July 1, 2016

Dr. Victor J. Dzau, M.D.
President
National Academy of Medicine
500 5th Street NW
Washington, DC 20001

Dear Dr. Dzau:

I am writing to you in regards to the provisional committee member appointments to the Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse committee (“opioid committee”) that the National Academy of Medicine (“NAM”) announced for public comment on June 14, 2016.\(^1\) I am concerned that the Academy’s review and the corresponding announcement failed to fully disclose or address important information related to potential conflicts of interest and bias.

Specifically, these omissions concern provisional committee members, Dr. Gregory Terman and Dr. Mary Lynn McPherson. In both cases, my concerns relate to leadership positions that they hold or have held in professional societies with substantial ties to the pharmaceutical industry, and, specifically, opioid manufacturers. These relationships suggest conflicts and biases that should have been made public when the provisional committee announcement was made last month, and require further examination by the Academy.

The proposed work on which the NAM is about to embark is of great importance to my constituents in Oregon, where prescription opioid abuse is a major public health problem, as well as the jurisdictional interests of the Senate Committee on Finance. Opioid addiction and treatment have a great impact on agencies in this Committee’s jurisdiction, such as Medicaid and Medicare. By 2020, public and private spending on the treatment of substance abuse disorder(s) are anticipated to reach $42.1 billion, compared with $24.3 billion in 2009.\(^2\) Medicare and Medicaid are expected to account for a third of this spending.\(^3\)

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\(^3\) *Ibid.*
The NAM announcement failed to disclose that Dr. Terman was president of the American Pain Society (“APS”) from 2014-2016, that he has been on the board of directors since 1998, or that he has been a member of the society for more than 30 years. In his role as a board member, Terman has represented APS, an advocacy group that has substantial financial ties to opioid manufacturers, before the Food and Drug Administration (“FDA”). Terman also acknowledged to the FDA in 2014 that APS receives money from opioid manufacturers:

The American Pain Society and that society has taken money from companies making long acting opiates in the past. Although I have never received money personally from such companies in other work for the FDA I have had to declare money given to the organization as well.

A closer review shows that the organization has received hundreds of thousands of dollars from opioid manufacturers, and, in return, provides industry sponsors significant access to the organization’s leadership.

The APS maintains a “corporate council” that is made up of pharmaceutical manufacturers who contribute to the APS. The council’s page currently show eight members of the council – AstraZeneca, Depomed, Endo, Mallinckrodt, Purdue, Pernix, Pfizer, Teva – that donated at least $132,500 to APS, based on financial contribution levels required to be classified as a member of the “Corporate Circle” ($25,000), “Executive Level” ($15,000) and “Associate” ($7,500). Please refer to Attachment 1 for more details about the benefits APS offers its corporate council members.

In addition, the APS lists commercial supporters on its website, which shows that in 2013 six pharmaceutical manufacturers contributed $225,000 to various APS programs. The contributors were Eli Lilly, Millennium, Purdue, Pfizer, Teva, and Zogenix. The contributions fund programs including grants, meeting sponsorship, awards, and sponsorship of the organization’s electronic newsletter.

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7 Ibid.
8 Ibid.
One of the roles of the APS board is to review and approve position statements. Several of the position statements are associated with federal actions related to opioids, including actions by the FDA. One such statement opposed more stringent labeling guidelines for the use of opioid painkillers, partly due to the organization’s assertion that there were insufficient data to justify changes. Terman was among the co-signers of this statement, which was sent to FDA. More recently, the American Pain Society submitted comments to the CDC on its opioid guidance. Major points in the letter included:

- Discouraging specific dosage limits;
- Criticizing the guidelines for being reliant on insufficient data;
- Encouraging exclusion of any reference to cancer pain;
- Raising concerns about qualifications of reviewers were confined to experts in toxicology and epidemiology; and
- Criticizing the exclusion of guidelines for pediatric pain care.14

The APS also is a member of the Pain Care Coalition, a policy advocacy coalition that includes the American Academy of Pain Medicine, and the American Society of Anesthesiologists. It bills itself as “a national coalition for responsible pain care.” Public records show that the coalition spent more than $121,000 for lobbying activities in 2015, a year during which Terman was president of APS, including pain care legislation, NIH appropriations, and meetings with the U.S. House of Representatives, the Department of Health and Human Services, and the Department of Justice.15

In addition to his ties to APS, the NAM failed to note that Terman is a temporary voting member of the FDA’s science board.16 This position presents another potential organizational conflict of interest since FDA has commissioned the Academies to conduct this study as part of the FDA’s reexamination of its approach to balancing the risks of opioid prescription use.17

Mary Lynn McPherson

Another provisional appointee at issue is Mary Lynn McPherson, who appears to have had significant ties to the pharmaceutical industry dating back at least two decades. Her extensive ties to opioid manufacturers and related businesses raise significant concerns about potential conflicts of interest and bias, and deserve further examination.

McPherson’s curriculum vitae show she has received grants and residencies worth at least $300,000 that were sponsored – or paid directly – by opioid manufacturers.18 Between 1997 and 2004, she listed three residencies funded by Purdue Pharma and three more funded by Purdue Frederick that totaled $253,500.19 In 2010, she received a $50,000 unrestricted educational grant from King Pharmaceuticals.20

McPherson’s association with opioid manufacturers is ongoing, as demonstrated by her authorship of a continuing education presentation that was supported by Purdue Pharma.21 This presentation was published in 2014 and is current through 2017. Another current continuing education activity she authored promotes the idea of “pseudoaddiction,” which has increasingly been viewed as a dangerous – and false – justification to overprescribe prescription opioids.22 Of this concept, former FDA Commissioner David A. Kessler recently wrote:

   Equally dangerous was the notion that there was virtually no dose ceiling. The mantra was: “Prescribe until patients achieve pain relief.” And then there was the flawed concept of pseudoaddiction: If the patient comes in and is showing signs of drug seeking, that doesn’t mean the patient is actually addicted to opioids; it more likely means that he or she just needs more opioids to control pain. So the first response should be to prescribe more.23

None of the ongoing financial ties with opioid manufacturers discussed above were noted by the NAM in its biography about McPherson. I believe these omissions were a significant oversight.

McPherson and the American Society of Pain Educators

McPherson’s biography on the NAM website did disclose her role as president of the American Society of Pain Educators (“ASPE”). What the NAM does not disclose, and what I have detailed below, is that:

19 Ibid.
20 Ibid.
- ASPE is sponsored in part by opioid manufacturers;
- APSE’s board of directors and advisory board include individuals closely associated with, and in some cases, employed as consultants by, opioid manufacturers; and
- ASPE does not appear to be an independent organization. Rather it was founded and is managed by Aventine HealthSciences, a communications firm that organizes continuing education events and conferences related to pain treatment and related services.

The APSE webpage lists two corporate members – AbbVie and Purdue Pharma L.P. – both of which are manufacturers of opioids. It is unclear how much these companies contributed to the organization because ASPE does not make available its tax forms on its website. The charitable information database Guidestar also does not appear to have tax records for the organization on file.

In addition to being president of ASPE, the organization’s website lists McPherson as chair of a seven-person board of directors. My staff found that at least three of the six other APSE board members have significant financial ties to the pharmaceutical industry. In addition to the financial ties to opioid manufacturers on the board of directors, two of the six members of the organization’s advisory board have significant financial ties to the pharmaceutical industry, and opioid manufacturers, specifically.

**ASPE and Aventine**

It also is not clear whether ASPE is an independent entity. ASPE was incorporated in 2004 by three employees of Aventine HealthSciences, a medical communications firm. The ASPE board’s current secretary is a managing partner of Aventine. Aventine continues to manage the daily operation of ASPE, and ASPE board members, including Dr. McPherson, participate in Aventine business activities such PAINWeek and PAINWeek Journal. If there are direct management and financial ties between ASPE and Aventine, then those relationships would be relevant to McPherson’s leadership role at ASPE and should be disclosed and reviewed for bias and potential conflicts of interest.

Aventine describes itself as a “highly niched medical communications agency focused on pain and neuroscience … [that] has become an information resource to all pain management stakeholders: pharmaceutical companies, payers, healthcare providers, and patients.” Since 2007, the company also has managed “PAINWeek,” which began as an annual conference in Las Vegas. Aventine has patented PAINWeek, describing it as providing “educational services, namely, conducting workshops, seminars and special events in the nature of exhibitions to promote awareness on pain issues.” The company appears to receive a great deal of

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26 Attachment 2
sponsorship money from the pharmaceutical industry, including several opioid manufacturers, for its PAINWeek franchise.

Aventine’s overlapping roles running ASPE and PAINWeek are significant concerns given Dr. McPherson’s leadership position at ASPE. The two franchises also appear to be very closely related both in terms of personnel and frequent cross-promotion of activities. McPherson and several members of the ASPE board are listed as presenters for PAINWeek and have video presentations on the organization’s website and social media channels. In addition, McPherson and four other members of ASPE’s boards are on the editorial board of PAINWeek Journal. McPherson’s curriculum vitae also show that she received a $65,000 unrestricted education grant from Aventine in 2011.

PAINWeek receives financial support from numerous pharmaceutical manufacturers and opioid makers. The 2015 national conference included sponsored programs “presented by AstraZeneca, Cara Therapeutics, Depomed, Indivior, Iroko, kaléo, Pernix, Purdue Pharma, Salix, and Teva Pharmaceuticals.” The company’s website also includes numerous banner advertisements from opioids manufacturers, and a video-and-slide presentation sponsored by Zogenix, the manufacturer of Zohydror. The PAINWeek franchise has expanded to include regional conferences held in 11 different states, which also include multiple sponsored programs and presentations, as well as “PAINWeek at Sea,” an ocean cruise offering CME classes.

In 2015, Aventine sold the rights to PainWEEK to a media firm, Tarsus Group plc, in a deal worth as much as $50 million, depending on deferred payments linked to performance. A press release at the time of the sale stated that PainWEEK provided “Tarsus with increased exposure to a key area of the preventative medicine market.” The release noted that Aventine would continue to manage PainWeek through at least 2018.

The Academy’s Disclosures and Due Diligence

The potential sources of bias and conflicts of interests for Terman and McPherson described in this letter should have been publicly disclosed, since they meet or exceed the NAM test of “relevant information bearing on the committee's composition and balance … concerning

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37 Ibid.
38 Ibid.
potential sources of bias and conflict of interest pertaining to his or her service on the committee.”

If NAM was aware of these relationships and did not publicize them, the omissions may undermine the public’s confidence that the organization has done everything it can to ensure that the committee can “address its charge objectively.” If NAM was unaware of these relationships or made the committee selections knowing that the relationships existed, the Academy should consider restarting the provisional appointment process, including a de novo review of committee members’ experience and potential biases and conflicts of interest.

The National Academy’s history of vetting potential committee members to study issues related to pain and opioid use leaves much to be desired. I have recently raised conflict of interest concerns with Health and Human Services Secretary Sylvia Burwell regarding Myra Christopher who was a member of the committee that produced the 2011 Institute of Medicine report Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. At the time, Christopher had a significant financial relationship with the opioid manufacturer Purdue Pharma through its funding of Christopher’s employer – the Center for Practical Bioethics, and an endowed chair.

My staff has been unable to thoroughly examine all of the members given the limited time available to review the provisional Committee members. Still, the omissions that have been identified are extremely troubling, and strongly suggest that the Academy should undertake a more thorough review not only of Drs. Terman and McPherson, but other provisional members of the committee.

Please include this letter in the permanent record for consideration before committee membership is finalized. Thank you for your consideration of this important issue,

Sincerely,

Ron Wyden
Ranking Member

Enclosures: American Pain Society Corporate Council website
American Society for Pain Educators certificate of incorporation

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41 Ibid.
Corporate Council

Connect Directly with Pain Professionals

The APS Corporate Council provides industry partners with a direct connection to APS members, a multidisciplinary community of more than 2,500 leaders in the study and treatment of pain. Companies whose products and services support the pain profession can meet with APS leaders annually at a 1-day Corporate Council Roundtable to engage in ongoing dialogue on hot topics and future trends in the field. In addition, council members can network at the annual scientific meeting’s President’s Recognition Reception, a private reception with APS Board members, committee chairs, and other leaders where award recipients are recognized.

Why Join?

- Reach more than 2,500 leaders in the study and treatment of pain.
- Meet with the leaders in pain to exchange ideas and knowledge.
- Join APS to enhance patient outcomes.

Membership Levels

APS has tailored membership tiers to offer you various levels of involvement based on your company’s objectives.
and financial resources. Corporate Council dues are set on a 12-month cycle. Click here to see a list of current Corporate Council members.

**Corporate Circle ($25,000)**

An exclusive, high-level corporate partnership is available to a limited group of industry supporters, offering benefits that will reinforce your company’s industry leadership position, offer key networking opportunities, and fulfill multiple marketing objectives.

**Executive ($15,000)**

A mid-level partnership that offers enhanced benefits designed to maximize your impact on the leaders in the study and treatment of pain. This level will provide additional opportunities for visibility, research, and communication.

**Associate ($7,500)**

An entry-level corporate partnership that offers a variety of benefits designed to fit the needs of your company and reach leaders in the study and treatment of pain.

**Benefits**

**Corporate Council Roundtable**

Meet with APS leaders to exchange ideas and knowledge. This 1-day meeting is designed to facilitate an ongoing dialogue between industry and APS leaders. This is a unique opportunity for open discussion on hot topics and future trends in the field of pain and is a way for both the association and industry to capitalize on each other’s strengths to advance the specialty of pain and enhance patient care. The purpose of the roundtable is to

- inform the Corporate Council about the APS strategic plan and achievements
- provide socioeconomic updates
- review practice development initiatives
- offer industry feedback and guidance to the society.

**President’s Recognition Reception**

You will be invited to network with APS Board members, committee chairs, and leaders at a private reception during the APS Annual Scientific Meeting. The reception recognizes the many award recipients, including the Clinical Centers of Excellence in Pain Management Award.

**APS Communications**

Receive all APS communications and stay informed. You will receive *The Journal of Pain*, APS’s official, frequently cited, indexed journal. The journal provides a forum for scholarly presentations and commentaries on issues and controversies. Each issue presents reports of original clinical and scientific research. *APS E-News* delivers relevant monthly information such as the latest pain news, information on advocacy related to pain, and clinical trials.

**Clinical Practice Guidelines**

Receive access to clinical practice guidelines that are created by interdisciplinary panels with expertise in methods used to critique and synthesize published research and other sources.

**Contact**

Joseph Maginot  
Professional Relations and Development  
847.375.4873
New Jersey Division of Revenue

Certificate of Amendment to the Certificate of Incorporation
(For Use by Domestic Non-profit Corporations)

Pursuant to the provisions of Title 15A:9-4 New Jersey Non-profit Corporation Act, the undersigned corporation executes the following Certificate of Amendment to its Certificate of Incorporation:

1. Name of the Corporation: American Society of Pain Educators, Inc.
2. Corporation Number: 0100919991
3. Article 5 of the Certificate of Incorporation is hereby amended to read as follows:
   The Corporation shall have no members.
4. The corporation □ has ☑ does not have members.
   A. For Corporations WITH members:
      Number entitled to vote  7  Voting FOR  7  Voting AGAINST  0
      If any class or classes of members are entitled to vote as a class, set forth the number of members of each class, the series of votes of each class voting for and against, and the number of members present at the meeting, OR

         ☑ Adoption was by unanimous written consent without meeting.
         Date of Adoption: March 1, 2006

   B. For Corporations WITHOUT members:
      Number of Trustees  Voting FOR  Voting AGAINST
      Trustees present at meeting  OR

         ☑ Adoption was by unanimous written consent without meeting
         Date of Adoption:

5. Other Provisions:

Signature: B. Eliot Cole, MD
(Must be Ch. Of Bd. Pres. Or Vice Pres)

Name: B. Eliot Cole, President
(Type Name and Title)

Date: 8/10/06

This document MUST be filed in triplicate.

NJ Division of Revenue, PO Box 308, Trenton, NJ 08646
New Jersey Division of Revenue

CERTIFICATE of CHANGE of REGISTERED OFFICE
&/or REGISTERED AGENT
(For Use by Domestic and Foreign, Profit and Non-profit Corporations)

CORPORATION NAME: American Society of Pain Educators Inc.

STATE OF ORIGINAL INCORPORATION: N.J.

IMPORTANT - INCLUDE INFORMATION ON BOTH THE PRIOR AND NEW AGENT

PRIOR AGENT NAME: Jeffrey Tarnoff

NEW AGENT NAME: Jeffrey Tarnoff

PRIOR AGENT STREET ADDRESS
7 Oak Pl, Suite 7

NEW AGENT STREET ADDRESS
6 Erie St.

CITY Montclair STATE NJ ZIP 07042

CITY Montclair STATE NJ ZIP 07042

The corporation states that the address of its new registered office and the address of its new registered agent are identical. Further, the changes designated on this form were authorized by resolution duly adopted by its board of directors or members.

By (Signature of Officer)

Title Chairman of the Board (Type)

Date: 6/18/2007

NOTE - This form must be executed by the chairman of the board, the president, or the vice president of the corporation.

FEES: Change of Agent Name-$25.00
Change of Agent Address-$25.00
Change of Both-$25.00

MAIL TO: NJ Division of Revenue
PO Box 308
Trenton, NJ 08646

Make checks payable to: TREASURER, STATE of NEW JERSEY (NO CASH PLEASE)
This is to Certify that, there is hereby organized a corporation under and by virtue of the above noted statute of the New Jersey Statutes.

1. Name of the Corporation: **American Society of Pain Educators Inc.**

2. The purpose for which this corporation is organized is: The mission is to facilitate the creation of Credentialed Clinical Pain Educators and provide continuing education activities for their training. The Credentialed Clinical Pain Educator will serve to assist primary care healthcare providers in the development of appropriate diagnoses, best treatment options, and management of all varieties of pain, with an emphasis on patient counseling and education.

3. Registered Agent: Jeffrey Tarnoff

4. Registered Office: Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042

5. The corporation: _X_ Yes __ No
   If yes, qualification will be set forth in the bylaws.

6. Method of electing trustees will be as set forth in the bylaws

7. The first board of directors shall consist of 3 directors.
   The names and addresses of the initial directors:
   Jeffrey Tarnoff, Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042
   Debra Weiner, Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042
   Barry Cole, MD, MPA, Aventine HealthSciences, 7 Oak Place, Suite 7, Montclair, New Jersey 07042

8. The duration of the corporation is: perpetual.

9. Set forth Name and Address of Incorporator:

   Business Filings Incorporated, Mark Schiff, AVP
   8025 Excelsior Dr. Suite 200, Madison, WI 53717.
10. This corporation is organized exclusively for charitable, religious, educational, and scientific purposes, including, for such purposes, the making of distributions to corporations that qualify as exempt corporations under section 501(c)(3) of the Internal Revenue Code, or the corresponding section of any future federal tax code.

Notwithstanding any other provisions of these articles, this corporation shall not carry on any activities not permitted to be carried on by a corporation exempt from Federal income tax under section 501(c)(3) of the Internal Revenue Code of 1986 or the corresponding provision of any future United States Internal Revenue law.

No part of the net earnings of the organization shall inure to the benefit of, or be distributable to its members, trustees, officers, or other private persons, except that the organization shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purpose set forth in the purpose clause hereof. No substantial part of the activities of the organization shall be the carrying on of propaganda, or otherwise attempting to influence legislation, and the organization shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of any candidate for public office.

Upon the dissolution of the corporation, assets shall be distributed for one or more exempt purposes within the meaning of section 501(c)(3) of the Internal Revenue Code of 1986, or corresponding section of any future Federal tax code, or shall be distributed to the Federal, state, or local government for a public purpose. Any such assets not so disposed of shall be disposed of by a court of competent jurisdiction of the county in which the principal office of the corporation is then located, exclusively for such purposes.

In Testimony whereof, each undersigned incorporator has caused this certificate to be signed this 4th day of February, 2004.

Signature: ________________________________
Mark Schiff, AVP of
Business Filings Incorporated

Prepared for: American Society of Pain Educators Inc.