COMMITTEE:
ENERGY AND COMMERCE

SUBCOMMITTEES:
CHAIRMAN, COMMERCE, MANUFACTURING AND TRADE
COMMUNICATIONS AND TECHNOLOGY
ENVIRONMENT AND ECONOMY

Mary Bono Mack
Congress of the United States
45th District, California

WASHINGTON OFFICE:
104 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5330
FAX: (202) 225-2961

DISTRICT OFFICES:
36-953 COOK STREET
SUITE 104
PALM DESERT, CA 92211
(760) 320-1076
FAX: (760) 320-0596

1600 EAST FLORIDA AVENUE
SUITE 301
HEMET, CA 92544
(951) 658-2312
FAX: (951) 652-2562

July 26, 2012

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

Thank you for meeting with members of the Congressional Caucus on Prescription Drug Abuse last week. We hope that finding meaningful solutions to prevent the prescription drug abuse epidemic are a top priority for your agency, and we look forward to continuing the dialogue on how best to implement regulations and policies to achieve our common goal – to save thousands of lives and spare families the tragedy and suffering caused by prescription drug abuse and addiction.

As you know, the Centers for Disease Control and Prevention (CDC) found that the quantity of painkillers sold to pharmacies, hospitals, and doctor's offices was four times larger in 2010 than in 1999. Enough prescription painkillers were prescribed in 2010 to medicate every American adult around-the-clock for one month. As the sales of these drugs have increased, so too, have the number of deaths from prescription drugs and the rate of substance abuse treatment admissions.

As we mentioned during our meeting, more than 30 clinicians, researchers, and health officials from the fields of Pain, Addiction, Primary Care, Internal Medicine, Anesthesiology, Psychiatry, Neurology, Emergency Medicine, Toxicology, Rheumatology, and Public Health recently submitted a Citizen Petition to FDA requesting the following changes to opioid analgesic labels:

1. Strike the term "moderate" from the indication for non-cancer pain.
2. Add a maximum daily dose, equivalent to 100 milligrams of morphine for non-cancer pain.
3. Add a maximum duration of 90-days for continuous (daily) use for non-cancer pain.

We believe that if a labeling change were made to opioid analgesics to reflect the uncertainty and lack of evidence surrounding safety and effectiveness of these drugs for treatment of chronic non-cancer pain, physicians would think twice before prescribing these highly addictive narcotics for "moderate" pain such as a toothache or sore knee. While those who seek treatment for cancer pain and other diseases that cause "severe" pain would not be affected, the number of individuals prescribed opiate painkillers without evidence of the long-term safety and effectiveness may decrease and limit those susceptible to developing opioid dependence.

For these reasons, we request an expedited review of the Citizen Petition submitted to FDA, and look forward to a timely response.

Sincerely,

MARY BONO MACK
Member of Congress

HAL ROGERS
Member of Congress

NICK RAHALL
Member of Congress

WILLIAM KEATING
Member of Congress

ROBERT DOLD
Member of Congress

VERN BUCHANAN
Member of Congress