United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

July 26, 2017

John H. Hammergren
Chairman, President, and CEO
McKesson Corporation
One Post, 1 Post St
San Francisco, CA 94104

Dear Mr. Hammergren:

I am writing to request information from McKesson, as one of the three largest drug distributors in the United States,[1] concerning its distribution of opioid products. 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 increased 165% between 2006 and 2015, and one out of three Part D recipients received at least one prescription opioid in 2016 at a cost of $4.1 billion.[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 has reportedly arisen, in part, from the failure of opioid distributors to monitor the flow of hundreds of millions of painkillers to pharmacies across the United States and then on to the black market. Under the Controlled Substances Act (CSA), drug distributors have an obligation to report suspicious orders of controlled substances, which include "orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency."[5] As the *Washington Post* has reported, however, at least 13 distributors, including three companies that

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[1] MDM, *2016 MDM Market Leaders: Top Pharmaceutical Distributors* (www.mdm.com/2016-top-pharmaceuticals-distributors).

[2] Department of Health and Human Services Office of Inspector General, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns* (June 21, 2016) (OEI-02-16-00290); Department of Health and Human Services Office of Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing* (July 13, 2017) (OEI-02-17-00250).

[3] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data* (Dec. 16, 2016) (www.cdc.gov/drugoverdose/data/overdose.html).

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

[5] *See* 21 C.F.R. 1301.74(b).

control 85% of all U.S. pharmaceutical distribution, "knew or should have known that hundreds of millions of pills were ending up on the black market."[6] In some cases, distributors continued to send pills "[e]ven when they were alerted to suspicious pain clinics or pharmacies by the [Drug Enforcement Administration (DEA)] and their own employees."[7] Over just six years, for example, distributors shipped 780 million hydrocodone and oxycodone pills to West Virginia—enough to provide "433 pain pills for every man, woman and child."[8] A single pharmacy in the town of Kermit, population 392, received 9 million hydrocodone pills over a two-year period, even as the surrounding Mingo County population suffered the fourth-highest rate of prescription opioid overdose in the United States.[9] Each of the "Big Three" distributors—Cardinal Health, Inc., AmerisourceBergen Corporation, and McKesson Corporation—witnessed dramatic increases in the opioid shipments they distributed to West Virginia counties. McKesson for example, "saturated Mingo County with more hydrocodone pills in one year…than it supplied over five other consecutive years combined."[10]

At the same time, the CEOs of these three companies have received compensation packages worth more than $450 million over the past four years.[11] The International Brotherhood of Teamsters, among other shareholder groups, has suggested these salaries fail to reflect the management lapses that contributed to opioid diversion, and the union has called for a means to recover executive compensation to encourage future compliance.[12] The West Virginia Attorney General has also alleged in a 2016 complaint that McKesson, in particular, has "paid its sales force and managers bonuses and commissions on the sale of most or all of the highly addictive prescription pain killers supplied" to West Virginia counties.[13]

In response to the concerns outlined above, DEA has concluded significant settlements with major opioid distributors. In January 2017, for example, McKesson agreed to pay a $150 million penalty to resolve allegations that it "failed to design and implement an effective system

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[6] *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Washington Post (Oct. 22, 2016).

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[8] *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, Charleston Gazette-Mail (Dec. 17, 2016) (www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses).

[9] *Id.*

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[12] *Ken Hall: A Shareholder's Prescription for the Big Three Opioid Distributors*, Charleston Gazette-Mail (Apr. 8, 2017) (www.wvgazettemail.com/gazette-op-ed-commentaries/20170408/ken-hall-a-shareholders-prescription-for-the-big-three-opioid-distributors).

[13] Amended Complaint (Jan. 21, 2016), *State of West Virginia v. McKesson Corporation*, Circuit Ct. of Boone Cty. (Civil Action No.: 16-C-1).

to detect and report 'suspicious orders' for controlled substances distributed to its independent and small chain pharmacy customers."[14] In December 2016, Cardinal Health resolved similar allegations, paying $44 million after allegedly violating the CSA in Maryland, Florida, and New York.[15]

Yet these settlements, coming years after similar allegations against distributors, raise the implication that DEA actions have been "too little, too late."[16] McKesson, for example, paid $13.25 million to settle allegations regarding three of its warehouses—and "millions of doses of controlled substances…diverted from legitimate channels"—nine years before its January 2017 settlement.[17] In 2008, Cardinal Health paid a $34 million fine after its warehouses filled "thousands of suspicious orders from Internet pharmacies without reporting them," but DEA investigators found evidence of widespread drug diversion at a Cardinal Health client in 2010, and the company settled a related administrative case without paying a fine in 2012.[18] Similarly, an AmerisourceBergen warehouse escaped paying a fine to DEA in 2007 "amid allegations that it was not controlling shipments of hydrocodone."[19] In response to these events, I requested that the Department of Justice Office of the Inspector General (DOJ OIG) investigate whether DEA

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[14] U.S. Department of Justice, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017) (www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders).

[15] U.S. Department of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) (www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act). This settlement also resolved "a civil investigation in the Western District of Washington concerning alleged violations of CSA record keeping requirements."

[16] *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, ProPublica (Jan. 27, 2017) (www.propublica.org/article/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic).

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[18] *Id.*

[19] *Id.*

has the capacity to hold distributors accountable for their lack of diversion oversight.[20] On June 1, 2017, DOJ OIG announced it would undertake this review.[21]

Recent DEA actions against distributors have also paralleled a federal effort to hold opioid manufacturers accountable for failing to monitor and report suspicious deliveries of their products. In April 2017, the manufacturer Mallinckrodt agreed to pay a $35 million fine following DEA allegations that the company "ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012—66 percent of all oxycodone sold in the state."[22] (DOJ confirmed the settlement on July 11, 2017.[23]) DEA alleged, for example, that Mallinckrodt continued to supply opioids—as many as 2.1 million tablets of oxycodone—to a Florida distributor despite knowing the company delivered oxycodone to the operator of a notorious Florida "pill mill" clinic.[24] Mallinckrodt had also allegedly continued to pay "chargebacks," in which manufacturers provide distributors certain reimbursements following sales to pharmacies, in connection with this clinic.[25] In total, DEA estimated that Mallinckrodt failed to report at least 43,991 opioid orders.[26]

For its part, Mallinckrodt has argued that it has no responsibility to "know its customer's customer," and prosecutors did, in fact, note internally "that the DEA had provided conflicting guidance to Mallinckrodt about its responsibilities to report suspicious orders from retailers."[27] At the very least, however, the recent Mallinckrodt settlement raises serious concerns about the actions manufacturers and distributors have undertaken—or not—to meet their anti-diversion obligations under the law.

To aid the Committee in understanding the role of manufacturers and distributors in overseeing opioid shipments and preventing diversion, please provide responses to the document and information requests below:

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[20] Letter from Sen. Claire McCaskill to Inspector General Michael E. Horowitz, Department of Justice Office of Inspector General (March 6, 2017).

[21] Department of Justice Office of the Inspector General, *Ongoing Work, Review of the Drug Enforcement Administration's Opioid Enforcement Efforts* (June 1, 2017) (oig.justice.gov/ongoing/all.htm).

[22] *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Washington Post (Apr. 2, 2017) (www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.c64eb53804f5).

[23] *Mallinckrodt Settles U.S. Opioid Drug Probe for $35 Million*, Reuters (July 11, 2017) (www.reuters.com/article/us-malinckrodt-settlement-idUSKBN19W2EL).

[24] *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Washington Post (Apr. 2, 2017).

[25] *Id.*

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[27] *Id.*

1) Please provide the names and addresses of McKesson distribution centers serving pharmacies, distributors, or other customers in Missouri since January 2012;

2) Please provide any internal estimates McKesson has generated, or any estimates McKesson has received from outside vendors or consultants, since January 2012 concerning the risk of diversion associated with opioid products McKesson distributes;

3) Please provide any audits of incentive or compensation policies McKesson has conducted, or commissioned from outside consultants, since January 2012;

4) Please provide any reports or audits McKesson has created, or any reports or audits McKesson has commissioned from any Independent Review Organization (or the equivalent), since January 2012 pursuant to any settlement agreement with any government agency;

5) Please provide a list of any McKesson facilities for which DEA has suspended or revoked registrations since January 2012, including the date the DEA imposed the suspension or revocation, the reason for the suspension or revocation, and the length of the suspension, if applicable;

6) Using the template in Attachment A or a similar format, please provide a list of all suspicious order notifications McKesson has provided to DEA regarding opioid orders originating from Missouri since January 2012, including the date of the notification, the name and address of the ordering pharmacy, distributor, or other customer, the substances ordered, and the strength and quantity of each substance in terms of number of pills, metric measurement of liquids, or the strength and number of doses for pre-packaged single-use items;

7) For each Missouri pharmacy, distributor, or other customer to which McKesson has distributed any opioid products since January 2012, please provide, using the template in Attachment A or a similar format:
    a. The name and address of the customer;
    b. A list of opioid products McKesson has distributed to each customer, including the date of the distribution, the names of the substances distributed, and the strength and quantity of each substance in terms of number of pills, metric measurement of liquids, or the strength and number of doses for pre-packaged single-use items;
    c. A list of instances in which McKesson has refused to fill any order for opioid products, including a description of the order and the date of refusal, to the extent these refused orders differ from suspicious orders McKesson has reported; and
    d. A list of audits or investigations McKesson has undertaken following indications of suspicious orders, including the outcome of the audit or

investigation and any subsequent actions by McKesson concerning the customer at issue;

8) Please describe the role of compliance metrics in determining McKesson executive compensation and produce any written performance reviews of your Chief Compliance Officer since January 2012. This response should list particular executives or positions to which compliance metrics apply, any instances since January 2012 in which McKesson has withheld compensation from executives due to compliance issues, and any reductions in compensation, along with the reason for the reduction, applicable to your Chief Compliance Officer since January 2012;

9) Please describe any compensation McKesson provides, whether commission, incentive, or as a factor in a bonus, that is in any way derived or partially derived from revenue or profitability targets or expectations for sales of opioid products; and

10) Please provide, for any McKesson employee receiving compensation described in Request 9 since January 2012, the position of each employee, the year or years in which the compensation occurred, and the particular sales incentives or compensation plans applicable to each employee.

Please provide your responses as soon as possible, but in no event later than August 30, 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

July 26, 2017

George S. Barrett
Chairman and CEO
Cardinal Health, Inc.
7000 Cardinal Place
Dublin, OH 43017

Dear Mr. Barrett:

I am writing to request information from Cardinal Health, as one of the three largest drug distributors in the United States,[1] concerning its distribution of opioid products. 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 increased 165% between 2006 and 2015, and one out of three Part D recipients received at least one prescription opioid in 2016 at a cost of $4.1 billion.[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 has reportedly arisen, in part, from the failure of opioid distributors to monitor the flow of hundreds of millions of painkillers to pharmacies across the United States and then on to the black market. Under the Controlled Substances Act (CSA), drug distributors have an obligation to report suspicious orders of controlled substances, which include "orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency."[5] As the *Washington Post* has reported, however, at least 13 distributors, including three companies that

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control 85% of all U.S. pharmaceutical distribution, "knew or should have known that hundreds of millions of pills were ending up on the black market."[6] In some cases, distributors continued to send pills "[e]ven when they were alerted to suspicious pain clinics or pharmacies by the [Drug Enforcement Administration (DEA)] and their own employees."[7] Over just six years, for example, distributors shipped 780 million hydrocodone and oxycodone pills to West Virginia—enough to provide "433 pain pills for every man, woman and child."[8] A single pharmacy in the town of Kermit, population 392, received 9 million hydrocodone pills over a two-year period, even as the surrounding Mingo County population suffered the fourth-highest rate of prescription opioid overdose in the United States.[9] Each of the "Big Three" distributors—Cardinal Health, Inc., AmerisourceBergen Corporation, and McKesson Corporation—witnessed dramatic increases in the opioid shipments they distributed to West Virginia counties. McKesson for example, "saturated Mingo County with more hydrocodone pills in one year…than it supplied over five other consecutive years combined."[10]

At the same time, the CEOs of these three companies have received compensation packages worth more than $450 million over the past four years.[11] The International Brotherhood of Teamsters, among other shareholder groups, has suggested these salaries fail to reflect the management lapses that contributed to opioid diversion, and the union has called for a means to recover executive compensation to encourage future compliance.[12] The West Virginia Attorney General has also alleged in a 2016 complaint that McKesson, in particular, has "paid its sales force and managers bonuses and commissions on the sale of most or all of the highly addictive prescription pain killers supplied" to West Virginia counties.[13]

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Recent DEA actions against distributors have also paralleled a federal effort to hold opioid manufacturers accountable for failing to monitor and report suspicious deliveries of their products. In April 2017, the manufacturer Mallinckrodt agreed to pay a $35 million fine following DEA allegations that the company "ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012—66 percent of all oxycodone sold in the state."[22] (DOJ confirmed the settlement on July 11, 2017.[23]) DEA alleged, for example, that Mallinckrodt continued to supply opioids—as many as 2.1 million tablets of oxycodone—to a Florida distributor despite knowing the company delivered oxycodone to the operator of a notorious Florida "pill mill" clinic.[24] Mallinckrodt had also allegedly continued to pay "chargebacks," in which manufacturers provide distributors certain reimbursements following sales to pharmacies, in connection with this clinic.[25] In total, DEA estimated that Mallinckrodt failed to report at least 43,991 opioid orders.[26]

For its part, Mallinckrodt has argued that it has no responsibility to "know its customer's customer," and prosecutors did, in fact, note internally "that the DEA had provided conflicting guidance to Mallinckrodt about its responsibilities to report suspicious orders from retailers."[27] At the very least, however, the recent Mallinckrodt settlement raises serious concerns about the actions manufacturers and distributors have undertaken—or not—to meet their anti-diversion obligations under the law.

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5) Please provide a list of any Cardinal Health facilities for which DEA has suspended or revoked registrations since January 2012, including the date the DEA imposed the suspension or revocation, the reason for the suspension or revocation, and the length of the suspension, if applicable;

6) Using the template in Attachment A or a similar format, please provide a list of all suspicious order notifications Cardinal Health has provided to DEA regarding opioid orders originating from Missouri since January 2012, including the date of the notification, the name and address of the ordering pharmacy, distributor, or other customer, the substances ordered, and the strength and quantity of each substance in terms of number of pills, metric measurement of liquids, or the strength and number of doses for pre-packaged single-use items;

7) For each Missouri pharmacy, distributor, or other customer to which Cardinal Health has distributed any opioid products since January 2012, please provide, using the template in Attachment A or a similar format:
    a. The name and address of the customer;
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Sincerely,

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Ranking Member

cc: Ron Johnson
Chairman

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

July 26, 2017

Steven H. Collis
Chairman, President, and CEO
AmerisourceBergen Corporation
1300 Morris Drive
Chesterbrook, PA 19087

Dear Mr. Collis:

I am writing to request information from AmerisourceBergen, as one of the three largest drug distributors in the United States,[1] concerning its distribution of opioid products. 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 increased 165% between 2006 and 2015, and one out of three Part D recipients received at least one prescription opioid in 2016 at a cost of $4.1 billion.[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]

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[5] *See* 21 C.F.R. 1301.74(b).

control 85% of all U.S. pharmaceutical distribution, "knew or should have known that hundreds of millions of pills were ending up on the black market."[6] In some cases, distributors continued to send pills "[e]ven when they were alerted to suspicious pain clinics or pharmacies by the [Drug Enforcement Administration (DEA)] and their own employees."[7] Over just six years, for example, distributors shipped 780 million hydrocodone and oxycodone pills to West Virginia—enough to provide "433 pain pills for every man, woman and child."[8] A single pharmacy in the town of Kermit, population 392, received 9 million hydrocodone pills over a two-year period, even as the surrounding Mingo County population suffered the fourth-highest rate of prescription opioid overdose in the United States.[9] Each of the "Big Three" distributors—Cardinal Health, Inc., AmerisourceBergen Corporation, and McKesson Corporation—witnessed dramatic increases in the opioid shipments they distributed to West Virginia counties. McKesson for example, "saturated Mingo County with more hydrocodone pills in one year…than it supplied over five other consecutive years combined."[10]

At the same time, the CEOs of these three companies have received compensation packages worth more than $450 million over the past four years.[11] The International Brotherhood of Teamsters, among other shareholder groups, has suggested these salaries fail to reflect the management lapses that contributed to opioid diversion, and the union has called for a means to recover executive compensation to encourage future compliance.[12] The West Virginia Attorney General has also alleged in a 2016 complaint that McKesson, in particular, has "paid its sales force and managers bonuses and commissions on the sale of most or all of the highly addictive prescription pain killers supplied" to West Virginia counties.[13]

In response to the concerns outlined above, DEA has concluded significant settlements with major opioid distributors. In January 2017, for example, McKesson agreed to pay a $150 million penalty to resolve allegations that it "failed to design and implement an effective system

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[6] *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job*," Washington Post (Oct. 22, 2016).

[7] *Id.*

[8] *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, Charleston Gazette-Mail (Dec. 17, 2016) (www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses).

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Ken Hall: A Shareholder's Prescription for the Big Three Opioid Distributors*, Charleston Gazette-Mail (Apr. 8, 2017) (www.wvgazettemail.com/gazette-op-ed-commentaries/20170408/ken-hall-a-shareholders-prescription-for-the-big-three-opioid-distributors).

[13] Amended Complaint (Jan. 21, 2016), *State of West Virginia v. McKesson Corporation*, Circuit Ct. of Boone Cty. (Civil Action No.: 16-C-1).

to detect and report 'suspicious orders' for controlled substances distributed to its independent and small chain pharmacy customers."[14] In December 2016, Cardinal Health resolved similar allegations, paying $44 million after allegedly violating the CSA in Maryland, Florida, and New York.[15]

Yet these settlements, coming years after similar allegations against distributors, raise the implication that DEA actions have been "too little, too late."[16] McKesson, for example, paid $13.25 million to settle allegations regarding three of its warehouses—and "millions of doses of controlled substances…diverted from legitimate channels"—nine years before its January 2017 settlement.[17] In 2008, Cardinal Health paid a $34 million fine after its warehouses filled "thousands of suspicious orders from Internet pharmacies without reporting them," but DEA investigators found evidence of widespread drug diversion at a Cardinal Health client in 2010, and the company settled a related administrative case without paying a fine in 2012.[18] Similarly, an AmerisourceBergen warehouse escaped paying a fine to DEA in 2007 "amid allegations that it was not controlling shipments of hydrocodone."[19] In response to these events, I requested that the Department of Justice Office of the Inspector General (DOJ OIG) investigate whether DEA

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[14] U.S. Department of Justice, *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017) (www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders).

[15] U.S. Department of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act* (Dec. 23, 2016) (www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act). This settlement also resolved "a civil investigation in the Western District of Washington concerning alleged violations of CSA record keeping requirements."

[16] *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, ProPublica (Jan. 27, 2017) (www.propublica.org/article/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic).

[17] *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Washington Post (Oct. 22, 2016); U.S. Department of Justice, *McKesson Corporation Agrees to Pay More than $13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications* (May 2, 2008) (www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html).

[18] *Id.*

[19] *Id.*

has the capacity to hold distributors accountable for their lack of diversion oversight.[20] On June 1, 2017, DOJ OIG announced it would undertake this review.[21]

Recent DEA actions against distributors have also paralleled a federal effort to hold opioid manufacturers accountable for failing to monitor and report suspicious deliveries of their products. In April 2017, the manufacturer Mallinckrodt agreed to pay a $35 million fine following DEA allegations that the company "ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012—66 percent of all oxycodone sold in the state."[22] (DOJ confirmed the settlement on July 11, 2017.[23]) DEA alleged, for example, that Mallinckrodt continued to supply opioids—as many as 2.1 million tablets of oxycodone—to a Florida distributor despite knowing the company delivered oxycodone to the operator of a notorious Florida "pill mill" clinic.[24] Mallinckrodt had also allegedly continued to pay "chargebacks," in which manufacturers provide distributors certain reimbursements following sales to pharmacies, in connection with this clinic.[25] In total, DEA estimated that Mallinckrodt failed to report at least 43,991 opioid orders.[26]

For its part, Mallinckrodt has argued that it has no responsibility to "know its customer's customer," and prosecutors did, in fact, note internally "that the DEA had provided conflicting guidance to Mallinckrodt about its responsibilities to report suspicious orders from retailers."[27] At the very least, however, the recent Mallinckrodt settlement raises serious concerns about the actions manufacturers and distributors have undertaken—or not—to meet their anti-diversion obligations under the law.

To aid the Committee in understanding the role of manufacturers and distributors in overseeing opioid shipments and preventing diversion, please provide responses to the document and information requests below:

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[20] Letter from Sen. Claire McCaskill to Inspector General Michael E. Horowitz, Department of Justice Office of Inspector General (March 6, 2017).

[21] Department of Justice Office of the Inspector General, *Ongoing Work, Review of the Drug Enforcement Administration's Opioid Enforcement Efforts* (June 1, 2017) (oig.justice.gov/ongoing/all.htm).

[22] *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Washington Post (Apr. 2, 2017) (www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.c64eb53804f5).

[23] *Mallinckrodt Settles U.S. Opioid Drug Probe for $35 Million*, Reuters (July 11, 2017) (www.reuters.com/article/us-malinckrodt-settlement-idUSKBN19W2EL).

[24] *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Washington Post (Apr. 2, 2017).

[25] *Id.*

[26] *Id.*

[27] *Id.*

1) Please provide the names and addresses of AmerisourceBergen distribution centers serving pharmacies, distributors, or other customers in Missouri since January 2012;

2) Please provide any internal estimates AmerisourceBergen has generated, or any estimates AmerisourceBergen has received from outside vendors or consultants, since January 2012 concerning the risk of diversion associated with opioid products AmerisourceBergen distributes;

3) Please provide any audits of incentive or compensation policies AmerisourceBergen has conducted, or commissioned from outside consultants, since January 2012;

4) Please provide any reports or audits AmerisourceBergen has created, or any reports or audits AmerisourceBergen has commissioned from any Independent Review Organization (or the equivalent), since January 2012 pursuant to any settlement agreement with any government agency;

5) Please provide a list of any AmerisourceBergen facilities for which DEA has suspended or revoked registrations since January 2012, including the date the DEA imposed the suspension or revocation, the reason for the suspension or revocation, and the length of the suspension, if applicable;

6) Using the template in Attachment A or a similar format, please provide a list of all suspicious order notifications AmerisourceBergen has provided to DEA regarding opioid orders originating from Missouri since January 2012, including the date of the notification, the name and address of the ordering pharmacy, distributor, or other customer, the substances ordered, and the strength and quantity of each substance in terms of number of pills, metric measurement of liquids, or the strength and number of doses for pre-packaged single-use items;

7) For each Missouri pharmacy, distributor, or other customer to which AmerisourceBergen has distributed any opioid products since January 2012, please provide, using the template in Attachment A or a similar format:
    a. The name and address of the customer;
    b. A list of opioid products AmerisourceBergen has distributed to each customer, including the date of the distribution, the names of the substances distributed, and the strength and quantity of each substance in terms of number of pills, metric measurement of liquids, or the strength and number of doses for pre-packaged single-use items;
    c. A list of instances in which AmerisourceBergen has refused to fill any order for opioid products, including a description of the order and the date of refusal, to the extent these refused orders differ from suspicious orders AmerisourceBergen has reported; and
    d. A list of audits or investigations AmerisourceBergen has undertaken following indications of suspicious orders, including the outcome of the audit

or investigation and any subsequent actions by AmerisourceBergen concerning the customer at issue;

8) Please describe the role of compliance metrics in determining AmerisourceBergen executive compensation and produce any written performance reviews of your Chief Compliance Officer since January 2012. This response should list particular executives or positions to which compliance metrics apply, any instances since January 2012 in which AmerisourceBergen has withheld compensation from executives due to compliance issues, and any reductions in compensation, along with the reason for the reduction, applicable to your Chief Compliance Officer since January 2012;

9) Please describe any compensation AmerisourceBergen provides, whether commission, incentive, or as a factor in a bonus, that is in any way derived or partially derived from revenue or profitability targets or expectations for sales of opioid products; and

10) Please provide, for any AmerisourceBergen employee receiving compensation described in Request 9 since January 2012, the position of each employee, the year or years in which the compensation occurred, and the particular sales incentives or compensation plans applicable to each employee.

Please provide your responses as soon as possible, but in no event later than August 30, 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