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United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

May 8, 2012

Catherine Underwood
Executive Director
American Pain Society
4700 W. Lake Avenue
Glenview, IL 60025

Dear Ms. Underwood:

As Chairman and a senior member of the Senate Finance Committee, we have a responsibility to the more than 100 million Americans who receive health care under Medicare, Medicaid, and CHIP. As part of that responsibility, this Committee has investigated the marketing practices of pharmaceutical and medical device companies as well as their relationships with physicians and non-profit medical organizations.

It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers such as Oxycontin (oxycodone), Vicodin (hydrocodone), and Opana (oxymorphone). According to CDC data, "more than 40% (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers.[1] Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs,[2] and now kill more people than heroin and cocaine combined.[3] More people in the United States now die from drugs than car accidents as a result of this new epidemic.[4] Additionally, the CDC reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs."[5]

In Montana, prescription drug abuse is characterized by the state's Department of Justice as an "invisible epidemic" killing at least 300 people per year and contributing to increases in

[1] Center for Disease Control, "Drug Poisoning Deaths in the United States, 1980-2008, NCHS Data Brief, No. 81, December 2011 at http://www.cdc.gov/nchs/data/databriefs/db81.pdf.
[2] Id.
[3] CDC Press Release, "Prescription painkiller overdoses at epidemic levels," November 1, 2011 at http://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.
[4] LA Times, "Drug deaths now outnumber traffic fatalities in U.S., data show," September 17. 2011 at http://articles.latimes.com/2011/sep/17/local/la-me-drugs-epidemic-20110918.
[5] International Business Times, "Prescription Painkiller Overdoses Cost Insurers $72.5 Billion Yearly: CDC," November 3, 2011 at http://www.ibtimes.com/articles/242437/20111103/prescription-painkiller-overdoses-cost-insurers-72-5.htm.

addiction and crime.[6] The University of Montana Bureau of Business and Economic Research estimated that prescription drug abuse is costing the state $20 million annually in additional law enforcement, social services, and lost productivity.[7]

In Iowa, "the use of opioid painkillers such as hydrocodone and oxycodone has increased dramatically in the last decade," according to the Governor's Office of Drug Control Policy. Annual overdose deaths from opioids "increased more than 1,233% from 3 deaths in 2000 to 40 deaths in 2009."[8] Data from Iowa's prescription drug monitoring program demonstrates that in 2010, 89,500,000 doses of hydrocodone and oxycodone were prescribed totaling nearly 40% of all controlled substance prescriptions.[9]

Concurrent with the growing epidemic, the *New York Times* reports that, based on federal data, "over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses."[10]

There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness. Recent investigative reporting from the *Milwaukee Journal Sentinel/MedPage Today* and *ProPublica* revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State Medical Boards, the University of Wisconsin Pain and Policy Study Group, and the Joint Commission.

In a *ProPublica* story published in the *Washington Post*, the watchdog organization examined the American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry."[11] *ProPublica* wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers play down the risks associated with opioids and exaggerate their benefits. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research."[12]

According to the *Milwaukee Journal Sentinel/MedPage Today*, a "network of national organizations and researchers with financial connections to the makers of narcotic painkillers…helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient literature, position statements, books and doctor education

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[6] See the Montana Department of Justice website at http://doj.mt.gov/prescriptionabuse/.
[7] Bureau of Business and Economic Research, "The Economic Cost of Prescription Drug Abuse in Montana", June 2011 at http://mbcc.mt.gov/PlanProj/Projects/PDMP/Prescription%20Drug%20Abuse%2020110629.pdf.
[8] Iowa Governor's Office of Drug Control Policy, "Iowa Drug Control Strategy: 2012," November 1, 2011 at http://www.iowa.gov/odcp/drug_control_strategy/Strategy2012.Final.pdf
[9] Id.
[10] NY Times, "Tightening the Lid on Pain Prescriptions," April 8, 2012 at http://www.nytimes.com/2012/04/09/health/opioid-painkiller-prescriptions-pose-danger-without-oversight.html.
[11] ProPublica, "The Champion of Painkillers," December 23, 2011 at http://www.propublica.org/article/the-champion-of-painkillers.
[12] Id.

courses."[13] Specifically, a patient guide funded by three drug companies and available on the American Pain Foundation website states that "there is no ceiling does for opioids as long as they are not combined with other drugs such as acetaminophen."[14] However, a 2011 Archives of Internal Medicine paper "found that the risk of death for high-dose patients was three times greater than in lower-dose patients."[15]

Although it is critical that patients continue to have access to opioids to treat serious pain, pharmaceutical companies and health care organizations must distribute accurate and unbiased information about these drugs in order to prevent improper use and diversion to drug abusers.

As part of our effort to understand the relationship between opioid manufacturers and non-profit health care organizations, please provide the following information:

1) Provide a detailed account of all payments/transfers received from corporations and any related corporate entities and individuals that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present. [16] For each payment identified, provide:

    a. Date of payment.
    b. Payment description (general support, project specific etc.).
    c. Amount of payment.
    d. Year end or year-to-date payment total and cumulative total payments for each organization or individual.
    e. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.

2) Has the American Pain Society received any funding from the federal government? If yes, describe the year, amount, and purpose of this funding.

3) In addition to financial support, identify and describe any collaborative activity between the organizations identified in request #1 and the American Pain Society from 2007 to the present.

4) In the event any activity identified in request #3 above pertains to information distributed to physicians and patients concerning prescription pain medications, please identify any materials developed, in whole or in part, by organizations identified in request #1 and provide copies of these materials.

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[13] Milwaukee Journal Sentinel/MedPage Today, "Follow the Money: Pain, Policy, and Profit," February 19, 2012 at http://www.medpagetoday.com/Neurology/PainManagement/31256.
[14] Milwaukee Journal Sentinel, "Painkiller Boom Fueled by Netowrking," February 18, 2012 at http://www.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html
[15] Id.
[16] Include any charitable foundation established by a pharmaceutical company.

5) Please identify the name, job title, job description, and dates employed of any American Pain Society employees who communicated with any organization identified in question #1 regarding the content of any materials distributed to patients and physicians pertaining to opioid use from 2007 to the present.

In cooperating with the Committee's review, no documents, records, data, or other information related to these matters, either directly or indirectly, shall be destroyed, modified, removed, or otherwise made inaccessible to the Committee.

We look forward to hearing from you by no later than June 8, 2012. All documents responsive to this request should be sent electronically, on a disc, in searchable PDF format to my staff. If you have any questions, please do not hesitate to contact Christopher Law with Senator Baucus at (202) 224-4515 or Erika Smith with Senator Grassley at (202) 224-5225.

Sincerely,



Charles E. Grassley
Senator



Max Baucus
Chairman