MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, J.R., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA

United States Senate

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Dr. David Charles Chairman Alliance for Patient Access 1275 Pennsylvania Avenue, NW Suite 1100A Washington, DC 20004

Dear Dr. Charles,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

This Committee has a long history of investigating pharmaceutical manufacturers and their relationships with tax-exempt entities that influence pain treatment practices and policy. In 2012, Chairman Grassley, along with then-Chairman Max Baucus, initiated a bipartisan investigation into the connection between opioid manufacturers and non-profit medical organizations and physicians.¹ The purpose of this investigation was to understand the nature of these relationships and to determine the extent to which they were responsible for promoting misleading information about opioid safety and effectiveness.² During the investigation, the Committee stressed the importance of distributing accurate information about these drugs in order to prevent improper use of opioids for chronic pain, but was unable to complete the investigation before the end of the 112th Congress.³

 2 Id.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, JR., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Ms. Debra J. Drew President American Society for Pain Management Nursing 4400 College Boulevard, Suite 220 Overland Park, KS 66211

Dear Ms. Drew,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

 $^{^{2}}$ Id.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, J.R., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA

United States Senate

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Ms. Debra Weiner Secretary American Society of Pain Educators 6 Erie Street Montclair, NJ 07042

Dear Ms. Weiner,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

This Committee has a long history of investigating pharmaceutical manufacturers and their relationships with tax-exempt entities that influence pain treatment practices and policy. In 2012, Chairman Grassley, along with then-Chairman Max Baucus, initiated a bipartisan investigation into the connection between opioid manufacturers and non-profit medical organizations and physicians.¹ The purpose of this investigation was to understand the nature of these relationships and to determine the extent to which they were responsible for promoting misleading information about opioid safety and effectiveness.² During the investigation, the Committee stressed the importance of distributing accurate information about these drugs in order to prevent improper use of opioids for chronic pain, but was unable to complete the investigation before the end of the 112th Congress.³

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

 $^{^2}$ Id.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, J.R., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Dr. Humayun J. Chaudhry President & CEO Federation of State Medical Boards 400 Fuller Wiser Road Euless, TX 76039

Dear Dr. Chaudhry,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

² *Id*.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, J.R., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Mr. John G. Carney President & CEO Center for Practical Bioethics 1111 Main Street, Suite 500 Kansas City, MO 64105

Dear Mr. Carney,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

² *Id*.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, JR., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Dr. Med. Lars Arendt-Nielsen President International Association for the Study of Pain 1510 H Street, NW, Suite 600 Washington, DC 20005

Dear Dr. Arendt-Neilsen,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

² *Id.*

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, IMONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, J.R., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Dr. Mark R. Chassin President & CEO The Joint Commission One Renaissance Boulevard Oakbrook Terrace, IL 60181

Dear Dr. Chassin,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

² *Id.*

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOLTH DAKOTA RICHARD BURR, NORTH CAROLINA IDANNYI SAKSON, GEORGIA JOHNYI SIAKSON, GEORGIA ROB PORTMAN, OHHO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOLTH CAROLINA BILL CASSIDY, IOUISANIA JAMES LANKFORD, OKLAHOMA STEVE DAINES, MONTANA RON WYDEN, OREGON DEBBIE SYABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERBEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHO MICHAEL F. BENNET, COLORADO ROBERT F. CASEY, J.m., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITENOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA

United States Senate

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Ms. Penney Cowan Founder, CEO & Executive Director American Chronic Pain Association P.O. Box 850 Rocklin, CA 95677

Dear Ms. Cowan,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

This Committee has a long history of investigating pharmaceutical manufacturers and their relationships with tax-exempt entities that influence pain treatment practices and policy. In 2012, Chairman Grassley, along with then-Chairman Max Baucus, initiated a bipartisan investigation into the connection between opioid manufacturers and non-profit medical organizations and physicians.¹ The purpose of this investigation was to understand the nature of these relationships and to determine the extent to which they were responsible for promoting misleading information about opioid safety and effectiveness.² During the investigation, the Committee stressed the importance of distributing accurate information about these drugs in order to prevent improper use of opioids for chronic pain, but was unable to complete the investigation before the end of the 112th Congress.³

In recent years, Ranking Member Wyden has identified a dozen individuals and taxexempt organizations with significant financial ties to opioid manufacturers who have been

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

² Id.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

- 1. Please provide complete Form 990s that your organization has filed with the Internal Revenue Service for each year from 2012 to the present. In your submission, please also provide complete Schedule Bs.
- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20

Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:

- a. Date of payment.
- b. Source or entity making the payment.
- c. Payment description (general support, project specific etc.).
- d. Amount of payment.
- e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
- f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b 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 Question 2, please provide copies of these materials.

⁸ 42 U.S.C. §1320a-7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrey

Chuck Grassley Chairman

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, INONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, JR., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Dr. Peter C. Esselman President American Academy of Physical Medicine and Rehabilitation 9700 West Bryn Mawr Avenue, Suite 200 Rosemont, IL 60018

Dear Dr. Esselman,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

 $^{^{2}}$ Id.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B. ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, INONTANA TODD YOUNG, INDIANA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R. CARPER, DELAWARE BENJAMIN L. CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F. BENNET, COLORADO ROBERT P. CASEY, J.R., PENNSYLVANIA MARK R. WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ MASTO, NEVADA



WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

June 28, 2019

Dr. William Maixner President American Pain Society 8735 West Higgins Road, Suite 300 Chicago IL 60631

Dear Dr. Maixner,

We write to request information regarding your organization and its financial relationship with opioid manufacturers and other entities that manufacture products to treat pain. As Chairman and Ranking Member of the Senate Finance Committee, we have a responsibility to ensure transparency and accountability in matters that directly affect Federal healthcare programs and tax-exempt organizations. This responsibility includes examining the extent to which pharmaceutical manufacturers fund tax-exempt organizations and how these payments may influence pain treatment practices and policy.

¹ Baucus, Grassley Seek Answers About Opioid Manufacturers' Ties to Medical Groups, SENATE FINANCE (May 2, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medicalgroups.

 $^{^{2}}$ Id.

³ Id.

The stakes are high. The Centers for Disease Control and Prevention has estimated that 130 people die each and every day from deaths involving prescription opioids and that around 68 percent of the more than 70,200 drug overdose deaths in 2017 involved an opioid.⁶ These figures demonstrate that the U.S. continues to suffer from an opioid epidemic and that taking prescription opioids for an extended period of time or in higher doses increase a patient's risk of opioid addiction, overdose, and death.⁷ At the same time, the relationship between opioid manufacturers and non-profit medical organizations remains robust, which calls into question their ability to make impartial recommendations to the medical community and to patients on opioid prescribing practices.

We acknowledge that the answer to the opioid epidemic continues to be anything but simple. However, we believe that it is important to shed light on these financial relationships to ensure transparency and accountability in matters that affect Federal healthcare programs and the patients that participate in them. Therefore, we ask that you please provide the following information to the Committee no later than July 29, 2019:

⁴ HHS's Task Force was established by Congress to issue best practices and recommendations for managing chronic and acute pain in Federal healthcare programs. Comprehensive Addiction and Recovery Act of 2016, P.L. 114-198, 130 Stat. 695, § 101 (2016); *See also Letter to Secretary Azar from Ranking Member Wyden*, SENATE FINANCE (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20Secretary%20Azar%20re%20Pain%20 Task%20Force.pdf.

⁵ Dr. Jianguo Cheng currently sits on the Task Force. Open Payments shows he received \$24,600 from Purdue Pharma in 2017 for "consulting". See *Jianguo Cheng*, OpenPaymentsData.CMS.gov,

https://openpaymentsdata.cms.gov/physician/163794/general-payments (last visited June 4, 2019).

⁶ Understanding the Epidemic, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).

⁷ Prescription Opioids, CENTERS FOR DISEASE CONTROL AND PREVENTION,

https://www.cdc.gov/drugoverdose/opioids/prescribed.html (last updated Aug. 29, 2017).

- 2. Please provide a detailed accounting of all payments/transfers (including but not limited to contributions, grants, advertising, program sponsorship, and other revenue or remuneration) received from any manufacturer of drugs, devices, biologicals or medical supplies⁸ and individuals that produce, market, or promote products on these entities' behalf. Please provide this information in hard copy, PDF, and in a Microsoft Excel workbook. For each payment identified, provide:
 - a. Date of payment.
 - b. Source or entity making the payment.
 - c. Payment description (general support, project specific etc.).
 - d. Amount of payment.
 - e. Year-end or year-to-date payment total and cumulative total payments for each organization or individual.
 - f. For each year a payment was received, the percentage of funding from organizations identified above relative to total revenue.
- 3. In addition to financial support, identify and describe any collaborative activity between your organization and the entities identified in Question 2 from 2012 to the present and the timeframe in which such activity took place.
- 4. Does your organization maintain a conflict of interest policy? If so, please provide us a copy of the current policy and tell us how long this policy has been in effect. In addition, please describe any additional mechanisms your organization uses to police conflicts of interest and to promote transparency of funding sources.
- 5. Regarding involvement with the Federal government:
 - a. Has your organization received any funding from the Federal government since 2012? If yes, please list the year, amount, and purpose of this funding in hard copy, PDF, and in a Microsoft Excel workbook.
 - b. Please provide copies of all comments or other written materials that your organization has made to Federal task forces, committees, advisory groups or other similar entities from 2012 to present.
 - c. In the event any activity identified in Questions 5a and 5b pertains to information distributed to physicians and patients concerning prescription pain medications,

⁸ 42 U.S.C. §1320a–7h(e)(9) (defining manufacturers of a covered, drug, device, biological, or medical supply).

- d. Please provide a list of all instances from 2012 to present in which a board member, executive, staff or affiliated volunteer has served on any Federal task force, committee, advisory group or other entity.
- 6. Please identify any person employed by your organization who communicated with an entity identified in Question 2 regarding the content of materials distributed to patients and physicians pertaining to opioid use and/or prescribing practices from 2012 to the present. Please include their name, position, dates of employment, and job description. Please provide this information in hard copy, PDF, and in a Microsoft Excel Workbook.

Thank you for your prompt attention to this matter. If you have any questions, please contact Caitlin Soto of Chairman Grassley's staff or Peter Gartrell of Ranking Member Wyden's staff at (202) 224-4515.

Chuck Andrew

Ron Wyden

Ron Wyden Ranking Member