U.S. FOOD & DRUG ADMINISTRATION

November 15, 2024
FOIA request #: 2015-5986

Public.Resource.Org
Attention: Carl Malamud
1005 Gravenstein Highway North
Sebastopol, CA 95472
carl@media.org

Dear Carl Malamud:

This letter is in response to your Freedom of Information Act (FOIA) request July 22, 2015, and received by the Food and Drug Administration (FDA) on July 24, 2015. Your request asked for the following regarding LCDR Colburn's services on the Boards of Directors of the American National Standards Institute and ASTM International between 01/01/2012 – 07/22/2015:

- Legal Advisory LA-13-05 states "it is a best practice for agencies to commit the scope of an employee's permissible activities to writing in a memorandum of understanding between the agency, the employee and the nonprofit organization." I am requesting a copy of any such memoranda and supporting documents leading to the issuance of such memoranda. If instead LCDR Colburn's service with ANSI and/or ASTM is or was in his individual capacity and not his official capacity, I would request any documents discussing such status and/or any waiver requested or approved.

- Legal Advisory LA-13-05 states "the employee may not receive any supplementation of salary, including personal reimbursement of travel expenses, from the nonprofit organization" and any such reimbursement must come from the nonprofit organization directly to the government. I am requesting records detailing the amounts and nature of such reimbursements from ANSI and ASTM International

- Legal Advisory LA-13-05 outlines a number of additional limitations, such as "limiting or prohibiting the employee from participating in the development of regulations that could affect the nonprofit organization." I am requesting any memoranda, email, or other records that discuss instances where LCDR Colburn is limited or prohibited from working on matters with the nonprofit organization or has been recused, limited, or prohibited from working on matters for the government in his official capacity.

The Center for Devices and Radiological Health (CDRH) conducted a reasonable search of:

- Office of Strategic Partnerships and Technology Innovation (OST)

After a reasonable search, we located 14 pages of records responsive to your request. Upon completion of our review, it has been determined that portions of the records require withholding pursuant to the FOIA (5 U.S.C. § 552) (b)(6).

Exemption 6: Permits withholding of records and information about individuals when disclosure would be a clearly unwarranted invasion of personal privacy.

In determining to withhold such information, FDA considered 5 USC 552(a)(8)(i), when applicable, and whether FDA reasonably foresees that disclosure of such information would harm an interest protected by the relevant exemption(s) and whether disclosure is prohibited by law.

In accordance with 45 CFR § 5.61 and 21 CFR § 20.41(b)(5), you have the right to appeal this determination. Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency's adverse determination should be reconsidered. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, U.S. Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, or emailed within 90 days from the date of this response to FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter or email "FDA Freedom of Information Act Appeal." Items arriving or delivered after 5 p.m. Eastern Time will be deemed received on the next workday.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Michael Jenack who processed this request by email at michael.jenack@fda.hhs.gov. You may also contact the FDA FOIA Public Liaison for assistance at: Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001; Telephone: 202-741-5770; Toll-Free: 1-877-684-6448; email: ogis@nara.gov; Fax: 202-741-5769.

X The following charges may be included in a monthly invoice:

Reproduction: $0.00 Search: $0.00 Review: $0.00 Other: $0.00 Total: $0.00

DO NOT SEND ANY PAYMENT UNTIL YOU RECEIVE AN INVOICE

Sincerely,

Leif M. Collins

Digitally signed by Leif M. Collins
Date: 2024.11.15 13:40:00 -05'00'

Leif M. Collins
Assistant Director, FOI Disclosure Team A
Division of Information Disclosure
Office of Communication and Content Development
Office of Communication, Information Disclosure, Training and Education (OCITE)
Center for Devices and Radiological Health
U.S. Food and Drug Administration

From: McMurry-Heath, Michelle
Subject: Fw: Nomination of Candidates for the 2013 ANSI Board of Directors- LCDR Scott Colburn
Date: Friday, June 1, 2012 12:49:38 PM
Attachments: 2013 ANSI Board of Directors Nomination- Scott Colburn.PDF

Michelle McMurry-Heath, MD, PhD
Associate Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration
White Oak 66, Room 5428
Direct 301-796-7647
Cell (b) (6)
Email: Michelle.McMurry-Heath@fda.hhs.gov

From: Lloyd, Lindsay
Sent: Friday, June 01, 2012 12:44 PM
To: McMurry-Heath, Michelle
Subject: Nomination of Candidates for the 2013 ANSI Board of Directors- LCDR Scott Colburn

Dear Ms. Power,

Please find attached the nomination materials for LCDR Scott Colburn, Director of the Standards Program, Office of the Center Director, in the Center for Devices and Radiological Health, FDA to the Board of Directors of the American National Standards Institute. As a board member, LCMD Colburn would be the FDA representative to the governing board of ANSI, and would present and receive information and views on behalf of the FDA. I am submitting this material on behalf of our Center Director, Dr. Jeff Shuren.

If selected, LCDR Colburn may serve in his official capacity. As an authorized agency representative, he may permit the use of his official Government title, serve on Government time, use Government equipment and services, and may travel on Government travel orders. Other conditions which apply to LCDR Colburn's service are as follows:

• He should participate actively and on an equal basis with other members. Active participation includes full involvement in discussions, and technical debates, registering opinions, voting, and if selected, serving as chairpersons or in other official capacities.

• He may serve as a representative of the Food and Drug Administration, and should not express views which are inconsistent with established Agency policy.

• His participation in this outside organization does not necessarily demonstrate the agency's endorsement of all decisions reached by the organization.

• He may not participate in, or vote on, the business or internal affairs of the organization, including personnel actions, financial management, or fundraising activities.

• He is prohibited from participating in a matter, as an FDA employee, that could have a direct and predictable affect on the financial interests of the organization.

• He must not accept compensation from this organization for his service. However, requests for acceptance of payments from a non-Federal source for travel expenses may be approved, provided proper authorization is granted.

• He must not represent this organization before any Federal agency or Federal court, with the intent to influence Government action, or where the Federal Government has an substantial interest in the matter.

If you have any questions please feel free to contact me at michelle.mcmurry-heath@fda.hhs.gov at 301-796-7647.

Sincerely,

Michelle McMurry-Heath, M.D., Ph.D.
Associate Director for Science
Center for Devices and Radiological Health
10903 New Hampshire Avenue Building 66, Room 5428
Silver Spring, MD 20993
Michelle McMurry-Heath, MD, PhD
Associate Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration
White Oak 66, Room 5428
Direct 301-796-7647
Cell (b) (6)
Email: Michelle.McMurry-Heath@fda.hhs.gov

Nomination Reply Form
please respond by June 1, 2012

NOMINATION OF CANDIDATES FOR THE

2013 ANSI Board of Directors

Please return completed form and required documentation* by June 1, 2012, to:

American National Standards Institute
ATTN: Tricia Power
25 West 43rd Street, Fourth Floor
New York, NY 10036-7414

>>>>> TEL: 212-642-4881
>>>>> FAX: 212.840.2298 or 212.398.0023
>>>>> E-mail: tpower@ansi.org

*** Required Documentation** (please refer to details in the accompanying information document)

- Letter of Corporate Support
- Biographical Statement

Full Membership in the Institute shall be a prerequisite for participation on the ANSI Board of Directors unless the Board or the Executive Committee grants an exception.

Submitted on behalf of:

ANSI Member _____

Submitted by _____

E-mail _____

Nomination for the: **ANSI Board of Directors (BoD)**

Name	Scott A. Colburn	
Title	Director, Center for Devices and Radiological Health Standards Program	
Organization	Food and Drug Administration	
Street Address	White Oak BLDG 66 – Rm 3628	
	10903 New Hampshire Ave.	
City	Silver Spring	**State**: MD **Zip**: 20993
Phone	301-796-6287 / BB 240-319-1456	**Fax**: 301-847-8138
E-mail	Scott.colburn@fda.hhs.gov	

Reply requested by June 1, 2012

Respond via fax to **212.840.2298 or 212.398.0023**; via e-mail to tpower@ansi.org

Bio for LCDR Scott A. Colburn

LCDR Scott A. Colburn, MS, BSN, RN is the Director of the Standards Program at the Food and Drug Administration's Center for Devices and Radiological Health (CDRH). Since joining FDA in January of 2004, LCDR Colburn has served in numerous roles as a nurse consultant in the area of premarket review and voluntary consensus standards development within the General Hospital Devices Branch/Office of Device Evaluation. He has held the positions of lead reviewer and Acting Chief of the General Hospital Devices Branch and since August 2009 has served as Deputy Director of the CDRH Standards Program. Scott is a member to numerous national and international medical device standards working groups and is the convener to both the U.S. Technical Advisory Group (TAG) and International ISO/IEC Joint Working Group (ISO TC210 JWG4/IEC SC62D JWG10) charged with developing a manufacturing standard to address the risks associated with medical device small bore misconnections that lead to adverse and fatal events for patients. Scott has been appointed to the ANSI Executive Standards Council (ExSC), the ANSI Government Member Forum (GMF), the Interagency Committee on Standards Participation (ICSP) and the AAMI Standards Board.

Prior to coming to FDA, Scott completed his bachelor's degree in Nursing from Marquette University and was commissioned in the US Army Nurse Corps where he served four years at the Waler Reed Army Medical Center in D.C. Since coming to the FDA, he has earned a Masters of Science in Biomedical Technology Development and Management from Georgetown University and Virginia Polytechnic Institute and State University.

LCDR Colburn transferred to the U.S. Public Health Service Commissioned Corps in January 2004. Prior to his commission into the USPHS, Scott was enlisted in the Army as a combat medic prior to his Commission in the US Army Nurse Corps in 1999.

Updated: 2012-05-20

From: McMurry-Heath, Michelle
To: Shuren, Jeff; Benedetti, Frank V.; Colburn, Scott A
Cc: Maisel, William
Subject: RE: ASTM BOD Nomination
Date: Monday, June 18, 2012 9:29:45 AM

Great, thanks. Scott, could you double check with Vince Tolino in Ethics and send the ASTM folks the same ethics boilerplate we used for the ANSI nomination letter. I've pasted it below:

(Beginning of text)

If selected, LCDR Colburn may serve in his official capacity. As an authorized agency representative, he may permit the use of his official Government title, serve on Government time, use Government equipment and services, and may travel on Government travel orders. Other conditions which apply to LCDR Colburn's service are as follows:

> He should participate actively and on an equal basis with other members. Active participation includes full involvement in discussions, and technical debates, registering opinions, voting, and if selected, serving as chairpersons or in other official capacities.
>
> He may serve as a representative of the Food and Drug Administration, and should not express views which are inconsistent with established Agency policy.
>
> His participation in this outside organization does not necessarily demonstrate the agency's endorsement of all decisions reached by the organization.
>
> He may not participate in, or vote on, the business or internal affairs of the organization, including personnel actions, financial management, or fundraising activities.
>
> He is prohibited from participating in a matter, as an FDA employee, that could have a direct and predictable affect on the financial interests of the organization.
>
> He must not accept compensation from this organization for his service. However, requests for acceptance of payments from a non-Federal source for travel expenses may be approved, provided proper authorization is granted.
>
> He must not represent this organization before any Federal agency or Federal court, with the intent to influence Government action, or where the Federal Government has an substantial interest in the matter.

(end of text)

From: Shuren, Jeff
Sent: Monday, June 18, 2012 9:18 AM
To: McMurry-Heath, Michelle; Benedetti, Frank V.
Cc: Maisel, William
Subject: Re: ASTM BOD Nomination

I'm fine with it if, as you point out, we comply with the applicable ethics requirements and guidelines.

Jeff

From: McMurry-Heath, Michelle
Sent: Monday, June 18, 2012 09:16 AM
To: Shuren, Jeff; Benedetti, Frank V.
Cc: Maisel, William
Subject: FW: ASTM BOD Nomination

Jeff and Frank,

This is outstanding news from Scott. He would like clearance to serve both on the ASTM BOD to which he was just elected and the ANSI BOD if elected. Assuming he follows the same ethical guidelines we laid out for his ANSI nomination, is that OK with you?

Michelle

From: Colburn, Scott A
Sent: Friday, June 15, 2012 11:44 AM
To: McMurry-Heath, Michelle
Cc: Maisel, William
Subject: ASTM BOD Nomination

Hello Michelle,

I hope you are beginning to feel better.
About a month ago I had mentioned that in addition to ANSI my name was put forward to ASTM for consideration on their Board of Director's. At that time we agreed to allow my nomination to be considered.

I just got off the phone with the ASTM President, Jim Thomas, who personally notified me that my nomination was confirmed pending my acceptance. The term would be for 3 years beginning Jan 2013.

I expressed my appreciation and informed him that I will confirm after speaking with Sr. Management.

I did discuss the limitations I would have as a member to the Board related to financial matters and so forth to which he was in complete understanding and had expressed this is common for Government officials on the BOD's.

I would like to reply back to Jim either later today or early next week regarding my official response. Could we either discuss quickly or by email so I can respond to Jim/ASTM?

I will be in the CDER Awards Ceremony until ~2pm then back in my office. Otherwise I will see you next week. Take care and get better!

Scott

Scott A. Colburn, MS, BSN, RN
Lieutenant Commander
United States Public Health Service
Director, CDRH Standards Program
Office of the Center Director
Center for Devices and Radiological Health, FDA
Office: 301-796-6287 BB: 240-319-1456
scott.colburn@fda.hhs.gov

From: McMurry-Heath, Michelle
To: Colburn, Scott A
Subject: Re: ASTM International Announces Slate of Candidates for 2013 Board of Directors
Date: Friday, June 22, 2012 12:44:05 PM

No problem!
Michelle McMurry-Heath, MD, PhD
Associate Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration
White Oak 66, Room 5428
Direct 301-796-7647
Cell (b) (6)
Email: Michelle.McMurry-Heath@fda.hhs.gov

From: Colburn, Scott A
Sent: Friday, June 22, 2012 12:38 PM
To: McMurry-Heath, Michelle
Subject: RE: ASTM International Announces Slate of Candidates for 2013 Board of Directors

Thank you!
Sorry I missed you yesterday at the MDICC meeting. I was 1 block down at the ICSP and ANSI GMF meeting all day on L ST.

There, we talked a lot about the MDICC model re: innovation pathways for standards development that can be used for other sectors. I explained how we saw an opportunity in collaborating with SDOs and other stakeholders to develop a consensus approach to this area of science to reduce duplication and streamline processes. There was a lot of praise and interest in the concept we are undertaking in interoperability and beginning with combination products.

Exciting times to come for standards development and CDRH!

Have a great weekend.

Scott Colburn
CDRH Standards Program
301-796-6287

From: McMurry-Heath, Michelle
Sent: Friday, June 22, 2012 12:32 PM
To: Colburn, Scott A; Maisel, William; Shuren, Jeff; CDRH-OSEL-OD-SMS
Subject: Re: ASTM International Announces Slate of Candidates for 2013 Board of Directors

Congrats Scott!

Michelle McMurry-Heath, MD, PhD
Associate Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration
White Oak 66, Room 5428
Direct 301-796-7647
Cell (b) (6)
Email: Michelle.McMurry-Heath@fda.hhs.gov

From: Colburn, Scott A
Sent: Friday, June 22, 2012 12:14 PM
To: McMurry-Heath, Michelle; Maisel, William; Shuren, Jeff; CDRH-OSEL-OD-SMS
Subject: FW: ASTM International Announces Slate of Candidates for 2013 Board of Directors

It's official;

Thank you for your support. I look forward to representing our Center and Agency in this organization. I learned yesterday that the nomination came from members within the Interagency Committee on Standards Participation (ICSP). Mary McKiel (EPA) who co-chairs the ICSP along with Mary Saunders (NIST) I'm sure had a strong role.

This summer and fall I would like to take time to discuss with you this role and opportunities that we should explore. I will also be asking other CDRH members in similar positions within other standards organizations get together to ensure we have a consensus approach to our representation. The FDA/CDRH Standards Program is a widely respected entity that many across the US community and abroad look to and we should all be very proud to be a product of this.

Once again, I thank you and all of our staff involved with the Standard's Program for your support of this very important undertaking.

Scott

Subject: ASTM International Announces Slate of Candidates for 2013 Board of Directors

ASTM International is pleased to announce the following slate of candidates selected by the Nominating Committee to serve on the 2013 Board of Directors:

Chairman of the Board

Mary C. McKiel, U.S. Environmental Protection Agency

Vice Chairman (two-year term)

Michael R. Withers, Walt Disney Imagineering

Director (three-year terms)

Scott A. Colburn, FDA, Center for Devices and Radiological Health

Jeffrey S. Goldfinger, L-3 Communications

Robin E. Graves, Vulcan Materials Company

Daniel S. Janikowski, Plymouth Tube Company

Richard Peri, Aircraft Electronics Association

Taco van der Maten, PANalytical B.V.

You will receive instructions to access biographies of each candidate as well as a hyperlink to the election e-ballot in a subsequent e-mail message. Please contact Maureen Houck at mhouck@astm.org should you require further information in the interim.


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From: Frampton, David W
Subject: Voice Message from Frampton, David W (83017965962)
Date: Tuesday, May 29, 2012 8:24:46 AM
Attachments: VoiceMessage.wav

Subject: Transcription of Voice Message from Frampton, David W (83017965962)

Date: Tuesday, May 29, 2012 8:24:46 AM

From: Frampton, David W

To: Colburn, Scott A

Duration: 00:43

Hi Scott, this is Dave Frampton. Um, I just wanted to get together with you, um (clears throat) hopefully you'll have some time maybe um uh this morning, tomorrow morning, uh, what's that, the Wednesday, Thursday morning I'm on leave on Friday, but whatever. Um, I actually got some interesting information back from Vince Tolino, um, about board positions when it's truly standard setting organizations and as long as they refrain from internal operations. Plus, I also wanted to talk to you about all the review I've done about all the different outside, uh, positions. So, I have questions and want to run some things by you, so, hopefully we can get together, um, and discuss that sometime this week. Thanks, goodbye.