices. These tasks are part of FDA's more comprehensive review of its regulations and guidance documents in an effort to harmonize the goal of protecting the public health with First Amendment interests."

– Leslie Kux, Response to MIWG Petition (June 2, 2014)

"The FDCA's misbranding provisions cannot constitutionally criminalize, and therefore do not reach, the act of truthful and non-misleading speech promoting off-label use." ***Amarin Pharma, Inc. v. FDA***


© Getty Images


New
Release
May 2003

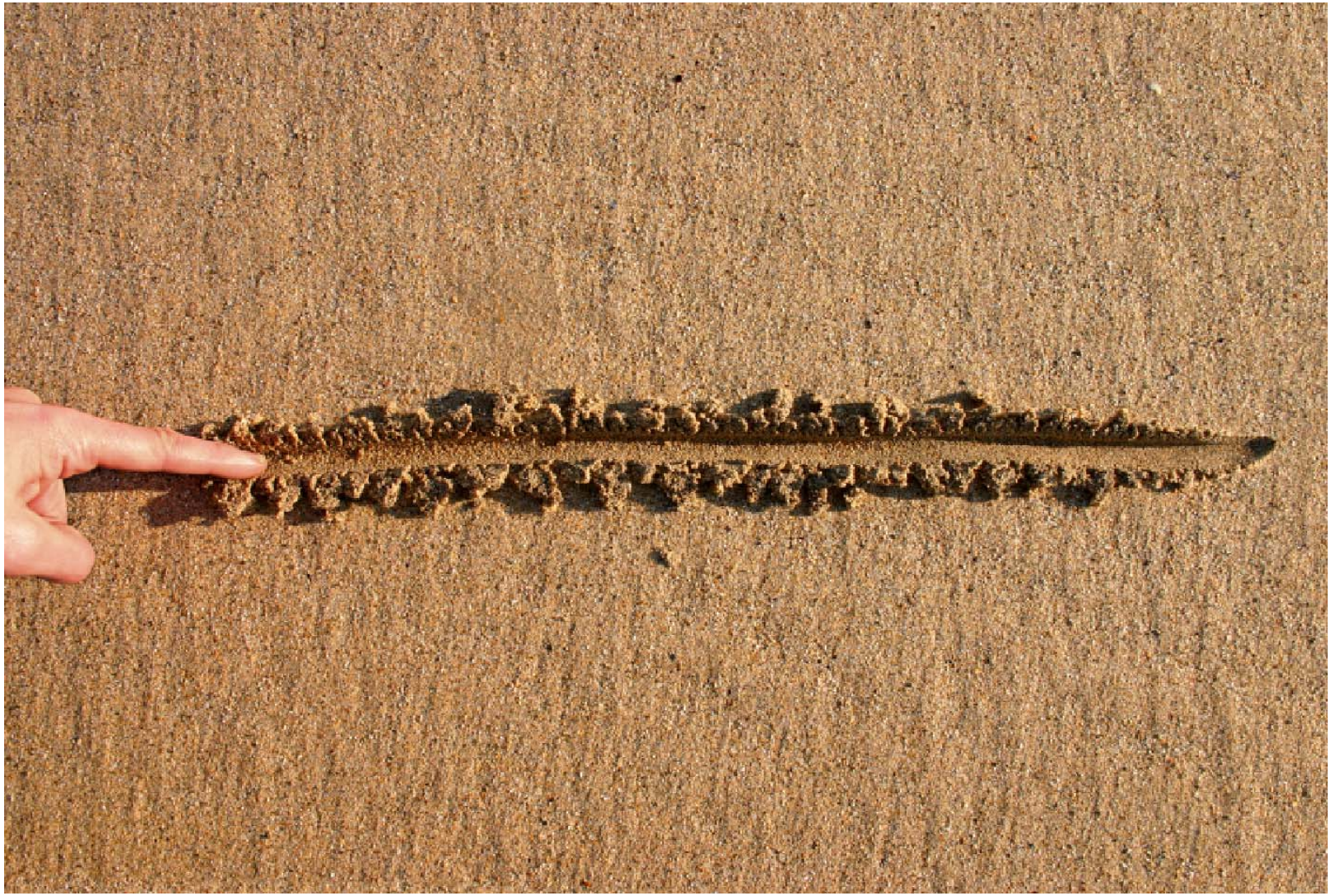
Guidance for Industry
Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices

Additionally, the scientific or medical journal article distributed by a manufacturer *should*:

Be disseminated with a comprehensive bibliography, when such information exists, of publications discussing adequate and well-controlled clinical studies published in scientific journals, medical journals, or scientific texts about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography).


LOOK RIGHT

The government cannot restrict commercial speech through "rote invocation of the words 'potentially misleading'" ***Ibanez v. Fla. Dept. of Bus. & Prof'l Reg.*****, 512 U.S. 136 (1994)**



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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PACIRA PHARMACEUTICALS, INC., DR. LOREN J. HARRIS, and DR. JOSEPH W. BELL,

Plaintiffs,

v.

Civil Action No. _____

1. Through this Complaint against the United States and, in particular, the Food and Drug Administration ("FDA"), Pacira Pharmaceuticals, Inc. ("Pacira") seeks to establish its right to speak in a truthful and non-misleading fashion about lawful uses of its product EXPAREL.

COMPLAINT FOR
DECLARATORY AND INJUNCTIVE RELIEF

Thank You

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