

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

CHRISTOPHER R. HIXON, STAFF DIRECTOR
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

March 28, 2017

Santosh Vetticaden
Interim CEO
Insys Therapeutics, Inc.
1333 S. Spectrum Blvd #100
Chandler, AZ 85286

Dear Mr. Vetticaden:

I am writing to request information from Insys, as the manufacturer of one of the top five opioid products by 2015 sales,¹ related to the sales, marketing, and educational strategies it has employed to promote opioid use. In the United States today, too many opioids are prescribed, too many are abused, and too many are purchased by the federal government. Medicare Part D spending on commonly abused opioids has increased 165% between 2006 and 2015, reaching a cost of \$4.1 billion, and almost 30% of Part D recipients received at least one commonly abused opioid in 2015.² Financial waste is just one measure of the cost of our national opioid epidemic; in 2015, more than 15,000 Americans died from overdoses involving prescription opioids,³ and opioid-related hospitalizations and emergency room visits in Missouri, for example, doubled between 2005 and 2014.⁴

This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers. To achieve this goal, manufactures have reportedly sought to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses. In May 2007, for example, Purdue Pharma paid \$635 million in fines to settle criminal and civil charges related to its misrepresentation of the addictive qualities of OxyContin, with three Purdue executives pleading guilty to criminal misbranding.⁵ An October 2016 complaint filed by the City of

¹ *Americans Consume Vast Majority of the World's Opioids*, CNBC (Apr. 27, 2016).

² HHS OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (June 2016) (OEI-02-16-00290).

³ Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (online at <https://www.cdc.gov/drugoverdose/data/overdose.html>).

⁴ Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (online at http://www.mhanet.com/mhaimages/HIDIHealthStats/Opioids_HealthStats_1015.pdf).

⁵ *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007).

Chicago against Janssen, among other parties, similarly alleges that the company employed “[d]eceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms” as a “foundation of [its] marketing campaign.”⁶ At the same time, certain manufacturers allegedly premised their sales and marketing approach on the addictive qualities of opioids. Alec Burlakoff, former sales vice president for Insys, which manufactures a fentanyl spray—Subsys—that is 100 times more powerful than morphine, reportedly stated, for example: “If you can keep [patients] on [Subsys] for four months, they’re hooked. Then they’ll be on it for a year, maybe longer.”⁷

Opioid manufacturers have also allegedly used illegal kickbacks through “speakers programs” and other inducements to encourage a wide variety of physicians to prescribe their high-powered products. For example, according to a federal indictment against six top officials of Insys, company executives and sales representatives “led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe” the product.⁸ These efforts allegedly resulted in “large numbers of prescriptions for...patients, most of whom were not diagnosed with cancer.”⁹ Other manufacturers have simply targeted physicians with abnormally high opioid prescribing histories. Early in its campaign for OxyContin, for example, Purdue focused on the highest opioid prescribers in the country, with one market research report indicating this effort improved Purdue profit margins by 3%.¹⁰ As recently as 2013, Purdue reportedly maintained a database of hundreds of doctors suspected of overprescribing opioids, nominally to steer sales representatives away from these physicians; according to the *Los Angeles Times*, however, Purdue “has done little to alert law enforcement or medical authorities” to these prescribers.¹¹

Opioid manufacturers have also apparently attempted to influence prescribing behavior through the creation of continuing medical education (CME) to promote opioids for pain management. In a study by Georgetown University, Dr. Adriane Fugh-Berman found that industry-sponsored CME failed to mention opioid death altogether, compared to 26 mentions of

⁶ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

⁷ *Murder Incorporated: Insys Therapeutics, Part II*, Southern Investigative Reporting Foundation (Dec. 9, 2015).

⁸ Department of Justice, *Pharmaceutical Executives Charges in Racketeering Scheme* (Dec. 8, 2016) (online at <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>).

⁹ *Id.*

¹⁰ Dr. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, *American Journal of Public Health* (Feb. 2009).

¹¹ *OxyContin Maker Closely Guards Its List of Suspect Doctors*, *Los Angeles Times* (Aug. 11, 2013).

the risk of death in non-industry sponsored presentations.¹² Physicians viewing industry-created CME later noted their impression that opioids were underprescribed for chronic pain, and less frequently mentioned risks of addiction than their peers viewing non-industry CME.¹³ This practice appears to be widespread across the opioid manufacturing industry. The City of Chicago has alleged in a recent complaint, for example, that major opioid manufacturers, including Purdue and Janssen, have “sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating...deceptive and biased messages,” including presentations that “focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.”¹⁴

Manufacturers have also worked with licensing and accreditation bodies to influence physician behavior. Purdue, for example, partnered with the Joint Commission—an accrediting body for U.S. hospitals—to publish a guide stating “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”¹⁵ In 2001, the Joint Commission also issued new standards emphasizing communication with patients concerning pain and prioritizing pain treatment.¹⁶ Similarly, the Federation of State Medical Boards (FSMB) promoted a policy calling for punishment of physicians for the undertreatment of pain; the policy also assured physicians they would not face disciplinary action for overprescription of narcotics.¹⁷ Purdue Pharma, among other opioid manufacturers, funded a book outlining this policy, with \$280,000 in proceeds going to FSMB.¹⁸ Manufacturers have also allegedly provided funding to advocacy groups like the American Geriatrics Society (AGS) and the American Academy of Pain Medicine (AAPM) to develop materials supportive of opioid use; Janssen, for example, allegedly partnered with AGS and AAPM to create a guide stating that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”¹⁹

The alleged practices detailed above represent significant challenges government programs, insurers, and pharmacy benefit managers face when attempting to prevent opioid fraud

¹² Adriane Fugh-Berman, PharmeOut, *Marketing Messages in Industry-Funded CME* (June 25, 2010) (online at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf).

¹³ *Id.*

¹⁴ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

¹⁵ *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

and overuse. More importantly, they show an industry apparently focused not on preventing abuse but on fostering addiction as a central component of its business model. One former Insys sales representative described the motto of this approach to patients as “Start them high and hope they don’t die.”²⁰

To aid the Committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government, please provide responses to the document and information requests below:

- 1) Documents showing any internal Insys estimates of the risk of misuse, abuse, addiction, overdose, diversion or death arising from the use of any opioid product Insys has manufactured, or any estimates of these risks produced by third-party contractors or vendors.
- 2) Any reports Insys has generated since January 2012 summarizing or concerning compliance audits of its sales and marketing policies.
- 3) Marketing and business plans, including plans for direct-to-consumer and physician marketing, Insys has developed since January 2012 for each opioid product Insys has offered.
- 4) Any slide decks, presentations, talking points, or other materials Insys has provided to participants or speakers in Insys speakers programs since January 2012.
- 5) Quotas for Insys sales representatives dedicated to opioid products concerning the recruitment of physicians for speakers programs since January 2012, broken down by year and quarter.
- 6) Documents sufficient to show Insys expenses relating to the entertainment of physicians by sales representatives dedicated to opioid products since January 2012, broken down by year and quarter.
- 7) Documents sufficient to show Insys funding of CME modules or other educational presentations for physicians, nurses, pharmacists, or other medical professionals since January 2012, documents sufficient to show the recipients of the funding, and copies of the slides, videos, handouts, promotional materials, and any other related materials produced.
- 8) Documents sufficient to show funding Insys Therapeutics, Inc. has provided to the following entities since January 2012, including the date of specific payments, the amount of each payment, the purpose of each payment (CME funding, research

²⁰ Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.* (D. Ariz. Oct. 27, 2014).

funding, etc.), if specified, year-end or year-to-date payment totals per year, and the cumulative total payments to each organization:

- a. American Academy of Pain Medicine
 - b. American Pain Society
 - c. American Pain Foundation
 - d. American Geriatrics Society
 - e. American Chronic Pain Association
 - f. American Society of Pain Educators
 - g. The National Pain Foundation
 - h. Pain & Policy Studies Group
 - i. Federation of State Medical Boards
 - j. American Society of Pain Management Nursing
 - k. Academy of Integrative Pain Management
 - l. U.S. Pain Foundation
 - m. Cancer Action Network
 - n. Washington Legal Foundation
 - o. The Center for Practical Bioethics
 - p. The Joint Commission
 - q. Pain Care Forum
 - r. Any other organization receiving funding from Insys for the purpose of developing guidelines on pain management or opioid use
- 9) Any reports Insys has issued to government agencies since January 2012 in accordance with corporate integrity agreements or other settlement agreements.
- 10) Any document productions Insys has made since January 2012 to the Department of Justice, the Department of Health and Human Services Office of Inspector General, state attorneys general, any committee or subcommittee of the U.S. Congress, and any U.S. Attorney's office related to the issues outlined in the requests above or Insys's opioid products generally.

Please provide your responses as soon as possible, but in no event later than April 25, 2017. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Amanda_Trosen@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman

United States Senate

CHRISTOPHER R. HIXON, STAFF DIRECTOR
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

March 28, 2017

James A. Schoeneck
President and Chief Executive Officer
Depomed
7999 Gateway Blvd, Suite 300
Newark, CA 94560

Dear Mr. Schoeneck:

I am writing to request information from Depomed, as the manufacturer of one of the top five opioid products by 2015 sales,¹ related to the sales, marketing, and educational strategies it has employed to promote opioid use. In the United States today, too many opioids are prescribed, too many are abused, and too many are purchased by the federal government. Medicare Part D spending on commonly abused opioids has increased 165% between 2006 and 2015, reaching a cost of \$4.1 billion, and almost 30% of Part D recipients received at least one commonly abused opioid in 2015.² Financial waste is just one measure of the cost of our national opioid epidemic; in 2015, more than 15,000 Americans died from overdoses involving prescription opioids,³ and opioid-related hospitalizations and emergency room visits in Missouri, for example, doubled between 2005 and 2014.⁴

This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers. To achieve this goal, manufactures have reportedly sought to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses. In May 2007, for example, Purdue Pharma paid \$635 million in fines to settle criminal and civil charges related to its misrepresentation of the addictive qualities of OxyContin, with three Purdue executives pleading guilty to criminal misbranding.⁵ An October 2016 complaint filed by the City of

¹ *Americans Consume Vast Majority of the World's Opioids*, CNBC (Apr. 27, 2016).

² HHS OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (June 2016) (OEI-02-16-00290).

³ Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (online at <https://www.cdc.gov/drugoverdose/data/overdose.html>).

⁴ Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (online at http://www.mhanet.com/mhaimages/HIDIHealthStats/Opioids_HealthStats_1015.pdf).

⁵ *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007).

Chicago against Janssen, among other parties, similarly alleges that the company employed “[d]eceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms” as a “foundation of [its] marketing campaign.”⁶ At the same time, certain manufacturers allegedly premised their sales and marketing approach on the addictive qualities of opioids. Alec Burlakoff, former sales vice president for Insys, which manufactures a fentanyl spray—Subsys—that is 100 times more powerful than morphine, reportedly stated, for example: “If you can keep [patients] on [Subsys] for four months, they’re hooked. Then they’ll be on it for a year, maybe longer.”⁷

Opioid manufacturers have also allegedly used illegal kickbacks through “speakers programs” and other inducements to encourage a wide variety of physicians to prescribe their high-powered products. For example, according to a federal indictment against six top officials of Insys, company executives and sales representatives “led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe” the product.⁸ These efforts allegedly resulted in “large numbers of prescriptions for...patients, most of whom were not diagnosed with cancer.”⁹ Other manufacturers have simply targeted physicians with abnormally high opioid prescribing histories. Early in its campaign for OxyContin, for example, Purdue focused on the highest opioid prescribers in the country, with one market research report indicating this effort improved Purdue profit margins by 3%.¹⁰ As recently as 2013, Purdue reportedly maintained a database of hundreds of doctors suspected of overprescribing opioids, nominally to steer sales representatives away from these physicians; according to the *Los Angeles Times*, however, Purdue “has done little to alert law enforcement or medical authorities” to these prescribers.¹¹

Opioid manufacturers have also apparently attempted to influence prescribing behavior through the creation of continuing medical education (CME) to promote opioids for pain management. In a study by Georgetown University, Dr. Adriane Fugh-Berman found that industry-sponsored CME failed to mention opioid death altogether, compared to 26 mentions of

⁶ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

⁷ *Murder Incorporated: Insys Therapeutics, Part II*, Southern Investigative Reporting Foundation (Dec. 9, 2015).

⁸ Department of Justice, *Pharmaceutical Executives Charged in Racketeering Scheme* (Dec. 8, 2016) (online at <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>).

⁹ *Id.*

¹⁰ Dr. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, *American Journal of Public Health* (Feb. 2009).

¹¹ *OxyContin Maker Closely Guards Its List of Suspect Doctors*, *Los Angeles Times* (Aug. 11, 2013).

the risk of death in non-industry sponsored presentations.¹² Physicians viewing industry-created CME later noted their impression that opioids were underprescribed for chronic pain, and less frequently mentioned risks of addiction than their peers viewing non-industry CME.¹³ This practice appears to be widespread across the opioid manufacturing industry. The City of Chicago has alleged in a recent complaint, for example, that major opioid manufacturers, including Purdue and Janssen, have “sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating...deceptive and biased messages,” including presentations that “focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.”¹⁴

Manufacturers have also worked with licensing and accreditation bodies to influence physician behavior. Purdue, for example, partnered with the Joint Commission—an accrediting body for U.S. hospitals—to publish a guide stating “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”¹⁵ In 2001, the Joint Commission also issued new standards emphasizing communication with patients concerning pain and prioritizing pain treatment.¹⁶ Similarly, the Federation of State Medical Boards (FSMB) promoted a policy calling for punishment of physicians for the undertreatment of pain; the policy also assured physicians they would not face disciplinary action for overprescription of narcotics.¹⁷ Purdue, among other opioid manufacturers, funded a book outlining this policy, with \$280,000 in proceeds going to FSMB.¹⁸ Manufacturers have also allegedly provided funding to advocacy groups like the American Geriatrics Society (AGS) and the American Academy of Pain Medicine (AAPM) to develop materials supportive of opioid use; Janssen, for example, allegedly partnered with AGS and AAPM to create a guide stating that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”¹⁹

The alleged practices detailed above represent significant challenges government programs, insurers, and pharmacy benefit managers face when attempting to prevent opioid fraud and overuse. More importantly, they show an industry apparently focused not on preventing

¹² Adriane Fugh-Berman, PharmedOut, *Marketing Messages in Industry-Funded CME* (June 25, 2010) (online at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf).

¹³ *Id.*

¹⁴ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

¹⁵ *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

abuse but on fostering addiction as a central component of its business model. One former Insys sales representative described the motto of this approach to patients as “Start them high and hope they don’t die.”²⁰

To aid the Committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government, please provide responses to the document and information requests below:

- 1) Documents showing any internal Depomed estimates of the risk of misuse, abuse, addiction, overdose, diversion or death arising from the use of any opioid product Depomed has manufactured, or any estimates of these risks produced by third-party contractors or vendors.
- 2) Any reports Depomed has generated since January 2012 summarizing or concerning compliance audits of its sales and marketing policies.
- 3) Marketing and business plans, including plans for direct-to-consumer and physician marketing, Depomed has developed since January 2012 for each opioid product Depomed has offered.
- 4) Any slide decks, presentations, talking points, or other materials Depomed has provided to participants or speakers in Depomed speakers programs since January 2012.
- 5) Quotas for Depomed sales representatives dedicated to opioid products concerning the recruitment of physicians for speakers programs since January 2012, broken down by year and quarter.
- 6) Documents sufficient to show Depomed expenses relating to the entertainment of physicians by sales representatives dedicated to opioid products since January 2012, broken down by year and quarter.
- 7) Documents sufficient to show Depomed funding of CME modules or other educational presentations for physicians, nurses, pharmacists, or other medical professionals since January 2012, documents sufficient to show the recipients of the funding, and copies of the slides, videos, handouts, promotional materials, and any other related materials produced.
- 8) Documents sufficient to show funding Depomed has provided to the following entities since January 2012, including the date of specific payments, the amount of each payment, the purpose of each payment (CME funding, research funding, etc.), if

²⁰ Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.* (D. Ariz. Oct. 27, 2014).

specified, year-end or year-to-date payment totals per year, and the cumulative total payments to each organization:

- a. American Academy of Pain Medicine
 - b. American Pain Society
 - c. American Pain Foundation
 - d. American Geriatrics Society
 - e. American Chronic Pain Association
 - f. American Society of Pain Educators
 - g. The National Pain Foundation
 - h. Pain & Policy Studies Group
 - i. Federation of State Medical Boards
 - j. American Society of Pain Management Nursing
 - k. Academy of Integrative Pain Management
 - l. U.S. Pain Foundation
 - m. Cancer Action Network
 - n. Washington Legal Foundation
 - o. The Center for Practical Bioethics
 - p. The Joint Commission
 - q. Pain Care Forum
 - r. Any other organization receiving funding from Depomed for the purpose of developing guidelines on pain management or opioid use
- 9) Any reports Depomed has issued to government agencies since January 2012 in accordance with corporate integrity agreements or other settlement agreements.
- 10) Any document productions Depomed has made since January 2012 to the Department of Justice, the Department of Health and Human Services Office of Inspector General, state attorneys general, any committee or subcommittee of the U.S. Congress, and any U.S. Attorney's office related to the issues outlined in the requests above or Depomed's opioid products generally.

Please provide your responses as soon as possible, but in no event later than April 25, 2017. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Amanda_Trosen@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman

RON JOHNSON, WISCONSIN, CHAIRMAN

JOHN McCAIN, ARIZONA
ROB PORTMAN, OHIO
RAND PAUL, KENTUCKY
JAMES LANKFORD, OKLAHOMA
MICHAEL B. ENZI, WYOMING
JOHN HOEVEN, NORTH DAKOTA
STEVE DAINES, MONTANA

CLAIRE McCASKILL, MISSOURI
THOMAS R. CARPER, DELAWARE
JON TESTER, MONTANA
HEIDI HEITKAMP, NORTH DAKOTA
GARY C. PETERS, MICHIGAN
MARGARET WOOD HASSAN, NEW HAMPSHIRE
KAMALA D. HARRIS, CALIFORNIA

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

March 28, 2017

CHRISTOPHER R. HIXON, STAFF DIRECTOR
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

Alex Gorsky
Chairman and Chief Executive Officer
Janssen Pharmaceuticals, Inc.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Dear Mr. Gorsky:

I am writing to request information from Janssen, as the manufacturer of one of the top five opioid products by 2015 sales,¹ related to the sales, marketing, and educational strategies it has employed to promote opioid use. In the United States today, too many opioids are prescribed, too many are abused, and too many are purchased by the federal government. Medicare Part D spending on commonly abused opioids has increased 165% between 2006 and 2015, reaching a cost of \$4.1 billion, and almost 30% of Part D recipients received at least one commonly abused opioid in 2015.² Financial waste is just one measure of the cost of our national opioid epidemic; in 2015, more than 15,000 Americans died from overdoses involving prescription opioids,³ and opioid-related hospitalizations and emergency room visits in Missouri, for example, doubled between 2005 and 2014.⁴

This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers. To achieve this goal, manufactures have reportedly sought to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses. In May 2007, for example, Purdue Pharma paid \$635 million in fines to settle criminal and civil charges related to its misrepresentation of the addictive qualities of OxyContin, with three Purdue executives pleading guilty to criminal misbranding.⁵ An October 2016 complaint filed by the City of

¹ *Americans Consume Vast Majority of the World's Opioids*, CNBC (Apr. 27, 2016).

² HHS OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (June 2016) (OEI-02-16-00290).

³ Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (online at <https://www.cdc.gov/drugoverdose/data/overdose.html>).

⁴ Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (online at http://www.mhanet.com/mhaimages/HIDIHealthStats/Opioids_HealthStats_1015.pdf).

⁵ *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007).

Chicago against Janssen, among other parties, similarly alleges that the company employed “[d]eceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms” as a “foundation of [its] marketing campaign.”⁶ At the same time, certain manufacturers allegedly premised their sales and marketing approach on the addictive qualities of opioids. Alec Burlakoff, former sales vice president for Insys, which manufactures a fentanyl spray—Subsys—that is 100 times more powerful than morphine, reportedly stated, for example: “If you can keep [patients] on [Subsys] for four months, they’re hooked. Then they’ll be on it for a year, maybe longer.”⁷

Opioid manufacturers have also allegedly used illegal kickbacks through “speakers programs” and other inducements to encourage a wide variety of physicians to prescribe their high-powered products. For example, according to a federal indictment against six top officials of Insys, company executives and sales representatives “led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe” the product.⁸ These efforts allegedly resulted in “large numbers of prescriptions for...patients, most of whom were not diagnosed with cancer.”⁹ Other manufacturers have simply targeted physicians with abnormally high opioid prescribing histories. Early in its campaign for OxyContin, for example, Purdue focused on the highest opioid prescribers in the country, with one market research report indicating this effort improved Purdue profit margins by 3%.¹⁰ As recently as 2013, Purdue reportedly maintained a database of hundreds of doctors suspected of overprescribing opioids, nominally to steer sales representatives away from these physicians; according to the *Los Angeles Times*, however, Purdue “has done little to alert law enforcement or medical authorities” to these prescribers.¹¹

Opioid manufacturers have also apparently attempted to influence prescribing behavior through the creation of continuing medical education (CME) to promote opioids for pain management. In a study by Georgetown University, Dr. Adriane Fugh-Berman found that industry-sponsored CME failed to mention opioid death altogether, compared to 26 mentions of

⁶ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

⁷ *Murder Incorporated: Insys Therapeutics, Part II*, Southern Investigative Reporting Foundation (Dec. 9, 2015).

⁸ Department of Justice, *Pharmaceutical Executives Charges in Racketeering Scheme* (Dec. 8, 2016) (online at <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>).

⁹ *Id.*

¹⁰ Dr. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, *American Journal of Public Health* (Feb. 2009).

¹¹ *OxyContin Maker Closely Guards Its List of Suspect Doctors*, *Los Angeles Times* (Aug. 11, 2013).

the risk of death in non-industry sponsored presentations.¹² Physicians viewing industry-created CME later noted their impression that opioids were underprescribed for chronic pain, and less frequently mentioned risks of addiction than their peers viewing non-industry CME.¹³ This practice appears to be widespread across the opioid manufacturing industry. The City of Chicago has alleged in a recent complaint, for example, that major opioid manufacturers, including Purdue and Janssen, have “sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating...deceptive and biased messages,” including presentations that “focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.”¹⁴

Manufacturers have also worked with licensing and accreditation bodies to influence physician behavior. Purdue, for example, partnered with the Joint Commission—an accrediting body for U.S. hospitals—to publish a guide stating “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”¹⁵ In 2001, the Joint Commission also issued new standards emphasizing communication with patients concerning pain and prioritizing pain treatment.¹⁶ Similarly, the Federation of State Medical Boards (FSMB) promoted a policy calling for punishment of physicians for the undertreatment of pain; the policy also assured physicians they would not face disciplinary action for overprescription of narcotics.¹⁷ Purdue Pharma, among other opioid manufacturers, funded a book outlining this policy, with \$280,000 in proceeds going to FSMB.¹⁸ Manufacturers have also allegedly provided funding to advocacy groups like the American Geriatrics Society (AGS) and the American Academy of Pain Medicine (AAPM) to develop materials supportive of opioid use; Janssen, for example, allegedly partnered with AGS and AAPM to create a guide stating that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”¹⁹

The alleged practices detailed above represent significant challenges government programs, insurers, and pharmacy benefit managers face when attempting to prevent opioid fraud

¹² Adriane Fugh-Berman, PharmOut, *Marketing Messages in Industry-Funded CME* (June 25, 2010) (online at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf).

¹³ *Id.*

¹⁴ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

¹⁵ *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

and overuse. More importantly, they show an industry apparently focused not on preventing abuse but on fostering addiction as a central component of its business model. One former Insys sales representative described the motto of this approach to patients as “Start them high and hope they don’t die.”²⁰

To aid the Committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government, please provide responses to the document and information requests below:

- 1) Documents showing any internal Janssen estimates of the risk of misuse, abuse, addiction, overdose, diversion or death arising from the use of any opioid product Janssen has manufactured, or any estimates of these risks produced by third-party contractors or vendors.
- 2) Any reports Janssen has generated since January 2012 summarizing or concerning compliance audits of its sales and marketing policies.
- 3) Marketing and business plans, including plans for direct-to-consumer and physician marketing, Janssen has developed since January 2012 for each opioid product Janssen has offered.
- 4) Any slide decks, presentations, talking points, or other materials Janssen has provided to participants or speakers in Janssen speakers programs since January 2012.
- 5) Quotas for Janssen sales representatives dedicated to opioid products concerning the recruitment of physicians for speakers programs since January 2012, broken down by year and quarter.
- 6) Documents sufficient to show Janssen expenses relating to the entertainment of physicians by sales representatives dedicated to opioid products since January 2012, broken down by year and quarter.
- 7) Documents sufficient to show Janssen funding of CME modules or other educational presentations for physicians, nurses, pharmacists, or other medical professionals since January 2012, documents sufficient to show the recipients of the funding, and copies of the slides, videos, handouts, promotional materials, and any other related materials produced.
- 8) Documents sufficient to show funding Johnson & Johnson has provided to the following entities since January 2012, including the date of specific payments, the amount of each payment, the purpose of each payment (CME funding, research

²⁰ Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.* (D. Ariz. Oct. 27, 2014).

funding, etc.), if specified, year-end or year-to-date payment totals per year, and the cumulative total payments to each organization:

- a. American Academy of Pain Medicine
 - b. American Pain Society
 - c. American Pain Foundation
 - d. American Geriatrics Society
 - e. American Chronic Pain Association
 - f. American Society of Pain Educators
 - g. The National Pain Foundation
 - h. Pain & Policy Studies Group
 - i. Federation of State Medical Boards
 - j. American Society of Pain Management Nursing
 - k. Academy of Integrative Pain Management
 - l. U.S. Pain Foundation
 - m. Cancer Action Network
 - n. Washington Legal Foundation
 - o. The Center for Practical Bioethics
 - p. The Joint Commission
 - q. Pain Care Forum
 - r. Any other organization receiving funding from Janssen for the purpose of developing guidelines on pain management or opioid use
- 9) Any reports Janssen has issued to government agencies since January 2012 in accordance with corporate integrity agreements or other settlement agreements.
- 10) Any document productions Janssen has made since January 2012 to the Department of Justice, the Department of Health and Human Services Office of Inspector General, state attorneys general, any committee or subcommittee of the U.S. Congress, and any U.S. Attorney's office related to the issues outlined in the requests above or Janssen's opioid products generally.

Please provide your responses as soon as possible, but in no event later than April 25, 2017. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Amanda_Trosen@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

CHRISTOPHER R. HIXON, STAFF DIRECTOR
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

March 28, 2017

Heather Bresch
Chief Executive Officer
Mylan
1000 Mylan Blvd
Canonsburg, PA 15317

Dear Ms. Bresch:

I am writing to request information from Mylan, as the manufacturer of one of the top five opioid products by 2015 sales,¹ related to the sales, marketing, and educational strategies it has employed to promote opioid use. In the United States today, too many opioids are prescribed, too many are abused, and too many are purchased by the federal government. Medicare Part D spending on commonly abused opioids has increased 165% between 2006 and 2015, reaching a cost of \$4.1 billion, and almost 30% of Part D recipients received at least one commonly abused opioid in 2015.² Financial waste is just one measure of the cost of our national opioid epidemic; in 2015, more than 15,000 Americans died from overdoses involving prescription opioids,³ and opioid-related hospitalizations and emergency room visits in Missouri, for example, doubled between 2005 and 2014.⁴

This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers. To achieve this goal, manufactures have reportedly sought to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses. In May 2007, for example, Purdue Pharma paid \$635 million in fines to settle criminal and civil charges related to its misrepresentation of the addictive qualities of OxyContin, with three Purdue executives pleading guilty to criminal misbranding.⁵ An October 2016 complaint filed by the City of

¹ *Americans Consume Vast Majority of the World's Opioids*, CNBC (Apr. 27, 2016).

² HHS OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (June 2016) (OEI-02-16-00290).

³ Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (online at <https://www.cdc.gov/drugoverdose/data/overdose.html>).

⁴ Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (online at http://www.mhanet.com/mhaimages/HIDIHealthStats/Opioids_HealthStats_1015.pdf).

⁵ *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007).

Chicago against Janssen, among other parties, similarly alleges that the company employed “[d]eceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms” as a “foundation of [its] marketing campaign.”⁶ At the same time, certain manufacturers allegedly premised their sales and marketing approach on the addictive qualities of opioids. Alec Burlakoff, former sales vice president for Insys, which manufactures a fentanyl spray—Subsys—that is 100 times more powerful than morphine, reportedly stated, for example: “If you can keep [patients] on [Subsys] for four months, they’re hooked. Then they’ll be on it for a year, maybe longer.”⁷

Opioid manufacturers have also allegedly used illegal kickbacks through “speakers programs” and other inducements to encourage a wide variety of physicians to prescribe their high-powered products. For example, according to a federal indictment against six top officials of Insys, company executives and sales representatives “led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe” the product.⁸ These efforts allegedly resulted in “large numbers of prescriptions for...patients, most of whom were not diagnosed with cancer.”⁹ Other manufacturers have simply targeted physicians with abnormally high opioid prescribing histories. Early in its campaign for OxyContin, for example, Purdue focused on the highest opioid prescribers in the country, with one market research report indicating this effort improved Purdue profit margins by 3%.¹⁰ As recently as 2013, Purdue reportedly maintained a database of hundreds of doctors suspected of overprescribing opioids, nominally to steer sales representatives away from these physicians; according to the *Los Angeles Times*, however, Purdue “has done little to alert law enforcement or medical authorities” to these prescribers.¹¹

Opioid manufacturers have also apparently attempted to influence prescribing behavior through the creation of continuing medical education (CME) to promote opioids for pain management. In a study by Georgetown University, Dr. Adriane Fugh-Berman found that industry-sponsored CME failed to mention opioid death altogether, compared to 26 mentions of

⁶ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

⁷ *Murder Incorporated: Insys Therapeutics, Part II*, Southern Investigative Reporting Foundation (Dec. 9, 2015).

⁸ Department of Justice, *Pharmaceutical Executives Charges in Racketeering Scheme* (Dec. 8, 2016) (online at <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>).

⁹ *Id.*

¹⁰ Dr. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, *American Journal of Public Health* (Feb. 2009).

¹¹ *OxyContin Maker Closely Guards Its List of Suspect Doctors*, *Los Angeles Times* (Aug. 11, 2013).

the risk of death in non-industry sponsored presentations.¹² Physicians viewing industry-created CME later noted their impression that opioids were underprescribed for chronic pain, and less frequently mentioned risks of addiction than their peers viewing non-industry CME.¹³ This practice appears to be widespread across the opioid manufacturing industry. The City of Chicago has alleged in a recent complaint, for example, that major opioid manufacturers, including Purdue and Janssen, have “sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating...deceptive and biased messages,” including presentations that “focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.”¹⁴

Manufacturers have also worked with licensing and accreditation bodies to influence physician behavior. Purdue, for example, partnered with the Joint Commission—an accrediting body for U.S. hospitals—to publish a guide stating “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”¹⁵ In 2001, the Joint Commission also issued new standards emphasizing communication with patients concerning pain and prioritizing pain treatment.¹⁶ Similarly, the Federation of State Medical Boards (FSMB) promoted a policy calling for punishment of physicians for the undertreatment of pain; the policy also assured physicians they would not face disciplinary action for overprescription of narcotics.¹⁷ Purdue Pharma, among other opioid manufacturers, funded a book outlining this policy, with \$280,000 in proceeds going to FSMB.¹⁸ Manufacturers have also allegedly provided funding to advocacy groups like the American Geriatrics Society (AGS) and the American Academy of Pain Medicine (AAPM) to develop materials supportive of opioid use; Janssen, for example, allegedly partnered with AGS and AAPM to create a guide stating that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”¹⁹

The alleged practices detailed above represent significant challenges government programs, insurers, and pharmacy benefit managers face when attempting to prevent opioid fraud

¹² Adriane Fugh-Berman, PharmedOut, *Marketing Messages in Industry-Funded CME* (June 25, 2010) (online at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf).

¹³ *Id.*

¹⁴ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

¹⁵ *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

and overuse. More importantly, they show an industry apparently focused not on preventing abuse but on fostering addiction as a central component of its business model. One former Insys sales representative described the motto of this approach to patients as “Start them high and hope they don’t die.”²⁰

To aid the Committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government, please provide responses to the document and information requests below:

- 1) Documents showing any internal Mylan estimates of the risk of misuse, abuse, addiction, overdose, diversion or death arising from the use of any opioid product Mylan has manufactured, or any estimates of these risks produced by third-party contractors or vendors.
- 2) Any reports Mylan has generated since January 2012 summarizing or concerning compliance audits of its sales and marketing policies.
- 3) Marketing and business plans, including plans for direct-to-consumer and physician marketing, Mylan has developed since January 2012 for each opioid product Mylan has offered.
- 4) Any slide decks, presentations, talking points, or other materials Mylan has provided to participants or speakers in Mylan speakers programs since January 2012.
- 5) Quotas for Mylan sales representatives dedicated to opioid products concerning the recruitment of physicians for speakers programs since January 2012, broken down by year and quarter.
- 6) Documents sufficient to show Mylan expenses relating to the entertainment of physicians by sales representatives dedicated to opioid since January 2012, broken down by year and quarter.
- 7) Documents sufficient to show Mylan funding of CME modules or other educational presentations for physicians, nurses, pharmacists, or other medical professionals since January 2012, documents sufficient to show the recipients of the funding, and copies of the slides, videos, handouts, promotional materials, and any other related materials produced.
- 8) Documents sufficient to show funding Mylan has provided to the following entities since January 2012, including the date of specific payments, the amount of each payment, the purpose of each payment (CME funding, research funding, etc.), if

²⁰ Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.* (D. Ariz. Oct. 27, 2014).

specified, year-end or year-to-date payment totals per year, and the cumulative total payments to each organization:

- a. American Academy of Pain Medicine
 - b. American Pain Society
 - c. American Pain Foundation
 - d. American Geriatrics Society
 - e. American Chronic Pain Association
 - f. American Society of Pain Educators
 - g. The National Pain Foundation
 - h. Pain & Policy Studies Group
 - i. Federation of State Medical Boards
 - j. American Society of Pain Management Nursing
 - k. Academy of Integrative Pain Management
 - l. U.S. Pain Foundation
 - m. Cancer Action Network
 - n. Washington Legal Foundation
 - o. The Center for Practical Bioethics
 - p. The Joint Commission
 - q. Pain Care Forum
 - r. Any other organization receiving funding from Mylan for the purpose of developing guidelines on pain management or opioid use
- 9) Any reports Mylan has issued to government agencies since January 2012 in accordance with corporate integrity agreements or other settlement agreements.
- 10) Any document productions Mylan has made since January 2012 to the Department of Justice, the Department of Health and Human Services Office of Inspector General, state attorneys general, any committee or subcommittee of the U.S. Congress, and any U.S. Attorney's office related to the issues outlined in the requests above or Mylan's opioid products generally.

Please provide your responses as soon as possible, but in no event later than April 25, 2017. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Amanda_Trosen@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman

RON JOHNSON, WISCONSIN, CHAIRMAN

JOHN MCCAIN, ARIZONA
ROB PORTMAN, OHIO
RAND PAUL, KENTUCKY
JAMES LANKFORD, OKLAHOMA
MICHAEL B. ENZI, WYOMING
JOHN HOEVEN, NORTH DAKOTA
STEVE DAINES, MONTANA

CLAIRE McCASKILL, MISSOURI
THOMAS R. CARPER, DELAWARE
JON TESTER, MONTANA
HEIDI HEITKAMP, NORTH DAKOTA
GARY C. PETERS, MICHIGAN
MARGARET WOOD HASSAN, NEW HAMPSHIRE
KAMALA D. HARRIS, CALIFORNIA

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

March 28, 2017

Mark Timney
President and Chief Executive Officer
Purdue Pharma
One Stamford Forum
201 Tresser Blvd
Stamford, CT 06901

Dear Mr. Timney:

I am writing to request information from Purdue, as the manufacturer of one of the top five opioid products by 2015 sales,¹ related to the sales, marketing, and educational strategies it has employed to promote opioid use. In the United States today, too many opioids are prescribed, too many are abused, and too many are purchased by the federal government. Medicare Part D spending on commonly abused opioids has increased 165% between 2006 and 2015, reaching a cost of \$4.1 billion, and almost 30% of Part D recipients received at least one commonly abused opioid in 2015.² Financial waste is just one measure of the cost of our national opioid epidemic; in 2015, more than 15,000 Americans died from overdoses involving prescription opioids,³ and opioid-related hospitalizations and emergency room visits in Missouri, for example, doubled between 2005 and 2014.⁴

This epidemic is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful—and often deadly—painkillers. To achieve this goal, manufactures have reportedly sought to downplay the risk of addiction to their products and encourage physicians to prescribe opioids for all cases of pain and in high doses. In May 2007, for example, Purdue Pharma paid \$635 million in fines to settle criminal and civil charges related to its misrepresentation of the addictive qualities of OxyContin, with three Purdue executives pleading guilty to criminal misbranding.⁵ An October 2016 complaint filed by the City of

¹ *Americans Consume Vast Majority of the World's Opioids*, CNBC (Apr. 27, 2016).

² HHS OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (June 2016) (OEI-02-16-00290).

³ Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (online at <https://www.cdc.gov/drugoverdose/data/overdose.html>).

⁴ Hospital Industry Data Institute, *Alarming Trends in Hospital Utilization for Opioid Overuse in Missouri* (Oct. 2015) (online at http://www.mhanet.com/mhaimages/HIDIHealthStats/Opioids_HealthStats_1015.pdf).

⁵ *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007).

Chicago against Janssen, among other parties, similarly alleges that the company employed “[d]eceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms” as a “foundation of [its] marketing campaign.”⁶ At the same time, certain manufacturers allegedly premised their sales and marketing approach on the addictive qualities of opioids. Alec Burlakoff, former sales vice president for Insys, which manufactures a fentanyl spray—Subsys—that is 100 times more powerful than morphine, reportedly stated, for example: “If you can keep [patients] on [Subsys] for four months, they’re hooked. Then they’ll be on it for a year, maybe longer.”⁷

Opioid manufacturers have also allegedly used illegal kickbacks through “speakers programs” and other inducements to encourage a wide variety of physicians to prescribe their high-powered products. For example, according to a federal indictment against six top officials of Insys, company executives and sales representatives “led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe” the product.⁸ These efforts allegedly resulted in “large numbers of prescriptions for...patients, most of whom were not diagnosed with cancer.”⁹ Other manufacturers have simply targeted physicians with abnormally high opioid prescribing histories. Early in its campaign for OxyContin, for example, Purdue focused on the highest opioid prescribers in the country, with one market research report indicating this effort improved Purdue profit margins by 3%.¹⁰ As recently as 2013, Purdue reportedly maintained a database of hundreds of doctors suspected of overprescribing opioids, nominally to steer sales representatives away from these physicians; according to the *Los Angeles Times*, however, Purdue “has done little to alert law enforcement or medical authorities” to these prescribers.¹¹

Opioid manufacturers have also apparently attempted to influence prescribing behavior through the creation of continuing medical education (CME) to promote opioids for pain management. In a study by Georgetown University, Dr. Adriane Fugh-Berman found that industry-sponsored CME failed to mention opioid death altogether, compared to 26 mentions of

⁶ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

⁷ *Murder Incorporated: Insys Therapeutics, Part II*, Southern Investigative Reporting Foundation (Dec. 9, 2015).

⁸ Department of Justice, *Pharmaceutical Executives Charges in Racketeering Scheme* (Dec. 8, 2016) (online at <https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme>).

⁹ *Id.*

¹⁰ Dr. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, *American Journal of Public Health* (Feb. 2009).

¹¹ *OxyContin Maker Closely Guards Its List of Suspect Doctors*, *Los Angeles Times* (Aug. 11, 2013).

the risk of death in non-industry sponsored presentations.¹² Physicians viewing industry-created CME later noted their impression that opioids were underprescribed for chronic pain, and less frequently mentioned risks of addiction than their peers viewing non-industry CME.¹³ This practice appears to be widespread across the opioid manufacturing industry. The City of Chicago has alleged in a recent complaint, for example, that major opioid manufacturers, including Purdue and Janssen, have “sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating...deceptive and biased messages,” including presentations that “focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.”¹⁴

Manufacturers have also worked with licensing and accreditation bodies to influence physician behavior. Purdue, for example, partnered with the Joint Commission—an accrediting body for U.S. hospitals—to publish a guide stating “there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”¹⁵ In 2001, the Joint Commission also issued new standards emphasizing communication with patients concerning pain and prioritizing pain treatment.¹⁶ Similarly, the Federation of State Medical Boards (FSMB) promoted a policy calling for punishment of physicians for the undertreatment of pain; the policy also assured physicians they would not face disciplinary action for overprescription of narcotics.¹⁷ Purdue Pharma, among other opioid manufacturers, funded a book outlining this policy, with \$280,000 in proceeds going to FSMB.¹⁸ Manufacturers have also allegedly provided funding to advocacy groups like the American Geriatrics Society (AGS) and the American Academy of Pain Medicine (AAPM) to develop materials supportive of opioid use; Janssen, for example, allegedly partnered with AGS and AAPM to create a guide stating that “[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain.”¹⁹

The alleged practices detailed above represent significant challenges government programs, insurers, and pharmacy benefit managers face when attempting to prevent opioid fraud

¹² Adriane Fugh-Berman, PharmedOut, *Marketing Messages in Industry-Funded CME* (June 25, 2010) (online at pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf).

¹³ *Id.*

¹⁴ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

¹⁵ *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Third Amended Complaint, *City of Chicago v. Purdue Pharma L.P., et al.*, No. 14-cv-04361 (N.D. Ill. Oct. 25, 2016).

and overuse. More importantly, they show an industry apparently focused not on preventing abuse but on fostering addiction as a central component of its business model. One former Insys sales representative described the motto of this approach to patients as “Start them high and hope they don’t die.”²⁰

To aid the Committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government, please provide responses to the document and information requests below:

- 1) Documents showing any internal Purdue estimates of the risk of misuse, abuse, addiction, overdose, diversion or death arising from the use of any opioid product Purdue has manufactured, or any estimates of these risks produced by third-party contractors or vendors.
- 2) Any reports Purdue has generated since January 2012 summarizing or concerning compliance audits of its sales and marketing policies.
- 3) Marketing and business plans, including plans for direct-to-consumer and physician marketing, Purdue has developed since January 2012 for each opioid product Purdue has offered.
- 4) Any slide decks, presentations, talking points, or other materials Purdue has provided to participants or speakers in Purdue speakers programs since January 2012.
- 5) Quotas for Purdue sales representatives dedicated to opioid products concerning the recruitment of physicians for speakers programs since January 2012, broken down by year and quarter.
- 6) Documents sufficient to show Purdue expenses relating to the entertainment of physicians by sales representatives dedicated to opioid products since January 2012, broken down by year and quarter.
- 7) Documents sufficient to show Purdue funding of CME modules or other educational presentations for physicians, nurses, pharmacists, or other medical professionals since January 2012, documents sufficient to show the recipients of the funding, and copies of the slides, videos, handouts, promotional materials, and any other related materials produced.
- 8) Documents sufficient to show funding Purdue Pharma has provided to the following entities since January 2012, including the date of specific payments, the amount of each payment, the purpose of each payment (CME funding, research funding, etc.), if

²⁰ Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc.* (D. Ariz. Oct. 27, 2014).

specified, year-end or year-to-date payment totals per year, and the cumulative total payments to each organization:

- a. American Academy of Pain Medicine
 - b. American Pain Society
 - c. American Pain Foundation
 - d. American Geriatrics Society
 - e. American Chronic Pain Association
 - f. American Society of Pain Educators
 - g. The National Pain Foundation
 - h. Pain & Policy Studies Group
 - i. Federation of State Medical Boards
 - j. American Society of Pain Management Nursing
 - k. Academy of Integrative Pain Management
 - l. U.S. Pain Foundation
 - m. Cancer Action Network
 - n. Washington Legal Foundation
 - o. The Center for Practical Bioethics
 - p. The Joint Commission
 - q. Pain Care Forum
 - r. Any other organization receiving funding from Purdue for the purpose of developing guidelines on pain management or opioid use
- 9) Any reports Purdue has issued to government agencies since January 2012 in accordance with corporate integrity agreements or other settlement agreements.
- 10) Any document productions Purdue has made since January 2012 to the Department of Justice, the Department of Health and Human Services Office of Inspector General, state attorneys general, any committee or subcommittee of the U.S. Congress, and any U.S. Attorney's office related to the issues outlined in the requests above or Purdue's opioid products generally.

Please provide your responses as soon as possible, but in no event later than April 25, 2017. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Amanda_Trosen@hsgac.senate.gov.

Sincerely,



Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman