IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN FOUNDATION, INC., Plaintiff, v. FOOD & DRUG ADMINISTRATION and DEPARTMENT OF HEALTH & HUMAN SERVICES, Defendants.	Civil Action No. 16-781 (APM)

DECLARATION OF RACHEL CLATTENBURG

I, Rachel Clattenburg, declare as follows:

1. I am counsel for the plaintiff in this case.

2. In April 2016, I examined the curricula vitae (CVs) of advisory committee members that were posted on websites for FDA's advisory committees. I counted how many CVs were posted and how many of those CVs contained redactions. As of April 6, 2016, of the 150 CVs posted for members of Center for Drug Evaluation and Research advisory committees, 138 had redactions. Of the 57 CVs posted for members of Center for Biological Evaluation and Research advisory committees, 49 had redactions. Of the 128 CVs posted for members of Center for Devices and Radiological Health advisory committees, 126 had redactions. All of the CVs posted for members of the Tobacco Products Scientific Advisory Committee and the Pediatric Advisory Committee had redactions. All of the 16 CVs posted for members of Center for Radiation Emitting Products advisory committees had redactions.

3. On June 28, 2016, I visited FDA's Electronic Reading Room, http://www.fda.gov/RegulatoryInformation/foi/ElectronicReadingRoom/default.htm, and printed the webpage. A true and correct copy of that printout is attached as Exhibit 5.

Public Citizen's Letter to FDA

4. By letter dated February 4, 2014, Public Citizen wrote to the Food and Drug Administration's (FDA) Commissioner and Chief Counsel concerning the redactions on the CVs of advisory committee members that are posted on FDA's website. A true and correct copy of that letter is attached as Exhibit 1, and is available at http://www.citizen.org/documents/2181.pdf.

5. By letter dated July 2, 2014, Sarah Kotler, FDA's Deputy Director, Freedom of Information Division, responded that FDA would not post unredacted CVs of its advisory committee members. A true and correct copy of that letter is attached as Exhibit 2.

Public Citizen's FOIA Request

6. On May 19, 2014, Public Citizen submitted a FOIA request to FDA seeking unredacted copies of the CVs of all FDA advisory committee members whose CVs were currently posted on FDA's website and requested a public interest fee waiver. A true and correct copy of the FOIA request is attached as Exhibit 3 at page 1.

7. By letter dated May 27, 2014, FDA acknowledged receipt of Public Citizen's FOIA request, and by letter dated June 3, 2014, FDA granted the request for a public interest fee waiver. True and correct copies of those letters are attached as Exhibit 3 at pages 3-4.

8. By letter dated July 11, 2014, the Center for Food Safety and Applied Nutrition (CFSAN) replied to Public Citizen's FOIA request by directing Public Citizen to the online CVs. A true and correct copy of that response is attached as Exhibit 4 at page 1.

9. By letter dated August 26, 2014, the Center for Tobacco Products (CTP), a Center located within FDA, responded to Public Citizen's FOIA request. CTP sent a compact disc with electronic copies of partially redacted CVs. A true and correct copy of CTP's letter that accompanied the compact disc of CVs is attached as Exhibit 4 at page 2.

10. On September 18, 2014, Public Citizen submitted an appeal of the partial denial by CTP and the constructive denial by CFSAN. A true and correct copy of that appeal letter is attached as Exhibit 4 at page 3.

11. By letter dated September 19, 2014, the Department of Health and Human Services (HHS) acknowledged receipt of the September 18, 2014, appeal.

12. By letter dated October 9, 2014, CFSAN sent another response including a compact disc containing CVs with redactions. A true and correct copy of the cover letter CFSAN sent with the compact disc is attached as Exhibit 4 at page 8.

13. By email dated October 20, 2014, CTP sent Public Citizen revised versions of ten CVs, still with redactions.

14. By email dated March 27, 2015, CFSAN sent electronic copies of revised CVs, most with redactions.

15. By letter dated November 19, 2015, the Center for Biologics Evaluation and Research (CBER), responded to Public Citizen's FOIA request and enclosed a disc containing redacted CVs. A true and correct copy of CBER's letter that accompanied the compact disc of CVs is attached as Exhibit 4 at page 9.

16. By letter dated December 2, 2015, Public Citizen appealed CBER's response. A true and correct copy of that appeal letter is attached as Exhibit 4 at page 10.

17. By letter dated December 7, 2015, HHS acknowledged receipt of the FOIA appeal of CBER's partial denial (although HHS mistakenly referred to it as an appeal of CTP's and CFSAN's responses). A true and correct copy of that acknowledgment letter is attached as Exhibit 4 at page 13.

18. By letter dated May 24, 2016, the Office of the Commissioner responded to the FOIA request and sent a disc containing electronic copies of CVs with redactions. A true and correct copy of the cover letter of that response is attached as Exhibit 4 at page 14.

19. By letter dated June 8, 2016, the Center for Devices and Radiological Health (CDRH) responded to the FOIA request and sent a disc containing electronic copies of CVs with redactions. A true and correct copy of the cover letter of that response is attached hereto as Exhibit 4 at page 15.

20. With a letter dated June 21, 2016, CDRH sent a disc containing one CV that it said was missing from its June 8, 2016, response. A true and correct copy of the June 21, 2016, letter is attached as Exhibit 4 at page 16.

21. To date, FDA's Center for Drug Evaluation and Research (CDER) has not responded to Public Citizen's FOIA request. To date, HHS has not substantively responded to Public Citizen's appeals.

22. I have reviewed the CVs FDA released in response to Public Citizen's FOIA request and the vast majority of these CVs contain redactions under FOIA exemptions 4 or 6 or both.

23. I searched FDA's online advisory committee rosters to determine whether the advisory committee members whose CVs FDA released are still serving on their respective committees. Because of FDA's delay in responding to Public Citizen's FOIA request, committee

membership has changed and approximately half of the CVs FDA released to Public Citizen belong to individuals who are no longer serving on advisory committees. For instance, 83 of the 155 CVs CDRH released to Public Citizen belong to individuals who are no longer serving on those advisory committees.

Advisory Committee Members' CVs And Other Publicly Available Information On Advisory Committee Members

24. I searched Google for a sampling of FDA advisory committee members and located many instances where the advisory committee members had made their CVs available online without any redactions: William Bugbee, http://www.drbugbee.com/; Amanda Corbett, https://pharmacy.unc.edu/directory/ahcorbet/; Til Stürmer, http://sph.unc.edu/adv_profile/til-sturmer-md-phd/; James Neaton, http://sph.umn.edu/faculty1/name/james-neaton/; Shrikant Bangdiwala, https://www.med.unc.edu/ibs/about-us/faculty-biographies/shrikant-bangdiwala-phd; Thomas Grieger, http://www.griegermd.com/; Michael McGuire, http://guidedsmiles.periohealth.com/pdf/Michael-K-McGuire-DDS-FullCV-2009.pdf; Stephen Hillis, http://perception.radiology.uiowa.edu/People/SteveHillisPhD/tabid/216/Default.aspx; Yulei Jiang, https://radiology.uchicago.edu/page/yulei-jiang-curriculum-vitae; John Holcomb, https://med.uth.edu/surgery/faculty/john-b-holcomb/; Warren Bickel, http://research.vtc.vt.edu/people/warren-k-bickel; David Brent, https://www.childpsychresearch.com/faculty; John Connett, http://sph.umn.edu/faculty1/name/john-connett/; James de Lemos, http://profiles.utsouthwestern.edu/profile/11722/james-de-lemos-biography.html; Ralph D'Agostino, Sr., http://www.bu.edu/math/people/faculty/probability-and-statistics/dagostino/; David Pickar, http://www.davidpickar.com/background/biography/; Abdelmonem Afifi, www.biostat.ucla.edu/people/afifi; Michael Jaff, http://www.primacea.com/profile/michael-r-jaff.

25. On June 27, 2016, I obtained from FDA's website a copy of the CV for Oncologic Drugs Advisory Committee member Jeffrey Lancet, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM456838.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 6 at 1-11, and also as Exhibit 7 at 7-17.

26. On July 9, 2016, I searched Open Payments, the statutorily required database of payments to hospitals and physicians that is maintained by Centers for Medicare & Medicaid Services, for "Jeffrey Lancet" and that website showed that in 2014, Jeffrey Lancet received $375,689.01 in total associated research funding from the health care industry. That information is available at https://openpaymentsdata.cms.gov/physician/173910 (select year 2014).

27. On June 27, 2016, I obtained from FDA's website a copy of the CV for Oncologic Drugs Advisory Committee member Vassiliki A. Papadimitrakopoulou, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM456842.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 6 at 12-18.

28. On July 9, 2016, I searched Open Payments for "Vassiliki Papadimitrakopoulou" and that website showed that in 2014, he received $1,968,386.84 in total associated research funding from the health care industry. That information is available at https://openpaymentsdata.cms.gov/physician/51844 (select year 2014).

29. On June 27, 2016, I obtained from FDA's website a copy of the CV for Oncologic Drugs Advisory Committee member Alberto Pappo, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/

UCM456840.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 6 at 19-20.

30. On July 9, 2016, I searched Open Payments for "Alberto Pappo" and that website showed that in 2014, he received $53,949.74 in total associated research funding from the health care industry. That information is available at https://openpaymentsdata.cms.gov/physician/904039 (select year 2014).

31. On June 27, 2016, I obtained from FDA's website a copy of the CV for Oncologic Drugs Advisory Committee member Bruce Roth, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM495956.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 6 at 21-25.

32. On June 27, 2016, I searched Open Payments for "Bruce Roth" and that website showed that in 2014, he received $186,727.53 in total associated research funding from the health care industry. That information is available at https://openpaymentsdata.cms.gov/physician/612100 (select year 2014).

33. On June 27, 2016, I obtained from FDA's website a copy of the CV for Anesthetic and Analgesic Drug Products Advisory Committee member Jeffrey Galinkin, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeeting Materials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM406481.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 7 at 1-6.

34. On June 27, 2016, I obtained from FDA's website a copy of the CV for Cardiovascular and Renal Drugs Advisory Committee member James de Lemos, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Cardi

ovascularandRenalDrugsAdvisoryCommittee/UCM362044.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 7 at 27-33, and also as Exhibit 29 at 1.

35. On June 27, 2016, I obtained from James de Lemos's faculty page an unredacted copy of his CV, available at http://www.utsouthwestern.edu/facultydata/11722/files/de%20Lemos%20CV%20new%20format.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 7 at 34-40.

36. On June 27, 2016, I obtained from FDA's website a copy of the CV for Cardiovascular and Renal Drugs Advisory Committee member Roxana Mehran, which is available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM473660.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 7 at 20-26, and also as Exhibit 8 at 1-7.

37. On June 27, 2016, I obtained from FDA's website a copy of the CV for Arthritis Drugs Advisory Committee member Liron Caplan, which is available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM410335.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 7 at 18-19.

38. On June 27, 2016, I searched ClinicalTrials.gov for "Roxana Mehran" and the site returned 11 clinical trials. The search results are available at https://clinicaltrials.gov/ct2/results?term=roxana+mehran&Search=Search. I clicked on the links for the first three clinical trials listed and printed them. True and correct copies of the first three ClinicalTrials.gov results are attached as Exhibit 8 at 8-16.

39. On June 27, 2016, I searched ClinicalTrials.gov for "placebo controlled trial of memantine (10mg BID)" and the website returned 13 results, available at https://clinicaltrials.gov/ct2/results?term=placebo+controlled+trial+of+memantine+%2810mg+BID%29&Search=Search. I printed out a copy of the first result, Clinical Trials Identifier NCT00545974, available at https://clinicaltrials.gov/ct2/show/NCT00545974, and a true and correct copy of that printout is attached as Exhibit 9 at 4-7.

40. True and correct copies of the pertinent pages of the CV for Brian Appleby as released to Public Citizen by CBER are attached as Exhibit 9 at 1-3.

41. True and correct copies of the pertinent pages of the CV for James Maguire as released to Public Citizen by CBER are attached as Exhibit 10 at 1-3.

42. On July 3, 2016, I obtained from FDA's website a copy of the CV for Blood Products Advisory Committee member Meera Chitlur, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM496206.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 10 at 17-24.

43. On June 27, 2016, I obtained from FDA's website a copy of the CV for Endocrinologic and Metabolic Drugs Advisory Committee member James Neaton, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM430473.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 10 at 4-10.

44. On June 27, 2016, I obtained from James Neaton's faculty website a copy of his CV, available at http://sph.umn.edu/faculty1/wp-content/uploads/CV_forms/james-neaton.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 10 at 11-16. To comply with LCvR 5.4(f), I redacted his birthdate.

45. On June 27, 2016, I obtained from FDA's website a copy of the CV for Tobacco Products Scientific Advisory Committee member Suchitra Krishnan-Sarin, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM457609.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 11 at 1-4.

46. True and correct copies of the pertinent pages of the CV for A. Catharine Ross as released to Public Citizen by CFSAN are attached as Exhibit 11 at 7-9, and as Exhibit 24 at 6.

47. True and correct copies of the pertinent pages of the CV for Sridhar Basavaraju as released to Public Citizen by CBER are attached as Exhibit 11 at 5-6.

48. On June 27, 2016, I obtained from FDA's website a copy of the CV for Orthopaedic and Rehabilitation Devices Panel member Scott Evans, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM495349.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 11 at 10-12.

49. On June 27, 2016, I obtained from FDA's website a copy of the CV for Orthopaedic and Rehabilitation Devices Panel member Yusef Sayeed, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM495347.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 11 at 16-17.

50. On June 27, 2016, I obtained from FDA's website a copy of the CV for Arthritis Drugs Advisory Committee member Mara L. Becker, available at

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM466135.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 11 at 13-15.

51. On June 28, 2016, I visited the physician profile website for Kimberley Amrami on the website of the Mayo Clinic, and clicked on the link for her publications, available at http://www.mayo.edu/research/searchpublications/publications?authid=11757761. A true and correct copy of that website, showing her publications, is attached as Exhibit 12 at 6-21.

52. True and correct copies of the pertinent pages of the CV for Orthopaedic and Rehabilitation Devices Panel member Kimberley Amrami as released to Public Citizen by CDRH are attached as Exhibit 12 at 1-5.

53. On June 28, 2016, I visited the physician profile website for Caleb Alexander on the website of Johns Hopkins University, and clicked on the link for his publications, available at https://jhu.pure.elsevier.com/en/persons/george-caleb-alexander/publications/. A true and correct copy of that website, showing his publications, is attached as Exhibit 12 at 32-43.

54. On June 28, 2016, I obtained from FDA's website a copy of the CV for Peripheral and Central Nervous System Drugs Advisory Committee member Caleb Alexander, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM406661.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 12 at 22-31 and also Exhibit 28 at 1-8.

55. True and correct copies of the pertinent pages of the CV for Michael Jaff as released to Public Citizen by CDRH are attached as Exhibit 13 at 1-8.

56. On June 27, 2016, I obtained a copy of Michael Jaff's CV from his physician profile page on the website of Primacea. That CV is available at http://www.primacea.com/profile/michael-r-jaff, and true and correct copies of the pertinent pages of that CV are attached as Exhibit 13 at 9-15.

57. On June 27, 2016, I visited the physician profile website for Michael Jaff on the website of Massachusetts General Hospital, available at http://www.massgeneral.org/doctors/doctor.aspx?id=17575#. A true and correct copy of that physician profile page, showing the link to his publications on PubMed, is attached as Exhibit 13 at 16.

58. I compared the redacted and unredacted CVs of Michael Jaff, attached as Exhibit 13, to identify the publications FDA redacted on Michael Jaff's CV. I searched PubMed.gov for these articles. A true and correct copy of the PubMed.gov citation for the redacted publication numbered 179 on Michael Jaff's FDA CV is attached as Exhibit 13 at 17, and is available at http://www.ncbi.nlm.nih.gov/pubmed/25011086. A true and correct copy of the PubMed.gov citation for the redacted publication numbered 178 on Michael Jaff's FDA CV is attached as Exhibit 13 at 18, and is available at http://www.ncbi.nlm.nih.gov/pubmed/24997415. A true and correct copy of the PubMed.gov citation for the redacted publication numbered 177 on Michael Jaff's FDA CV is attached as Exhibit 13 at 19, and is available at http://www.ncbi.nlm.nih.gov/pubmed/24975395. A true and correct copy of the PubMed.gov citation for the redacted publication numbered 169 on Michael Jaff's FDA CV is attached as Exhibit 13 at 20, and is available at http://www.ncbi.nlm.nih.gov/pubmed/24684771. A true and correct copy of the PubMed.gov citation for the redacted publication numbered 168 on Michael Jaff's FDA CV is attached as Exhibit 13 at 21, and is available at http://www.ncbi.nlm.nih.gov/pubmed/24811601. A true and correct copy of the PubMed.gov

citation for redacted publication numbered 145 on Michael Jaff's FDA CV is attached as Exhibit 13 at 22, and is available at http://www.ncbi.nlm.nih.gov/pubmed/23243262.

59. True and correct copies of the pertinent pages of the CV for Joanna Cohen as released to Public Citizen by CTP are attached as Exhibit 14 at 1-3.

60. True and correct copies of the pertinent pages of the CV for Carolyn Hendricks as released to Public Citizen by CDRH are attached as Exhibit 14 at 4-5.

61. True and correct copies of the pertinent pages of the CV of Michael Hudgens as released to Public Citizen by CBER are attached as Exhibit 15 at 1-2.

62. True and correct copies of the pertinent pages the CV of Jason Connor as released to Public Citizen by CDRH are attached as Exhibit 15 at page 3-5

63. True and correct copies of the pertinent pages the CV of Timothy Cripe as released to Public Citizen by CBER are attached as Exhibit 16 at 1-8, and as Exhibit 24 at 2-3.

64. On June 29, 2016, I obtained from FDA's website a copy of the CV for Blood Products Advisory Committee member John Holcomb, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM461276.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 17 at 1-3.

65. On June 29, 2016, I obtained a copy of John Holcomb's unredacted CV from his faculty profile on the University Of Texas, McGovern Medical School website, available at https://med.uth.edu/surgery/files/2013/08/Holcomb-CV.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 17 at 4-7 (birthdate redacted, LCvR 5.4(f)).

66. On June 29, 2016, I obtained from FDA's website a copy of the CV for Oncologic Drugs Advisory Committee member Harold Burstein, available at

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM407388.pdf. True and correct copies of the pertinent pages of that CV are attached at Exhibit 18 at 1-3.

67. On June 29, 2016, I searched Google.com for "Harold Burstein cv." The fifth result was an unredacted "Short Bio" of Harold Burstein, with identical language to a portion of his CV located on the FDA's website. That bio is available at http://www.comtecmed.com/conpo/2013/Uploads/Editor/Burstein%20CV%20June%202012.pdf, and a true and correct copy is attached as Exhibit 18 at 4.

68. True and correct copies of the pertinent pages of the CV of Scott Bruder as released to Public Citizen by CBER are attached at Exhibit 19 at 1-2.

69. On June 29, 2016, I searched Google.com for "Scott Bruder obtained clearance for over" and the third result was a link to his CV, available at http://www2.kenes.com/biomed/conference/Documents/Bruder%20Biosketch%20Feb%202013.pdf. The phrase "obtained clearance for over" is from the CV for Scott Bruder that FDA released to Public Citizen, and FDA redacted terms from the rest of that sentence under exemption 4. True and correct copies of the pertinent pages of the unredacted CV are attached as Exhibit 19 at 3-4.

70. On June 29, 2016, I obtained from FDA's website the CV of Pharmacy Compounding Advisory Committee member Ned Braunstein, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PharmacyCompoundingAdvisoryCommittee/UCM426984.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 20.

71. On June 29, 2016, I obtained from FDA's website the CV of Tobacco Products Safety Advisory Committee member Gary Giovino, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM436737.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 21 at 4-8.

72. True and correct copies of the pertinent pages of the CV for Brian Appleby as released to Public Citizen by CBER are attached as Exhibit 21 at 1-3.

73. On June 30, 2016, I obtained from FDA's website the CV of Psychopharmacologic Drugs Advisory Committee member David Brent, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM434876.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 22 at 1-6.

74. True and correct copies of the pertinent pages of the CV of Abdelmonem Afifi as released to Public Citizen by CDRH are attached as Exhibit 22 at 7-12.

75. True and correct copies of the pertinent pages of the CV of Evan Snyder as released to Public Citizen by CBER are attached as Exhibit 22 at 13-20.

76. On June 29, 2016, I obtained from FDA's website the CV of Antimicrobial Drugs Advisory Committee member Amanda Corbett, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM471800.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 23 at 1-9, and as Exhibit 24 at 4-5.

77. On June 29, 2016, I obtained a copy of Amanda Corbett's unredacted CV from her faculty page on the website of the University of North Carolina Eshelman School of

Pharmacy, available at https://pharmacy.unc.edu/files/2015/06/Corbett-CV-Nov2015.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 23 at 10-18.

78. True and correct copies of the pertinent pages of the CV for Alan Russell as released to Public Citizen by the Office of the Commissioner are attached as Exhibit 24 at 1.

79. On June 29, 2016, I obtained a copy of the CV of Arthritis Advisory Committee member Mara Becker, available at, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM466135.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 25.

80. True and correct copies of the pertinent pages of the CV of Orthopaedic and Rehabilitation Devices Panel member Kimberly Amrami as released to Public Citizen by CDRH are attached as Exhibit 26.

81. On June 29, 2016, I obtained a copy of the CV of Orthopaedic and Rehabilitation Devices Panel member Raj Rao, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM419379.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 27 and also as Exhibit 31 at 13-14.

82. On June 29, 2016, I visited the faculty page for Caleb Alexander, available at http://www.jhsph.edu/faculty/directory/profile/2761/caleb-alexander. A true and correct copy of the "print view" of his faculty page is attached as Exhibit 28 at 9-11.

83. On June 30, 2016, I obtained from FDA's website a copy of the CV of Pulmonary Allergy Drugs Advisory Committee member Dennis Ownby, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulm

onary-AllergyDrugsAdvisoryCommittee/UCM389191.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 29 at 2-3 and Exhibit 30 at 1-2

84. On June 30, 2016, I obtained from FDA's website a copy of the CV of Pulmonary Allergy Drugs Advisory Committee member Steven Georas, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM377188.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 29 at 4.

85. On June 30, 2016, I obtained from FDA's website a copy of the CV of Pulmonary Allergy Drugs Advisory Committee member Jennifer Li, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM362049.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 29 at 5.

86. On June 30, 2016, I visited the "Look Up A Licensee" webpage of the Georgia Composite Medical Board, http://medicalboard.georgia.gov/look-licensee. I searched for "Ownby" and clicked to view the physician profile of Dennis Ownby. That physician profile is available at http://www.gaphysicianprofile.org/profile.ShowProfileAction.action?lic_nbr=044978. A true and correct copy of the printed version of that physician profile webpage is attached as Exhibit 30 at 3-6.

87. On June 30, 2016, I obtained from FDA's website a copy of the CV of Bone, Reproductive and Urologic Drug Advisory Committee member Vivian Lewis, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM404036.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 31 at 1-3.

88. On June 30, 2016, I obtained from FDA's website a copy of the CV of Endocrinologic and Metabolic Drugs Advisory Committee member William Hiatt, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM354664.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 31 at 4-6.

89. On June 30, 2016, I obtained from FDA's website a copy of the CV of Gastrointestinal Drugs Advisory Committee member Linda Feagins, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/GastrointestinalDrugsAdvisoryCommittee/UCM405981.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 31 at 7-9.

90. On June 30, 2016, I obtained from FDA's website a copy of the CV of Anesthesiology and Respiratory Therapy Devices Panel member Steven Nathan, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/AnesthesiologyandRespiratoryTherapyDevicesPanel/UCM442331.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 31 at 10-12.

91. True and correct copies of the pertinent pages of the CV of Kurt Ribisl as released to Public Citizen by CTP are attached as Exhibit 32 at 1-2. A true and correct copy of Kurt Ribisl's entire CV as released to Public Citizen by CTP is attached as Exhibit 41 at 1-22.

92. On June 30, 2016, I visited the faculty profile webpage for Kurt Ribisl on the website of the University of North Carolina, Gillings School of Global Public Health, and obtained a copy of his CV, available at http://sph.unc.edu/files/2016/06/

HB_cv_ribisl_june2016.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 32 at 3-4 and Exhibit 41 at 58-63.

93. True and correct copies of the pertinent pages of the CV of Edgar Marcuse as released to Public Citizen by CBER are attached as Exhibit 32 at 5-6.

94. On June 30, 2016, I obtained a copy of the CV of Edgar Marcuse from the website of BestStart Washington, for which he is listed as a co-founder and Board member, http://beststartwa.org/about/leadership/. His CV is available at http://beststartwa.org/cms/wp-content/uploads/Edgar-Marcuse-CV.pdf, and a true and correct copy of that CV is attached as Exhibit 32 at 7-9.

95. True and correct copies of the pertinent pages of the CV of Dental Products Panel member William Giannobile as released to Public Citizen by CDRH are attached as Exhibit 33 at 5-8.

96. On June 30, 2016, I obtained from FDA's website a copy of the CV William Giannobile, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/UCM382729.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 33 at 1-4.

97. True and correct copies of the pertinent pages of the CV of Marjorie Jeffcoat as released to Public Citizen by CDRH are attached as Exhibit 33 at 10.

98. On June 30, 2016, I obtained from FDA's website a copy of the CV of Dental Products Panel member Marjorie Jeffcoat available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryC

ommittee/DentalProductsPanel/UCM393309.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 33 at 9.

99. On June 30, 2016, I obtained from FDA's website a copy of the CV of Ophthalmic Devices Panel member Jayne Weiss, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/UCM423996.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 34.

100. On June 30, 2016, I obtained from FDA's website a copy of the CV of Orthopaedic and Rehabilitation Devices Panel member Maureen Finnegan, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/UCM419381.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 35.

101. On June 30, 2016, I obtained from FDA's website a copy of the CV of Ophthalmic Devices Panel member Andrew Huang, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/UCM424000.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 36 at 1-2.

102. On June 30, 2016, I visited the faculty page for Andrew Huang, available at http://ophthalmology.wustl.edu/Faculty/Huang_A.aspx. A true and correct copy of the printed version of that faculty page is attached as Exhibit 36 at 3.

103. On June 30, 2016, I obtained from FDA's website a copy of the CV of Ophthalmic Devices Panel member Kuldev Singh, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryC

ommittee/OphthalmicDevicesPanel/UCM378427.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 36 at 4-6.

104. On June 30, 2016, I visited the faculty page for Kuldev Singh, available at https://med.stanford.edu/profiles/kuldev-singh?tab=bio. A true and correct copy of the printed version of that faculty page is attached as Exhibit 36 at 7-9.

105. On June 30, 2016, I obtained from FDA's website a copy of the CV of Psychopharmacologic Drugs Advisory Committee member Thomas Grieger, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM402229.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 37 at 1-5.

106. On June 30, 2016, I obtained a copy of Thomas Grieger's CV from his website, http://www.griegermd.com. That CV is available at http://griegermd.com/Thomas%20Grieger%20Curriculum%20Vitae.pdf, and true and correct copies of the pertinent pages of that CV are attached as Exhibit 37 at 6-10.

107. On June 30, 2016, I obtained from FDA's website a copy of the CV of Psychopharmacologic Drugs Advisory Committee member David Pickar, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM451488.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 37 at 11-13.

108. On June 30, 2016, I obtained a copy of David Pickar's CV from his website, http://www.davidpickar.com/background/biography/. That CV is available at http://www.davidpickar.com/wp-content/uploads/2015/07/CV_Pickar_6.24.5.pdf, and true and correct copies of the pertinent pages of that CV are attached as Exhibit 37 at 14-15.

109. On June 30, 2016, I obtained from FDA's website a copy of the CV of Anesthesiology and Respiratory Therapy Devices member Christopher Lettieri, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/AnesthesiologyandRespiratoryTherapyDevicesPanel/UCM442336.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 37 at 16-17.

110. A true and correct copy of the CV of K.B. Wallace as released to Public Citizen by CFSAN in October 2014 is attached as Exhibit 38 at 1-25.

111. A true and correct copy of the CV of K.B. Wallace as released to Public Citizen by CFSAN in March 2015 is attached as Exhibit 38 at 26-39.

112. A true and correct copy of the CV of James Swain as released to Public Citizen by CFSAN in October 2014 is attached as Exhibit 39 at 1-15.

113. A true and correct copy of the CV of James Swain as released to Public Citizen by CFSAN in March 2015 is attached as Exhibit 39 at 16-29.

114. On June 30, 2016, I obtained from FDA's website the CV of Nonprescription Drugs Advisory Committee member Christianne Roumie, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/UCM363827.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 40.

115. On July 8, 2016, I searched Google for "sph.unc.edu kurt m. ribisl 2012 curriculum vitae" and the third result was a link to Kurt Ribisl's CV, dated June 4, 2012, as posted on his faculty page, available at https://sph.unc.edu/files/2013/07/706269233_cv.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 41 at 49-52.

116. On July 8, 2016, I searched Google for "ribisl june 2015 cv" and the first result was a link to Kurt Ribisl's CV, dated June 2015, as posted on his faculty page, available at https://sph.unc.edu/files/2015/08/HB_cv_ribisl_june2015.pdf. True and correct copies of the pertinent pages of that CV are attached as Exhibit 41 at 53-57.

117. On July 8, 2016, I searched Google for "kurt ribisl fda advisory committee cv" and the first result was a link to Kurt Ribisl's CV, dated April 22, 2015, as posted on FDA's website, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM455747.pdf. A true and correct copy of that CV is attached as Exhibit 41 at 23-48.

118. True and correct copies of the pertinent pages of the CV of Richard Durst, as released to Public Citizen by CFSAN in October 2014 are attached as Exhibit 42 at 1.

119. True and correct copies of the pertinent pages of the CV of Richard Durst, as released to Public Citizen by CFSAN in March 2015 are attached as Exhibit 42 at 2.

120. On July 8, 2016, I obtained a copy of Richard Durst's CV from his faculty page, available at http://blogs.cornell.edu/durst/curriculum-vitae/. True and correct copies of the pertinent pages of that CV are attached as Exhibit 42 at 3-4.

121. True and correct copies of the pertinent pages of the CV of Richard Weber, as released to Public Citizen by CBER, are attached as Exhibit 33 at 11.

122. True and correct copies of the pertinent pages of the CV of Leisha Emens, as released to Public Citizen by CBER, are attached as Exhibit 33 at 12.

Pursuant to 28 U.S.C. § 1746, I hereby certify under penalty of perjury that the foregoing is true and correct.

Executed in Washington, D.C. on July 11, 2016.

/s/ Rachel M. Clattenburg
Rachel M. Clattenburg

EXHIBIT 1

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

February 4, 2014

Margaret Hamburg
Officer of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Elizabeth Dickinson
Office of Chief Counsel
Food and Drug Administration
White Oak 32, Room 4532
Silver Spring, MD 20993

Dear Commissioner Hamburg and Chief Counsel Dickinson:

We are writing concerning the redactions on the curricula vitae of advisory committee members that are posted on the FDA's website. A great many of the members' CVs have significant redactions with the notation either (b)(4) or (b)(6), referring to the Freedom of Information Act (FOIA) exemptions from disclosure that protect confidential commercial information and personal privacy. These redactions are unjustified under FOIA, and we ask that you promptly revise the web pages so that CVs appear in full. Further, we ask that you ensure that CVs posted in the future are not redacted in this way.

The extent of the agency's redactions is significant. The agency is redacting information from an overwhelming majority of CVs. Of the 180 CVs posted for members of Center for Drug Evaluation and Research advisory committees as of January 29, 2014, 167 have redactions—93 percent. Similarly, of the 68 CVs posted for members of Center for Biologics Evaluation and Research advisory committees, 64 had redactions—94 percent. Of the 15 posted CVs for the Food Advisory Committee, 12 are redacted—80 percent. Of the 132 CVs posted for committees of the Center for Devices and Radiological Health, 132 had redactions—100 percent. Of the 11 CVs posted for members of the Tobacco Products Scientific Advisory Committee, 10 have redactions.

The redactions appear to be wholly unwarranted by any legitimate need or the FOIA exemptions on which they purportedly are based.

The Exemptions Used

Although some CVs (including all CVs from device-related advisory committees) show redactions with no indication of the basis for them, the majority of the redactions are designated as (b)(4) or (b)(6).

The bulk of the FDA redactions are labeled "(b)(4)." Exemption 4 protects from disclosure "trade secrets or commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Where, as here, the information is provided to the government as a condition of obtaining a government benefit (here, membership in an advisory committee), the exemption does not apply unless disclosure is "likely to cause" the person who submitted it "substantial competitive harm" or likely "to impair the Government's ability to collect necessary information in the future." *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992). Where information is provided to the government voluntarily, exemption 4 applies only where the information "is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Critical Mass*, 975 F.2d at 880. The redactions designated (b)(4) easily fail even the less rigorous standard.

Almost by definition, the fact that information is included on a CV disqualifies it from falling within the scope of exemption 4, because information included on a CV cannot conceivably be "trade secret" or "confidential," even if it were "commercial or financial." Indeed, it is difficult to conceive of how an academic appointment, presentation, or delivered speech can be considered "confidential," yet many are redacted with that designation. Some of the redacted information is decades old, making the claim even more tenuous and often simply frivolous.

Notably, in some instances, the same CV that the FDA has redacted to protect "confidential" "commercial or financial" information appears elsewhere online unredacted, such as on the website of the medical school at which a member is on the faculty. The same CVs that the FDA redacted, even some that it redacted significantly, invariably had no redactions at all when we found them elsewhere. Similarly, some members appear on the website LinkedIn, where the descriptions they created for themselves seem to reveal information that the FDA redacted on the ground that the information is "confidential."

Exemption 6 protects from disclosure information "the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "[T]he test is not merely whether the information is in some sense personal but whether it is 'of the same magnitude as highly personal or as intimate in nature as that at stake in personnel and medical records.'" *Kurzon v. HHS*, 649 F.2d 65, 68 (1st Cir. 1981) (quoting *Board of Trade of the City of Chicago v. Commodity Futures Trading Comm'n*, 627 F.2d 392, 398 (D.C. Cir. 1980)). "Information relating to business judgments and relationships does not qualify for exemption…. This is so even if disclosure might tarnish someone's professional reputation." *Washington Post Co. v. DOJ*, 863 F.2d 96, 101 (D.C. Cir. 1988) (citing *Sims v. CIA*, 642 F.2d 562, 574 (D.C.Cir.1980)).

On its face, the notion that a rational person would include on her CV information that satisfies this standard is hard to fathom. Again, this observation is supported by the CVs we found on other websites and on LinkedIn.

Examples of Typical Redactions

Examples illustrate the problem. We use these examples because unredacted versions of these CVs were available elsewhere online, not to say anything in particular about these individual advisory committee members. The fact that each has posted his or her unredacted CV elsewhere strongly suggests that the FDA is making the redactions on its own initiative. The unredacted versions reveal that the FDA's redactions are random and unwarranted.

For instance, the FDA redacted portions of the CV of Yu Shyr, a member of the Anti-Infective Drugs Advisory Committee, including entries under "Teaching, Workshops, and Seminars."[1] This member's CV is also posted on the website of Vanderbilt Medical School.[2] Comparison of the two shows that the FDA made so-called (b)(4) redactions for information about seminars and papers such as

> "The Challenges of the High-Density Biomarker Adaptive Trials," seminar given at Adaptive Designs in Clinical Drug Development, London, England, 2012.
>
> "Statistical Bioinformatics Challenges for Clinical Trial Design in the Era of High-Density Data Analysis," seminar given at AACR Annual Meeting, Chicago, IL, 2012.
>
> Hansen AG, Freeman T, Washington MK, Fan K, Shyr Y, Beauchamp RD, Zijlstra A. Elevated alcam shedding in colorectal cancer correlates with poor patient outcome. Abstract presented at: Markers in Cancer: A Joint Meeting by ASCO, EORTC, and NCI, Hollywood, FL, October 11-13, 2012.

The (b)(6) redactions cover information including the name of a co-editor on the Journal of Concrete and Applicable Mathematics, and this item under "Academic Service": "1998 Chinese Youth Goodwill Mission from Taiwan: Co-sponsor, 1998." Other (b)(6) redactions include the fact that Dr. Shyr gave a presentation in 2005 "With Dr. Don Hong" and participation in this event: "47th Anniversary Annual Conference, The American Associate for Chinese Studies: Chair and local organizing committee: Member, Nashville, TN, 2005." In addition, the (b)(6) redactions include all content under "Mentoring," which is publicly available in full through his bio page on the Vanderbilt website.

[1] The CV is posted on the FDA's website here: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM326163.pdf.

[2] The CV is available through a link from Dr. Shyr's page on the Vanderbilt website: https://medschool.vanderbilt.edu/cqs/people/Yu/Shyr/cqs-faculty-members.

The CV of Amanda Corbett, a member of the Antiviral Drugs Advisory Committee, is also available in full online.[3] On the FDA website, her CV has extensive (b)(4) redactions in several categories.[4] On her list of 19 funded grants, the FDA has blacked out 9, including:

> Corbett A, Principal Investigator. Pharmacokinetics of Lopinavir/ritonavir in Breast milk and Breastfeeding Infants. Abbott Laboratories. October 2008 - December 2009. $31,000.
>
> Corbett A, Principal Investigator. Characterization of novel antiretroviral resistance among HIV-infected patients in the UNC-CH cohort. Virco Laboratories. May 2008 - December 2009. $15,000.
>
> Kashuba, ADM, Principal Investigator, Corbett A, Co-Investigator. Eron J, Co-Investigator. The Pharmacokinetic Interaction of a Triple Protease Inhibitor Regimen Containing Fosamprenavir, Lopinavir and Ritonavir in Healthy Volunteers. GlaxoSmithKline (Investigator Initiated Research), 2002 - 2003. $59,000.
>
> Kashuba ADM, Principal Investigator, Corbett A, Co-Investigator. Ortho-McNeil Infectious Diseases Academic Fellowship. American College of Clinical Pharmacy. 2002 – 2003. $20,000.

The FDA has also redacted all 4 items on her list of "Grants and Contracts Submitted (not funded)," 17 of 18 "Research Initiatives," and 4 of her 22 "Manuscripts and Reviews." Not one of these redactions appears to be covered by exemption 4—even putting aside the immediately disqualifying fact that the CV is available in full online. In the latter category, all 4 redacted items are articles that have been published, such as:

> Brown K, Hosseinipour M, Hoskins J, Tien H, Kazembe P, McLeod H, Kashuba A, Corbett A. Genotype correlation in nevirapine exposures in Malawians. Pharmacogenomics 2012;13(1):113-121.

One is even available electronically on a government website, PubMed.gov[5]:

> Heil E, Corbett A. Guidelines for the use of extended-release nevirapine in HIV-infected patients. Expert Opin pharmacother 2011; epub ahead of print.

Yet the FDA has blacked it out, with a designation indicating that it is "confidential" and "commercial" information.

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[3] The CV is posted here: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&ved=0CCwQFjAA&url=https%3A%2F%2Fpharmacy.unc.edu%2FDirectory%2Fahcorbet%2Fcurriculum-vitae%2Fat_download%2Fcv&ei=cRlwUs3zMqOEyAGV7YDgDg&usg=AFQjCNG0piJWbNW9PnuPHicUEa2MsL7RPw&sig2=toM00bI.

[4] The CV is posted on the FDA's website here: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/200bDrugs/200bAntiviralDrugsAdvisoryCommittee/UCM310262.pdf.

[5] http://www.ncbi.nlm.nih.gov/pubmed/22035406.

Among the silly (b)(6) "privacy" redactions" are the number of her North Carolina pharmacy license (available online both through her unredacted CV and through the North Carolina Board of pharmacy),[6] the fact of her Reiki training, and the names of the directors of the university programs through which she got her pharmacy education and training in 1999-2001.

The CV of Jennifer Kuzma, a member of CBER's Blood Products Advisory Committee, similarly illustrates that the FDA's redactions are unjustified by (b)(4) and (b)(6).[7] [8] The FDA redacted with the (b)(4) notation every one of her "Manuscripts in Preparation," although the CV posted on her university's website includes the full information. The FDA redacted as (b)(4) and/or (b)(6) a great deal of information about her recent grant support, although she posts it in full on her university's website. The FDA redacted as (b)(6) the names of her student advisees and research assistants, including in one instance the name of a prize awarded to one of her advisees, and the names of her mentors in the early to mid-1990s, when she was a research fellow and a PhD candidate. Not only is this information included in the CV on her university's website, it plainly presents no legitimate invasion-of-privacy concern.

Finally, the FDA posting of the CV of Maria Luz Fernandez, a member of the Food Advisory Committee, redacts (with no exemption indicated) her 6 most recent publications.[9] Not surprisingly, the CV as posted on her university's website shows all of her publications.[10]

Again, the Shyr, Corbett, Kuzma, and Fernandez CV redactions are illustrative of the problem, but the redactions on their CVs appear to be no different in kind from those on the many other redacted CVs on the FDA's website. We could have chosen any number of other member CVs to make the point.

Conclusions

The very notion that a CV would include confidential commercial or financial information or information the disclosure of which a person would consider to violate his personal privacy is at odds with the very nature of a CV. The CV is written by a person for the purpose of touting her education and accomplishments to other people. The person chooses what information to include and how to state it. If the person thought that a piece of information was too private to make public or that its private nature outweighed its value on the CV, she would not include in the first place. Similarly, the fact that a piece of information is on a CV belies the notion that the information is "confidential." Confidential information does not appear on documents crafted for the express purpose of sharing with other people.

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[6] http://www.ncbop.org/ncbop_verification.htm.
[7] The unredacted CV on the website of the University of Minnesota is available from a link on this page: http://www.hhh.umn.edu/people/jkuzma/.
[8] The CV is posted on the FDA's website here: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/UCM277892.pdf.
[9] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm226096.htm.
[10] http://www.canr.uconn.edu/nutsci/nutsci/hpg/mluz.html.

The CV redactions are troubling for several reasons. First, they appear to be completely unjustified by the FOIA exemptions on which they are purportedly based and, for that reason, suggest a lack of training within the agency as to the scope of FOIA exemptions.

For example, citing "(b)(6)," the FDA has broadly redacted the names of co-investigators, mentors, trainees, and even co-authors. Exemption 6, however, does not provide a general protection from disclosure for names of individuals within a document in the government's possession; it protects such disclosure only when revealing a name would constitute a "clearly unwarranted invasion of personal privacy." "[I]nformation connected with professional relationships does not qualify for the exemption." *Sims v. CIA*, 642 F.2d at 574; *id*. at 575 ("[E]xemption 6 was developed to protect intimate details of personal and family life, not business judgments and relationships."). Similarly, the FDA has often redacted the year in which a member graduated from college or graduate school. Such information on its face does not seem "private," but even beyond that, disclosure of the characteristics of people chosen by the FDA to serve on advisory committee sheds light on the FDA decision making, and thus serves a public interest that would seem easily to outweigh any privacy interest.[11]

Likewise, information about professional training, experience, and publications does not fall within the scope of exemption 6. "Exemption 6 was developed to protect details of personal and family life, not information regarding professional activities." *Camaranesi v. DOJ*, 941 F. Supp. 2d 1173, 1185 (N.D. Cal. 2013).

The FDA specifies "(b)(4)" for a range of redactions including the titles of presentations and publications, and information about research grants, both funded and unfunded. Even putting aside the problem that very little of the information would qualify as "commercial or financial," unless the presentations were made under a cone of silence and the publications printed in secret journals (possibilities excluded by the fact that the publicly available, unredacted CVs provide citations), the information could not possibly be considered confidential. On the whole, the many (b)(4) redactions appear to be without method or pattern, making it difficult even to say what erroneous rationale was guiding the agency when it redacted the CVs.

Indeed, a great many CVs are redacted with *no* indication of why. The CVs of members of device advisory committees offers 132 examples of this practice. Further, the information redacted in these examples is hard to reconcile with any FOIA exemption. For instance, on almost all the device-committee CVs, the dates of educational degrees are redacted, and often the dates of professional training and internships. Professionals include such information on CVs because it is not private and is relevant to the assessment of professional experience. We cannot help but wonder whether the failure to indicate a FOIA exemption for such redactions reflects a recognition that none applies.

Second, we are concerned that the redactions reflect an agency view that favors secrecy over disclosure. FOIA is a pro-disclosure statute. Its exemptions, as the courts have long recognized, are to be narrowly construed. *Milner v. U.S. Dep't of Navy*, 131 S. Ct. 1259, 1262

[11] One advisory committee member included his social security number on his CV, and the FDA redacted the number. This redaction seems to be a unique instance of the FDA identifying information that the member should have kept private and redacting it for the member's own good.

(2011). "[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976). We are concerned that the CV redactions evidence a general policy that flips the FOIA presumption of disclosure, by favoring non-disclosure over disclosure.

Third, because the redaction of advisory committee member CVs is unjustified by FOIA, the FDA staff has wasted considerable time identifying lines to black out among long lists of academic credentials, presentations, and appointments on hundreds of CVs. Now, more time will be required to unredact the CVs—which should be done promptly. The decision to spend time on the unwarranted review and redaction of CVs, when the FDA's backlog of FOIA requests is considerable, shows a poor use of resources that likely harmed FOIA requesters waiting months and sometimes years for responses to requests.

Fourth, the redactions deny the public an easy way to learn complete information about the qualifications and background of advisory committee members. Although the public may be able to find full CVs elsewhere for some members, the public should not have to search for complete information when the agency lacks justification for redacting it.

Accordingly, we request that you correct the situation by promptly unredacting the CVs. In addition, we urge that staff responsible for redacting the CVs be (re)trained on the proper approach to FOIA and that overall FDA FOIA training be evaluated to ensure that staff understand the purpose of the statute and the narrow scope of the exemptions.

Please do not hesitate to contact me if I can answer any questions. Thank you for your prompt attention to this matter.

Sincerely,

Sidney M. Wolfe, MD
Founder and Senior Advisor
Public Citizen Health Research Group

Allison M. Zieve
Director
Public Citizen Litigation Group

EXHIBIT 2

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

Sidney M. Wolfe, MD
Founder and Senior Advisor
Public Citizen Health Research Group

JUL 2 2014

Allison M. Zieve
Director
Public Citizen Litigation Group

Dear Dr. Wolfe and Ms. Zieve:

This correspondence responds to your letter to Commissioner Hamburg and Chief Counsel Dickinson, dated February 4, 2014, concerning redactions to the curricula vitae (CV) of advisory committee members that are posted on the website of the United States Food and Drug Administration (FDA or we). Your letter expresses concern about "significant redactions" of information that you asserted were based on the improper use of exemptions from disclosure under the Freedom of Information Act (FOIA). Your letter requests that FDA revise its web pages so that the CVs appear without redaction and that FDA ensure that CVs posted in the future are not redacted.

As explained below, most of the specific issues raised in your letter qualify for an exemption from disclosure under FOIA, and the CVs generally appear to be properly redacted. Going forward, however, we are taking additional steps to ensure that the different FDA offices which redact these CVs are doing so correctly and referencing the appropriate FOIA exemption for each redaction.

FDA is also working to respond to your FOIA request, dated May 19, 2014, requesting unredacted copies of these CVs. FDA's FOIA staff of the various agency components will process your request on a first-in first-out basis within that component and will respond to you directly. If FDA identifies significant differences between the redactions to the CVs that are provided in response to this FOIA request and the CVs that are posted on FDA's website, to the extent that program resources permit FDA to convert them to the 508-compliant format for web posting, FDA will make them available on FDA's website.

We note that the posting of these CVs on our website is not required under FOIA or under the Federal Advisory Committee Act. Rather, FDA has proactively posted these CVs to provide additional information for the benefit of the public and to facilitate openness. In addition, we believe that the type of information that FDA makes public about its advisory committee members is consistent with the information that other federal agencies generally make available on their websites.

Before explaining the kinds of privacy and confidential commercial information that FDA generally redacts from CVs, I wanted to address several misperceptions in your letter. First, your

letter appears to suggest that information should not be considered confidential by virtue of the fact that the information is contained in a CV. We acknowledge that individuals often make their CVs public; however, FDA's responsibility is to ensure that nonpublic information is redacted when disclosing all documents to the public, regardless of the format in which the information appears. The CVs at issue were not provided to FDA for the purpose of making the information publicly available; rather, FDA required that its advisory committee members submit CVs to FDA for the purpose of providing FDA with information about their qualifications, including their work and academic history.

To limit the need for the redaction of information from CVs going forward, FDA plans to request, prior to the time the CV is submitted, that advisory committee members verify that they have removed confidential information from their CVs, such as confidential commercial information or personal privacy information. FDA also plans to request consent to disclose of the remaining information in the CV. As discussed further below, these steps will not eliminate all need for FDA review or the potential that certain information will still need to be redacted, but these steps should work to alleviate some of the concerns expressed in your letter.

Second, you note that it appears that the exact information subject to redaction on FDA's website is publicly available elsewhere in an unredacted form. In reviewing the CVs for proactive posting, we do not conduct searches of other possible domains in which the information included in an individual's CV may have otherwise been publicly disclosed to determine whether privacy or confidentiality may have been waived, as conducting such a review for the large number of CVs would be unduly burdensome. In addition, some CVs contain confidential commercial information or personal privacy information about a third party. For example, if an individual makes public information about an ongoing clinical trial that constitutes confidential commercial information (CCI), the confidentiality of the information is not waived.[1] As a result, FDA conducts an independent review of information in the CV to determine whether information in the CV must be withheld.

Finally, the redactions completed by FDA before posting CVs on our website is done at a single discreet point in time, and information is redacted consistent with our understanding of the applicable FOIA exemptions at the time the redactions are made. FDA is not obligated, nor would it be a wise use of FDA's limited resources, to review the posted CVs on an ongoing basis to verify whether redactions that were applicable at one time are still applicable. For example, FDA redacts as CCI most references to ongoing clinical trials. Such information may subsequently no longer constitute CCI once the product obtains approval. Assuming an ongoing obligation to update information that we voluntarily make available publicly would result in a substantial burden in terms of agency resources and is not legally required.

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[1] *See, e.g.,* Nat'l Archives & Records Admin v. Favish, 541 U.S. 157, 158 (2004) (accepting concept that unofficial leak and subsequent publication of death-scene photograph of body of presidential aide did not prevent agency from invoking Exemption 7(C) to protect privacy of surviving family members); Hanson v. U.S. Agency for Int'l Dev., 372 F.3d 286, 294 (4th Cir. 2004) (finding no waiver when attorney consulting for federal agency unilaterally released documents that he authored during course of attorney-client relationship between him and agency); Medina-Hincapie v. Dep't of State, 700 F.2d 737, 742 n.20 (D.C. Cir. 1983) (holding that official's ultra vires release does not constitute waiver).

REDACTIONS OF PERSONAL PRIVACY INFORMATION

FDA redacts personal privacy information such as the following prior to releasing documents under FOIA:

- Social Security number
- Home address, home phone number, personal cell phone number, home FAX, home e-mail address
- Race, gender, national origin
- Citizenship
- Marital or family relationships
- Birth date, place of birth, age
- Height, weight
- References to disability or other personal health information
- Names and related data of personal references
- Information related to relatives
- Information related to hobbies/outside activities not related to the primary job at FDA
- Name, address, and phone number of colleagues for private sector employment
- All references to non-government salary
- Military service not pertinent to FDA service
- Grades or transcripts; dates degrees were conferred (unless specific information is pertinent to FDA service)
- Medical board and professional association certification numbers
- Amounts of royalties received
- Names of graduate or doctoral students supervised, and any information relating to those students
- References to security clearances

Though the degree varies to which the information in the above examples are generally considered private, there is, in most cases, little, if any, public interest in disclosure of such information.[2] The redaction of the above-noted information is consistent with FOIA as well as existing federal regulations. *See, e.g.*, 5 CFR 293.311, 21 CFR 20.110.

Going forward, FDA will request that advisory committee members verify the removal or confidential information from their CVs and consent to the release of privacy information that is specific to that individual. However, even with such consent, FDA will continue to redact CVs for privacy information relating to other people.

REDACTIONS OF CONFIDENTIAL COMMERCIAL INFORMATION

Exemption 4 of FOIA protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4). Many of the CVs that

[2] *See Davis v. United States Dep't of Justice*, 968 F.2d 1276, 1282 (D.C. Cir. 1992) ("But even if a particular privacy interest is minor, nondisclosure remains justified where . . . the public interest in disclosure is virtually nonexistent.").

contain redactions made under Exemption 4 include information confidential financial information relating to non-government funded grants or information about an individual's participation in pending clinical trials or clinical trials that have not otherwise been publicly announced. Such information falls squarely within the bounds of Exemption 4 and is prohibited from disclosure under FDA's regulations, such as 21 CFR 314.430. The individual submitting the CV does not necessarily have the authority to make publicly available information that FDA is otherwise required by law to keep confidential. Significantly, a specific criminal statute, the Trade Secrets Act, 18 U.S.C. § 1905 (2006), prohibits the unauthorized disclosure of most information falling within Exemption 4; its practical effect is to constrain an agency's ability to make a discretionary disclosure of Exemption 4 information in the absence of an agency regulation (based upon federal statute) that expressly authorizes disclosure. [3]

In addition, FDA redacts information about pending publications because some individuals may have a commercial interest in keeping their studies confidential until they are published. Going forward, we will request consent from advisory committee members to make this information on their CVs publicly available.

CONCLUSION

The redactions made to the CVs of advisory committee members posted to our website are intended to reflect federal regulations and FOIA exemptions. Going forward, we will ensure that the relevant exemption is referenced where information is redacted, and we are taking steps that may lead to our ability to release additional information without redaction by requesting that the submitter of information verify that confidential information has been omitted from the CV and consent to the disclosure of the remaining information. We must, however, continue to take steps to ensure the confidentiality of certain information, and we will not be revising our web pages so that all of the CVs of advisory committee members are posted without redaction.

Sincerely,

Sarah B. Kotler -A

Digitally signed by Sarah B. Kotler -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300224183, cn=Sarah B. Kotler -A
Date: 2014.07.02 11:41:37 -04'00'

Sarah Kotler, JD
Deputy Director, Division of Freedom of Information
Office of the Commissioner, Office of the Executive Secretariat
U.S. Food & Drug Administration

[3] See, e.g., CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1144 (D.C. Cir. 1987); Chrysler Corp. v. Brown, 441 U.S. 281, 295-96 (1979); St. Mary's Hosp., Inc. v. Harris, 604 F.2d 407, 409-10 (5th Cir. 1979). Note also that FDA regulations bar the release of personal privacy information. See 21 CFR 20.63.

EXHIBIT 3

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

PUBLICCITIZEN
1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

May 19, 2014

BY FAX (301-827-9267)
Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

To Whom It May Concern:

On behalf of Public Citizen and pursuant to the Freedom of Information Act, 5 U.S.C. § 552, we are writing to request unredacted copies of the curricula vitae of all FDA advisory committee members whose CVs are currently posted on the FDA's website.

Currently, the FDA has posted the majority of these CVs with redactions—some labeled (b)(4) or (b)(6) and many with no indication at all of what FOIA exemption the FDA believes might apply. The information on advisory committee members' CVs does not fall within the scope of these or any other FOIA exemptions. Because the current posting of CVs reflects FDA's recognition that advisory committee members' CVs should be publicly available, we ask that you respond to the request by posting unredacted copies of the CVs online, rather than by sending the CVs to Public Citizen.

Public Citizen requests a public-interest fee waiver of all fees associated with this request because it is a non-profit, non-partisan public interest organization that educates the public about health and safety issues. Public Citizen regularly publishes reports and articles based on information acquired through FOIA. Public Citizen also has a demonstrated capacity to disseminate this information. It disseminates its reports via publication, through its website, and through various newsletters that are distributed to consumers, lawyers, academics, and other interested parties free of charge. Public Citizen staff members also serve as a resource for the media and testify before Congress. In addition, Public Citizen has long worked on issues related to the functioning of advisory committees, including conflicts of interest. For example, Public Citizen commented on FDA Draft Guidance concerning disclosure of conflicts of interest for participants in FDA advisory committees in 2002, and sent the FDA a letter concerning a potential conflict of interest between a silicone implant advisory committee member and Inamed Aesthetics in 2003. In 2006, two of its staff co-authored an article published in the Journal of the American Medical Association entitled "Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings." Public Citizen has monitored the functioning of advisory committees, reflected for example in

its 2006 letter in the medical journal Lancet concerning suboptimum use of FDA drug advisory committees and its 2007 petition asking the FDA to require that certain advisory committee meetings include an FDA staff presentation.[1] Public Citizen staff have also testified at FDA advisory committee meetings on many occasions. Disclosure of the information requested is in the public interest because it is likely to contribute to the public's understanding of the operations of the FDA, in particular the advisory committees that the agency uses to advise it about product approvals, product labeling changes, and policy decisions.

We expect a response within 20 working days as provided by law. 5 U.S.C. § 552(a)(6)(A). If you have any questions regarding this request, please contact Allison Zieve by phone or at the email address below.

Thank you.

Sincerely,

Sidney M. Wolfe, MD
Public Citizen Health Research Group

Allison M. Zieve
Public Citizen Litigation Group
azieve@citizen.org

[1] Each of the documents mentioned above is available on Public Citizen's website from this page: www.citizen.org/Page.aspx?pid=2506.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

PUBLIC CITIZEN
ALLISON M ZIEVE
1600 20TH STREET, N.W.
WASHINGTON DC 20009-1001

05/27/2014

In Reply refer to:

2014-4316

Your reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

FDA ADVISORY COMMITTEE MEMBERS - CVS POSTED ON FDA'S WEBSITE

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact the undersigned to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

If you have any questions about your request, please call Sarah B. Kotler, Denials & Appeals Officer, at (301) 796-8976 or write to us at:

Food and Drug Administration
Division of Freedom of Information
12420 Parklawn Drive, Room 1050
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.

Sincerely,

Sarah B. Kotler
Denials & Appeals Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Rockville, MD 20857

JUN 03 2014

Allison M. Zieve
Public Citizen
1600 20th St., NW
Washington, DC 20009

In reply refer to: 2014-4316

Dear Requester:

This is in response to your Freedom of Information request (copy enclosed) for waiver of fees for documents requested under the Freedom of Information Act.

As provided by Food and Drug Administration regulations at 21 CFR 20.46, Department of Health and Human Services' regulations at 45 CFR 5.34, and based on your justification, a waiver of fees has been granted.

Sincerely Yours,

Frederick J. Sadler
Director
Division of Freedom of Information

Enclosures

EXHIBIT 4

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 11 2014

Sidney Wolfe
Allison Zieve
Public Citizen
1600 20th Street, NW
Washington, DC 20009

F14-4316

Dear Mr. Wolfe
Ms. Zieve

This is in response to your request of May 19, 2014 for unredacted copies of the curricula vitae of all FDA Food Advisory committee members whose CVs are currently posted on the FDA's website.

Responsive information may be obtained from the following URL:

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommitte/ucm120672.htm

____Enclosed are the records you requested.

____We have searched our files and find no responsive information.

____Your request is also being referred to one of our component offices.

____Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination with respect to these records and would like FDA to reconsider any particular deletion, please let us know in writing at the following address: Food and Drug Administration, Division of Freedom of Information, 12420 Parklawn Drive, Room 1050 Rockville, MD 20850 within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed with respect to these records. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges for this request to date may be included in a monthly invoice:

Reproduction$ 0 Search$ 0 Review$ 0 Other$ 0 Total:$ 0

THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST. PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE.

Sincerely yours,

Government Information Specialist
Executive Secretariat Staff
Office of Foods and Veterinary Medicine/
Center for Food Safety and Applied Nutrition

NO Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Division of Freedom of Information
12420 Parklawn Drive
Rockville MD 20857

August 26, 2014

In Response Refer to File: 2014-4316

Public Citizen
1600 20th Street, NW
Washington, DC 20009

Dear Mr. Wolfe,

This is in response to your May 19, 2014 request for documents from the Food and Drug Administration pursuant to the Freedom of Information Act regarding copies of the curricula vitae of FDA advisory committee members whose CVs are currently posted on FDA's website. Your request was received at the Center for Tobacco Products on May 27, 2014.

CTP conducted a search and located 199 pages responsive to your request, of which 199 pages are enclosed.

I have determined to withhold portions of 82 pages under the FOIA exemption (b)(6).

Exemption (b)(6) permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy.

Since you were granted a fee waiver no charges have been assessed.

If you have reason to believe that the information withheld should not be exempt from disclosure, you may appeal. Your appeal should be sent within 30 days from the date you receive this letter, to the Director, News Division, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Parklawn Building, Room 19-01, 5600 Fishers Lane, Rockville, MD 20857. Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

This concludes the response for the Center for Tobacco Products. If you have any questions, please contact the CTP FOIA electronic mailbox at CTPFOIA@fda.hhs.gov.

Sincerely yours,

Anna L. Postell -S

Digitally signed by Anna L. Postell -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300436275, cn=Anna L. Postell -S
Date: 2014.08.26 09:42:27 -04'00'

Anna Postell
Government Information Specialist
Food and Drug Administration
Center for Tobacco Products

Enclosures

PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

September 18, 2014

Director, News Division
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Parklawn Building, Room 19-01
5600 Fishers Lane
Rockville, MD 20857

Re: Freedom of Information Act Appeal
FOIA File 2014-4316

Dear Director:

I am writing to appeal the partial denial by the Center for Tobacco Products (CTP) and the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA) of a May 19, 2014, FOIA request sent to FDA on behalf of Public Citizen for unredacted copies of the curricula vitae of advisory committee members whose CVs are posted on the FDA's website. A copy of that request is attached.

Center for Tobacco Products

CTP responded to our FOIA request by letter dated August 26, 2014, enclosing a disc containing 10 CVs. A copy of CTP's response is attached. According to the cover letter, the disc contains a total of 199 pages, 82 of which have redactions under FOIA exemption (b)(6). Review of the pages reveals that several also have redactions labeled (b)(4). These same redactions appear on the FDA's website.[1] Both the (b)(6) and the (b)(4) redactions, however, are unjustified under FOIA.

Exemption 6: The bulk of the redactions are labeled (b)(6). Exemption 6 protects from disclosure information "the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "[T]he test is not merely whether the information is in some sense personal but whether it is 'of the same magnitude as highly personal or as intimate in nature as that at stake in personnel and medical records.'" *Kurzon v. HHS*, 649 F.2d 65, 68 (1st

[1] The CVs posted online, which appear to be the same as those sent to Public Citizen, can be accessed here: http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180906.htm.

Cir. 1981) (quoting *Bd. of Trade of the City of Chicago v. Commodity Futures Trading Comm'n*, 627 F.2d 392, 398 (D.C. Cir. 1980)). "Information relating to business judgments and relationships does not qualify for exemption. [citation omitted] This is so even if disclosure might tarnish someone's professional reputation." *Washington Post Co. v. DOJ*, 863 F.2d 96, 101 (D.C. Cir. 1988) (citing *Sims v. CIA*, 642 F.2d 562, 574 (D.C. Cir. 1980), and discussing exemption 7(C), which provides greater protection for personal privacy than exemption 6). "Exemption 6 was developed to protect details of personal and family life, not information regarding professional activities." *Camaranesi v. DOJ*, 941 F. Supp. 2d 1173, 1185 (N.D. Cal. 2013).

On its face, the notion that a rational person would include on her CV information that satisfies this standard is hard to fathom. This common-sense conclusion is illustrated by the fact that, in many cases, the same CVs that the FDA/CTP has redacted appear unredacted elsewhere online, such as on the website of the member's primary employer.[2] The same CVs that the FDA redacted invariably had no redactions at all when we found them elsewhere. The point is not that the FDA should search online to see whether members have posted their CVs, but the online CVs reflect that CVs are created for the purpose of disclosing activities that one thinks are relevant to one's professional life. They thus demonstrate that the FDA is inappropriately redacting the CVs.

A sample of the (b)(6) redactions illustrates the point. The FDA has redacted, for example, an item dated 1983-1984 on the CV of Warren Bickel under the heading "Awards and Training Fellowships." Dr. Bickel's CV appears as well, unredacted, on Virginia Tech's website, where one can see that the 1983-1984 item is "Postdoctoral Fellow, Interdisciplinary Research Fellowships in Mental Retardation, Autism, and other Developmental Disabilities. National Institute of Child Health and Development. Biological Sciences Research Center, University of North Carolina School of Medicine, Chapel Hill, North Carolina." Likewise, in a lengthy list of "Editorial Activities," including a large number described as "Guest Reviewer," the FDA has redacted the final item, which turns out to be "Guest Reviewer, Research in Developmental Disabilities." Both the fact that Dr. Bickel's unredacted CV is posted on the website of his primary employer and the content of the redacted material show that the FDA's redactions are not supported by exemption 6: Dr. Bickel has no more than a de minimis privacy interest in shielding the redacted information about his professional work from the public (and has apparently made no effort to do so), while the public plainly has an interest in knowing the professional activities of a member of an FDA advisory committee.

Not only does the content of the redactions show that they are unsupported by exemption 6, but often the content need not be examined to make that determination. For example, on Dr. Bickel's CV, the FDA has redacted 7 items under "Published Articles and Book Chapters" and 1 item under "Invited Presentations and Symposia." Likewise, the FDA has redacted under exemption 6 a portion of the titles of 2 investigations in which he was the principal investigator in 1994 and 1995. The assertion of a privacy interest in a *published* piece of professional work or presentation, or the chemical compound named in the title of a 20-year-old investigation, is frivolous.[3]

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[2] Although the public may be able to find full CVs elsewhere for some members, the public should not have to search for complete information when the agency lacks justification for redacting it.

[3] The compound is discussed in articles publicly available online.

Other CVs have similar unwarranted (b)(6) redactions. For example, the FDA has redacted from the CV of Philip Huang the number of his Texas medical license. License numbers, however, as the FDA surely knows, are public information. (Texas makes license numbers available online: http://www.tmb.state.tx.us/page/look-up-a-license.) Also redacted are the fact that Mr. Huang served on the Texas Diabetes Council from 1992-2008, and the names of 2 *published* articles and 6 presentations delivered at conferences. On Kurt Ribisl's CV, the names of numerous *published* articles, abstracts, and book chapters are redacted as "(b)(6)," as well as the topics of various dissertation committees on which he sat, master's theses on which he advised, and 2 items related to his work with the American Social Health Association. Again, these examples show not only that exemption 6 does not justify these specific redactions but, more generally, that the FDA is using exemption 6 as the basis for a far broader range of redactions than the exemption can justify.

In addition, citing "(b)(6)," the FDA has redacted the names of advisees and post-docs that are mentioned on some CVs. Exemption 6, however, does not provide a general protection from disclosure for names of individuals within a document in the government's possession; it protects such disclosure only when revealing a name would constitute a "clearly unwarranted invasion of personal privacy." "[I]nformation connected with professional relationships does not qualify for the exemption." *Sims v. CIA*, 642 F.2d at 574; *id*. at 575 ("[E]xemption 6 was developed to protect intimate details of personal and family life, not business judgments and relationships."). The redactions do not meet this standard.

Exemption 4: Exemption 4 protects from disclosure "trade secrets or commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). There is no colorable argument that the redacted information meets this standard, as the FDA's own regulation makes this clear. *See* 21 C.F.R. § 20.61(b) ("Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.").

Moreover, where information is provided to the government as a condition of obtaining a government benefit (here, membership in an advisory committee), that information can be deemed "confidential" only if its disclosure is "likely to cause" the person who submitted it "substantial competitive harm" or likely "to impair the Government's ability to collect necessary information in the future." *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992). Where information is provided to the government voluntarily, exemption 4 applies only where the information "is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Critical Mass*, 975 F.2d at 880.

The redactions designated (b)(4) easily fail even the less rigorous standard for voluntarily-submitted information. Almost by definition, and even more easily under the FDA's regulation, the fact that information is included on a CV disqualifies it from falling within the scope of exemption 4.

There is no argument that the redacted information is confidential or privileged, commercial or financial, as required for withholding under exemption 4. Like the (b)(6) redactions, a sample of the (b)(4) redactions illustrates the point:

• The FDA has redacted from Dr. Bickel's CV the names of 11 "Published Articles and Book Chapters" and 7 "Manuscripts in Preparation/Submitted."

• The FDA has redacted from Richard O'Connor's CV the names of 11 "publications in peer-reviewed journals" and 2 "publications in edited volumes."

• The FDA has redacted from Dr. Ribisl's CV the information that he served as a member of the Rape Prevention Social Marketing Committee of the North Carolina Department of Health Services, Injury Prevention and Control Section from 1999-2000.

• The FDA has redacted from Dr. Samet's CV the name of a recent published journal article. (The CV appears on the FDA's website without that redaction.[4]) The FDA also redacted the fact that Dr. Samet served as a consultant in 2001-2002 on the development team for Pfizer's product Exubera (an insulin product approved by the FDA in 2006 and withdrawn from the market in 2007).

These redactions are illustrative of the problem, but no different in kind from those on the other CVs redacted by the FDA/CTP.

More generally, the very notion that a CV would include confidential commercial or financial information, or information the disclosure of which a person would consider to violate his personal privacy is at odds with the very nature of a CV. The CV is written by a person for the purpose of touting her education and accomplishments to other people. The person chooses what information to include and how to state it. If the person thought that a piece of information was too private to make public or that its private nature outweighed its value on the CV, she would not include it.

FOIA is a pro-disclosure statute. Its exemptions, as the courts have long recognized, are to be narrowly construed. *Milner v. U.S. Dep't of Navy*, 131 S. Ct. 1259, 1262 (2011). "[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976). Although the availability of CVs online and the public nature of much (or all) of the redacted information is useful to show the silliness of some of the redactions, the agency should not have needed online searches to determine that the information is not exempt under FOIA.

Center for Food Safety and Applied Nutrition

CFSAN replied to the FOIA request by letter dated July 11, 2014, and received at Public Citizen on August 5, 2014. A copy of that letter is attached.

[4] *See* CV posted at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM392675.pdf, at page 45.

The letter from CFSAN does not state that it is a final decision and does not state how to appeal. It merely directs us to a page on the FDA website where CVs are posted. Those CVs have redactions, and they appear to be the same redactions as in May, when we submitted the FOIA request. Although the letter neglects to state that our request is being denied in whole or in part, it appears to be a denial. Rather than requesting from CFSAN a formal statement of denial and appeal rights, Public Citizen hereby appeals in full. The redactions of the CVs at issue in the CFSAN denial are similar in nature to the CTP redactions and unwarranted for similar reasons.

For the foregoing reasons, unredacted copies of the records produced by the FDA (both CTP and CSFAN) in response to the May 19 FOIA request should be disclosed. We are happy to accept the posting of unredacted copies of all requested records on the FDA website, as opposed to copies sent to us directly, in response to this request, provided that the agency acts within FOIA's time limits.

Sincerely,

Allison M. Zieve
Public Citizen Litigation Group

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

10/09/2014

PUBLIC CITIZEN
ALLISON M ZIEVE
1600 20TH STREET, N.W.
WASHINGTON DC 20009-1001

In Reply refer to:
2014-4316
Requester Control #:

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

FDA A/C MEMBERS - UNREDACTED CV

Please find enclosed revised versions of the CFSAN CVs. These records have been revised in response to your appeal.

The following charges for this request to date may be included in a monthly invoice:

Reproduction	Search	Review	Fiche	Other	Total
Reproduction=$0.00	Search=$0.00	Review=$0.00	Fiche=$0.00	Other=$1.00	Total=$1.00

All communications regarding this request should be addressed to: Division of Freedom of Information, 5630 Fishers Lane, Room 1035, Rockville, MD 20857.

Sincerely Yours,

SARAH B. KOTLER
Regulatory Counsel

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

November 19, 2015

Public Citizen
Allison M. Zieve
1600 20th Street NW
Washington, DC 20009

In reply refer to file: **2014-4316**

Dear Ms. Zieve,

This is in response to your Freedom of Information Act request dated May 19, 2014 in which you requested "unredacted copies of the curricula vitae of all FDA advisory committee members whose CVs are currently posted on the FDA's website." Your request was received in the Center for Biologics Evaluation and Research (CBER) on May 27, 2014.

Enclosed are the documents responsive to your request.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential. The withholding of such information is permitted if disclosure is likely to cause substantial competitive harm to the person who submitted the information.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Katherine Uhl of FDA DFOI, spoke with you about our response and your pending appeal. Please email or call her if you have any questions at Katherine.uhl@fda.hhs.gov or 301-796-8975.

If you have any questions or if I can be of further assistance, please let me know by referencing the above file number. I can be reached by phone at 240-402-8026 or by e-mail at Beth.Brocknerryan@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2015.11.19 13:27:57 -05'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

December 2, 2015

Director, News Division
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Parklawn Building, Room 19-01
5600 Fishers Lane
Rockville, MD 20857

Re: Freedom of Information Act Appeal
FOIA File 2014-4316
(See related appeal #14-567AA)

Dear Director:

I am writing to appeal the partial denial by the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) of a May 19, 2014, FOIA request sent to FDA on behalf of Public Citizen for unredacted copies of the curricula vitae of advisory committee members whose CVs are posted on the FDA's website. A copy of that request is attached.

CBER responded to our FOIA request by letter dated November 19, 2015, enclosing a disc containing CVs. A copy of CBER's response is attached. Review of the pages reveals that they contain redactions marked (b)(4) and (b)(6). These same redactions appear on the FDA's website. Both the (b)(6) and the (b)(4) redactions, however, are unjustified under FOIA.

On September 18, 2014, Public Citizen appealed to this office from responses to the May 19 FOIA request received from FDA's Center for Tobacco Products and Center for Food Safety and Applied Nutrition. That appeal was assigned number 14-567AA. Although submitted more than 14 months ago, that appeal remains pending. Katherine Uhl, of FDA's FOIA office has suggested that, rather than detailing the bases for the appeal here, we refer you to that appeal. A summary of the basis for the appeal is below.

Exemption 6: Exemption 6 protects from disclosure information "the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). "[T]he test is not merely whether the information is in some sense personal but whether it is 'of the same magnitude as highly personal or as intimate in nature as that at stake in personnel and medical records.'" *Kurzon v. HHS*, 649 F.2d 65, 68 (1st Cir. 1981) (quoting *Bd. of Trade of the*

City of Chicago v. Commodity Futures Trading Comm'n, 627 F.2d 392, 398 (D.C. Cir. 1980)). "Information relating to business judgments and relationships does not qualify for exemption. [citation omitted] This is so even if disclosure might tarnish someone's professional reputation." *Washington Post Co. v. DOJ*, 863 F.2d 96, 101 (D.C. Cir. 1988) (citing *Sims v. CIA*, 642 F.2d 562, 574 (D.C. Cir. 1980), and discussing exemption 7(C), which provides greater protection for personal privacy than exemption 6). "Exemption 6 was developed to protect details of personal and family life, not information regarding professional activities." *Camaranesi v. DOJ*, 941 F. Supp. 2d 1173, 1185 (N.D. Cal. 2013).

On its face, the notion that a rational person would include on her CV information that satisfies this standard is hard to fathom. This common-sense conclusion is illustrated by the fact that, in several instances, the person's CV appears without redactions elsewhere online, such as on the website of the member's primary employer.[1] The same CVs that the FDA redacted invariably had no redactions at all when we found them elsewhere. The point is not that the FDA should search online to see whether members have posted their CVs, but the online CVs reflect that CVs are created for the purpose of disclosing activities that one thinks are relevant to one's professional life and not private. They thus demonstrate that the FDA is inappropriately redacting the CVs.

For examples of the types of redactions made, we refer you to our September 18, 2014 appeal from responses to the same FOIA request by Center for Tobacco Products and Center for Food Safety and Applied Nutrition. Again, Katherine Uhl, of FDA's FOIA office has suggested that, rather than detailing the bases for the appeal here, we refer you to that appeal.

Exemption 4: Exemption 4 protects from disclosure "trade secrets or commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). There is no colorable argument that the redacted information meets this standard, as the FDA's own regulation makes clear. *See* 21 C.F.R. § 20.61(b) ("Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.").

Moreover, where information is provided to the government as a condition of obtaining a government benefit (here, membership in an advisory committee), that information can be deemed "confidential" only if its disclosure is "likely to cause" the person who submitted it "substantial competitive harm" or likely "to impair the Government's ability to collect necessary information in the future." *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 878 (D.C. Cir. 1992). Where information is provided to the government voluntarily, exemption 4 applies only where the information "is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Critical Mass*, 975 F.2d at 880.

The redactions designated (b)(4) easily fail even the less rigorous standard for voluntarily-submitted information. Almost by definition, and even more easily under the FDA's

[1] Although the public may be able to find full CVs elsewhere for some members, the public should not have to search for complete information when the agency lacks justification for redacting it.

regulation, the fact that information is included on a CV disqualifies it from falling within the scope of exemption 4.

There is no argument that the redacted information is confidential or privileged, commercial or financial, as required for withholding under exemption 4. Like the (b)(6) redactions, we refer you to our September 18, 2014 appeal from responses to the same FOIA request by Center for Tobacco Products and Center for Food Safety and Applied Nutrition for examples of the types of redactions made.

More generally, the very notion that a CV would include confidential commercial or financial information or information the disclosure of which a person would consider to violate his personal privacy is at odds with the very nature of a CV. The CV is written by a person for the purpose of touting her education and accomplishments to other people. The person chooses what information to include and how to state it. If the person thought that a piece of information was too private to make public or that its private nature outweighed its value on the CV, she would not include it.

FOIA is a pro-disclosure statute. Its exemptions, as the courts have long recognized, are to be narrowly construed. *Milner v. U.S. Dep't of Navy*, 131 S. Ct. 1259, 1262 (2011). "[T]hese limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976). Although the availability of CVs online and the public nature of much (or all) of the redacted information is useful to show the silliness of some of the redactions, the agency should not have needed online searches to determine that the information is not exempt under FOIA.

For the foregoing reasons, unredacted copies of the records produced by the CBER in response to the May 19, 2014 FOIA request should be disclosed. We are happy to accept the posting of unredacted copies of all requested records on the FDA website, as opposed to copies sent to us directly, in response to this request, provided that the agency acts within FOIA's time limits.

Sincerely,

Allison M. Zieve
Public Citizen Litigation Group

cc: Katherine Uhl, FDA DFOI (by email)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Program Support Center

Division of FOIA Services
5600 Fishers Lane, Room 19-01
Rockville, Maryland 20857
PH: 301-443-3403
Fax: 301-480-4862

December 07, 2015

Appeal Case No. 16-0032-AA

Allison M. Zieve
Public Citizen
1600 20th Street NW
Washington, DC 20009

Dear Zieve:

This acknowledges receipt of your Freedom of Information Act (FOIA) appeal received by this office on the date above. Your appeal has been assigned the above-stated case number based on when it was received in this office. Please reference this number on your correspondence.

Your letter is summarized below:

Appealing the partial denial by the Center for Tobacco Products (CTP) and the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA) of FOIA Request 2014-4316, which sought copies of the curricula vitae of FDA advisory committee members whose CVs are currently posted on FDA's website.

The case number of the original request was **2014-4316.**

Pursuant to 45 CFR 5.35 (c) your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved. For more information about how your appeal will be processed please see 45 CFR 5.34 http://www.hhs.gov/foia/45cfr5.html

The FOIA and the HHS FOIA regulations are available at the following web addresses: http://www.justice.gov/oip/doj-foia-regulations and http://www.hhs.gov/foia/45cfr5.html.

Any questions regarding the status of your appeal should be directed to this office by calling (301) 443-3403, or write to us at the address above.

Sincerely,

Anthony T. Clemons -S

Digitally signed by Anthony T. Clemons -S
DN: c=US, o=U.S. Government, ou=HHS, ou=PSC, ou=People, 0.9.2342.19200300.100.1.1=2001877502, cn=Anthony T. Clemons -S
Date: 2015.12.07 17:25:52 -05'00'

Anthony Clemons
PSC FOIA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Rm 1035
Rockville MD 20857

May 24, 2016

In reply refer to file: 2014-4316

Public Citizen
Allison M. Zieve
1600 20th Street NW
Washington, DC 20009

Dear Ms. Zieve,

This is in response to your Freedom of Information Act request dated May 19, 2014 in which you requested unredacted copies of the curricula vitae of all FDA advisory committee members whose CVs are currently posted on the FDA's website.

The Office of the Commissioner conducted a search and located 1,367 pages responsive to your request, of which all pages are enclosed.

I have determined to withhold portions of pages under FOIA exemptions (b)(4) and (b)(6).

The FOIA exemption (b)(4) permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential. The withholding of such information is permitted if disclosure is likely to cause substantial competitive harm to the person who submitted the information.

Exemption (b)(6) permits the withholding of privacy information, the release of which would constitute a clearly unwarranted invasion of personal privacy.

This concludes the response for the Office of the Commissioner. If you have any questions, please contact Katherine Uhl at 301-796-8975. Your request is also open to CDRH and CDER and you will receive additional responses from them.

Sincerely yours,

Sarah Kotler
Director
Division of Freedom of Information

Enclosures

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

June 8, 2016
In reply refer to file: 2014-4316

Allison M. Zieve
Public Citizen
1600 20th Street NW
Washington, DC 20009

Dear Ms. Zieve,

This is in response to your Freedom of Information Act request dated May 19, 2014 in which you requested unredacted copies of the curricula vitae of all FDA advisory committee members who's CVs are currently posted on the FDA's website.

The Center for Devices and Radiological Health (CDRH) conducted a reasonable search of the Office of Device Evaluation's Advisory Committee Staff, the Office of Management Operation's Integrity, Committee, and Conference Management Branch and the FDA's Advisory Committee Oversight & Management Staff.

After a reasonable search, we located 3,714 pages of records responsive to your request. Portions of the records were withheld pursuant to exemption 4 and 6 of the FOIA. (5 U.S.C. § 552(b)(4) and (b)(6)).

Exemption 4: Protects trade secrets and commercial or financial information obtained from a person and privileged or confidential.

Exemption 6: Protects personnel and medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This concludes the response for the Center for Devices and Radiological Health. If you have any questions, please contact Katherine Uhl at 301-796-8975. Your request is also open to CDER and you will receive additional responses from them.

Sincerely,

Jasmine Howard

Jasmine Howard, Branch Chief
Division of Information Disclosure
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration

Enclosures

Rec'd 6/27/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

June 21, 2016
In reply refer to file: 2014-4316

Allison M. Zieve
Public Citizen
1600 20th Street NW
Washington, DC 20009

Dear Ms. Zieve,

This is in response to your Freedom of Information Act (FOIA) request dated May 19, 2014 in which you requested unredacted copies of the curricula vitae of all FDA advisory committee members who's CVs are currently posted on the FDA's website.

On June 8th, 2016, we sent you CVs responsive to your request. Unfortunately, the CV for the Circulatory Panel Committee was missing from our response. Attached is the redacted CV from Dr. John Somberg containing 44 pages.

Portions of the records were withheld pursuant to Exemption 6 of the FOIA. (5 U.S.C. § 552 (b)(6)).

Exemption 6: Protects personnel and medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This concludes the response for the Center for Devices and Radiological Health. If you have any questions, please contact Katherine Uhl at 301-796-8975. Your request is also open to CDER and you will receive additional responses from them.

Sincerely,

Jasmine Howard

Digitally signed by Jasmine Howard
DN: cn=Jasmine Howard, o=OCE/Division of Information Disclosure, ou=FDA/CDRH, email=jasmine.howard@fda.hhs.gov, c=US
Date: 2016.06.21 14:29:44 -04'00'

Jasmine Howard, Branch Chief
Division of Information Disclosure
Office of Communication and Education
Center for Devices and Radiological Health
Food and Drug Administration

Enclosures

EXHIBIT 5

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

Regulatory Information

Electronic Reading Room

This index contains categories of frequently requested FDA documents. Before submitting an FOIA request, please check to see if the records you seek are already available on an FDA Web site.[1] You can use this index to locate a specific category of documents. In addition, you can check specific FOI sites which have been established by the following agency offices:

CATEGORIES OF DOCUMENTS

Center for Drug Evaluation and Research (CDER)

- Drugs[2]
- CDER FOIA Electronic Reading Room[3]
- Drug Approvals and Databases[4]
- Clinical Investigator Inspection List (CIIL) Database Codes[5]

Center for Biologics Evaluation and Research (CBER)

- Biologics Electronic Reading Room (eFOI)[6]

Center for Devices and Radiological Health (CDRH)

- CDRH FOIA Electronic Reading Room[7]
- Medical Devices[8]
- PMA Approvals[9]
- 510(k) Clearances[10]

Center for Food Safety and Applied Nutrition (CFSAN)

- Foods[11]

Center for Veterinary Medicine (CVM)

- CVM FOIA Electronic Reading Room[12]
- Animal & Veterinary[13]
- FOIA Drug Summaries[14]

Division of Dockets Management Branch (DMB)

- Division of Dockets Management[15]
- Advisory Committees[16]

Office of Regulatory Affairs (ORA)

- ORA FOIA Electronic Reading Room[17]
- Guide to International Inspection and Travel[18]
- Inspection Guides[19]
- Enforcement Reports[20]
- Application Integrity Policy[21]
- Commissioning and Credentialing
- FDA Public Affairs Specialists[22]
- Import Alerts[23]
- Import Refusals[24]

- Inspection Technical Guides[25]
- Compliance Manuals[26]
- Clinical Investigators - Disqualification Proceedings[27]
- Inspections Database[28]
- FDA Data Dashboard[29]

Center for Tobacco Products

- CTP FOIA Electronic Reading Room[30]

Agency Manuals

- Manual of Compliance Policy Guides[31]
- Compliance Program Guidance Manual (CPGM)[32]
- Field Science[33]
- Investigations Operations Manual[34]
- Regulatory Procedures Manual[35]
- Staff Manual Guides[36]

Frequently Requested Regulatory Records

- Notice of Opportunity for Hearing (NOOH) - Proposal to Debar[37]
- FDA Memoranda of Understanding[38]

Page Last Updated: 03/31/2016
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Links on this page:

1. /default.htm
2. /Drugs/default.htm
3. /Drugs/GuidanceComplianceRegulatoryInformation/ucm113237.htm
4. /Drugs/InformationOnDrugs/default.htm
5. /Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm073059.htm
6. /AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm129132.htm
7. /AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElectronicReadingRoom/default.htm
8. /MedicalDevices/default.htm
9. /MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm
10. /MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm
11. /Food/default.htm
12. /AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm
13. /AnimalVeterinary/default.htm

Ex. 5, page 3

14. /AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm
15. /RegulatoryInformation/Dockets/default.htm
16. /AdvisoryCommittees/default.htm
17. /AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm
18. /ICECI/Inspections/ForeignInspections/ucm111443.htm
19. /ICECI/Inspections/InspectionGuides/default.htm
20. /Safety/Recalls/EnforcementReports/default.htm
21. /ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm
22. /AboutFDA/ContactFDA/default.htm
23. /ForIndustry/ImportProgram/ActionsEnforcement/ImportAlerts/default.htm
24. /ForIndustry/ImportProgram/ImportRefusals/default.htm
25. /ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/default.htm
26. /ICECI/ComplianceManuals/default.htm
27. /ICECI/EnforcementActions/ucm321308.htm
28. /ICECI/Inspections/ucm222557.htm
29. http://www.fda.gov/AboutFDA/Transparency/InspectionComplianceDataDashboard/default.htm
30. /TobaccoProducts/AboutCTP/ucm221165.htm
31. /ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm
32. /ICECI/ComplianceManuals/ComplianceProgramManual/default.htm
33. /ScienceResearch/FieldScience/LaboratoryManual/default.htm
34. /ICECI/Inspections/IOM/default.htm
35. /ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm
36. /AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm
37. /RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm
38. /AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/default.htm

EXHIBIT 6

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITAE

Jeffrey E. Lancet, M.D.

Current Position: Senior Member
Department of Malignant Hematology
H. Lee Moffitt Cancer Center and Research Institute
12902 Magnolia Dr., SRB4
Tampa, Florida 33612
(813) 745-6841
(813) 745-3071 Fax
Jeffrey.Lancet@moffitt.org

Current Academic: Professor
Department of Oncologic Sciences
University of South Florida

Education:

1988-1992: **M.D.** S.U.N.Y. Upstate Medical College at Syracuse, New York

1984-1988: **B.A.** University of Rochester, Rochester, New York
Biology, Psychology (Cum Laude)

Postgraduate Training and Fellowship Appointments:

2014 Fellow – The Leadership Academy at Moffitt Cancer Center (Physician Leadership Institute)

1996-1999: Hematology/Oncology Clinical and Research Fellowship - University of Rochester School of Medicine and Dentistry, Rochester, NY

1995-1996: Chief Resident & Instructor in Medicine - St. Mary's Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY

1993-1995: Residency - Internal Medicine, Strong Memorial Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY

1992-1993: Internship - Internal Medicine, Strong Memorial Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY

on Therapeutic Clinical Trials in Hematological Malignancies for H. Lee Moffitt Cancer Center and Research Institute

2005, 2013 Nomination for "Physician of the Year" H. Lee Moffitt Cancer Center and Research Institute

1988 Cum Laude Graduate, University of Rochester, Rochester, New York

RESEARCH SUPPORT

CURRENT

External Grants:

Account # 1R01CA168677-01A1
Name and Role: **Jeffrey Lancet, co-investigator** (PI: Martine Extermann, MD)
Source: NIH/NCI
Title: Decision Models to Compare Treatments in Older Patients with AML
% Effort: 10%
Direct Costs: $939,800
Award: $1,373,529

Clinical Trials: Principal Investigator (PI)

Name and Role: **Jeffrey Lancet ï PI**
Dates: 8/2013 – Present
Source: MCC
Title: MCC 17302: A Phase II Study Evaluating the Oral Smoothened Inhibitor PF-04449913 in Patients with Myelodysplastic Syndrome
Objective: **Investigator-initiated treatment research trial**
Planned Patient total: 35
MCC Accrual: 9
Total Amount: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

(b) (6)

Objective:
Planned Patient total
MCC Accrual:

Total Amount: (b) (4)
Per Patient:
Name and Role:
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual (to date
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total
MCC Accrual (to date)
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual (to date)
Per Patient:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual (to date):
Per Patient:

COMPLETED

External Grants:

Award #:	**5 P30 CA076292-11**
Name and Role	**Jeffrey Lancet -PI**
Dates:	02/1/09 – 01/31/11
Source:	National Institutes of Health
Title:	NIH-ASCO Cancer Foundation Clinical Investigator Team Leadership Award
% Effort:	12%
Total direct costs:	$57,594
Total Amount:	$96,182

Award #:	**R-6030-04** (University of Rochester)
Name and Role:	Jane Liesveld – PI, **Jeffrey Lancet ï Co-PI**
Dates:	10/1/03 – 09/30/05
Source:	Leukemia & Lymphoma Society
Title:	Effect of Farnesyltransferase Inhibition in AML and MDS
% Effort:	16%
Total direct costs:	(b) (4)
Total Amount:	

Contracts:

Account #:	19-15053-01-03
Name and Role:	**Jeffrey Lancet - PI**
Dates:	08/2006 – Present
Source:	NCI/CTEP Translational Research Initiative
Title:	MCC 14796*:* Phase I Dose-Escalation Study of R11577 (Tipifarnib) plus PS-341 (bortezomib) in Relapsed or Refractory Acute Leukemias
% Effort:	N/A
Total Direct Costs:	$31,290
Total Amount:	$51,316

Clinical Trials: Principal Investigator

Account #:	10-14398-99-01
Name and Role:	**Jeffrey Lancet ï National and Institutional PI**
Dates:	5/2011 – 7/2012
Source:	NCI-CTEP (Funded through institutional N-01 contract)
Title:	MCC 16572: Phase 2 Trial of R115777 in Previously Untreated Older Adults with AML and Baseline Presence of a Specific 2-Gene Expression Signature Ratio
Objective:	**Investigator-initiated treatment research trial**
Planned Patient total:	35
MCC Accrual:	8
Per Patient:	$6,393

Name and Role:	**Jeffrey Lancet ï PI**
Dates:	10/2007 – 12/2012
Source:	MCC
Title:	MCC 15025: Pilot trial of a WT-1 analog peptide vaccine in patients with myeloid neoplasms
Objective:	**Investigator-initiated treatment research trial**
Planned Patient total:	10
MCC Accrual:	13
Total Amount:	(b) (4)
Per Patient:	

Name and Role:	**Jeffrey Lancet ï PI**
Dates:	(b) (4)
Source:	
Title:	
Objective:	
MCC Accrual:	
Total Amount:	
Per Patient:	

Name and Role:	**Jeffrey Lancet ï Institutional PI**
Dates:	(b) (4)
Source:	
Title:	

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: 05/2009 – 6/2013
Source: SWOG
Title: S0535: A Phase II Study Of Atra, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients With Previously Untreated High-Risk Acute Promyelocytic Leukemia
Objective: **Investigator-initiated cooperative group treatment research trial**
Planned Patient total: 70

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 10/2009 – 00/2011
Source: SWOG
Title: MCC 15992: A Phase III Randomized, Double-Blind Study of Induction (Daunorubicin/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy + Midostaurin (PKC412) or Placebo in Newly Diagnosed Patients < 60 Years of Age with FLT3 Mutated Acute Myeloid Leukemia
Objective: SWOG treatment research trial
Planned Patient total: 300
MCC Accrual: 5

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual:

(b) (4)

Per Patient: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual
Per Patient: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: 7/2008 – 3/2009
Title: MCC 15332. A Phase IIB, Randomized, Double-Blinded, Placebo-Controlled Study of Low Dose Cytarabine and Lintuzumab Compared to Low Dose Cytarabine and Placebo in Patients 60 Years of Age and Older with Previously Untreated AML
Objective: Sponsored treatment research trial
Planned Patient total: 211
MCC Accrual: 7
Per patient (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
MCC Accrual:
Per Patient: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective: (b) (4)

Planned Patient total (b) (4)
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 05/2007 - Present
Source: SWOG
Title: MCC 15154: A Phase II Study of Lenolidomide (Revlimid) (NSC-703813) For Previously Untreated Non-M3, Deletion 5q Acute Myeloid Leukemia (AML) in Patients Age 60 or Older Who Decline Remission Induction Chemotherapy
Objective: SWOG treatment research trial
Planned Patient total: 37
MCC Accrual: 11

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 05/2007 – 8/2008
Source: SWOG
Title: MCC 15036: A Phase II Study of Cytarabine and Clofarabine in Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia
Objective: SWOG treatment research trial
Planned Patient total: 37
MCC Accrual: 6

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient tota
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI and co-author of trial**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual:

Per Patient: (b) (4)

Account #: 10-14398-99-01
Name and Role: **Jeffrey Lancet ï National and Institutional PI** (clinical trial),
Institutional N-01 Contract (to fund clinical trial),
PI – Daniel Sullivan, MD
Dates: 08/2006 – 12/2008
Source: NCI/CTEP
Title: MCC 14796*:* Phase I Dose-Escalation Study of R11577 (Tipifarnib) plus PS-341 (bortezomib) in Relapsed or Refractory Acute Leukemias
Objective: **Investigator-initiated translational research trial**
% Effort: 5%
Planned Patient total: 27
MCC Accrual: 19
Total Direct Costs: $2,600 per patient
Total Amount: $4,600 per patient

Account # 84-14604-01-01
Name and Role: **Jeffrey Lancet - PI**
Dates: (b) (4)
Source:
Title:

Objective:
Patient Total
Total Direct Costs:
Total Amount:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates:
Source:
Title:

Objective:
Planned patient Tota
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 08/2005 - 02/2006
Source: SWOG
Title: MCC 14486: Phase II Studies of Two Different Schedules and Two Different Doses of the Farnesyl Transferase Inhibitor R115777 (Tipifarnib, Zarnestra, NSC-702818) for Previously Untreated Acute Myeloid Leukemia (AML) in Patients of Age 70 or Older
Objective: SWOG treatment research trial.
Planned Patient total: 348
MCC Accrual: 13

Name and Role: **Jeffrey Lancet - Institutional PI**
Dates: 06/2005 - 01/2006
Source: NCI
Title: MCC 14492: Compound 506U78 (NSC 686673) in Patients With Relapsed or Refractory T-Cell ALL or T-Cell Lymphoblastic Lymphoma
Objective: NCI sponsored treatment research trial.
Patient Total: 2 (early termination by sponsor)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

SERVICE

H. Lee Moffitt Cancer Center Service

Administrative Appointments:

2013-present	**Chief of Medicine Services**, Moffitt Cancer Center
2005-2012	**Head of Clinical Research**, Malignant Hematology Division
2006-present	**Leukemia Section Head,** Malignant Hematology Division

Committees:

9/2013 – Present	**Member,** Medicine Safety Committee - Monthly
1/2012 – Present	**Member,** Moffitt Clinical Research Action Committee -Monthly
7/2011 – Present	**Member/Chair** Moffitt Conflict of Interest Committee – Monthly **(Chair, 6/2013)**
3/2011 – Present	**Member,** Moffitt Appointment, Promotion, and Tenure Committee - weekly
2010 – 2011	**Member,** Grand Rounds Steering Committee
2008 – 2011	**Member,** Clinical Research Governance Committee
3/2006 - 6/2011	**Vice-chair,** Protocol Monitoring Committee
2005-2007	**Member,** Clinical Investigations Steering Committee

University of Rochester Service

Committees:

2000 – 2004	**Member,** University of Rochester Peer Review Committee

Professional

July 2015	**Member,** Oncology Drug Advisory Committee of the US Food & Drug Administration

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

CURRICULUM VITAE

Vassiliki A. Papadimitrakopoulou, M.D.

PRESENT TITLE AND AFFILIATION

Primary Appointment

Professor, Department of Thoracic/Head and Neck Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

Jay and Lori Eisenberg Endowed Professorship, Department of Thoracic/Head and Neck Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

Dual/Joint/Adjunct Appointment

N/A

CITIZENSHIP

(b) (6)

OFFICE ADDRESS

The University of Texas MD Anderson Cancer Center
1515 Holcombe Boulevard
Unit Number: 432
Houston, TX 77030
Phone: (713) 792-6363
Fax: (713) 792-1220
Email: vpapadim@mdanderson.org

EDUCATION

Degree-Granting Education

University of Patras School of Medicine, Patras, Greece, MD, 1988, Medicine

Postgraduate Training

Clinical Internship, Metaxas Cancer Hospital, Piraeus, Greece, 1989-1990

Clinical Residency, Institut Gustave Roussy, Unite La Grange, Savigny Le Temple, France, 1990-1991

Clinical Residency, Internal Medicine, Columbia Presbyterian Medical Center, New York City, 1991-1994

Clinical Fellowship, Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, 1994-1997

Continuing Education, Heart of Leadership Course, The University of Texas, MD Anderson Cancer Center, Houston, TX, 2007-2007

Continuing Education, Faculty Leadership Academy, The University of Texas, MD Anderson Cancer Center, Houston, TX, 2008-2008

Continuing Education, The Path of Women Who Lead, Third WICR Leadership Development Workshop, American Association of Cancer Research, San Diego, CA, 2008-2008

Healthcare Management, Graduate Certificate in Healthcare Management, Rice University, Houston, TX, 2013-2014

Division of Medicine Team Science Award, The University of Texas MD Anderson Cancer Center, 2011

World Wide Who's Who Executives and Professionals in Research, Medicine and Healthcare, 2013

AACR Princess Takamatsu Memorial Lectureship Award Selection Committee, American Association for Cancer Research (AACR), 2014

Doctors of Excellence, Leaders in Healthcare Network, 2014

Excellence in Collaboration and Innovation Award, Bonnie Addario Lung Cancer Foundation, 2014

Invitation to FDA Center for Drug Evaluation and Research's (CDER) ODAC, United States Federal Drug Agency (FDA), 2014, 2015

RESEARCH

Grants and Contracts

Funded

Co-Investigator, 0.6 months, Institutional National Research Science Award, T32CA060374, NIH/NCI, PI - Jeffrey Myers, 7/1/2011-6/30/2016 ($121,836/year)

Co-Principal Investigator, 0.96 months, Personalizing NSCLC Therapy: Exploiting KRAS activated pathways, R01 CA155196-01A1, NIH/NCI, PI - Roy Herbst, 9/15/2011-7/31/2016 ($514,442/year)

(b) (4)

(b) (4)

(b) (4)

Principal Investigator, 15%, SWOG - CTI, The Hope Foundation, 1/1/2015-12/31/2015 ($(b) (4))

Pending

(b) (4)

Other

N/A

Completed

Principal Investigator, Young Investigator Award: Effects of Biochemoprevention on Cell Cycle Regulator Abnormalities During Head and Neck Tumorigenesis, American Society of Clinical Oncology (ASCO), 1998, $(b) (4)0

Co-Principal Investigator, Biochemoprevention Therapy in Advanced Laryngeal Dysplasia, CA79437-03, NIH/NCI, PI - Waun Ki Hong, 9/10/1998-6/30/2004, $441,815 ($88,363/year)

Principal Investigator, Randomized, Double-Blind, Placebo-Controlled, Phase IIB Trial of Ketorolac Mouth Rinse Evaluating the Effect of Cyclooxygenase Inhibition on Oropharyngeal Leukoplakia, CA70907, NIH/NCI, 1/31/2000-1/31/2001, $107,023

Co-Investigator, Clinical and Epidemiologic Center for Biomarkers of Upper Aerodigestive Tract Lesions, CA86390, NIH/NIBIB, 5/1/2000-2/28/2005, $123,267 ($24,653/year)

Principal Investigator, Alterations of Cell Cycle Regulators and their Signaling Partners as Predictors of Response to Chemoprevention and Cancer Risk in Upper Aerodigestive Tract Premalignancy, American Society of Clinical Oncology (ASCO), 7/1/2000-6/30/2003, $ (b) (6) (b) (6)

Principal Investigator Developmental Research Project, Multitargeted Therapy Aiming at Signal Transduction Pathways in Head and Neck Cancer, Department of Defense (DOD), PI - Hong WK, 3/15/2001-3/15/2009, $62,500

Principal Investigator, Project 4: SPORE in Head and Neck Cancer - Targeting EGFR for Chemoprevention of Head & Neck Cancers, P50 CA97007-01, NIH/NCI, 8/1/2001-6/30/2006, $211,391

Co-Investigator, 1.2 months, MDACC SPORE in Head and Neck Cancer, 3P50 CA97007 08, NIH/NCI (PP-3B), PI - Scott Lippman, 7/1/2002-7/31/2013 ($1,493,507/year)

Principal Investigator, Development Project, Multitargeted therapy aiming at signal transduction pathways in head and neck cancer, P50 CA97007-02, NIH/NCI, 9/30/2002-7/31/2007, $47,509 ($47,509/year)

Project 3 Co-Leader, 1.2 months, MD Anderson Cancer Center Head and Neck SPORE (PP-3), 5 P50 CA097007 09, NIH/NCI, PI - Jeffrey Myers, 9/30/2002-7/31/2013 ($1,493,507/year)

Project 1 Leader, 1.2 months, Molecular-Based Therapy for Oral Cancer Prevention, 5 P01 CA106451 06, NIH/NCI, PI - Scott Lippman, M.D., 8/1/2004-7/31/2012

Co-Investigator, 0.12 months, Early Therapeutic Development with Phase II Emphasis, N01 CM-62202 09, NIH/NCI, PI - David J Stewart, 1/1/2006-9/30/2011 ($8,317,052/year)

Co-PI, BATTLE Lung Cancer Program, W81XWH-06-1-0303, Department of Defense, PI - Hong, 4/1/2006-4/30/2011

Not Funded

N/A

Protocols

Funded

Principal Investigator, Induction biochemoprevention followed by fenretinide versus placebo maintenance for laryngeal dysplasia, ID98-017, 1998, NCI

Principal Investigator, Randomized, double blind, placebo-controlled, phase IIB trial of ketorolac mouth rinse evaluating the effect of cyclooxygenase inhibition on oropharyngeal leukoplakia: collaborative study of the NCI, NIDCD and the NIDR, ID99-302, 1999

(b) (4)

(b) (4)

Principal Investigator, Phase II ERCC1 and RRM1-based adjuvant therapy trial in patients with stage I non-small cell lung cancer (NSCLC), SWOGS0720, 2011, Southwest Oncology Group (SWOG)

(b) (4)

(b) (4)

Principal Investigator, Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer. Study A: MEDI4736; Study B: GDC-0032; Study C: Palbociclib; Study D: AZD4547; Study E: Rilotumumab + Erlotinib, SWOGS1400, 2014

(b) (4)

Unfunded

(b) (4)

(b) (6)

(b) (4)

(b) (6)

(b) (4)

(b) (6)

(b) (4)

(b) (4)

[redacted]

Patents and Technology Licenses

Patents

N/A

Technology Licenses

N/A

Grant Reviewer/Service on Study Sections

Study Section Review Committee for Clinical Translational and Population Based Research Projects under the Institutional Research Grants Program (IRG), MD Anderson Cancer Center, Member, 2014-2017

2015 AACR Princess Takamatsu Memorial Lectureship, American Association for Cancer Research, Member, 2014

PUBLICATIONS

Peer-Reviewed Original Research Articles

1. Cvitkovic FB, Haie-Meder C, Papadimitrakopoulou V, Armand JP, Cioloca C, Maugis N, Constans JP. Pilot study of 6 weeks of chemoradiotherapy with 5 FU and hydroxyurea in malignant gliomas. J Neurooncol 15(1):9-17, 1/1993. PMID: 8384255.
2. Kim SK, Fan Y, Papadimitrakopoulou V, Clayman G, Hittelman WN, Hong WK, Lotan R, Mao L. DPC4, a candidate tumor suppressor gene, is altered infrequently in head and neck squamous cell carcinoma. Cancer Res 56(11):2519-21, 6/1996. PMID: 8653689.
3. Sarris AH, Luthra R, Papadimitrakopoulou V, Kimopoulos M, McBride JA, Cabanillas F, Morris S, Deisseroth A, Pugh WC. Amplification of genomic DNA-PCR technique demonstrates the presence of the t (2; 5) rearrangement in anaplastic large cell lymphoma but no other non-Hodgkin's lymphomas; Hodgkin's disease or lymphomatoid papulosis. Blood 88:1771-1779, 1996.
4. Papadimitrakopoulou VA, Hong WK, Lee JS, Martin JW, Lee JJ, Batsakis JG, Lippman SM. Low-dose isotretinoin versus beta-carotene to prevent oral carcinogenesis: long-term follow-up. J Natl Cancer Inst 89(3):257-8, 2/1997. PMID: 9017007.
5. Papadimitrakopoulou VA, Dimery IW, Lee JJ, Perez C, Hong WK, Lippman SM. Cisplatin, fluorouracil, and L-leucovorin induction chemotherapy for locally advanced head and neck cancer: the M.D. Anderson Cancer Center experience. Cancer J Sci Am 3(2):92-9, Mar-Apr, 3/1997. PMID: 9099459.
6. Papadimitrakopoulou V, Izzo J, Lippman SM, Lee JS, Fan YH, Clayman G, Ro JY, Hittelman WN, Lotan R, Hong WK, Mao L. Frequent inactivation of p16INK4a in oral premalignant lesions. Oncogene 14(15):1799-803, 4/1997. PMID: 9150385.
7. Sarris AH, Papadimitrakopoulou V, Dimopoulos MA, Smith T, Pugh W, Ha CS, McLaughlin P, Callender D, Cox J, Cabanillas F. Primary parotid lymphoma: the effect of International Prognostic Index on outcome. Leuk Lymphoma 26(1-2):49-56, 6/1997. PMID: 9250787.
8. Sarris AH, Papadimitrakopoulou V, Waasdorp M, Dimopoulos MA, McBride JA, Cabanillas F, Duvic M, Deisseroth A, Morris SW, Pugh WC. Long-range amplification of genomic DNA detects the t(2;5)(p23;q35) in anaplastic large-cell lymphoma, but not in other non-Hodgkin's lymphomas, Hodgkin's disease, or lymphomatoid papulosis. Ann Oncology 8:S59-S63, 1997.
9. Sarris AH, Luthra R, Papadimitrakopoulou V, Waasdorp M, Dimopoulos M, McBride JA, Cabanillas F, Duvic M, Deisseroth A, Morris S, Pugh WC. Rapid amplification of genomic DNA detects the t(2;5)(p23;q35) in anaplastic large cell lymphoma, but not in other non-Hodgkin's lymphomas, Hodgkin's disease, or lymphomatoid papulosis. Ann Oncology 8 (Suppl 2):S1-S5, 1997.

CURRICULUM VITAE

NAME: ALBERTO S. PAPPO

PLACE OF BIRTH: (b) (6)

OFFICE ADDRESS: St Jude Children's Research Hospital
262 Danny Thomas Blvd, MS 260
Memphis, TN 38105
901 595 3300
alberto.pappo@stjude.org

ACADEMIC DEGREES:

M.D. 1978-1984 Medical School: Universidad Anahuac; Mexico City.

PROFESSIONAL APPOINTMENTS:

1985-1988	Pediatric Residency, The University of Texas Health Science Center at San Antonio, San Antonio, Texas
1988-1991	Pediatric Hematology Oncology fellowship: Children's Medical Center of Dallas and The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas
1991-1997	Assistant Professor, Department of Pediatrics, University of Tennessee, College of Medicine, Memphis, Tennessee
1991-1997	Assistant Member, Department of Hematology-Oncology, St. Jude Children's Research Hospital, Memphis, Tennessee
1997 -2001	Associate Professor, Department of Pediatrics, University of Tennessee, Present College of Medicine, Memphis, Tennessee
1997 -2001	Associate Member, Department of Hematology-Oncology, St. Jude Children's Research Hospital, Memphis, Tennessee
2001-2006	Professor of Pediatrics, The Hospital for Sick Children, Toronto ON, Canada
2001-2007	Head Solid Tumor Section, the Hospital for Sick Children, Toronto
2006-2009	Professor of Pediatrics Baylor College of Medicine. Head division of Solid Tumors Texas Children's Cancer Center
2010-	Member St Jude Children's Research Hospital and Professor of Pediatrics University of Tennessee Health Science Center and Head Division of Solid Malignancies St Jude Children's Research Hospital, Memphis, Tennessee

HONORS:

1989-1990	American Cancer Society Clinical Fellowship

Vice Chair NCCN AYA task force (2013-Present)
Member NCCN sarcoma Task Force (2013-Present)
GRANTS:

(b) (4)

160363010 (Pappo) 11/1/2012 – 05/31/17
CA184178 $ (b) (4)
MELBMS Ipilimumab Phase I Trial in Pediatric Melanoma

160395010 (Pappo) 07/15/2013 – 02/28/2016
LDKALK $ (b) (4)
Phase I Trial Malignancies with ALK alteration

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(b) (4)

5 P30 CA021765-33 MPL 03-01-11 – 02-28-12

COG Chair's Developmental Fund (Translational Research) Award Program: Epigenetic Status of KCNQ10T1 in Sporadic Non-Wilms' Tumor Embryonal Tumors Associated with Molecular Alterations of Chromosome 11p15. $48,834.00

Rare Tumors study Chair COG ref # U01 CA30969
term ended Dec 31, 2001 $11,572
term ended Dec 31, 2002 $19,227
For 2003: $20,195.00

Intergroup Rhabdomyosarcoma Study Group COG ref # U01 CA24507
term ended Dec 31, 2001 $14,043
term ended Dec 31, 2002 $ 9,448
For 2003 $10,179.00

CURRICULUM VITAE

Bruce J. Roth, M.D.

Address & Telephone Number:

Business Address:	Division of Oncology Campus Box 8056 Washington University School of Medicine 660 S. Euclid Avenue St. Louis, MO 63110
Business Phone:	(314) 362-5654
Fax:	(314) 362-7086
E-mail:	broth@dom.wustl.edu

Present Position

Professor of Medicine
Washington University School of Medicine
Department of Internal Medicine
Division of Oncology
Section of Medical Oncology

Education:

1976	B.S.	Pre-Professional Studies	University of Notre Dame
1980	M.D.	Medicine	Saint Louis University

Postgraduate Training:

1980 – 1983	Internship & Residency - Internal Medicine Indiana University Medical Center
1983 – 1986	Fellowship - Hematology/Oncology Indiana University Medical Center

Licensure/Certification:

Licensure:

Indiana	7/1981 - 2011	(retired)
Tennessee	3/1999 – 2012	(retired)
Missouri	3/2010 - Present	

Certification:

American Board of Internal Medicine, Internal Medicine, 1983
American Board of Internal Medicine, Medical Oncology, 1985

Academic Appointments:

2010 - 2012 Chairman, Expert Panel, “On The Line” Prostate Cancer Awareness Campaign, ASCO/ESPN
2010 - 2015 Specialty Editor (Testicular Cancer) for CancerProgress.net
2011 - 2012 Chair-Elect, Cancer Communications Committee
2011 - 2014 Member, Timely Oncology Perspectives Team
2011 - 2014 Member, Genitourinary Cancer Symposium News Planning Team
2011 - 2012 Member, ASCO PSA Testing for Prostate Cancer Screening Expert Panel
2012 - 2013 Chair, Cancer Communications Committee
2013 - 2014 Chair-Elect, Bylaws Committee
2014 - 2015 Chair, Bylaws Committee
2015 - 2016 Member, Bylaws Committee

Clinical Trials:

Gynecologic Oncology Group:

Study Co-Chairman, Phase II Trial of Cisplatin and Cyclophosphamide in the Treatment of Extraovarian Peritoneal Serous Papillary Carcinoma (GOG #138)
Study Chairman, Phase I Trial of Paclitaxel + Etoposide in Patients with Recurrent Ovarian Carcinoma (GOG 9203)

Grants, Fellowships, Awards (Direct Costs):

Indiana University

7/1983 – 6/1986	American Cancer Society Clinical Oncology Fellowship	
4/1989 - 3/1992	Co-Investigator, Veterans Administration Merit Review Award "Biology of Germ Cell Neoplasia"	
7/1989 - 6/1992	American Cancer Society Clinical Oncology Career Development Award	
	Principal Investigator, Phase II, Non-Comparative Trial of CL 286,558 in Advanced Carcinoma of the Bladder, American Cyanamid Division of Lederle Laboratories	
	Principal Investigator, Phase II, Non-Comparative Trial of CL 286,558 in Advanced Non-Small Cell Carcinoma of the Lung, American Cyanamid Division of Lederle Laboratories	
	Principal Investigator, Phase II Study of CI-973 in Patients with Advanced Stage Refractory or Recurrent Disseminated Germ Cell Tumors, Parke-Davis	
	Principal Investigator, Phase II Trial of Taxol in Refractory Germ Cell Tumors, Bristol-Myers Squibb	
	Principal Investigator, Phase II Trial of Taxol in Refractory Urothelial Malignancies, Bristol-Myers Squibb	
	Principal Investigator, Phase II Trial of Ifosfamide + Taxol + Filgrastim in Refractory Transitional Carcinoma of the Bladder, Bristol-Myers Squibb and Amgen	
7/1994 - 6/1999	Co-Investigator, Eastern Cooperative Oncology Group Institutional Grant (Patrick J. Loehrer, Principal Investigator),	
	Principal Investigator, Phase II Trial of Gemcitabine in Advanced Bladder Cancer, Eli Lilly	
	Principal Investigator, A Phase II, Open Label, Dose Escalation Study of BB-2516 in Patients with Serologically Progressing Prostate Cancer , British Biotech	
	Principal Investigator, Phase I Clinical and Pharmacokinetic Evaluation of LY300502 Administered Orally in Patients with Prostate Cancer, Eli Lilly	
	Principal Investigator, Open Label Extended Use Study of BB-2516 in Patients with Advanced Refractory Cancer Previously Exposed to BB-2516, British Biotech	
7/1/94 - 4/30/99	Co-Investigator, Clinical Trials in Human Oncology (Lawrence Einhorn, Principal Investigator), NIH-Outstanding Investigator Grant	
7/31/96 - 6/30/98	Principal Investigator, Clinical Trials of Inhibitors of Matrix Metalloproteinases in Patients with Advanced Prostate Cancer, Cancer Research Institute	
	Principal Investigator, Phase I Clinical and Pharmacological Evaluation of Escalating Doses of LY300502 Administered Orally in Patients with Metastatic Prostate Cancer, Eli Lilly	
	Principal Investigator, Clinical and Pharmacokinetic Evaluation of LY320236 Administered Orally in Patients with Prostate Cancer, Eli Lilly	
	Co-Investigator, Improving Quality of Life of Prostate Cancer Patients and their Spouses, (R. Brian Giesler, Ph.D., Principal Investigator), Walther Cancer Institute	
	Co-Investigator, "Quality of Life Following PSA Failures in Patients and Spouses/Partners",(Brian Giesler, Ph.D., Principal Investigator), American Cancer Society	

Vanderbilt University

9/1999 – 8/2004	Co-Investigator, Vanderbilt Cancer Center Core Support Grant (P30 CA68485-050, Harold Moses, M.D. Principal Investigator), NIH/National Cancer Institute	
	(b) (4)	
	Principal Investigator, A Phase II Trial of ABT-751 in Patients with Androgen-Independent Metastatic Prostate Cancer, Commonwealth Foundation	
	(b) (4)	

Washington University

	(b) (4)	

Invited Lectures:

5/1984	*Oncogenes* Union Hospital, Terre Haute, Indiana
6/1985	*AIDS-Related Neoplasms* Terre Haute Regional Medical Center, Terre Haute, Indiana
4/1986	*AIDS – Immunology and Associated Malignancies* St. Elizabeth's Hospital, Vincennes, Indiana
9/1986	*New Avenues in Preclinical Research* American Cancer Society Regional Meeting Indianapolis, Indiana
10/1986	*Chemotherapy of Genitourinary Cancers* Southeast Missouri Regional Cancer Center Cape Girardeau, Missouri
3/1987	*New Modalities of Cancer Therapy* Reid Memorial Hospital Richmond, Indiana
8/1987	*Cell Kinetics as a Prognostic Factor in Breast Cancer* Union Hospital Terre Haute, Indiana
11/1987	*Oncogenes – Insights into the Pathogenesis of Malignancy* American College of Physicians Regional Meeting Indianapolis, Indiana
3/1988	*Treatment of Early Stage Breast Cancer* Indianapolis V.A. Hospital Indianapolis, Indiana
8/1988	*Therapeutic Options in Metastatic Breast Cancer* Indianapolis V.A. Hospital

EXHIBIT 7

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

UNIVERSITY OF COLORADO HEALTH SCIENCE CENTER
Curriculum Vitae

March 2015

Jeffrey L. Galinkin, M.D., F.A.A.P.

(b) (6)

Office Address: Children's Hospital Colorado
Department of Anesthesiology
13123 East 16th Ave.
Box B090
Aurora, CO 80045
(720) 777-3399

Education:

9/1985-5/1989	B.S.	University of Illinois, Champaign-Urbana
8/1989-5/1993	M.D.	University of Illinois, Chicago

Postgraduate Training and Fellowship Appointments:

7/1993-6/1994	Intern in Medicine, University of Chicago Hospitals, Chicago, Illinois
7/1994-6/1997	Resident in Anesthesiology, University of Chicago Hospitals, Chicago, Illinois
7/1997-6/1998	Fellowship, Pediatric Anesthesiology, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania

Faculty Appointment:

7/2011 –present	Professor of Anesthesiology and Pediatrics The University of Colorado Denver Denver, Colorado
6/2008 -6/2011	Associate Professor of Anesthesiology and Pediatrics The University of Colorado Denver Denver, Colorado
9/2003 -6/2008	Associate Professor of Anesthesiology The University of Colorado Denver Denver, Colorado
7/1998-8/2003	Assistant Anesthesiologist The Children's Hospital of Philadelphia Philadelphia, Pennsylvania
6/1998-8/2003	Assistant Professor The University of Pennsylvania, School of Medicine Philadelphia, Pennsylvania

30. Postoperative Infections, Can we prevent them?, February, 2012, Colorado Review of Anesthesia and Ski Holiday (CRASH) 2012. Vail, Colorado.

31. Lightwand Intubation, February, 2012, Colorado Review of Anesthesia and Ski Holiday (CRASH) 2012. Vail, Colorado.

32. Anesthesiology Research at Children's Hospital Colorado: A Case Study in the Development of a Translational Research Program. June 2012. Children's Hospital of Philadelphia, Philadelphia, PA.

33. Practical applications of -omics technologies. June 2012. Children's Hospital of Philadelphia, Philadelphia, PA.

34. Utilization of -omics Technologies to Predict Drug Response for Pain Medication. March 2013, Las Vegas, NV, Pediatric Anesthesiology 2013 (The Society for Pediatric Anesthesiology Spring Meeting).

35. Medical Marijuana for Pediatric Pain: CON. October 11, 2013, San Francisco, CA, Society For Pediatric Anesthesiology 27th Annual Meeting.

36. Lightwand Intubation, February, 2014, Colorado Review of Anesthesia and Ski Holiday (CRASH) 2014. Vail, Colorado.

37. Prescription Drug Abuse in Teenagers and Risk Assessment: Current controversies. March 6, 2014, Fort Lauderdale, FL, First Annual Society for Pediatric Pain Medicine Meeting.

38. "A Clear and Present Danger" (Session focused on Drug Diversion) Moderator: March 8, 2014. Fort Lauderdale, FL, Pediatric Anesthesiology 2014 (The Society for Pediatric Anesthesiology Spring Meeting).

39. Keynote Address: What are our patients taking? Oct 17, 2014, Denver, CO. AORN 17th Annual Educational Seminar and Vendor Fair.

40. Lightwand Intubation, March, 2015, Colorado Review of Anesthesia and Ski Holiday (CRASH) 2015. Vail, Colorado.

41. "Do your REALLY know what your patients are taking?"March, 2015, Colorado Review of Anesthesia and Ski Holiday (CRASH) 2015. Vail, Colorado.

Grant Support:

Completed

1. 5UL 1RR025780-2 5% effort

Colorado Clinical Translational Sciences Institute

Role: Co-chair Scientific and Advisory Review Committee of The Children's Hospital Clinical Translational Research Center of the Colorado Clinical Translational Sciences Institute

(b) (4)

3. 3UL 1RR025780-02S6 09/30/2009 – 4/30/2011 15% effort

Supplement to CCTSI ($496,816)

Role: Multi-site Principal Investigator

Development Of A Small Volume Sampling Technique For Fentanyl Pharmacokinetic, Pharmacodynamic And Pharmacogenetic Analysis In Preterm And Term Neonates With And Without Cyanotic Congenital Heart Disease.

Primary Specific Aim

Determine the PK of fentanyl in preterm and term neonates with and without CHD utilizing a small volume sampling technique.

Secondary Specific Aims

1. Examine the PD of fentanyl using a validated observational pain scale as a clinical outcome correlate for fentanyl levels.
2. Development of a novel small-volume analytic technique to provide pharmacogenetic analysis of fentanyl in preterm infants and neonates with and without CHD.
3. Examine the pharmacogenetics of fentanyl in neonates by correlating drug effect with expression of drug transporters and receptors due to ontogeny.
4. Evaluation of potential new fentanyl metabolites in neonates.

4. 3UL1RR025744-02S3 09/30/2009 – 4/30/2011 5% effort

Supplement to CCTSI ($500,000)

Role: Site Principal Investigator, Program Director analytic site

Methadone vs. morphine PK/PD in infants and young children after cardiac surgery.

Primary Specific Aim

Define the PK of methadone and morphine and their metabolites in post-cardiac surgery children.

Secondary Specific Aims

Describe their relative efficacy of methadone and morphine in post-cardiac surgery children.

5. HD37255-02 (PI: Adamson) 1/1/2000 – 12/31/2003 20% effort NIH

Pediatric Pharmacology Research Unit
Role: Associate Clinical Pharmacologist

The major goals of this project are:
1. To provide a locus for the conduct of studies in bioavailability, formulations, drug metabolism, pharmacokinetics, pharmacodynamics, and safety and effectiveness of new drugs and drugs already in the market.
2. To gather and promote the accrual of the necessary clinical date for pediatric age-specific labeling of drugs.
3. To conduct research of new pediatric therapeutic modalities, including: a) molecular approaches to the treatment of diseases, b) application of new technology to pharmacodynamic studies and drug systems, c) development of pediatric formulations, and d) validation of new endpoints or surrogate markers.
4. To conduct studies on the developmental characteristics and genetic polymorphism of drug metabolizing enzymes, pharmacokinetic modeling, and simulation technology.
5. To provide a teaching environment in which pediatricians, pharmacists, nurses and other can gain supervised experience in pediatric clinical trials and training in evidence-based pediatric pharmacology.
6. The major goals of this project are to facilitate and promote pediatric labeling of new drugs or drugs already on the market. The overall goal of the PPRU Network is the safe and effective use of drugs in children.

6. H5U01HD 37255-04 (PI: Adamson) 11/1/2002 – 10/31/2003 15% effort NIH
Role: Co-PI

Pedatric Pharmacology Research Unit Supplement
The major goals of this project are:
1. To develop and validate a limited sampling strategy for oral midazolam and its metabolitesin children.
2. To genotype a group of pediatric patients for specific CYP3A4 and CYP3A5 polymorphisms.
3. To phenotype patients following oral midazolam administration using a limited sampling methodology for midazolam and its metabolites and CYP3A4 and CYP3A5 genotypes.


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ACTIVE

1. R01 HD070511-01 PI Christians 08/01/11- 4/31/16 10% effort
Funding: $249,999 annual
Role: PI Clinical Trial
In Vivo Assessment of Calcineurin Inhibitor Toxicity in Children
The proposed study seeks to assess the clinically relevant mechanisms of calcineurin inhibitor toxicity to develop plasma and urine metabolite biomarkers for the early detection of negative effects on kidney and vascular endothelial cells in pediatric patients with the nephrotic syndrome and in pediatric patients who undergo kidney transplantation. We will also determine whether these metabolite biomarkers have better sensitivity and specificity compared to markers in current clinical use such as serum creatinine and/or cystatin C levels.

(b) (4)

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CURRICULUM VITAE

Jeffrey E. Lancet, M.D.

Current Position: Senior Member
Department of Malignant Hematology
H. Lee Moffitt Cancer Center and Research Institute
12902 Magnolia Dr., SRB4
Tampa, Florida 33612
(813) 745-6841
(813) 745-3071 Fax
Jeffrey.Lancet@moffitt.org

Current Academic: Professor
Department of Oncologic Sciences
University of South Florida

Education:

1988-1992: **M.D.** S.U.N.Y. Upstate Medical College at Syracuse, New York

1984-1988: **B.A.** University of Rochester, Rochester, New York
Biology, Psychology (Cum Laude)

Postgraduate Training and Fellowship Appointments:

2014 Fellow – The Leadership Academy at Moffitt Cancer Center (Physician Leadership Institute)

1996-1999: Hematology/Oncology Clinical and Research Fellowship - University of Rochester School of Medicine and Dentistry, Rochester, NY

1995-1996: Chief Resident & Instructor in Medicine - St. Mary's Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY

1993-1995: Residency - Internal Medicine, Strong Memorial Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY

1992-1993: Internship - Internal Medicine, Strong Memorial Hospital, University of Rochester School of Medicine and Dentistry, Rochester, NY

on Therapeutic Clinical Trials in Hematological Malignancies for H. Lee Moffitt Cancer Center and Research Institute

2005, 2013 Nomination for "Physician of the Year" H. Lee Moffitt Cancer Center and Research Institute

1988 Cum Laude Graduate, University of Rochester, Rochester, New York

RESEARCH SUPPORT

CURRENT

External Grants:

Account # 1R01CA168677-01A1
Name and Role: **Jeffrey Lancet, co-investigator** (PI: Martine Extermann, MD)
Source: NIH/NCI
Title: Decision Models to Compare Treatments in Older Patients with AML
% Effort: 10%
Direct Costs: $939,800
Award: $1,373,529

Clinical Trials: Principal Investigator (PI)

Name and Role: **Jeffrey Lancet ï PI**
Dates: 8/2013 – Present
Source: MCC
Title: MCC 17302: A Phase II Study Evaluating the Oral Smoothened Inhibitor PF-04449913 in Patients with Myelodysplastic Syndrome
Objective: **Investigator-initiated treatment research trial**
Planned Patient total: 35
MCC Accrual: 9
Total Amount: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:

(b) (6)

Total Amount: (b) (4)
Per Patient:
Name and Role:
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual (to date
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total
MCC Accrual (to date)
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual (to date)
Per Patient:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual (to date):
Per Patient:

COMPLETED

External Grants:

Award #:	**5 P30 CA076292-11**
Name and Role	**Jeffrey Lancet -PI**
Dates:	02/1/09 – 01/31/11
Source:	National Institutes of Health
Title:	NIH-ASCO Cancer Foundation Clinical Investigator Team Leadership Award
% Effort:	12%
Total direct costs:	$57,594
Total Amount:	$96,182

Award #:	**R-6030-04** (University of Rochester)
Name and Role:	Jane Liesveld – PI, **Jeffrey Lancet ï Co-PI**
Dates:	10/1/03 – 09/30/05
Source:	Leukemia & Lymphoma Society
Title:	Effect of Farnesyltransferase Inhibition in AML and MDS
% Effort:	16%
Total direct costs:	(b) (4)
Total Amount:	

Contracts:

Account #:	19-15053-01-03
Name and Role:	**Jeffrey Lancet - PI**
Dates:	08/2006 – Present
Source:	NCI/CTEP Translational Research Initiative
Title:	MCC 14796*:* Phase I Dose-Escalation Study of R11577 (Tipifarnib) plus PS-341 (bortezomib) in Relapsed or Refractory Acute Leukemias
% Effort:	N/A
Total Direct Costs:	$31,290
Total Amount:	$51,316

Clinical Trials: Principal Investigator

Account #:	10-14398-99-01
Name and Role:	**Jeffrey Lancet ï National and Institutional PI**
Dates:	5/2011 – 7/2012
Source:	NCI-CTEP (Funded through institutional N-01 contract)
Title:	MCC 16572: Phase 2 Trial of R115777 in Previously Untreated Older Adults with AML and Baseline Presence of a Specific 2-Gene Expression Signature Ratio
Objective:	**Investigator-initiated treatment research trial**
Planned Patient total:	35
MCC Accrual:	8
Per Patient:	$6,393

Name and Role:	**Jeffrey Lancet ï PI**
Dates:	10/2007 – 12/2012
Source:	MCC
Title:	MCC 15025: Pilot trial of a WT-1 analog peptide vaccine in patients with myeloid neoplasms
Objective:	**Investigator-initiated treatment research trial**
Planned Patient total:	10
MCC Accrual:	13
Total Amount:	(b) (4)
Per Patient:	

Name and Role:	**Jeffrey Lancet ï PI**
Dates:	(b) (4)
Source:	
Title:	
Objective:	
MCC Accrual:	
Total Amount:	
Per Patient:	

Name and Role:	**Jeffrey Lancet ï Institutional PI**
Dates:	(b) (4)
Source:	
Title:	

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: 05/2009 – 6/2013
Source: SWOG
Title: S0535: A Phase II Study Of Atra, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients With Previously Untreated High-Risk Acute Promyelocytic Leukemia
Objective: **Investigator-initiated cooperative group treatment research trial**
Planned Patient total: 70

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 10/2009 – 00/2011
Source: SWOG
Title: MCC 15992: A Phase III Randomized, Double-Blind Study of Induction (Daunorubicin/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy + Midostaurin (PKC412) or Placebo in Newly Diagnosed Patients < 60 Years of Age with FLT3 Mutated Acute Myeloid Leukemia
Objective: SWOG treatment research trial
Planned Patient total: 300
MCC Accrual: 5

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual:

(b) (4)

Per Patient: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:
Objective:
Planned Patient total
MCC Accrual
Per Patient: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: 7/2008 – 3/2009
Title: MCC 15332. A Phase IIB, Randomized, Double-Blinded, Placebo-Controlled Study of Low Dose Cytarabine and Lintuzumab Compared to Low Dose Cytarabine and Placebo in Patients 60 Years of Age and Older with Previously Untreated AML
Objective: Sponsored treatment research trial
Planned Patient total: 211
MCC Accrual: 7
Per patient (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:
Objective:
MCC Accrual:
Per Patient: (b) (4)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:
Objective: (b) (4)

Planned Patient total (b) (4)
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 05/2007 - Present
Source: SWOG
Title: MCC 15154: A Phase II Study of Lenolidomide (Revlimid) (NSC-703813) For Previously Untreated Non-M3, Deletion 5q Acute Myeloid Leukemia (AML) in Patients Age 60 or Older Who Decline Remission Induction Chemotherapy
Objective: SWOG treatment research trial
Planned Patient total: 37
MCC Accrual: 11

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 05/2007 – 8/2008
Source: SWOG
Title: MCC 15036: A Phase II Study of Cytarabine and Clofarabine in Patients with Relapsed or Refractory Acute Lymphoblastic Leukemia
Objective: SWOG treatment research trial
Planned Patient total: 37
MCC Accrual: 6

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient tota
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI and co-author of trial**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total:
MCC Accrual:

Per Patient: (b) (4)

Account #: 10-14398-99-01
Name and Role: **Jeffrey Lancet ï National and Institutional PI** (clinical trial),
Institutional N-01 Contract (to fund clinical trial),
PI – Daniel Sullivan, MD
Dates: 08/2006 – 12/2008
Source: NCI/CTEP
Title: MCC 14796*:* Phase I Dose-Escalation Study of R11577 (Tipifarnib) plus PS-341 (bortezomib) in Relapsed or Refractory Acute Leukemias
Objective: **Investigator-initiated translational research trial**
% Effort: 5%
Planned Patient total: 27
MCC Accrual: 19
Total Direct Costs: $2,600 per patient
Total Amount: $4,600 per patient

Account # 84-14604-01-01
Name and Role: **Jeffrey Lancet - PI**
Dates: (b) (4)
Source:
Title:

Objective:
Patient Total
Total Direct Costs:
Total Amount:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective: (b) (4)
Planned Patient total:
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned patient Tota
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates: (b) (4)
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

Name and Role: **Jeffrey Lancet ï Institutional PI**
Dates: 08/2005 - 02/2006
Source: SWOG
Title: MCC 14486: Phase II Studies of Two Different Schedules and Two Different Doses of the Farnesyl Transferase Inhibitor R115777 (Tipifarnib, Zarnestra, NSC-702818) for Previously Untreated Acute Myeloid Leukemia (AML) in Patients of Age 70 or Older
Objective: SWOG treatment research trial.
Planned Patient total: 348
MCC Accrual: 13

Name and Role: **Jeffrey Lancet - Institutional PI**
Dates: 06/2005 - 01/2006
Source: NCI
Title: MCC 14492: Compound 506U78 (NSC 686673) in Patients With Relapsed or Refractory T-Cell ALL or T-Cell Lymphoblastic Lymphoma
Objective: NCI sponsored treatment research trial.
Patient Total: 2 (early termination by sponsor)

Name and Role: **Jeffrey Lancet ï National and Institutional PI**
Dates:
Source:
Title:

Objective:
Planned Patient total
MCC Accrual:
Per Patient:

(b) (4)

SERVICE

H. Lee Moffitt Cancer Center Service

Administrative Appointments:

2013-present	**Chief of Medicine Services**, Moffitt Cancer Center
2005-2012	**Head of Clinical Research**, Malignant Hematology Division
2006-present	**Leukemia Section Head,** Malignant Hematology Division

Committees:

9/2013 – Present	**Member,** Medicine Safety Committee - Monthly
1/2012 – Present	**Member,** Moffitt Clinical Research Action Committee -Monthly
7/2011 – Present	**Member/Chair** Moffitt Conflict of Interest Committee – Monthly **(Chair, 6/2013)**
3/2011 – Present	**Member,** Moffitt Appointment, Promotion, and Tenure Committee - weekly
2010 – 2011	**Member,** Grand Rounds Steering Committee
2008 – 2011	**Member,** Clinical Research Governance Committee
3/2006 - 6/2011	**Vice-chair,** Protocol Monitoring Committee
2005-2007	**Member,** Clinical Investigations Steering Committee

University of Rochester Service

Committees:

2000 – 2004	**Member,** University of Rochester Peer Review Committee

Professional

July 2015	**Member,** Oncology Drug Advisory Committee of the US Food & Drug Administration

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Caplan, Liron	Associate Professor of Medicine/Rheumatology
eRA COMMONS USER NAME XXXXXXX	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
University of Texas, Austin, TX	B.A.	08/90-05/94	Pre-Med/Comparative Religions
Baylor College of Medicine, Houston, TX	M.D.	08/95-05/99	Medicine
Emory University, Atlanta, GA	Certificate	07/99-06/02	Internal Medicine Residency
Washington Univ School of Medicine, St. Louis, MO	Certificate	07/02-06/04	Rheumatology Fellowship
Washington Univ School of Medicine, St. Louis, MO	Certificate	07/04-06/05	Post Doctoral Research Fellow
Saint Louis Univ School of Public Health, MO	--	08/04-04/05	Epidemiology and Biostatistics
Univ. of Colorado Graduate School, Denver, CO	Ph.D.	01/06-05/10	Health Services Research

A. Personal Statement

XXXXXXX

B. Positions and Honors

Positions and Employment

2005 Research Associate (WOC), Veterans Administration Medical Center, St. Louis, MO
2005-2012 Assistant Professor of Medicine/Rheumatology, University of Colorado, Denver, CO
2008-present Core Investigator, Colorado REAP to Improve Care Coordination for Veterans, Denver, CO
2007-present Site Principle Investigator, Veterans Affairs Rheumatoid Arthritis registry
2008-present Core Investigator and founding member, Pharmaco-Epidemiology Collaborative of Colorado
2009-present Executive Committee Member and Site Principle Investigator, Program to Understand the Longterm Outcomes in SpondyloARthritis (PULSAR) registry
2012-present Associate Professor of Medicine/Rheumatology, University of Colorado, Denver, CO
2013-present Founding Member of the Board of Directors, SPondyloArthritis Research and Treatment Network (SPARTAN, California Nonprofit Public Benefit Corporation)
2013-present Core Investigator, Denver Seattle Center of Innovation for Veteran-centered & Value-driven caRe (DiSCoVVR), Denver, CO
2014-present Section Chief, Rheumatology, Denver Veterans Affairs Medical Center, Denver, CO

Other Experience and Professional Memberships

2002-present Member, American College of Rheumatology
2002-present Diplomat, American Board of Internal Medicine, Certification in Internal Medicine
2005-present Diplomat, American Board of Internal Medicine, Certification in Rheumatology
2009-2011 Member, American College of Rheumatology Rheumatoid Arthritis Clinical Disease Activity Measures Working Group
2012 Moderator of Expert Panel, American College of Rheumatology Rheumatoid Arthritis Quality Measures Working Group
2012-present Member and Systematic Literature Review Lead, Am. Coll. of Rheum./SPARTAN/SAA Ankylosing Spondylitis and Axial Spondyloarthritis Treatment Guidelines Working Group
2013 Session moderator, Am. Coll of Rheum. Annual Scientific Meeting, Epidemiology and Health Services Research II: Healthcare Costs and Mortality in Rheumatic Disease
2014-present Member, U.S. Food and Drug Administration (FDA) Arthritis Advisory Committee

Honors

1990-1994 Four-Time College Scholar, Dean of Liberal Arts, Univ. of Texas, Austin
1994 Magna Cum Laude Scholar (with High Honors), College of Liberal Arts
1994 Member of Phi Beta Kappa Honor Society, Alpha of Texas Chapter
2003-2004 National Institutes of Health Rheumatology Training Grant (T32)
2004 American College of Rheumatology Fellow Award
2007 UC Denver Graduate Program, Outstanding Ph.D. Student Award in Health Services Research

6. Baker JF, Cannon GW, Ibrahim S, Haroldsen C, Caplan L, Mikuls TR. Predictors of Longterm Changes in Body Mass Index in Rheumatoid Arthritis. J Rheumatol. 2015 Apr 1. pii: jrheum.141363. [Epub ahead of print] PMID: 25834210

D. Research Support

Ongoing Research Support

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Awarded Research Support (declined due to support exceeding 1.0 FTE):

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Completed Research Support

CDA-07221 Caplan L (PI) 07/01/09-06/30/14
Veterans Heath Administration, Health Services Research and Development
"Preventing long-term adverse drug reactions: glucocorticoids as a model"
VA Career Development Award-2
This study will attempt to develop a model of provider adherence with measures to prevent glucocorticoid induced osteoporosis, using local and national data. It then develops a real-time decisional support intervention to improve provider practice.
Role: Principal Investigator

Number not assigned Davis LA (PI) 07/01/11-06/30/12
VA's Colorado Research Enhancement Award Program to Improve Care Coordination
"Cleaning of pharmacy data to understand the role of immunosuppression in cardiovascular disease among patients with psoriasis and psoriatic arthritis"
Pilot Grant
This grant develops and tests software-based algorithms for automatically detecting and correcting statistical outliers within methotrexate and anti-TNF pharmacy data. The resulting "cleaned" data are then used to determine if exposure to methotrexate or anti-TNF therapy diminishes the risk of myocardial infarction, stroke and death in patients with Ps/PsA.
Role: co-Principal Investigator

CURRICULUM VITAE

ROXANA MEHRAN, MD, FACC, FACP, FAHA, FCCP, FESC, FSCAI
One Gustave L. Levy Place, Box 1030, New York, NY 10029
Tel +1-212-659-9691/+1-212-659-9649; Fax +1-646-537-8547; e-mail: roxana.mehran@mountsinai.org

CURRENT POSITIONS

2010-Present	Professor of Medicine (Cardiology), Icahn School of Medicine at Mount Sinai, New York, NY
2010-Present	Professor of Health Evidence and Policy, Icahn School of Medicine at Mount Sinai, New York, NY
2010-Present	Director of Interventional Cardiovascular Research and Clinical Trials, The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, NY
2008-Present	Chief Scientific Officer, Cardiovascular Research Foundation, New York, NY
1999-2010	Director of Clinical Research and Data Coordinating Center Cardiovascular Research Foundation, New York, NY
1996-Present	Course Co-Director, *Transcatheter Cardiovascular Therapeutics*, Washington, DC

PREVIOUS POSITIONS

2004-2010	Associate Professor of Medicine in the Academic Track Department of Internal Medicine and Division of Cardiovascular Disease, Columbia University Medical Center, New York, NY
2004-2010	Director, Outcomes Research, Data Coordination & Analysis, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York, NY
2002-2004	Associate Clinical Professor of Medicine, New York University School of Medicine, New York, NY
1999-2004	Interventional Cardiologist, Lenox Hill Interventional Cardiology PC, Lenox Hill Hospital, New York, NY
1997-1999	Assistant Clinical Professor of Medicine, George Washington University School of Medicine, Washington, DC
1996-1999	Director of Clinical Research and Data Coordinating Center, Cardiology Research Foundation Washington Hospital Center, Washington, DC
1995-1999	Interventional Cardiologist, Washington Cardiology Center Washington Hospital Center, Washington, DC
1994-1995	Instructor of Medicine, Mount Sinai School of Medicine, New York, NY

POSTGRADUATE EXPERIENCE

1994-1995	Fellow, Interventional Cardiology, Cardiovascular Institute Mount Sinai Medical Center, New York, NY
1991-1994	Fellow, Cardiology, Cardiovascular Institute Mount Sinai Medical Center, New York, NY
1990-1991	Chief Resident, Internal Medicine, University of Connecticut School of Medicine Greater Hartford Integrated Internal Medicine Program, Hartford, Connecticut
1988-1990	Resident, Internal Medicine, University of Connecticut School of Medicine Greater Hartford Integrated Internal Medicine Program, Hartford, Connecticut
1987-1988	Medical Intern, Mount Sinai Hospital, Hartford, Connecticut

POSTDOCTORAL FELLOWSHIPS

1990-1991	Postdoctoral Fellow, Department of Cardiology and Physiology University of Connecticut School of Medicine, Farmington, Connecticut
1992-1993	Postdoctoral Fellow, Brookdale Center for Molecular Biology Mount Sinai School of Medicine, New York, NY

EDUCATION

1987	St. George's University School of Medicine Grenada, WI	MD
1983	New York University, New York, NY	BA (Chemistry)

CERTIFICATIONS

1990	Diplomat, American Board of Internal Medicine
1997-2011	Diplomat, American Board of Internal Medicine, Cardiovascular Disease
1999-2011	Diplomat, American Board of Internal Medicine, Interventional Cardiology
1985	Educational Commission for Foreign Medical Graduates
1985	FLEX

5. Course Co-Director, Transcatheter Cardiovascular Therapeutics (TCT) 1996-present.
6. Program Committee Member, American Heart Association Scientific Sessions (AHA) 1996-present.
7. American College of Cardiology (ACC). 1997-present.
8. Interventional Cardiology Fellows' Course. 1998-present.
9. Joint Interventional Meeting (JIM) Rome, Italy. 2000-present.
10. European Society of Cardiology (ESC). 2001-present
11. Sociedad Latino Americana de Cardiologia Intervencionista (SOLACI)
12. China Interventional Therapeutics (CIT)
13. Angioplasty Summit - TCT Asia Pacific- Korea
14. EuroPCR Congress. 2013.
15. Global Interventional Summit (GIS). 2010.
16. Società Italiana di Cardiologia Invasiva (GISE)
17. Cardiological Society of Argentina, Buenos Aires, Argentina. October 1998.

AWARDS and HONORS

1991	NASPE Fellow; Chicago, IL
2001	Innovation in Clinical Research: "Novel Approaches for the Inhibition of Stent Restenosis and Arteriopathy After Cardiac Transplantation" (Co-recipient: Steven O. Marx) Doris Duke Charitable Foundation, New York, NY
2013	F. Mason Sones, Jr., M.D., FSCAI, Distinguished Service Award (SCAI 36th Annual Scientific Sessions, Orlando FL, May 8-11, 2013)
2013	Elite Reviewer Service and Scholarship Award, Journal of the American College of Cardiology (JACC)
2013	Elite Reviewer Award, Catheterization and Cardiovascular Interventions (CCI)
2014	"The World's Most Influential Scientific Minds 2014" recognition, The IP & Science, Thomson Reuters

LICENSURE

New York State
Connecticut
District of Columbia

RESEARCH

ONGOING

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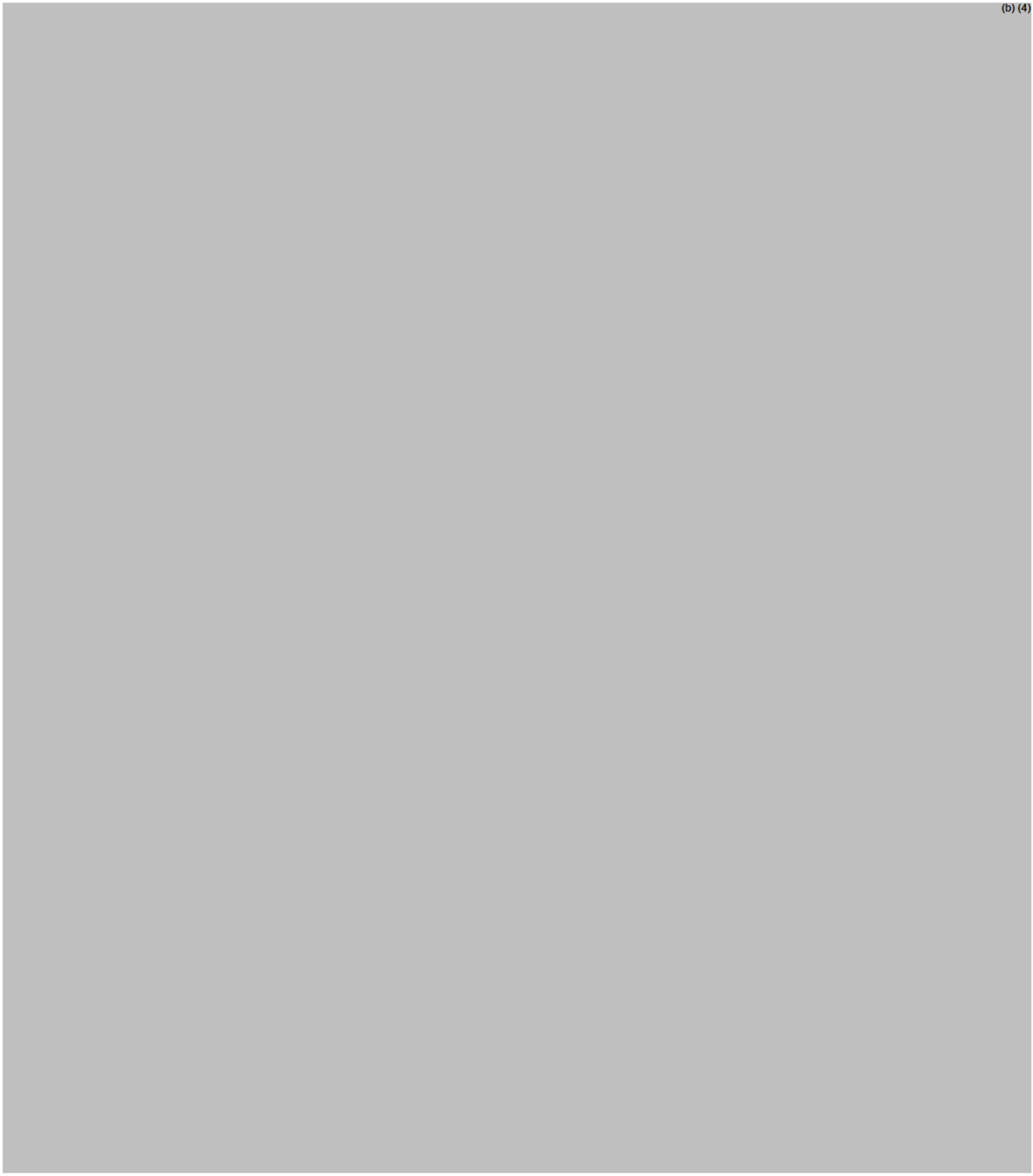
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6. **Co-Investigator:** Depression, Biobehavioral Mechanisms, & CHD/Mortality Outcomes **(PULSE)**. Funding Institution: NHLBI, Current Award # 5 P01 HL088117-02

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10. **Data Safety Monitoring Board: INFUSE-AMI Trial:** Cardiac MRI for Patients Enrolled in INFUSE-AMI; Sponsor: NHLBI

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12. **Co-Investigator: FREEDOM** Trial: Future Revascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease. Funding Institution: NHLBI.
13. **Co-Investigator**: Improving Med Adherence in Post-ACS Patients: Phase 1B Dose-Finding RCT. Funding Institution: NHLBI, Current Award # K24 HL084034
14. **Co-Investigator:** Multidisciplinary Training in Translational Cardiovascular Research. Funding Institution: NHLBI, Current Award #5 T32 HL08-7745-01
15. **Co-Investigator:** Cardiac Caregiver Study. Funding Institution: NHLBI. Award #2R01 HL075101-05A1
16. **Co-Investigator:** Family-Centered Intervention Trial for Heart Health (**FIT HEART II**). Funding Institution: NIH, Current Award # 2RO1HL075101-05A1

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26. **Principal Investigator: FREEDOM Trial Registry Substudy:** RO-1 Grant (September 2004 submission) A multicenter trial of CABG surgery versus sirolimus drug-eluting stent implantation in diabetic patients with multivessel coronary artery disease. Sponsor: NHLBI, NIH.

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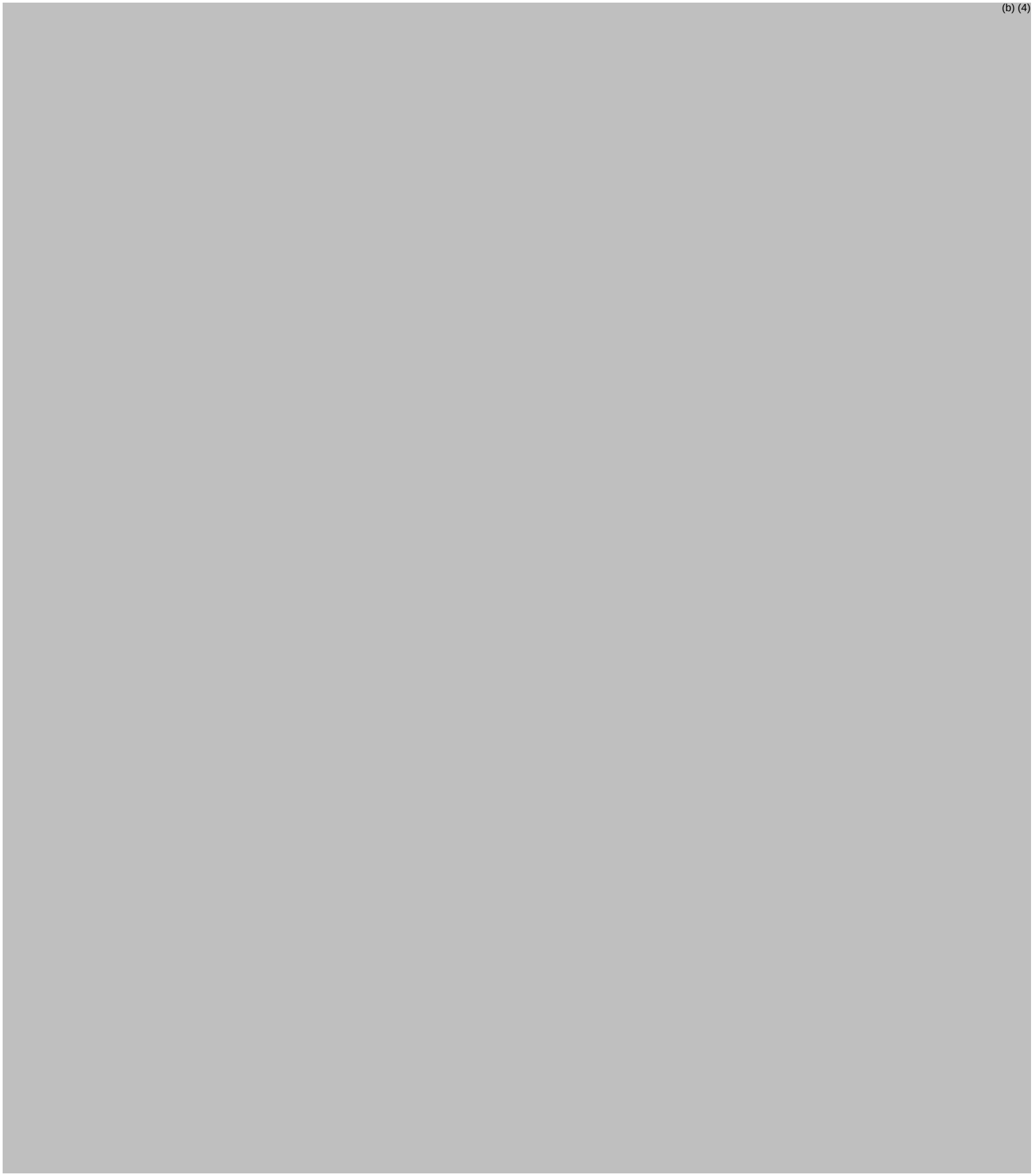

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85. Member of the Angiographic committee; **W**omen's **A**ngiographic **V**itamin and **E**strogen trial **(WAVE)**; NHLBI

(b) (4)

ABSTRACTS

Over 600 abstracts presented from 2008-2013 at national and international conferences including TCT, AHA, ACC, ESC, EuroPCR, and SCAI.

BOOK CHAPTERS

1. (b) (4) In Press.
2. Nikolsky E**, Mehran R.** Bleeding complications in patients undergoing percutaneous coronary intervention: prognostic implications and prevention. In: *Mechanical Reperfusion for STEMI: From Randomized Trials to Clinical Practice*. DeLuca G, Lansky A (eds), Informa Healthcare USA (New York), 2010.
3. **Mehran R**, Nikolsky E. Postprocedural complications II: contrast-induced renal insufficiency. In: *Textbook ofCoronary Stents*. Stone GW, Leon MB (eds). WB Saunders Co (Boston), 2010.
4. Kobayashi Y, **Mehran R**. Stenting in the elderly. In: *Textbook of Coronary Stenting.* Stone GW, Leon MB (eds). WB Saunders Co (Boston), 2010.
5. **Mehran R**, Nikolsky E. Classification of in-stent restenosis. In: *Textbook of Coronary Stenting*. Stone GW, Leon MB (eds). WB Saunders Co (Boston), 2010.
6. Turcot D, **Mehran R**, Moussa I, Dangas G. Treatment of in-stent restenosis with PTCA, laser, atherectomy, and repeat stenting. In: *Textbook of Coronary Stenting*. Stone GW, Leon MB (eds). WB Saunders Co (Boston), 2010.
7. Turcot D, Aymong E, **Mehran R**, Dangas G, Leon M. Heparin-coated stents III: Evidence of thromboresistance from registry studies. In: *Textbook of Coronary Stenting*. Stone GW, Leon MB (eds). WB Saunders Co (Boston), 2010.
8. Nikolsky E, **Mehran R**. Approach to patients with impaired renal function. In: *Problem-Oriented Approaches in Interventional Cardiology*. Colombo A, Stankovic G (eds), Informa Healthcare. (London), 2007
9. Kimura M, Nikolsky E, Balter S, **Mehran R**. Complications related to radiation and contrast media exposure. In: *Handbook of Chronic Total Occlusions.* Dangas G, **Mehran R**, Moses J (eds), Informa Healthcare. (London), 2007.

Curriculum vitae

Date Prepared: May 1, 2013

Name: James A. de Lemos

Office Address: 5323 Harry Hines Blvd, Room E05.728
Dallas, TX 75390-8830

Work Phone: **214-645-7500**

Work E-Mail: James.delemos@utsouthwestern.edu

Work Fax: 214-645-2480

(b) (6)

Education

Year	Degree (Honors)	Field of Study	Institution
1997	Certificate	Clinical Effectiveness Program	Harvard School of Public Health
1992	M.D.	Medicine	Harvard Medical School
1987	B.A. (Summa Cum Laude)	Liberal Arts	The University of Texas at Austin

Postdoctoral Training

Year(s)	Titles	Specialty/Discipline	Institution
1996-1999	Fellow	Cardiology	The Brigham and Women's Hospital, Boston, MA
1995-1996	Chief Resident	Internal Medicine	UT Southwestern Medical Center, Dallas, TX
1992-1995	Intern/Resident	Internal Medicine	UT Southwestern Medical Center, Dallas, TX

Current Licensure and Certification

Licensure
Texas (b) (6) 1993

Board and Other Certification
American Board of Internal Medicine Certification, 1995
Cardiovascular Subspecialty Certification, 1999, renewed 2009

	American Journal of Medicine
	Annals of Internal Medicine (Distinguished Reviewer 2005)
	Atherosclerosis
	Atherosclerosis, Thrombosis, and Vascular Biology
	Kidney International
	Clinical and Experimental Medicine
	Coronary Artery Disease
	Journal of Cardiac Failure

Grant Support

Present	*Grantor:* NIH/NHLBI T32HL007360-04
	Title of Project: Training in Cardiovascular Research (Hill PI)
	Role (Principal Investigator, Co-Investigator): Co-PI
	Annual amount and date (direct costs only): 2008-2013 $846, 521
	Total amount of award (if multi-year) and dates (direct costs only):
	The objective of this institutional training grant is to select talented and committed young investigators and to prepare them for careers in cardiovascular research
	Grantor: NIH/NCATS
	Title of Project: UT Southwestern Clinical and Translational Alliance for Research (UT-STAR)
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	*Annual amount and date (direct costs only): 2012 -2013 $*$4,412,465
	Total amount of award (if multi-year) and dates (direct costs only):
	The objective of this project is to improve the way biomedical research is conducted across the country, reduce time it takes for laboratory discoveries to become treatments for patients, improve population health, and train a new generation of clinical and translational researchers.
	(b) (4)
	(b) (4)

	[redacted] (b) (4)

Past	*Grantor:* NIH UL1RR024982
	Title of Project: North and Central Texas Clinical and Translational Science Initiative (Toto PI)
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Annual amount and date (direct costs only): 2007-2012
	Total amount of award (if multi-year) and dates (direct costs only): $22,000,000
	This award supported the inital UTSW CTSA
	Grantor: NIH RO1 HL087768
	Title of Project: The GoodNEWS Trial (De Haven PI)
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Annual amount and date (direct costs only): 2007-2012
	Total amount of award (if multi-year) and dates (direct costs only): $1,903,932
	This is a randomized controlled trial testing a community-based participatory intervention to lower cardiovascular risk in predominantly African American churches in Dallas.
	Grantor: NHLBI SBIR Contract HHSN2682010 00003C Subcontract IOS #31 92-NIH-ACS
	Title of Project: Lateral-flow immunoassay platform for multiplexed cardiac biomarkers measurement
	Role (Principal Investigator, Co-Investigator): Subcontract Principal Investigator
	Annual amount and date (direct costs only): 2009-2010 $169,997
	Total amount of award (if multi-year) and dates (direct costs only):
	The goal of this project was to develop a point of care test strip for cardiovascular biomarkers
	[redacted] (b) (4)

(b) (4)

Grantor: Donald W. Reynolds Foundation

Title of Project: Return to the Dallas Heart Study

Role (Principal Investigator, Co-Investigator): Co-Investigator

Annual amount and date (direct costs only): 2006-2009 (b) (4)

Total amount of award (if multi-year) and dates (direct costs only): (b) (4)

This grant supported the return visit for the Dallas Heart Study cohort

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Grantor: NIH 7 RO1 AT 0005-03

Title of Project: Effect of High Dose Alpha Tocopherol on Carotid Atherosclerosis

Role (Principal Investigator, Co-Investigator): Co-Investigator (10% effort)

Annual amount and date (direct costs only):

Total amount of award (if multi-year) and dates (direct costs only):2002-2005

The goal of this project was to evaluate the potential protective effects of vitamin E on carotid atherosclerosis

(b) (4)

(b) (4)

(b) (4)

Grantor: Brigham and Women's Hospital NIH Training Grant

	Title of Project: Public Health Services Grant HL07604-13
	Role (Principal Investigator, Co-Investigator): Trainee
	(b) (4) [redacted]

Teaching Activities

Year(s)	Activity
Medical and graduate school didactic and small group teaching	
2000-present	Core didactic lectures to Cardiology Fellows on management of acute coronary syndromes, annual
2006-present	Core didactic lectures to Internal Medicine residents on principles of management of acute coronary syndromes, annual
2006-present	Core didactic lectures to Emergency Medicine residents, "Management of Non ST elevation Acute Coronary Syndromes," annual since 2006
2000-present	Cardiology Clinical Conference (30 min case-based lecture), annual
2006-present	Fellows Journal Club, moderator, weekly
2004-present	Fellows research conference, moderator, weekly
Dissertation committees	
(b) (6) [redacted]	
Committees concerned with medical and graduate student education	
2012	Clinical Science Education Committee, Institutional Six Year Plan
2009	Clinical Science Education Committee, Institutional Five Year Plan
2002-2010	Acute Care Committee for Fourth Year Student Rotations
2000-2011	Curriculum Committee, Internal Medicine Residency Training Program
2005-2008	Committee to Evaluate Clinical Competence, Internal Medicine Training Program
Graduate student rotations	

Curriculum vitae

Date Prepared: January 2, 2012

Name: James A. de Lemos

Office Address: 5909 Harry Hines Blvd, Room HA9.133
Dallas, TX 75390-9047

Work Phone: **214-645-7500**

Work E-Mail: James.delemos@utsouthwestern.edu

Work Fax: 214-645-7501

Place of Birth: Riverside, CA

Education

Year	Degree (Honors)	Field of Study	Institution
1997	Certificate	Clinical Effectiveness Program	Harvard School of Public Health
1992	M.D.	Medicine	Harvard Medical School
1987	B.A. (Summa Cum Laude)	Liberal Arts	The University of Texas at Austin

Postdoctoral Training

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1996-1999	Fellow	Cardiology	The Brigham and Women's Hospital, Boston, MA
1995-1996	Chief Resident	Internal Medicine	UT Southwestern Medical Center, Dallas, TX
1992-1995	Intern/Resident	Internal Medicine	UT Southwestern Medical Center, Dallas, TX

Current Licensure and Certification

Licensure
Texas (J4073), 1993

Board and Other Certification
American Board of Internal Medicine Certification, 1995
Cardiovascular Subspecialty Certification, 1999, renewed 2009

2007-09	Pilot Awards Program	North and Central Texas Clinical and Translational Science Initiative (NCTCTSI)
2006	Peer Reviewer	VA Merit Awards
2005	Peer Reviewer	Health Services R&D Awards, Ireland

Editorial Activities

Year(s)	Journal Name
Editor/Associate Editor	
	Cardioexchange.com (Fellowship section co-editor)
Editorial Board	
	Journal of the American College of Cardiology
	The American Journal of Cardiology
	The American Heart Journal
	Cardiology in Review (past)
Ad Hoc Reviewer	
	New England Journal of Medicine
	Journal of the American Medical Association
	The Lancet
	Nature Medicine
	Circulation
	Journal of the American College of Cardiology (Elite Reviewer 2006,2007,2008,2009)
	The American Heart Journal
	The American Journal of Cardiology
	European Heart Journal
	Heart
	Clinical Chemistry
	Archives of Internal Medicine
	American Journal of Medicine
	Annals of Internal Medicine (Distinguished Reviewer 2005)
	Atherosclerosis
	Atherosclerosis, Thrombosis, and Vascular Biology
	Kidney International
	Clinical and Experimental Medicine
	Coronary Artery Disease
	Journal of Cardiac Failure

Grant Support

Present	*Grantor: NIH RO1 HL087768*
	Title of Project: The GoodNEWS Trial
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Annual amount and date (direct costs only): 2007-2012
	Total amount of award (if multi-year) and dates (direct costs only): $1,903,932
	This is a randomized controlled trial testing a community-based participatory intervention to lower cardiovascular risk in predominantly African American churches in Dallas.
	Grantor: Roche Diagnostics (Investigator-initiated Grant)
	Title of Project: Correlation of Changes in Biomarkers with Incidence and Progression of Subclinical Cardiovascular Disease in the Dallas Heart Study
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): 2011-2013 $159,432+ materials
	Total amount of award (if multi-year) and dates (direct costs only):
	This project will perform measurement of novel biomarker in the return DHS visit and correlate serial changes with changes in cardiovascular phenotypes over an 8 year period.
	Grantor: Abbott Diagnostics (Investigator-initiated Grant)
	Title of Project: Sensitive troponin measurements in cardiac transplant rejection and pulmonary hypertension
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): 2011-2013 $88,400+materials
	Total amount of award (if multi-year) and dates (direct costs only):
	This project will perform measurement of troponin T, using a novel highly sensitive assay, in two cohorts: one with cardiac transplant (to evaluate transplant rejection) and one with pulmonary hypertension

Past	*Grantor:* NHLBI SBIR Contract HHSN2682010 00003C Subcontract IOS #31 92-NIH-ACS
	Title of Project: Lateral-flow immunoassay platform for multiplexed cardiac biomarkers measurement
	Role (Principal Investigator, Co-Investigator): Subcontract Principal Investigator
	Annual amount and date (direct costs only): 2009-2010 $169,997
	Total amount of award (if multi-year) and dates (direct costs only):
	The goal of this project was to develop a point of care test strip for cardiovascular biomarkers
	Grantor: Roche Diagnostics (Investigator-initiated Grant)
	Title of Project: Highly sensitive troponin T in the Dallas Heart Study

	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): 2009-2010 $62,450
	Total amount of award (if multi-year) and dates (direct costs only):
	This project evaluated a novel, highly sensitive assay for cardiac troponin T as a screening test for cardiovascular disease in the community
	Grantor: Donald W. Reynolds Foundation
	Title of Project: Return to the Dallas Heart Study
	Role (Principal Investigator, Co-Investigator): Co-Investigator
	Annual amount and date (direct costs only): 2006-2009 $6,622,722
	Total amount of award (if multi-year) and dates (direct costs only):$6,622,722
	This grant supported the return visit for the Dallas Heart Study cohort
	Grantor: Biosite, Inc. (Investigator-initiated Grant)
	Title of Project: Biomarker Discovery in the Dallas Heart Study
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only):
	Total amount of award (if multi-year) and dates (direct costs only): 2006-2009 $255,000
	This is an ongoing discovery project designed to identify novel biomarkers of cardiovascular disease, with an ultimate goal of creating multiple biomarker panels for population screening.
	Grantor: Rules Based Medicine (Investigator-initiated Grant)
	Title of Project: Evaluation of a multiple biomarkers in a chest pain unit
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): 2007 $10,000
	Total amount of award (if multi-year) and dates (direct costs only):
	This was a pilot study evaluating a large biomarker panel in a chest pain unit population.
	Grantor: Glaxo-Smith-Kline (Investigator-initiated Grant)
	Title of Project: Evaluation of LP-PLA2 in the Dallas Heart Study
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): $52,000 2006
	Total amount of award (if multi-year) and dates (direct costs only):
	This project evaluated the associations between LP-PLA2, a novel inflammatory biomarker, and subclinical coronary and peripheral atherosclerosis.
	Grantor: Biosite, Inc. (Investigator-initiated Grant)
	Title of Project: Evaluation of a multiple biomarker panel to detect ischemia in a chest pain unit

	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): $80,000 2004
	Total amount of award (if multi-year) and dates (direct costs only):
	This project evaluated a poing of care device for biomarker measurement in the emergency room.
	Grantor: NIH 7 RO1 AT 0005-03
	Title of Project: Effect of High Dose Alpha Tocopherol on Carotid Atherosclerosis
	Role (Principal Investigator, Co-Investigator): Co-Investigator (10% effort)
	Annual amount and date (direct costs only):
	Total amount of award (if multi-year) and dates (direct costs only):2002-2005
	The goal of this project was to evaluate the potential protective effects of vitamin E on carotid atherosclerosis
	Grantor: Merck and Co.
	Title of Project: The A to Z Study
	Role (Principal Investigator, Co-Investigator): Co-Principal Investigator
	Annual amount and date (direct costs only):
	Total amount of award (if multi-year) and dates (direct costs only):2001-2004
	This was a two –phased multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of early intensive statin therapy in patients with acute coronary syndromes (phase Z). It also compared low molecular weight heparin vs unfractionated heparin (phase A).
	Grantor: Free Fatty Acid Sciences, Inc. (Investigator-initiated Grant)
	Title of Project: Development of Novel Biomarkers of Cardiac Ischemia
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): $62,500 2004
	Total amount of award (if multi-year) and dates (direct costs only):
	This study used a human model of cardiac ischemia (rapid atrial pacing) to evaluate unbound free fatty acid as a novel ischemia biomarker.
	Grantor: Ischemia Technologies, Inc. (Investigator-initiated Grant)
	Title of Project: Development of Novel Biomarkers of Cardiac Ischemia
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): $12,500 2004
	Total amount of award (if multi-year) and dates (direct costs only):
	This study used a human model of cardiac ischemia to evaluate Ischemia Modified Albumin as a novel ischemia biomarker

	Grantor: Roche Diagnostics (Investigator-initiated Grant)
	Title of Project: NT-proBNP, hs-CRP, and cTnT in the Dallas Heart Study
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only):
	Total amount of award (if multi-year) and dates (direct costs only):$332,744 2003-2004
	This study performed comprehensive evaluation of the cardiac and non-cardiac sources of variation of hs-CRP, cTnT, and NT-proBNP in the general population.
	Grantor: Glaxo-Smith-Kline (Career Development Award)
	Title of Project: Identification of Novel Protein Markers of Cardiac Ischemia
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only):
	Total amount of award (if multi-year) and dates (direct costs only): $100,000 2003-2004
	This study developed a discovery platform for identifying and validating potential ischemia biomarkers.
	Grantor: Pfizer (Investigator-initiated Grant)
	Title of Project: Prospective risk-factor intervention in a multi-ethnic population
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): $60,000 2001
	Total amount of award (if multi-year) and dates (direct costs only):
	This study tested a pharmacist-based program for lipid management in an underserved population
	Grantor: Merck and Co. (Investigator-initiated Grant)
	Title of Project: Cost-effectiveness analysis of tirofiban in acute coronary syndromes
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): $15,000 2001
	Total amount of award (if multi-year) and dates (direct costs only):
	A cost-effectiveness model was developed to evaluate tirofiban use in acute coronary syndromes
	Grantor: Spectral Diagnostics
	Title of Project: Use of a rapid bedside assay for myoglobin to predict reperfusion after thrombolytic therapy: a substudy of the TIMI 14 trial
	Role (Principal Investigator, Co-Investigator): Principal Investigator
	Annual amount and date (direct costs only): 1998
	Total amount of award (if multi-year) and dates (direct costs only):
	A rapid bedside test for myoglobin was used for risk assessment and noninvasive

	detection of reperfusion success after fibrinolytic therapy.
	Grantor: Brigham and Women's Hospital NIH Training Grant
	Title of Project: Public Health Services Grant HL07604-13
	Role (Principal Investigator, Co-Investigator): Trainee
	From 1998-2000, specific portions of the budgets for operational direction of these trials (and substudies within these trials) were designated for my salary support. TIMI 14 - Centocor Inc., Eli Lilly & Co. InTIME-II - Bristol Myers Squibb TACTICS/TIMI 18 – Merck and Co. ER/TIMI 19 –Centocor Inc. FASTER – Merck and Co. INTEGRITI – Cor Therapeutics Inc, Schering-Plough Research Institute A2Z – Merck and Co. PROVE IT – Bristol Myers Squibb

Teaching Activities

Year(s)	**Activity**
Medical and graduate school didactic and small group teaching	
2000-present	Core didactic lectures to Cardiology Fellows on management of acute coronary syndromes, annual
2006-present	Core didactic lectures to Internal Medicine residents on principles of management of acute coronary syndromes, annual
2006-present	Core didactic lectures to Emergency Medicine residents, "Management of Non ST elevation Acute Coronary Syndromes," annual since 2006
2000-present	Cardiology Clinical Conference (30 min case-based lecture), annual
2006-present	Fellows Journal Club, moderator, weekly
2004-present	Fellows research conference, moderator, weekly
Dissertation committees	
2010	Keith Bernardo
Committees concerned with medical and graduate student education	
2012	Clinical Science Education Committee, Institutional Six Year Plan
2009	Clinical Science Education Committee, Institutional Five Year Plan
2002-2010	Acute Care Committee for Fourth Year Student Rotations
2000-2011	Curriculum Committee, Internal Medicine Residency Training Program

EXHIBIT 8

Declaration of Rachel Clattenburg
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITAE

ROXANA MEHRAN, MD, FACC, FACP, FAHA, FCCP, FESC, FSCAI
One Gustave L. Levy Place, Box 1030, New York, NY 10029
Tel +1-212-659-9691/+1-212-659-9649; Fax +1-646-537-8547; e-mail: roxana.mehran@mountsinai.org

CURRENT POSITIONS

2010-Present	Professor of Medicine (Cardiology), Icahn School of Medicine at Mount Sinai, New York, NY
2010-Present	Professor of Health Evidence and Policy, Icahn School of Medicine at Mount Sinai, New York, NY
2010-Present	Director of Interventional Cardiovascular Research and Clinical Trials, The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, NY
2008-Present	Chief Scientific Officer, Cardiovascular Research Foundation, New York, NY
1999-2010	Director of Clinical Research and Data Coordinating Center Cardiovascular Research Foundation, New York, NY
1996-Present	Course Co-Director, *Transcatheter Cardiovascular Therapeutics*, Washington, DC

PREVIOUS POSITIONS

2004-2010	Associate Professor of Medicine in the Academic Track Department of Internal Medicine and Division of Cardiovascular Disease, Columbia University Medical Center, New York, NY
2004-2010	Director, Outcomes Research, Data Coordination & Analysis, Center for Interventional Vascular Therapy, Columbia University Medical Center, New York, NY
2002-2004	Associate Clinical Professor of Medicine, New York University School of Medicine, New York, NY
1999-2004	Interventional Cardiologist, Lenox Hill Interventional Cardiology PC, Lenox Hill Hospital, New York, NY
1997-1999	Assistant Clinical Professor of Medicine, George Washington University School of Medicine, Washington, DC
1996-1999	Director of Clinical Research and Data Coordinating Center, Cardiology Research Foundation Washington Hospital Center, Washington, DC
1995-1999	Interventional Cardiologist, Washington Cardiology Center Washington Hospital Center, Washington, DC
1994-1995	Instructor of Medicine, Mount Sinai School of Medicine, New York, NY

POSTGRADUATE EXPERIENCE

1994-1995	Fellow, Interventional Cardiology, Cardiovascular Institute Mount Sinai Medical Center, New York, NY
1991-1994	Fellow, Cardiology, Cardiovascular Institute Mount Sinai Medical Center, New York, NY
1990-1991	Chief Resident, Internal Medicine, University of Connecticut School of Medicine Greater Hartford Integrated Internal Medicine Program, Hartford, Connecticut
1988-1990	Resident, Internal Medicine, University of Connecticut School of Medicine Greater Hartford Integrated Internal Medicine Program, Hartford, Connecticut
1987-1988	Medical Intern, Mount Sinai Hospital, Hartford, Connecticut

POSTDOCTORAL FELLOWSHIPS

1990-1991	Postdoctoral Fellow, Department of Cardiology and Physiology University of Connecticut School of Medicine, Farmington, Connecticut
1992-1993	Postdoctoral Fellow, Brookdale Center for Molecular Biology Mount Sinai School of Medicine, New York, NY

EDUCATION

1987	St. George's University School of Medicine Grenada, WI	MD
1983	New York University, New York, NY	BA (Chemistry)

CERTIFICATIONS

1990	Diplomat, American Board of Internal Medicine
1997-2011	Diplomat, American Board of Internal Medicine, Cardiovascular Disease
1999-2011	Diplomat, American Board of Internal Medicine, Interventional Cardiology
1985	Educational Commission for Foreign Medical Graduates
1985	FLEX

5. Course Co-Director, Transcatheter Cardiovascular Therapeutics (TCT) 1996-present.
6. Program Committee Member, American Heart Association Scientific Sessions (AHA) 1996-present.
7. American College of Cardiology (ACC). 1997-present.
8. Interventional Cardiology Fellows' Course. 1998-present.
9. Joint Interventional Meeting (JIM) Rome, Italy. 2000-present.
10. European Society of Cardiology (ESC). 2001-present
11. Sociedad Latino Americana de Cardiologia Intervencionista (SOLACI)
12. China Interventional Therapeutics (CIT)
13. Angioplasty Summit - TCT Asia Pacific- Korea
14. EuroPCR Congress. 2013.
15. Global Interventional Summit (GIS). 2010.
16. Società Italiana di Cardiologia Invasiva (GISE)
17. Cardiological Society of Argentina, Buenos Aires, Argentina. October 1998.

AWARDS and HONORS

1991	NASPE Fellow; Chicago, IL
2001	Innovation in Clinical Research: "Novel Approaches for the Inhibition of Stent Restenosis and Arteriopathy After Cardiac Transplantation" (Co-recipient: Steven O. Marx) Doris Duke Charitable Foundation, New York, NY
2013	F. Mason Sones, Jr., M.D., FSCAI, Distinguished Service Award (SCAI 36th Annual Scientific Sessions, Orlando FL, May 8-11, 2013)
2013	Elite Reviewer Service and Scholarship Award, Journal of the American College of Cardiology (JACC)
2013	Elite Reviewer Award, Catheterization and Cardiovascular Interventions (CCI)
2014	"The World's Most Influential Scientific Minds 2014" recognition, The IP & Science, Thomson Reuters

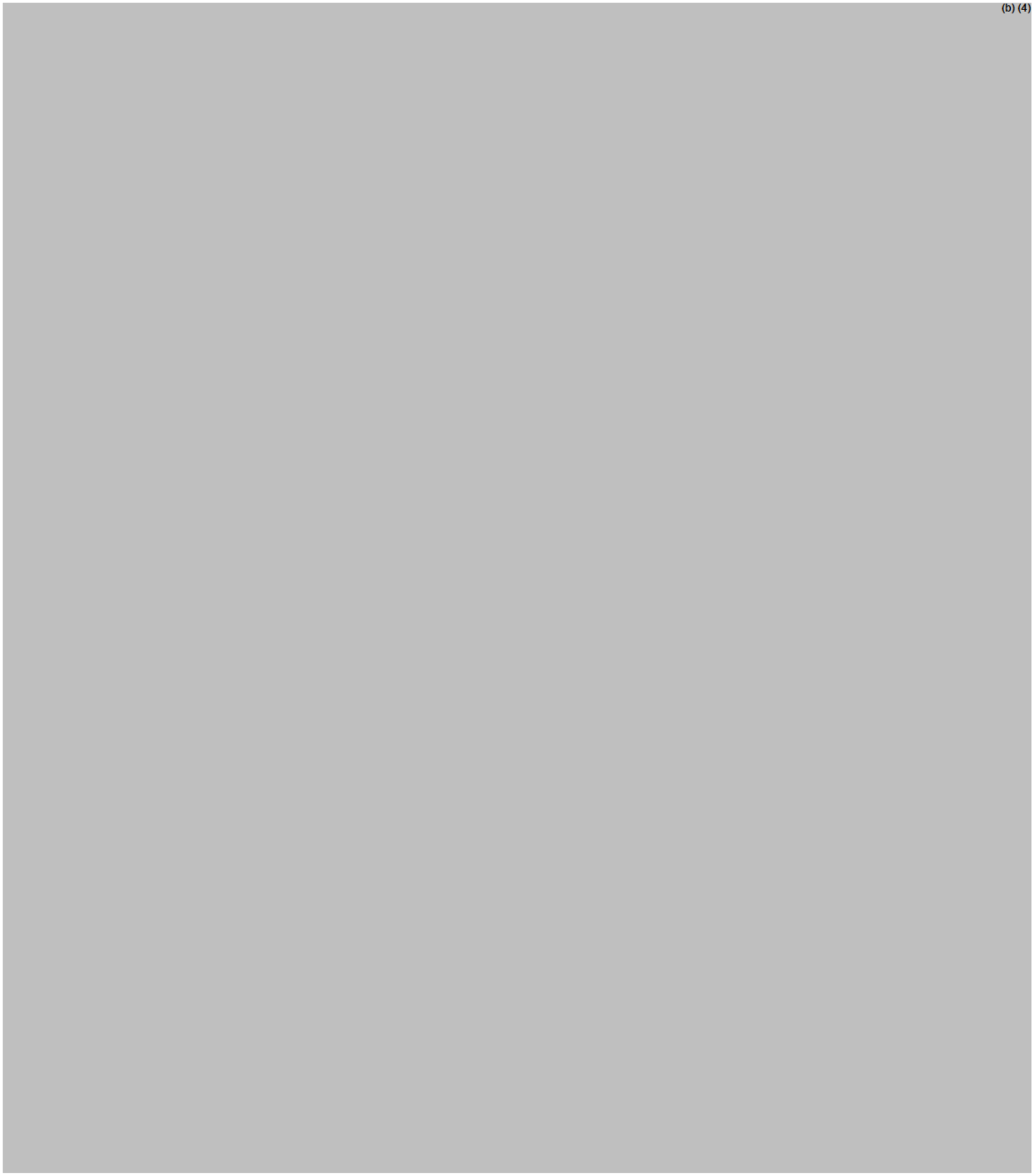
LICENSURE

New York State
Connecticut
District of Columbia

RESEARCH

ONGOING

(b) (4)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6. **Co-Investigator:** Depression, Biobehavioral Mechanisms, & CHD/Mortality Outcomes **(PULSE)**. Funding Institution: NHLBI, Current Award # 5 P01 HL088117-02

(b) (4)

10. **Data Safety Monitoring Board: INFUSE-AMI Trial:** Cardiac MRI for Patients Enrolled in INFUSE-AMI; Sponsor: NHLBI

(b) (4)

12. **Co-Investigator: FREEDOM** Trial: Future Revascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease. Funding Institution: NHLBI.
13. **Co-Investigator**: Improving Med Adherence in Post-ACS Patients: Phase 1B Dose-Finding RCT. Funding Institution: NHLBI, Current Award # K24 HL084034
14. **Co-Investigator:** Multidisciplinary Training in Translational Cardiovascular Research. Funding Institution: NHLBI, Current Award #5 T32 HL08-7745-01
15. **Co-Investigator:** Cardiac Caregiver Study. Funding Institution: NHLBI. Award #2R01 HL075101-05A1
16. **Co-Investigator:** Family-Centered Intervention Trial for Heart Health (**FIT HEART II**). Funding Institution: NIH, Current Award # 2RO1HL075101-05A1

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[redacted]

26. **Principal Investigator: FREEDOM Trial Registry Substudy:** RO-1 Grant (September 2004 submission) A multicenter trial of CABG surgery versus sirolimus drug-eluting stent implantation in diabetic patients with multivessel coronary artery disease. Sponsor: NHLBI, NIH.

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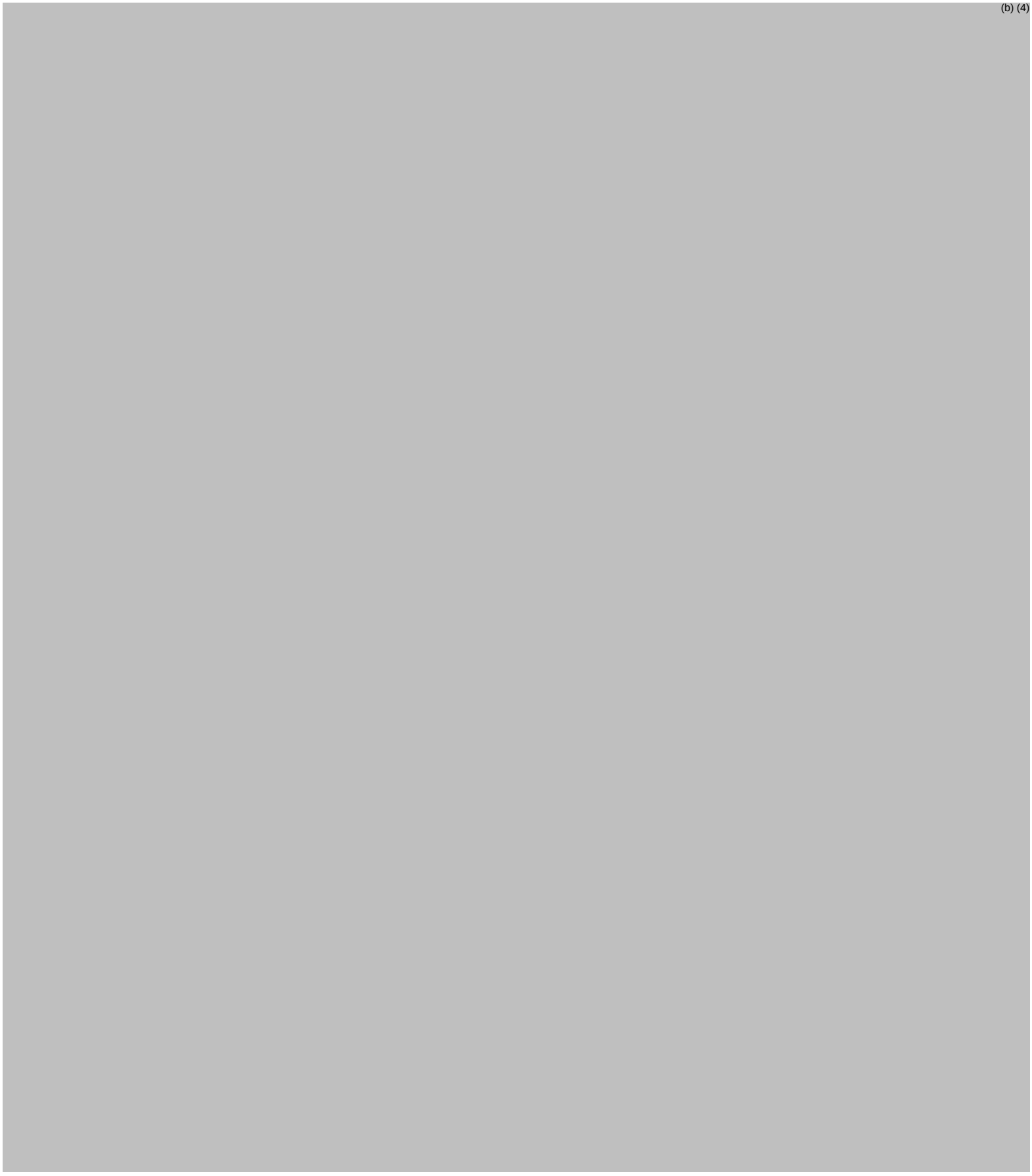
[redacted]

(b) (4)



(b) (4)

85. Member of the Angiographic committee; **W**omen's **A**ngiographic **V**itamin and **E**strogen trial **(WAVE)**; NHLBI

(b) (4)

ABSTRACTS

Over 600 abstracts presented from 2008-2013 at national and international conferences including TCT, AHA, ACC, ESC, EuroPCR, and SCAI.

BOOK CHAPTERS

1. (b) (4) In Press.
2. Nikolsky E**, Mehran R.** Bleeding complications in patients undergoing percutaneous coronary intervention: prognostic implications and prevention. In: *Mechanical Reperfusion for STEMI: From Randomized Trials to Clinical Practice*. DeLuca G, Lansky A (eds), Informa Healthcare USA (New York), 2010.
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7. Turcot D, Aymong E, **Mehran R**, Dangas G, Leon M. Heparin-coated stents III: Evidence of thromboresistance from registry studies. In: *Textbook of Coronary Stenting*. Stone GW, Leon MB (eds). WB Saunders Co (Boston), 2010.
8. Nikolsky E, **Mehran R**. Approach to patients with impaired renal function. In: *Problem-Oriented Approaches in Interventional Cardiology*. Colombo A, Stankovic G (eds), Informa Healthcare. (London), 2007
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ClinicalTrials.gov
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Trial record **3 of 11** for: roxana mehran

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PLATINUM Diversity

This study is ongoing, but not recruiting participants.

Sponsor:
Boston Scientific Corporation

Information provided by (Responsible Party):
Boston Scientific Corporation

ClinicalTrials.gov Identifier:
NCT02240810

First received: September 10, 2014
Last updated: May 25, 2016
Last verified: May 2016
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

To compile acute procedural performance and clinical outcomes data for the Promus PREMIER everolimus-eluting coronary stent system in understudied/underserved patient populations including women and minorities.

Condition	Intervention
Atherosclerosis Coronary Artery Disease	Device: Percutaneous coronary intervention (Promus PREMIER)

Study Type: Observational [Patient Registry]
Study Design: Observational Model: Cohort
Time Perspective: Prospective
Target Follow-Up Duration: 12 Months

Official Title: PLATINUM Diversity: Outcomes With the Promus PREMIER™ Stent in Women and Minorities (S2326)

Further study details as provided by Boston Scientific Corporation:

Primary Outcome Measures:

- Composite rate of Death, Myocardial Infarction (MI), and Target Vessel Revascularization (TVR) [Time Frame: Participants will be followed for the duration of hospital stay, an expected average of 1 day, through 12 months] [Designated as safety issue: Yes]

Estimated Enrollment: 1500
Study Start Date: October 2014
Estimated Study Completion Date: March 2017
Estimated Primary Completion Date: September 2016 (Final data collection date for primary outcome measure)

Groups/Cohorts	Assigned Interventions
Promus PREMIER Everolimus-Eluting Platinum Chromium CSS	Device: Percutaneous coronary intervention (Promus PREMIER) Interventional coronary artery stenting with Promus PREMIER study stent.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No
Sampling Method: Non-Probability Sample

Study Population

Population will be selected from clinical locations where subjects are treated with at least one Promus PREMIER everolimus-eluting coronary stent.

Criteria

Inclusion Criteria:

- Patient must be at least 18 years of age
- Patient must sign informed consent form
- Patient has received at least one Promus PREMIER stent
- Patient self-identifies as one or more of the following:
  - Female
  - Black of African Heritage
  - Hispanic/Latino
  - American Indian or Alaska native

Exclusion Criteria:

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02240810

Show 52 Study Locations

Sponsors and Collaborators

Boston Scientific Corporation

Investigators

Principal Investigator: **Roxana Mehran**, MD Icahn School of Medicine at Mount Sinai

Principal Investigator: Wayne Batchelor, MD Tallahassee Memorial Hospital

More Information

Responsible Party:	Boston Scientific Corporation
ClinicalTrials.gov Identifier:	NCT02240810 History of Changes
Other Study ID Numbers:	S2326
Study First Received:	September 10, 2014
Last Updated:	May 25, 2016
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Atherosclerosis	Arteriosclerosis
Coronary Artery Disease	Cardiovascular Diseases
Coronary Disease	Heart Diseases
Myocardial Ischemia	Vascular Diseases
Arterial Occlusive Diseases	

ClinicalTrials.gov processed this record on June 26, 2016

ClinicalTrials.gov
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Trial record **1 of 11** for: roxana mehran
Previous Study | Return to List | Next Study

Ticagrelor With Aspirin or Alone in High-Risk Patients After Coronary Intervention (TWILIGHT)

This study is currently recruiting participants. (see Contacts and Locations)

Verified September 2015 by Icahn School of Medicine at Mount Sinai

Sponsor:
Icahn School of Medicine at Mount Sinai

Collaborator:
AstraZeneca

Information provided by (Responsible Party):
Roxana Mehran, Icahn School of Medicine at Mount Sinai

ClinicalTrials.gov Identifier:
NCT02270242

First received: October 15, 2014
Last updated: September 8, 2015
Last verified: September 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to compare the use of ticagrelor alone versus ticagrelor and aspirin together. Both ticagrelor and aspirin stop platelets from sticking together and forming a blood clot that could block blood flow to the heart. This study will look to determine the effectiveness and safety of ticagrelor alone, compared to ticagrelor plus aspirin in reducing clinically relevant bleeding and in reducing ischemic adverse events among high-risk patients who have had a percutaneous intervention with at least one drug-eluting stent. A patient is considered high-risk if they meet certain clinical and/or anatomic criteria.

Up to 9000 subjects will be enrolled at the time of their index PCI. Subjects meeting randomization eligibility criteria at 3 months post enrollment will be randomized to either ticagrelor plus aspirin or ticagrelor plus placebo for an additional 12 months. Follow-up clinic visits will be performed at 3 months, 9 months and 15 months post enrollment.

Condition	Intervention	Phase
Cardiovascular Disease Interventional Cardiology	Drug: Aspirin Drug: Placebo Drug: ticagrelor	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Supportive Care

Official Title: Ticagrelor With Aspirin or Alone in High-Risk Patients After Coronary Intervention

Resource links provided by NLM:

Drug Information available for: Aspirin Ticagrelor

U.S. FDA Resources

Further study details as provided by Icahn School of Medicine at Mount Sinai:

Primary Outcome Measures:

- Bleeding episode [Time Frame: 12 months] [Designated as safety issue: No]

  the time to first occurrence of clinically relevant bleeding, defined as Bleeding Academic Research Consortium (BARC) Types 2, 3 or 5 bleeding.

Secondary Outcome Measures:

- Ischemic episode [Time Frame: 12 months] [Designated as safety issue: Yes]

  the time to first occurrence of confirmed cardiovascular death, non-fatal myocardial infarction, ischemic stroke or ischemia-driven revascularization

Estimated Enrollment: 9000

Study Start Date: July 2015
Estimated Study Completion Date: October 2017
Estimated Primary Completion Date: October 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Aspirin + Ticagrelor enteric coated aspirin 81mg daily p.o. for 12 months and ticagrelor 90mg tablet bid for 15 months	Drug: Aspirin Other Name: Ecotrin Drug: ticagrelor Other Names: • Brilinta • Brilique
Placebo Comparator: Placebo + Ticagrelor placebo pill daily p.o. for 12 months - match for enteric coated aspirin 81mg and ticagrelor 90mg tablet bid for 15 months	Drug: Placebo Drug: ticagrelor Other Names: • Brilinta • Brilique

Detailed Description:

This is a multicenter, prospective, blinded dual-arm study. Up to 9000 high-risk patients who have undergone successful elective or urgent PCI with at least one locally approved drug eluting stent discharged on DAPT with aspirin and ticagrelor of at least 3 months intended duration from centers still to be determined in the U.S., Canada, South America and Europe. The primary objective of this study is to determine the impact of antiplatelet monotherapy with ticagrelor alone versus DAPT with ticagrelor plus aspirin for 12 months in reducing clinically relevant bleeding (efficacy) among high-risk patients undergoing PCI who have completed a 3-month course of aspirin plus ticagrelor.

The secondary objective of this study is to determine the impact of antiplatelet monotherapy with ticagrelor alone versus DAPT with ticagrelor plus aspirin for 12 months in reducing major ischemic adverse events (safety) among high-risk patients undergoing PCI who have completed a 3-month course of aspirin plus ticagrelor.

Exploratory objectives include assessing the comparative safety and efficacy of the different DAPT regimens for individual components of the primary efficacy and secondary safety objectives.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- High-risk patients who have undergone successful elective or urgent PCI with at least one locally approved drug eluting stent discharged on DAPT with aspirin and ticagrelor of at least 3 months intended duration will be eligible for the TWILIGHT study.
- Enrollment into the study will require meeting at least one clinical inclusion, one angiographic inclusion and none of the exclusion criteria.

Clinical Inclusion Criteria:

- Adult patients ≥ 65 years of age
- Recent (≥3 days) presentation with acute coronary syndrome with clinical stabilization and decreasing cardiac enzymes
- Established vascular disease defined as previous MI, documented PAD or CAD/PAD revascularization
- Diabetes mellitus treated with medications (oral hypoglycemic, subcutaneous injection of insulin)
- Chronic kidney disease defined as an estimated glomerular filtration rate (eGFR) < 60 ml/min/1.73m2 or creatinine clearance (CrCl) < 60 ml/min

Angiographic Inclusion Criteria:

- Multivessel coronary artery disease
- Target lesion requiring total stent length >30 mm
- SYNTAX score ≥23
- Bifurcation lesions with Medina X,X,1 classification requiring at least 2 stents
- Left main (≥50%) or proximal LAD (≥70%) lesion
- Calcified target lesion requiring atherectomy

Exclusion Criteria:

- Under 18 years of age
- Contraindication to aspirin
- Contraindication to ticagrelor
- Planned surgery within 90 days
- Planned coronary revascularization (surgical or percutaneous) within 90 days
- Need for chronic oral anticoagulation
- Prior stroke
- Dialysis-dependent renal failure
- Active bleeding or extreme-risk for major bleeding (e.g. active peptic ulcer disease, gastrointestinal pathology with a raised risk for bleeding, malignancies with a raised risk for bleeding)
- Emergent or salvage PCI or STEMI presentation.
- Liver cirrhosis
- Life expectancy < 1 year

- Unable or unwilling to provide informed consent
- Women of child bearing potential (as determined by hospital standard of care)
- Fibrinolytic therapy within 24 hours of index PCI
- Concomitant therapy with a strong cytochrome P-450 3A inhibitor or inducer
- Platelet count < 100,000 mm3
- Requiring ongoing treatment with aspirin > 325 mg daily

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02270242

Contacts

Contact: Pamela Kivitz	212-659-8372	TWILIGHTStudy@mountsinai.org
Contact: Theresa Franklin-Bond, PA-C	212-659-9647	theresa.franklin-bond@mountsinai.org

Locations

United States, New York

Icahn School of Medicine at Mount Sinai **Recruiting**
New York, New York, United States, 10029
Principal Investigator: **Roxana Mehran**, MD

Sponsors and Collaborators

Icahn School of Medicine at Mount Sinai

AstraZeneca

Investigators

Study Director:	**Roxana Mehran**, MD	Icahn School of Medicine at Mount Sinai
Study Chair:	Usman Baber, MD	Icahn School of Medicine at Mount Sinai

More Information

Publications:

Anderson JL, Adams CD, Antman EM, Bridges CR, Califf RM, Casey DE Jr, Chavey WE 2nd, Fesmire FM, Hochman JS, Levin TN, Lincoff AM, Peterson ED, Theroux P, Wenger NK, Wright RS, Smith SC Jr, Jacobs AK, Halperin JL, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura R, Ornato JP, Page RL, Riegel B; American College of Cardiology; American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction); American College of Emergency Physicians; Society for Cardiovascular Angiography and Interventions; Society of Thoracic Surgeons; American Association of Cardiovascular and Pulmonary Rehabilitation; Society for Academic Emergency Medicine. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction): developed in collaboration with the American College of Emergency Physicians, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons: endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation and the Society for Academic Emergency Medicine. Circulation. 2007 Aug 14;116(7):e148-304. Epub 2007 Aug 6. Erratum in: Circulation. 2008 Mar 4;117(9):e180.

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Dupont AG, Gabriel DA, Cohen MG. Antiplatelet therapies and the role of antiplatelet resistance in acute coronary syndrome. Thromb Res. 2009 May;124(1):6-13. doi: 10.1016/j.thromres.2009.01.014. Epub 2009 Mar 25. Review.

Geisler T, Zürn C, Simonenko R, Rapin M, Kraibooj H, Kilias A, Bigalke B, Stellos K, Schwab M, May AE, Herdeg C, Gawaz M. Early but not late stent thrombosis is influenced by residual platelet aggregation in patients undergoing coronary interventions. Eur Heart J. 2010 Jan;31(1):59-66. doi: 10.1093/eurheartj/ehp402. Epub 2009 Oct 6.

Hochholzer W, Trenk D, Bestehorn HP, Fischer B, Valina CM, Ferenc M, Gick M, Caputo A, Büttner HJ, Neumann FJ. Impact of the degree of peri-interventional platelet inhibition after loading with clopidogrel on early clinical outcome of elective coronary stent placement. J Am Coll Cardiol. 2006 Nov 7;48(9):1742-50. Epub 2006 Oct 17.

Marcucci R, Gori AM, Paniccia R, Giusti B, Valente S, Giglioli C, Buonamici P, Antoniucci D, Abbate R, Gensini GF. Cardiovascular death and nonfatal myocardial infarction in acute coronary syndrome patients receiving coronary stenting are predicted by residual platelet reactivity to ADP detected by a point-of-care assay: a 12-month follow-up. Circulation. 2009 Jan 20;119(2):237-42. doi: 10.1161/CIRCULATIONAHA.108.812636. Epub 2008 Dec 31.

Jernberg T, Payne CD, Winters KJ, Darstein C, Brandt JT, Jakubowski JA, Naganuma H, Siegbahn A, Wallentin L. Prasugrel achieves greater inhibition of platelet aggregation and a lower rate of non-responders compared with clopidogrel in aspirin-treated patients with stable coronary artery disease. Eur Heart J. 2006 May;27(10):1166-73. Epub 2006 Apr 18.

Wallentin L, Varenhorst C, James S, Erlinge D, Braun OO, Jakubowski JA, Sugidachi A, Winters KJ, Siegbahn A. Prasugrel achieves greater and faster P2Y12receptor-mediated platelet

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Trial record **2 of 11** for: roxana mehran
Previous Study | Return to List | Next Study

Antithrombotic Strategy Variability In ATrial Fibrillation and Obstructive Coronary Disease Revascularized With PCI - The AVIATOR 2 Registry

This study is currently recruiting participants. (see **Contacts and Locations**)

Verified June 2016 by *Icahn School of Medicine at Mount Sinai*

Sponsor:
Icahn School of Medicine at Mount Sinai

Collaborator:
Bristol-Myers Squibb

Information provided by (Responsible Party):
Icahn School of Medicine at Mount Sinai

ClinicalTrials.gov Identifier:
NCT02362659

First received: February 9, 2015
Last updated: June 16, 2016
Last verified: June 2016
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

The purpose of this observational registry is to compare the safety and efficacy of an antithrombotic regimen comprising one single antiplatelet agent plus an oral anti-thrombotic versus those consisting of DAPT alone or DAPT plus oral antithrombotic therapy. This registry will assess whether the antithrombotic therapy intensity will vary positively with physician perceived ischemic risk at the time of percutaneous coronary intervention (PCI), and whether an inverse association will be observed with perceived bleeding risk.

This study will also evaluate the physician use of objective benefit-risk assessment scores and their influence on prescription of antithrombotic therapy in atrial fibrillation (AF) patients undergoing PCI. Additionally the study will investigate whether patient perceived relevance and accessibility of anti-platelet and anticoagulant treatment regiments will predict treatment adherence and whether non-adherence will independently influence outcome.

Approximately 2500 subjects with non-valvular AF undergoing all-comer PCI with stenting will be enrolled in North America and Europe, sites to be determined. Follow-up will be done via telephone by trained research coordinators at each participating site at 30 days, 6 months and 12 months.

Condition
Non-valvular Atrial Fibrillation

Study Type:	Observational [Patient Registry]
Study Design:	Observational Model: Cohort Time Perspective: Prospective
Target Follow-Up Duration:	12 Months
Official Title:	Antithrombotic Strategy Variability In ATrial Fibrillation and Obstructive Coronary Disease Revascularized With PCI

Resource links provided by NLM:

Genetics Home Reference related topics: familial atrial fibrillation

MedlinePlus related topics: Atrial Fibrillation Blood Thinners Coronary Artery Disease

Genetic and Rare Diseases Information Center resources: Familial Atrial Fibrillation

U.S. FDA Resources

Further study details as provided by Icahn School of Medicine at Mount Sinai:

Primary Outcome Measures:

- Number of participants with adverse events [Time Frame: 12 months] [Designated as safety issue: Yes]

  Efficacy as measured by composite of All-cause death, non-fatal MI, ischemic stroke, stent thrombosis, clinically driven target lesion revascularization at 1 year - MACCE (major adverse cardiovascular and cerebrovascular events)

- bleeding risk [Time Frame: 12 months] [Designated as safety issue: Yes]

  Safety as measured by bleeding according to the Bleeding Academic Research Consortium (BARC) bleeding definitions (BARC 2,3 or 5)

Secondary Outcome Measures:

- Net adverse clinical events [Time Frame: 12 months] [Designated as safety issue: Yes]

  Net adverse clinical events (NACE) - composite occurrence of all MACCE and major bleeding.

- Association between subjective and objective measures of ischemic and bleeding risk [Time Frame: 12 months] [Designated as safety issue: Yes]

  Ischemic events assessed by CHADS, CHA2DS2-VASc is a non-valvular AF thromboembolism risk score.

- Modes of antithrombotic therapy cessation [Time Frame: 12 months] [Designated as safety issue: Yes]

  Modes of antiplatelet and antithrombotic therapy cessation: discontinuation (physician recommended), interruption (e.g. for surgery/procedures), disruption (non-recommended)

Estimated Enrollment:	2500
Study Start Date:	April 2015
Estimated Study Completion Date:	September 2017
Estimated Primary Completion Date:	September 2017 (Final data collection date for primary outcome measure)

Groups/Cohorts
Antiplatelet agent plus anticoagulant an antithrombotic regimen comprising one single antiplatelet agent plus an anticoagulant
DAPT alone an antithrombotic regimen consisting of dual antiplatelet therapy (DAPT) alone
DAPT plus anticoagulant an antithrombotic regimen consisting of DAPT plus anticoagulant therapy

Detailed Description:

The current AHA guidelines on AF for patients undergoing PCI are non-specific as they recommend "low-dose aspirin (less than 100 mg per d) and/or clopidogrel (75 mg per d), which may be given concurrently with anticoagulation to prevent myocardial ischemic events, but these strategies have not been thoroughly evaluated and are associated with an increased risk of bleeding.

Finding the right balance that minimizes bleeding risk and maintains anti-ischemic efficacy remains a complex and controversial clinical dilemma in these unique patients. The arrival of novel antiplatelet agents and antithrombotics on the scene has led to an exponential increase in the combinations that may be employed by clinicians in real-life situations. The sheer number of combinations means that the best APT and OAC combination based on RCT data will not be known for many years. It has therefore become imperative that the investigators strive to create better methods to gauge the comparative safety and efficacy for various antiplatelet and antithrombotic combination strategies in AF patients undergoing PCI. To the best of the investigators knowledge, no contemporary prospective registry of real-life patients with AF undergoing PCI exists or has been initiated to date. Additionally, the factors influencing physician choice of treatment strategy as well as factors predicting patient adherence in this population is largely unknown.

This is a multi-center, multinational, observational prospective registry prospective analysis of 2500 patients with non-valvular AF undergoing all-comer PCI with stenting at up to 50 Northern American and European centers. Patients will be followed for 12 months following implantation of stent. Data will be collected prospectively. All-antiplatelet and anti-thrombotic treatment regimen will be at the physicians' discretion. The investigators will study various combinations of antiplatelet and antithrombotic therapies, characterize the bleeding and ischemic risk in patients with atrial fibrillation undergoing PCI and to determine physician and patient centered factors influencing prescription patterns and patient adherence.

Patients with non-valvular atrial fibrillation who have undergone successful PCI will be enrolled as soon as possible post procedure and no later than before discharge of the index admission. The treating physician (interventional or non-interventional cardiologist) that prescribes the anti-platelet or/and anticoagulant therapy must complete the physician questionnaire. A different, patient centered questionnaire will be completed by the patient. The Principal Investigator or designee will provide instructions to enrolled subjects and physicians on how to use the hand held

electronic device or how to complete the paper questionnaire and clarify any questions about the questionnaires. The enrolled subjects and physicians will themselves enter the responses to the questionnaire on the electronic hand held device or the paper questionnaire. Only patients with completed questionnaires will be considered enrolled.

Treatment will be according to physician.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

2500 patients with non-valvular AF undergoing all-comer PCI with stenting at up to 50 Northern American and European hospital centers.

Criteria

Inclusion Criteria:

- Diagnosis of non-valvular atrial fibrillation during hospitalization.
- Preexisting atrial fibrillation.
- Successful all-comer percutaneous coronary intervention:

Procedural success is defined as a reduction of residual luminal diameter stenosis to <50% without in-hospital death, AMI or the need for emergency CABG.

- Over 18 years of age
- Able to provide written informed consent

Exclusion Criteria:

- Atrial fibrillation due to reversible causes (e.g., thyrotoxicosis, pericarditis)
- Valvular atrial fibrillation secondary to severe mitral stenosis or prosthetic heart valve
- Women who are of childbearing potential Treatment with other investigational drugs or devices within 30 days before enrolment or planned use of investigational drugs or devices during the study
- Life expectancy <12 months due to non-cardiac comorbidities
- Active alcohol, drug abuse, psychosocial reasons making study participation impractical
- Severe renal insufficiency (calculated creatinine clearance < 30 mL/min) or dialysis
- Clinically overt stroke within the last 3 months
- Known hypersensitivity or contraindication to aspirin, clopidogrel, prasugrel, ticagrelor, dabigatran, rivaroxaban, apixaban, edoxaban or warfarin

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02362659

Contacts

Contact: Susan Mahoney, MS	212-659-9646	susan.mahoney@mountsinai.org
Contact: Theresa Franklin-Bond, PA-C	212-659-9647	theresa.franklin-bond@mountsinai.org

Locations

United States, New York

Icahn School of Medicine at Mount Sinai **Recruiting**
New York, New York, United States, 10029
Principal Investigator: Annapoorna Kini, MD

Sponsors and Collaborators

Icahn School of Medicine at Mount Sinai

Bristol-Myers Squibb

Investigators

Principal Investigator:	**Roxana Mehran**, MD	Icahn School of Medicine at Mount Sinai
Study Director:	Usman Baber, MD	Icahn School of Medicine at Mount Sinai

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Chandrasekhar J, Mastoris I, Baber U, Sartori S, Schoos M, Bansilal S, Dangas G, Mehran R. Antithrombotic strategy variability in ATrial fibrillation and obstructive coronary disease revascularized with PCI-rationale and study design of the prospective observational multicenter AVIATOR 2 registry. Am Heart J. 2015 Dec;170(6):1234-42. doi: 10.1016/j.ahj.2015.08.023. Epub 2015 Sep 21.

Responsible Party:	Icahn School of Medicine at Mount Sinai
ClinicalTrials.gov Identifier:	NCT02362659 History of Changes
Other Study ID Numbers:	GCO 14-1543-00002 CV185-376 PD14-03987
Study First Received:	February 9, 2015
Last Updated:	June 16, 2016
Health Authority:	United States: Institutional Review Board

Keywords provided by Icahn School of Medicine at Mount Sinai:
non-valvular
atrial fibrillation
percutaneous coronary intervention

Additional relevant MeSH terms:

Atrial Fibrillation	Heart Diseases
Coronary Artery Disease	Myocardial Ischemia
Coronary Disease	Pathologic Processes
Arrhythmias, Cardiac	Vascular Diseases
Arterial Occlusive Diseases	Anticoagulants
Arteriosclerosis	Platelet Aggregation Inhibitors
Cardiovascular Diseases	

ClinicalTrials.gov processed this record on June 26, 2016