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1550 MAIN STREET, 4TH FLOOR SPRINGFIELD, MA 01103 413-785-4610

May 24, 2018

The Honorable Alex Azar Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, DC 20201

#### Dear Secretary Azar:

I write regarding the role opioid manufacturers play in designing and promoting continuing education (CE) classes on opioid prescribing. According to a recent news report, pharmaceutical companies have coopted these courses — often taken by prescribers to fulfill state education requirements — to promote the use of prescription painkillers in ways that scientific and medical data do not support. I am concerned that the industry's profit motives may be improperly influencing the education that prescribers receive and endangering countless American lives.

Health professionals depend on CE courses for the most current information and professional education on a wide range of medical issues. Under the Risk Evaluation and Mitigation Strategies (REMS) instituted by the Food and Drug Administration (FDA), opioid manufacturers are required to provide education for prescribers of opioid medications. This mandate is fulfilled through CE activities funded by grants from opioid manufactures. Aside from the FDA loosely outlining these opioid-prescriber courses, there is little quality control over, or evaluation of, their content. The confluence of industry-funded education and minimal government oversight leaves these CE classes rife for abuse.

A recent investigation by *Mother Jones* into the courses' content revealed significant and troubling shortcomings. Much of the opioid prescribing curriculum does not even conform to the current Guideline for Prescribing Opioids for Chronic Pain promulgated by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Indeed, the classes often do not cover the most recent

<sup>&</sup>lt;sup>1</sup> Julia Lurie, *Doctors Receive Opioid Training. Big Pharma Funds It. What Could Go Wrong?*, MOTHER JONES (Apr. 27, 2018), https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/.

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science on the treatment of chronic pain or the inherently addictive nature of these opioid compounds. Perhaps even more disturbing, opioid manufacturers may be using opioid prescribing and pain management CE courses to promote their products, at the expense of the public's health. As *Mother Jones* reported: "One medical school professor tried to incorporate information into a REMS course about tapering off opioids and using non-pharmacological options, but 'that was not what we were being paid to do,' he told [the reporter]."<sup>3</sup>

A question and answer from an opioid-manufacturer-sponsored CE class highlighted in the *Mother Jones* report is telling. Prescribers are asked whether a doctor should continue to prescribe opioids to a patient who has a history of alcoholism, smokes a pack of cigarettes a day, has a family history of substance abuse, and is already taking opioids every few hours for back pain. The answer? The CE course recommends increasing the patient's dose of non-opioid painkillers *and* switching her to long-acting opioids that she should take every 12 hours. But as the *Mother Jones* report points out, "there's no evidence that opioids work for chronic pain, according to guidelines released in 2016 by the Centers for Disease Control and Prevention." The course's answer — more but different opioids — is as troubling as it is unsurprising, because pharmaceutical companies that sponsor CE courses have a vested interest in promoting further opioid use.

In short, it appears that opioid prescribers taking industry-funded CE classes are not learning about the current nature of the opioid overdose epidemic, the latest information questioning opioid prescribing for chronic pain, or the effectiveness of non-opioid alternatives. To address these shortcomings, I have introduced legislation entitled the "Safer Prescribing of Controlled Substances Act." Under my bill, those who apply to the Drug Enforcement Administration for a federal license to prescribe controlled substances must complete mandatory prescriber education approved by the Department of Health and Human Services.

<sup>&</sup>lt;sup>3</sup> Julia Lurie, *Doctors Receive Opioid Training, Big Pharma Funds It. What Could Go Wrong?*, MOTHER JONES (Apr. 27, 2018), https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/.

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<sup>&</sup>lt;sup>6</sup> CDC guidelines at a glance state: "we don't have enough information about the benefits of opioids long term", https://www.cdc.gov/drugoverdose/pdf/guidelines\_at-a-glance-a.pdf

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The Honorable Alex Azar May 24, 2018 Page 3

opioids. The lesson is clear: preventing opioid addiction begins with the prescribers and ensuring that they know the best opioid prescribing practices.

To better understand the role opioid manufacturers play in designing or promoting the education that prescribers receive, I respectfully request that by June 14, 2018 you respond to the following questions about your oversight of pain management and substance abuse CE courses.

- 1. How do the opioid education initiatives required under REMS receive accreditation as a CE course?
- 2. Have any agencies within HHS independently evaluated the content of pain management and substance abuse CE courses? If so, has any content raised concerns about its promotion of continued opioid use or conflict with current practice guidelines?
- 3. What oversight efforts, if any, has HHS taken to ensure that opioid manufacturers are not able to design or influence the content of CE courses?
- 4. What oversight efforts, if any, has HHS taken to ensure that CE course instructors do not have financial ties to opioid manufacturers that may present a conflict of interest?
- 5. What additional authorities or resources would HHS need to help ensure that CE courses are adhering to the most recent science and CDC Guideline around opioid prescribing?

Thank you in advance for your attention to these requests. If you have any questions, please contact Dr. Avenel Joseph of my staff at 202-224-2742.

Sincerely,

Edward J. Markey

Edward J. Markey

United States Senator

<sup>8</sup> https://www.cdc.gov/drugoverdose/data/heroin.html.

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May 24, 2018

Dr. Graham McMahon, MD, MMSc President and CEO Accreditation Council for Continuing Medical Education 401 N. Michigan Ave. Suite 1850 Chicago, IL 60611

#### Dear Dr. McMahon:

I write regarding the role opioid manufacturers play in designing and promoting continuing education (CE) classes on opioid prescribing. According to a recent news report, pharmaceutical companies have coopted these courses — often taken by prescribers to fulfill state education requirements — to promote the use of prescription painkillers in ways that scientific and medical data do not support. I am concerned that the industry's profit motives may be improperly influencing the education that prescribers receive and endangering countless American lives.

Health professionals depend on CE courses for the most current information and professional education on a wide range of medical issues. Under the Risk Evaluation and Mitigation Strategies (REMS) instituted by the Food and Drug Administration (FDA), opioid manufacturers are required to provide education for prescribers of opioid medications. This mandate is fulfilled through CE activities funded by grants from opioid manufactures. Aside from the FDA loosely outlining these opioid-prescriber courses, there is little quality control over, or evaluation of, their content. The confluence of industry-funded education and minimal government oversight leaves these CE classes rife for abuse.

A recent investigation by *Mother Jones* into the courses' content revealed significant and troubling shortcomings. Much of the opioid prescribing curriculum does not even conform to the current Guideline for Prescribing Opioids for Chronic Pain promulgated by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Indeed, the classes often do not cover the most recent

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science on the treatment of chronic pain or the inherently addictive nature of these opioid compounds. Perhaps even more disturbing, opioid manufacturers may be using opioid prescribing and pain management CE courses to promote their products, at the expense of the public's health. As *Mother Jones* reported: "One medical school professor tried to incorporate information into a REMS course about tapering off opioids and using non-pharmacological options, but 'that was not what we were being paid to do,' he told [the reporter]."<sup>3</sup>

A question and answer from an opioid-manufacturer-sponsored CE class highlighted in the *Mother Jones* report is telling. Prescribers are asked whether a doctor should continue to prescribe opioids to a patient who has a history of alcoholism, smokes a pack of cigarettes a day, has a family history of substance abuse, and is already taking opioids every few hours for back pain. The answer? The CE course recommends increasing the patient's dose of non-opioid painkillers *and* switching her to long-acting opioids that she should take every 12 hours. But as the *Mother Jones* report points out, "there's no evidence that opioids work for chronic pain, according to guidelines released in 2016 by the Centers for Disease Control and Prevention." The course's answer — more but different opioids — is as troubling as it is unsurprising, because pharmaceutical companies that sponsor CE courses have a vested interest in promoting further opioid use.

In short, it appears that opioid prescribers taking industry-funded CE classes are not learning about the current nature of the opioid overdose epidemic, the latest information questioning opioid prescribing for chronic pain, or the effectiveness of non-opioid alternatives. To address these shortcomings, I have introduced legislation entitled the "Safer Prescribing of Controlled Substances Act." Under my bill, those who apply to the Drug Enforcement Administration for a federal license to prescribe controlled substances must complete mandatory prescriber education approved by the Department of Health and Human Services.

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Dr. Graham McMahon May 24, 2018 Page 3

opioids. The lesson is clear: preventing opioid addiction begins with the prescribers and ensuring that they know the best opioid prescribing practices.

To better understand the role opioid manufacturers play in designing or promoting the education that prescribers receive, I respectfully request that by June 14, 2018 you respond to the following questions about your oversight of pain management and substance abuse CE courses.

- 1. What steps does AACME take to ensure that CE that are accredited for pain management and substance abuse reflect the most recent science and medical practice?
- 2. Do you require that any courses on chronic pain management reflect information and recommendations provided in the CDC Guideline for Prescribing Opioids for Chronic Pain?
- 3. How frequently do you audit approved and accredited CE courses? Is every course audited over a particular time frame? What is the criteria you examine upon auditing? If changes are needed to a CE course, how are those changes recommended and implemented?
- 4. Are there any penalties or actions you take when it's found that a course provides misleading or incorrect information?
- 5. When you have evaluated the content of pain management and substance abuse CE courses for accreditation, or during your process of auditing, has any content raised concerns about its promotion of continued opioid use or conflict with current federal practice guidelines?
- 6. What oversight efforts, if any, has AACME taken to ensure that opioid manufacturers are not able to design or influence the content of CE courses?
- 7. What oversight efforts, if any, has AACME taken to ensure that CE course instructors do not have financial ties to opioid manufacturers that may present a conflict of interest?

Thank you in advance for your attention to these requests. If you have any questions, please contact Dr. Avenel Joseph of my staff at 202-224-2742.

Sincerely,

Edward J. Markey

<sup>8</sup> https://www.cdc.gov/drugoverdose/data/heroin.html.

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Dr. Loressa Cole Chief Executive Officer American Nurses Association American Nurses Credentialing Center 8515 Georgia Avenue, Suite 400 Silver Spring, MD 20910-3492

#### Dear Dr. Cole:

I write regarding the role opioid manufacturers play in designing and promoting continuing education (CE) classes on opioid prescribing. According to a recent news report, pharmaceutical companies have coopted these courses — often taken by prescribers to fulfill state education requirements — to promote the use of prescription painkillers in ways that scientific and medical data do not support. I am concerned that the industry's profit motives may be improperly influencing the education that prescribers receive and endangering countless American lives.

Health professionals depend on CE courses for the most current information and professional education on a wide range of medical issues. Under the Risk Evaluation and Mitigation Strategies (REMS) instituted by the Food and Drug Administration (FDA), opioid manufacturers are required to provide education for prescribers of opioid medications. This mandate is fulfilled through CE activities funded by grants from opioid manufactures. Aside from the FDA loosely outlining these opioid-prescriber courses, there is little quality control over, or evaluation of, their content. The confluence of industry-funded education and minimal government oversight leaves these CE classes rife for abuse.

A recent investigation by *Mother Jones* into the courses' content revealed significant and troubling shortcomings. Much of the opioid prescribing curriculum does not even conform to the current Guideline for Prescribing Opioids for Chronic Pain promulgated by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Indeed, the classes often do not cover the most recent science on the treatment of chronic pain or the inherently addictive nature of these opioid

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compounds. Perhaps even more disturbing, opioid manufacturers may be using opioid prescribing and pain management CE courses to promote their products, at the expense of the public's health. As Mother Jones reported: "One medical school professor tried to incorporate information into a REMS course about tapering off opioids and using non-pharmacological options, but 'that was not what we were being paid to do,' he told [the reporter]."3

A question and answer from an opioid-manufacturer-sponsored CE class highlighted in the Mother Jones report is telling. Prescribers are asked whether a doctor should continue to prescribe opioids to a patient who has a history of alcoholism, smokes a pack of cigarettes a day, has a family history of substance abuse, and is already taking opioids every few hours for back pain. The answer? The CE course recommends increasing the patient's dose of non-opioid painkillers and switching her to long-acting opioids that she should take every 12 hours. 4 But as the Mother Jones report points out, "there's no evidence that opioids work for chronic pain, according to guidelines released in 2016 by the Centers for Disease Control and Prevention."5,6 The course's answer — more but different opioids — is as troubling as it is unsurprising, because pharmaceutical companies that sponsor CE courses have a vested interest in promoting further opioid use.

In short, it appears that opioid prescribers taking industry-funded CE classes are not learning about the current nature of the opioid overdose epidemic, the latest information questioning opioid prescribing for chronic pain, or the effectiveness of non-opioid alternatives. To address these shortcomings, I have introduced legislation entitled the "Safer Prescribing of Controlled Substances Act." Under my bill, those who apply to the Drug Enforcement Administration for a federal license to prescribe controlled substances must complete mandatory prescriber education approved by the Department of Health and Human Services.

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Dr. Loressa Cole May 24, 2018 Page 3

opioids. The lesson is clear: preventing opioid addiction begins with the prescribers and ensuring that they know the best opioid prescribing practices.

To better understand the role opioid manufacturers play in designing or promoting the education that prescribers receive, I respectfully request that by June 14, 2018 you respond to the following questions about your oversight of pain management and substance abuse CE courses.

- 1. What steps does ANCC take to ensure that CE that are accredited for pain management and substance abuse reflect the most recent science and medical practice?
- 2. Do you require that any courses on chronic pain management reflect information and recommendations provided in the CDC Guideline for Prescribing Opioids for Chronic Pain?
- 3. How frequently do you audit approved and accredited CE courses? Is every course audited over a particular time frame? What is the criteria you examine upon auditing? If changes are needed to a CE course, how are those changes recommended and implemented?
- 4. Are there any penalties or actions you take when it's found that a course provides misleading or incorrect information?
- 5. When you have evaluated the content of pain management and substance abuse CE courses for accreditation, or during your process of auditing, has any content raised concerns about its promotion of continued opioid use or conflict with current federal practice guidelines?
- 6. What oversight efforts, if any, has ANCC taken to ensure that opioid manufacturers are not able to design or influence the content of CE courses?
- 7. What oversight efforts, if any, has ANCC taken to ensure that CE course instructors do not have financial ties to opioid manufacturers that may present a conflict of interest?

Thank you in advance for your attention to these requests. If you have any questions, please contact Dr. Avenel Joseph of my staff at 202-224-2742.

Edward J. Markey

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May 24, 2018

Sharon Luke
Executive Director
Accreditation Review Commission on Education for the Physician Assistant
12000 Findley Road, Ste. 275
Johns Creek, GA, 30097

#### Dear Ms. Luke:

I write regarding the role opioid manufacturers play in designing and promoting continuing education (CE) classes on opioid prescribing. According to a recent news report, pharmaceutical companies have coopted these courses — often taken by prescribers to fulfill state education requirements — to promote the use of prescription painkillers in ways that scientific and medical data do not support. I am concerned that the industry's profit motives may be improperly influencing the education that prescribers receive and endangering countless American lives.

Health professionals depend on CE courses for the most current information and professional education on a wide range of medical issues. Under the Risk Evaluation and Mitigation Strategies (REMS) instituted by the Food and Drug Administration (FDA), opioid manufacturers are required to provide education for prescribers of opioid medications. This mandate is fulfilled through CE activities funded by grants from opioid manufactures. Aside from the FDA loosely outlining these opioid-prescriber courses, there is little quality control over, or evaluation of, their content. The confluence of industry-funded education and minimal government oversight leaves these CE classes rife for abuse.

A recent investigation by *Mother Jones* into the courses' content revealed significant and troubling shortcomings. Much of the opioid prescribing curriculum does not even conform to the current Guideline for Prescribing Opioids for Chronic Pain promulgated by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Indeed, the classes often do not cover the most recent science on the treatment of chronic pain or the inherently addictive nature of these opioid

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Page 2

compounds. Perhaps even more disturbing, opioid manufacturers may be using opioid prescribing and pain management CE courses to promote their products, at the expense of the public's health. As *Mother Jones* reported: "One medical school professor tried to incorporate information into a REMS course about tapering off opioids and using non-pharmacological options, but 'that was not what we were being paid to do,' he told [the reporter]."<sup>3</sup>

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In short, it appears that opioid prescribers taking industry-funded CE classes are not learning about the current nature of the opioid overdose epidemic, the latest information questioning opioid prescribing for chronic pain, or the effectiveness of non-opioid alternatives. To address these shortcomings, I have introduced legislation entitled the "Safer Prescribing of Controlled Substances Act." Under my bill, those who apply to the Drug Enforcement Administration for a federal license to prescribe controlled substances must complete mandatory prescriber education approved by the Department of Health and Human Services.

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opioids. The lesson is clear: preventing opioid addiction begins with the prescribers and ensuring that they know the best opioid prescribing practices.

To better understand the role opioid manufacturers play in designing or promoting the education that prescribers receive, I respectfully request that by June 14, 2018 you respond to the following questions about your oversight of pain management and substance abuse CE courses.

- 1. What steps does ARC-PA take to ensure that CE that are accredited for pain management and substance abuse reflect the most recent science and medical practice?
- 2. Do you require that any courses on chronic pain management reflect information and recommendations provided in the CDC Guideline for Prescribing Opioids for Chronic Pain?
- 3. How frequently do you audit approved and accredited CE courses? Is every course audited over a particular time frame? What is the criteria you examine upon auditing? If changes are needed to a CE course, how are those changes recommended and implemented?
- 4. Are there any penalties or actions you take when it's found that a course provides misleading or incorrect information?
- 5. When you have evaluated the content of pain management and substance abuse CE courses for accreditation, or during your process of auditing, has any content raised concerns about its promotion of continued opioid use or conflict with current federal practice guidelines?
- 6. What oversight efforts, if any, has ARC-PA taken to ensure that opioid manufacturers are not able to design or influence the content of CE courses?
- 7. What oversight efforts, if any, has ARC-PA taken to ensure that CE course instructors do not have financial ties to opioid manufacturers that may present a conflict of interest?

Thank you in advance for your attention to these requests. If you have any questions, please contact Dr. Avenel Joseph of my staff at 202-224-2742.

Edward J. Markey

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May 24, 2018

Mary Borysewicz Director Commission for Continuing Education Provider Recognition 211 East Chicago Avenue Chicago, Illinois 60611

#### Dear Ms. Borysewicz:

I write regarding the role opioid manufacturers play in designing and promoting continuing education (CE) classes on opioid prescribing. According to a recent news report, pharmaceutical companies have coopted these courses — often taken by prescribers to fulfill state education requirements — to promote the use of prescription painkillers in ways that scientific and medical data do not support. I am concerned that the industry's profit motives may be improperly influencing the education that prescribers receive and endangering countless American lives.

Health professionals depend on CE courses for the most current information and professional education on a wide range of medical issues. Under the Risk Evaluation and Mitigation Strategies (REMS) instituted by the Food and Drug Administration (FDA), opioid manufacturers are required to provide education for prescribers of opioid medications. This mandate is fulfilled through CE activities funded by grants from opioid manufactures. Aside from the FDA loosely outlining these opioid-prescriber courses, there is little quality control over, or evaluation of, their content. The confluence of industry-funded education and minimal government oversight leaves these CE classes rife for abuse.

A recent investigation by *Mother Jones* into the courses' content revealed significant and troubling shortcomings. Much of the opioid prescribing curriculum does not even conform to the current Guideline for Prescribing Opioids for Chronic Pain promulgated by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Indeed, the classes often do not cover the most recent

<sup>&</sup>lt;sup>1</sup> Julia Lurie, *Doctors Receive Opioid Training. Big Pharma Funds It. What Could Go Wrong?*, MOTHER JONES (Apr. 27, 2018), https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/.

<sup>&</sup>lt;sup>2</sup> Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

science on the treatment of chronic pain or the inherently addictive nature of these opioid compounds. Perhaps even more disturbing, opioid manufacturers may be using opioid prescribing and pain management CE courses to promote their products, at the expense of the public's health. As *Mother Jones* reported: "One medical school professor tried to incorporate information into a REMS course about tapering off opioids and using non-pharmacological options, but 'that was not what we were being paid to do,' he told [the reporter]."<sup>3</sup>

A question and answer from an opioid-manufacturer-sponsored CE class highlighted in the *Mother Jones* report is telling. Prescribers are asked whether a doctor should continue to prescribe opioids to a patient who has a history of alcoholism, smokes a pack of cigarettes a day, has a family history of substance abuse, and is already taking opioids every few hours for back pain. The answer? The CE course recommends increasing the patient's dose of non-opioid painkillers *and* switching her to long-acting opioids that she should take every 12 hours. But as the *Mother Jones* report points out, "there's no evidence that opioids work for chronic pain, according to guidelines released in 2016 by the Centers for Disease Control and Prevention." The course's answer — more but different opioids — is as troubling as it is unsurprising, because pharmaceutical companies that sponsor CE courses have a vested interest in promoting further opioid use.

In short, it appears that opioid prescribers taking industry-funded CE classes are not learning about the current nature of the opioid overdose epidemic, the latest information questioning opioid prescribing for chronic pain, or the effectiveness of non-opioid alternatives. To address these shortcomings, I have introduced legislation entitled the "Safer Prescribing of Controlled Substances Act." Under my bill, those who apply to the Drug Enforcement Administration for a federal license to prescribe controlled substances must complete mandatory prescriber education approved by the Department of Health and Human Services.

<sup>&</sup>lt;sup>3</sup> Julia Lurie, Doctors Receive Opioid Training, Big Pharma Funds It. What Could Go Wrong?, MOTHER JONES (Apr. 27, 2018), https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/.

<sup>4</sup> Id.

<sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> CDC guidelines at a glance state: "we don't have enough information about the benefits of opioids long term", https://www.cdc.gov/drugoverdose/pdf/guidelines\_at-a-glance-a.pdf

https://www.cdc.gov/drugoverdose/data/prescribing.html.

opioids. The lesson is clear: preventing opioid addiction begins with the prescribers and ensuring that they know the best opioid prescribing practices.

To better understand the role opioid manufacturers play in designing or promoting the education that prescribers receive, I respectfully request that by June 14, 2018 you respond to the following questions about your oversight of pain management and substance abuse CE courses.

- 1. What steps does the Commission for Continuing Education Provider Recognition take to ensure that CE that are accredited for pain management and substance abuse reflect the most recent science and medical practice?
  - 2. Do you require that any courses on chronic pain management reflect information and recommendations provided in the CDC Guideline for Prescribing Opioids for Chronic Pain?
  - 3. How frequently do you audit approved and accredited CE courses? Is every course audited over a particular time frame? What is the criteria you examine upon auditing? If changes are needed to a CE course, how are those changes recommended and implemented?
  - 4. Are there any penalties or actions you take when it's found that a course provides misleading or incorrect information?
  - 5. When you have evaluated the content of pain management and substance abuse CE courses for accreditation, or during your process of auditing, has any content raised concerns about its promotion of continued opioid use or conflict with current federal practice guidelines?
- 6. What oversight efforts, if any, has the Commission for Continuing Education Provider Recognition taken to ensure that opioid manufacturers are not able to design or influence the content of CE courses?
- 7. What oversight efforts, if any, has the Commission for Continuing Education Provider Recognition taken to ensure that CE course instructors do not have financial ties to opioid manufacturers that may present a conflict of interest?

Thank you in advance for your attention to these requests. If you have any questions, please contact Dr. Avenel Joseph of my staff at 202-224-2742.

Edward J. Markey

<sup>8</sup> https://www.cdc.gov/drugoverdose/data/heroin.html.

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# United States Senate

May 24, 2018

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David Hebert Chief Executive Officer American Association of Nurse Practitioners 225 Reinekers Lane Suite 525 Alexandria, VA 22314

#### Dear Mr. Hebert:

I write regarding the role opioid manufacturers play in designing and promoting continuing education (CE) classes on opioid prescribing. According to a recent news report, pharmaceutical companies have coopted these courses — often taken by prescribers to fulfill state education requirements — to promote the use of prescription painkillers in ways that scientific and medical data do not support. I am concerned that the industry's profit motives may be improperly influencing the education that prescribers receive and endangering countless American lives.

Health professionals depend on CE courses for the most current information and professional education on a wide range of medical issues. Under the Risk Evaluation and Mitigation Strategies (REMS) instituted by the Food and Drug Administration (FDA), opioid manufacturers are required to provide education for prescribers of opioid medications. This mandate is fulfilled through CE activities funded by grants from opioid manufactures. Aside from the FDA loosely outlining these opioid-prescriber courses, there is little quality control over, or evaluation of, their content. The confluence of industry-funded education and minimal government oversight leaves these CE classes rife for abuse.

A recent investigation by *Mother Jones* into the courses' content revealed significant and troubling shortcomings. Much of the opioid prescribing curriculum does not even conform to the current Guideline for Prescribing Opioids for Chronic Pain promulgated by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Indeed, the classes often do not cover the most recent science on the treatment of chronic pain or the inherently addictive nature of these opioid compounds. Perhaps even more disturbing, opioid manufacturers may be using opioid

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prescribing and pain management CE courses to promote their products, at the expense of the public's health. As *Mother Jones* reported: "One medical school professor tried to incorporate information into a REMS course about tapering off opioids and using non-pharmacological options, but 'that was not what we were being paid to do,' he told [the reporter]."<sup>3</sup>

A question and answer from an opioid-manufacturer-sponsored CE class highlighted in the *Mother Jones* report is telling. Prescribers are asked whether a doctor should continue to prescribe opioids to a patient who has a history of alcoholism, smokes a pack of cigarettes a day, has a family history of substance abuse, and is already taking opioids every few hours for back pain. The answer? The CE course recommends increasing the patient's dose of non-opioid painkillers and switching her to long-acting opioids that she should take every 12 hours. But as the *Mother Jones* report points out, "there's no evidence that opioids work for chronic pain, according to guidelines released in 2016 by the Centers for Disease Control and Prevention." The course's answer — more but different opioids — is as troubling as it is unsurprising, because pharmaceutical companies that sponsor CE courses have a vested interest in promoting further opioid use.

In short, it appears that opioid prescribers taking industry-funded CE classes are not learning about the current nature of the opioid overdose epidemic, the latest information questioning opioid prescribing for chronic pain, or the effectiveness of non-opioid alternatives. To address these shortcomings, I have introduced legislation entitled the "Safer Prescribing of Controlled Substances Act." Under my bill, those who apply to the Drug Enforcement Administration for a federal license to prescribe controlled substances must complete mandatory prescriber education approved by the Department of Health and Human Services.

I believe that unbiased and scientifically sound instruction will help encourage responsible prescribing practices. Over-prescribing of opioids is a leading cause of the opioid abuse epidemic that the country is experiencing. According to the CDC, "[a]n estimated 1 out of 5 patients with non-cancer pain or pain-related diagnoses are prescribed opioids in office-based settings." The CDC also reports that, among new heroin users, approximately three out of four abused prescription opioids before using heroin, and among people who started using opioids in 2015 and presented for opioid addiction treatment, about two out of three started with prescription opioids. The lesson is clear: preventing opioid addiction begins with the prescribers and ensuring that they know the best opioid prescribing practices.

<sup>&</sup>lt;sup>3</sup> Julia Lurie, Doctors Receive Opioid Training. Big Pharma Funds It. What Could Go Wrong?, MOTHER JONES (Apr. 27, 2018), https://www.motherjones.com/politics/2018/04/doctors-are-required-to-receive-opioid-training-big-pharma-funds-it-what-could-go-wrong/.

4 Id.

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<sup>7</sup> https://www.cdc.gov/drugoverdose/data/prescribing.html.

<sup>8</sup> https://www.cdc.gov/drugoverdose/data/heroin.html.

To better understand the role opioid manufacturers play in designing or promoting the education that prescribers receive, I respectfully request that by June 14, 2018 you respond to the following questions about your oversight of pain management and substance abuse CE courses.

- 1. What steps does AANP take to ensure that CE that are accredited for pain management and substance abuse reflect the most recent science and medical practice?
- 2. Do you require that any courses on chronic pain management reflect information and recommendations provided in the CDC Guideline for Prescribing Opioids for Chronic Pain?
- 3. How frequently do you audit approved and accredited CE courses? Is every course audited over a particular time frame? What is the criteria you examine upon auditing? If changes are needed to a CE course, how are those changes recommended and implemented?
- 4. Are there any penalties or actions you take when it's found that a course provides misleading or incorrect information?
- 5. When you have evaluated the content of pain management and substance abuse CE courses for accreditation, or during your process of auditing, has any content raised concerns about its promotion of continued opioid use or conflict with current federal practice guidelines?
- 6. What oversight efforts, if any, has AANP taken to ensure that opioid manufacturers are not able to design or influence the content of CE courses?
- 7. What oversight efforts, if any, has AANP taken to ensure that CE course instructors do not have financial ties to opioid manufacturers that may present a conflict of interest?

Thank you in advance for your attention to these requests. If you have any questions, please contact Dr. Avenel Joseph of my staff at 202-224-2742.

Sincerely,

Edward J. Markey