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 MICHAEL CAROME

I, Michael Carome, M.D., declare as follows:

1. I am the director of Public Citizen Health Research Group (HRG), an arm of Public Citizen Foundation. I have worked at Public Citizen for five years. I am in charge of directing Public Citizen's advocacy for safer, more effective drugs, medical devices, and other products; physician accountability; and protections for human subjects in research studies, among other issues.

2. I am currently a member of the Food and Drug Administration (FDA) Pharmacy Compounding Advisory Committee (PCAC).

3. I retired from the U.S. Public Health Service in 2010 after serving more than 24 years in uniformed service. I was also a staff nephrologist at the Walter Reed Army Medical Center's Department of Medicine from 1992 to 2010.

4. Public Citizen HRG advocates on issues related to the quality and efficacy of FDA-regulated drugs and devices and has done so since its founding in 1971. To further its advocacy on these issues, Public Citizen monitors FDA advisory committees and advocates on issues related to the proper functioning of FDA advisory committees. For example, Public Citizen has petitioned the FDA to include a presentation by FDA staff at advisory committee meetings to help balance out the information provided to advisory committees. That petition is available at http://www.citizen.org/Page.aspx?pid=741. Public Citizen has also studied potential conflicts of interest among advisory committee members. For instance, Public Citizen's letter to the Commissioner of the FDA about a potential conflict of interest of an advisory committee member is available at http://www.citizen.org/documents/2218.pdf. Its research on conflicts of interest and voting patterns of advisory committee members is available at http://jama.jamanetwork.com/article.aspx?articleid=202754.

5. Public Citizen's HRG staff frequently testify before FDA advisory committees. In 2015, Public Citizen staff testified 13 times before FDA advisory committees, and I testified on three of those occasions. A list of Public Citizen's testimony before FDA advisory committees and its health research publications is available at http://www.citizen.org/hrgpublications.

6. Two other Public Citizen staff members serve or served on FDA advisory committees—one on the Bone, Reproductive and Urologic Drugs Advisory Committee and the other on the Drug Safety and Risk Management Advisory Committee.

7. By letter dated February 14, 2014, Robert Weissman, Public Citizen's President, nominated me to be the consumer representative member of the PCAC. A copy of my curriculum vitae (CV), dated January 2014, was submitted with my nomination. On August 14, 2014, I received a telephone call from an FDA official informing me that my nomination to be the

consumer representative member of the PCAC had been forwarded to the FDA Commissioner for approval.

8. On October 1, 2014, I received an email from the FDA informing me that I had passed the initial screening and was being considered for membership on the committee. I was asked to complete 17 forms required for my appointment as a special government employee, including a confidential financial disclosure report, and to submit an updated CV. The email provided the following instructions regarding my CV: "Additionally, we are required to publically post your CV on the FDA website. Because we cannot post personal information, to avoid having to post a heavily redacted document, we ask that you review your CV and remove any personal information including addresses other than business, birthdates of family members (yours too, if included), family names, and other similar information. In your email reply to me, please attach a copy of your updated CV without the personal information." A true and correct copy of that email is attached as Exhibit A.

9. On October 1, 2014, I submitted to the FDA by email an updated CV dated October 2014. In my email, I stated that "the CV may be made public without any redactions." The FDA replied the same day by email, stating that "I will need to send your CV forward for redaction review by agency staff and will share the result with you upon completion, if this is fine with you."

10. On December 10, 2014, I received an email from the FDA with an attached letter dated November 13, 2014, inviting me to be a consumer representative member on the PCAC. I replied by email on the same day with my written acknowledgment and acceptance of the invitation.

11. The CVs I submitted to the FDA listed, among other things, my military service and awards and a grant that I had received for 1996-1997 from the National Kidney Foundation for research examining stress protein target antigens in kidney transplant recipients.

12. On or about December 16, 2014, I noticed that the FDA had posted my January 2014 CV on its website, but had redacted under exemption 4 the amount of the grant from the National Kidney Foundation and had redacted under exemption 6 my military service and awards.

13. On May 18, 2016, the FDA sent me an email asking me to send a copy of my 2016 CV. I responded by email the same day and attached my updated CV, dated May 2016. I also specified that the FDA could publicly post my CV without any redactions.

14. The FDA responded by email and asked that I sign and return a document called "Considerations Related to CVs and Consent to Web Posting." A true and correct copy of the Consent to Web Posting form I received from the FDA is attached as Exhibit B.

15. As of June 28, 2016, my January 2014 CV was still redacted on the FDA's website. A true and correct copy of my CV as redacted by the FDA and posted on the FDA's website as of June 28, 2016, is attached hereto as Exhibit C.

16. In my experience—30 years in the medical field and over 20 years overseeing and conducting clinical medical research studies—medical researchers do not include confidential information in the titles of clinical trials that they are conducting or have conducted or in the titles of journal articles that they have authored and that have been published or accepted for publication in scientific journals. Moreover, in my experience, medical researchers rarely, if ever, have a commercial interest in listings of journal articles they have authored and of clinical trials that they have conducted or are conducting. Furthermore, detailed information about

ongoing and previously conducted clinical trials and titles and abstracts of accepted or published journal articles are generally publicly available on the U.S. National Library of Medicine's ClinicalTrials.gov website and on the websites of scientific journals, respectively.

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 8, 2016.

/s/ Michael A. Carome
Michael A. Carome, M.D.

EXHIBIT A

Declaration of Michael Carome, M.D.
Public Citizen v. FDA et al., 16-cv-781

Rachel Clattenburg

From: Reese, Cicely <Cicely.Reese@fda.hhs.gov>
Sent: Wednesday, October 01, 2014 3:53 PM
To: Michael Carome
Subject: FDA Pharmacy Compounding Advisory Committee
Attachments: Memorandum Form 2725_Last Name .doc

Dear Dr. Carome,

Thank you for your interest and willingness to serve as a member of the Food and Drug Administration's Pharmacy Compounding Advisory Committee. We are pleased to inform you that you have passed the initial screening and are being considered for membership on the Committee. We are working to make the final decisions and empanel the Committee as soon as possible, and we need you to provide certain information so that we can make a final decision on your candidacy and complete the necessary paperwork. Most urgently in moving this process forward we need to receive the attached form back from you indicating key pieces of information including your:
your:

1) place of birth
2) date of birth
3) home address
4) full business title and address
5) indication of preferred mailing address

These few pieces of information are necessary for us to complete your membership package and submit it for review. Please provide this information via email by close of business on October 2. Once we receive this information, we will immediately mail you, via UPS, a government appointment CD package. Your CD package will contain 17 forms to be completed, signed and mailed back to our office via the preaddressed return envelope. Approximately 2-3 forms will need to be notarized and returned along with the other documents within **two weeks** (the deadline date will be noted on the CD). Due to the time sensitive nature of the appointment process and our hope to be able to convene the Committee for its first meeting early next year, we request that you please adhere to the timeframes requested, as any delay in completion of the necessary forms may delay your appointment and may preclude your participation in any meeting that may be planned.

Additionally, we are required to publically post your CV on the FDA website. Because we cannot post personal information, to avoid having to post a heavily redacted document, we ask that you review your CV and remove any personal information including addresses other than business, birthdates of family members (yours too, if included), family names, and other similar information. In your email reply to me, please attach a copy of your updated CV without the personal information.

Once your membership nomination has been completed by agency staff, you will receive via email 1) a Letter of Invitation and 2) a Letter of Acknowledgement. These documents will need to be signed and either faxed or scanned and emailed back to the person indicated in the email. We cannot move to finalize your appointment without these documents and request that you send them in right away. If you feel that you are unable to continue to be considered for membership, please indicate by email reply to the person indicated in the email.

We thank you for working to fulfill this process. If you have any questions, please do not hesitate to contact me via email or by calling me at 301-796-9025. We look forward to working with you on upcoming advisory committee meetings.

Sincerely,

Cicely Reese

Cicely Reese, Pharm.D.
LCDR, USPHS
Deputy Director |Division of Advisory Committee and
Consultant Management |Office of Executive Programs
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue |WO31-2420
Silver Spring, MD 20993
Tel: 301-796-9001|Fax: 301-847-8533
Email: Cicely.Reese@fda.hhs.gov

EXHIBIT B

Declaration of Michael Carome, M.D.
Public Citizen v. FDA et al., 16-cv-781

Considerations Related to CVs and Consent to Web Posting

We request that the CV you submit include only that information that can be made public. The following are examples of confidential information that we request be removed from your CV:

- Social Security number
- Home address, home phone number, personal cell phone number, home FAX, home e-mail address
- Race, gender, national origin
- Citizenship
- Information about 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
- Date of high school graduation
- 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
- Peer-reviewed papers that are "in progress" and not yet published that you do not wish to have made public
- Information about pending government grants that you do not wish to have made public
- Any information about private grants
- Patents currently under review (i.e., no patent number) by the Patent Office that you do not wish to be made public
- Any confidential-commercial information (for example, references to clinical investigations for pending applications)

Please select one of the following options:

X I consent to the web posting of my curriculum vitae (CV), without redaction.

____ I consent to the web posting of my CV but have redacted that information which I do not wish to be made public.

(Note that regardless of consent to web posting, if FDA receives a valid Freedom of Information Act (FOIA) request for a CV, it will be released in accordance with FOIA, likely with certain redactions made by FDA.)

Signature Michael A. Carome

Date 5/18/16

EXHIBIT C

Declaration of Michael Carome, M.D.
Public Citizen v. FDA et al., 16-cv-781

CURRICULUM VITAE

Michael Anthony Carome, MD, FACP
January 2014

CONTACT INFORMATION:

Work Address: Public Citizen
1600 20th Street, NW
Washington, DC 20009
Work Telephone: 202-588-7781
Work Fax: 202-588-7796
Work E-mail: mcarome@citizen.org

PRESENT POSITIONS:

Director
Health Research Group
Public Citizen
Washington, DC
June 2013-present

PREVIOUS PROFESSIONAL APPOINTMENTS/POSITIONS:

Deputy Director
Health Research Group
Public Citizen
Washington, DC
January 2011-May 2013

Associate Director for Regulatory Affairs
Office for Human Research Protections
Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
Rockville, MD
June 2002-December 2010

Staff Nephrologist
Nephrology Service
Department of Medicine
Walter Reed Army Medical Center
Washington, D.C.
July 1992-December 2010

Director
Division of Compliance Oversight
Office for Human Research Protections
Office of Public Health and Science
Department of Health and Human Services
Rockville, MD
September 2000-January 2003

Chief
Compliance Oversight Branch
Division of Human Subject Protections
Office for Human Research Protections
Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
Rockville, MD
June 2000-September 2000

Chief
Compliance Oversight Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
February 1999-June 2000

Acting Chief
Compliance Oversight Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
October 1998-January 1999

Human Subject Protections Coordinator
Compliance Oversight Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
July 1998-September 1998

Assurance Coordinator
Assurance Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
October 1997-June 1998

Assistant Professor of Medicine
Department of Medicine
Uniformed Services University of Health Sciences
Bethesda, Maryland
1992-1998

Chief, Research Review Service
and Assistant Chief
Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, D.C.
1995-1997

Medical Director, Nephrology Laboratory
Nephrology Service
Walter Reed Army Medical Center
Washington, D.C.
1993-1995

Guest Researcher
Renal Cell Biology Section
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland
1990-1993

Instructor
Department of Medicine
Uniformed Services University of Health Sciences
Bethesda, MD
1989-1992

Laboratory Assistant in Microbiology
Department of Biology
Johns Hopkins University
Baltimore, Maryland
1981-1982

EDUCATION:

College:	Georgetown University Washington, D.C. 1977-1981 - B.S., Psychology
Medical School:	Case Western Reserve University Cleveland, Ohio 1982-1986
Internship/Residency:	Internal Medicine Walter Reed Army Medical Center Washington, D.C. 1986-1989
Fellowship:	Nephrology Walter Reed Army Medical Center Washington, D.C. 1989-1992

COMMITTEE APPOINTMENTS:

Department of Medicine Representative
Clinical Investigation Committee
Walter Reed Army Medical Center
1993-1995

Chairperson
Clinical Investigation Committee
Walter Reed Army Medical Center
1995-1997

Co-Chairperson
Human Use Committee/Institutional Review Board
Walter Reed Army Medical Center
1995-1997

Chairperson
Institutional Animal Use and Care Committee
Walter Reed Army Medical Center
1995-1996

Member, Research Committee
National Kidney Foundation of the National Capital Area, Inc
1996-1997

Member, Interdivisional Policy Coordinating Committee
Office for Human Research Protections
Department of Health and Human Services
2001-present

Ex Officio Member
Secretary's Advisory Committee on Genetics, Health, and Society
Department of Health and Human Services
2003-present

OHRP Liaison to Subcommittee on Research Involving Children
Secretary's Advisory Committee on Human Research Protections
Department of Health and Human Services
2003-2005

OHRP Liaison to Subpart A Subcommittee
Secretary's Advisory Committee on Human Research Protections
Department of Health and Human Services
2005-present

RESEARCH GRANTS:

National Kidney Foundation of the National Capital Area Research Grant, 1996-97, Title: Are Stress Proteins Target Antigens in Renal Allograft Recipients? ((b) (4))

MICHAEL A. CAROME, M.D.
CURRICULUM VITAE, JANUARY 2014 – PAGE 5

EDITORIAL ACTIVITIES:

Reviewer, Kidney International, 1993
PLOS Medicine, 2012

BOARD CERTIFICATION:

American Board of Internal Medicine
Diplomate in Internal Medicine, 1989
No expiration date

American Board of Internal Medicine
Diplomate in Nephrology, 1992; re-certified 2002
Expired 2012

STATE LICENSES:

Ohio, License #35-04-4155 (1986-1998)
Virginia, License #0101-055891 (1997-present)

HONORS/AWARDS:

Psi Chi, Honorary Society of Psychology, 1980

Graduated magna cum laude, Georgetown University, 1981

First Place-Basic Science, Fellows Competition, National Kidney Foundation of the National Capital Area, 1992

(b) (6)

Bailey K. Ashford Clinical Research Award, Walter Reed Army Medical Center, 1992

(b) (6)

(b) (6)

(b) (6)

Special Recognition Award for Service in Support of NIH-Wide Grants Management Initiatives, Vision Steering Committee, NIH, 2000

Assistant Secretary for Health's Outstanding Team Performance Award, 2001

Public Health Service Unit Commendations, 2001 and 2005

Public Health Service Crisis Response Service Awards, 2004 and 2006

Public Health Service Outstanding Service Medals, 2004 and 2008

Public Health Service Outstanding Unit Citations, January 24, 2007 and January 26, 2007

Public Health Service Field Medical Readiness Badge, 2007

SERVICE IN THE U.S. PUBLIC HEALTH SERVICE

Category:	Medical Officer,
Rank/Grade	Captain/O-6, Regular Corps
Places:	Office for Protection from Research Risks, National Institutes of Health
	Office for Human Research Protections, Office of the Secretary
Dates:	October 1997-December 2010 (Retired)

PROFESSIONAL MEMBERSHIPS AND SOCIETIES:

American College of Physicians, Member, 1990-1993; Fellow 1993-present
Physicians for a National Health Plan, Member, 2011-present

MICHAEL A. CAROME, M.D.
CURRICULUM VITAE, JANUARY 2014 – PAGE 7

BIBLIOGRAPHY:

PUBLICATIONS

1. Carome MA, Moore J: Nephrotic syndrome in adults: a diagnostic and management challenge. Postgrad Med. 1992;92:209-220.

2. Eliasson AH, Phillips YY, Stajduhar KC, Carome MA, Cowsar JD. Oxygen consumption and ventilation during normal labor. Chest. 1992;102:467-471.

3. Peten EP, Striker LJ, Carome MA, Elliot SJ, Yang CW, Striker GE: The contribution of increased collagen synthesis to human glomerulosclerosis: a quantitative analysis of α2IV collagen mRNA expression by competitive polymerase chain reaction. J Ex Med. 1992. 176: 1571-1576.

4. Moore J, Carome MA. Proteinuria. Clin in Lab Med. 1993; 13:21-31.

5. Carome MA, Striker LJ, Peten EP, Moore J, Yang CW, Stetler-Stevenson WG, Striker GE. Human glomeruli express tissue inhibitor of metalloproteinase-1 (TIMP-1) mRNA and TIMP-2 protein and mRNA in vivo. Am J Physiol. 1993;264:F923-F929.

6. Striker GE, Peten EP, Carome MA, Pesce CM, Schmidt K, Yang CW, Elliot SJ, Striker LJ. The kidney disease of diabetes mellitus (KDDM): A cell and molecular biology approach. Diabetes/Metabolism Reviews. 1993;9:37-56.

7. Carome MA, Striker LJ, Peten EP, Elliot SJ, Yang CW, Stetler-Stevenson WG, Reponen P, Tryggvason K, Striker GE. Assessment of 72 kDa gelatinase and TIMP-1 gene expression in normal and sclerotic murine glomeruli. J Am Soc Nephrol. 1994;5:1391-1399.

8. Yang CW, Hattori M, Vlassara H, He CJ, Carome MA, Yamato E, Elliot SJ, Striker GE, Striker LJ. Overexpression of TGF-ß1 mRNA is associated with upregulation of glomerular tenascin and laminin gene expression in diabetic NOD mice. J Am Soc Nephrol. 1995;5:1610-1617.

9. Yuan CM, Bohen EM, Musio F, Carome MA. Sub-lethal heat shock and cyclosporine exposure produce tolerance against subsequent cyclosporine toxicity. Am J Physiol. 1996;271:F571-F578.

10. Musio F, Carome MA, Bohen EM, Sabnis S, Yuan CM. The effect of glycine on the cis-platin nephrotoxicity and heat shock protein 70 expression in the rat kidney. Renal Failure. 1997 ;19:33-46.

11. Carome MA, Kang YH, Bohen EM, Nicholson DE, Carr FE, Kiandoli LC, Brummel SE, Yuan CM. Distribution of the cellular uptake of phosphorothioate oligodeoxynucleotides in the rat kidney. Nephron. 1997;75:82-87.

12. Borror K, Carome M, McNeilly P, Weil C. A review of OHRP compliance oversight letters. IRB: Ethics & Hum Res. 2003;25:1-4.

13. Carome M. Deadly meningitis outbreak was completely avoidable. CNN Opinion. CNN.com. http://www.cnn.com/2012/10/16/opinion/carome-meningitis/index.html. October 16, 2012.

14. Carome M. Room For Debate: Getting your prescriptions, without a prescription: should more medications be made available over the counter, like Claritin was in 2002? For some drugs, a clear 'yes.' for others, a loud 'no.' NYTimes.com. http://www.nytimes.com/roomfordebate/2012/09/16/getting-your-

prescriptions-without-a-prescription/statins-should-require-a-prescription. September 16, 2012.

15. Carome M, Wolfe S. Public Citizen: The SUPPORT study was even worse than we thought. The Hasting Center Bioethics Forum Blog. http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=6367&blogid=140#. May 21, 2013.

ABSTRACTS

1. Carome MA, Striker LJ, Elliot SJ, Peten EP, Stetler-Stevenson WG, Striker GE. TIMP1 and α1 type IV collagen mRNAs in mouse mesangial cells at low and high density. J Am Soc Nephrol. 1991;2:572 (presented at the 24th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 17-20, 1991).

2. Carome MA, Peten EP, Moore J, Stetler-Stevenson WG, Striker GE, Striker LJ: Tissue inhibitor of metalloproteinase-1 (TIMP-1) and TIMP-2 mRNAs. Detection and quantitation in isolated whole human glomeruli by RT-PCR. Renal Failure. 1992;14:609 (presented at the International Meeting on Molecular Approaches to Nephrology: Prospects in Diagnosis and Management, Bari, Italy, March 19-21, 1992).

3. Peten EP, Striker LJ, Carome MA, Garcia-Perez A, Striker GE. Quantitation of α1 and α2 type IV collagen mRNAs in single mouse and human microdissected glomeruli by reverse transcription and competitive polymerase chain reaction (RT-PCR) Renal Failure. 1992;14:598 (presented at the International Meeting on Molecular Approaches to Nephrology: Prospects in Diagnosis and Management, Bari, Italy, March 19-21, 1992).

4. Carome MA, Peten EP, Reponen P, Trygvason K, Striker GE, Striker LJ. 72 kDa gelatinase (72GEL) mRNA is expressed in normal mouse glomeruli in vivo and is up-regulated in sclerotic glomeruli. J Am Soc Nephrol. 1992;3:578 (presented at the 25th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 15-18, 1992).

5. Carome MA, Peten EP, Elliot SJ, Moore J, Yang CW, Stetler-Stevenson WG, Striker GE, Striker LJ. Human glomeruli express 72 kDa gelatinase (72GEL), tissue inhibitor of metalloproteinase-1 (TIMP-1), and TIMP-2 mRNAs in vivo. J Am Soc Nephrol. 1992;3:651 (presented at the 25th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 15-18 1992).

6. Peten EP, Carome MA, Elliot SJ, Yang CW, Striker SJ, Striker GE. Expression of α2IV, α3IV, and α5IV collagen mRNAs in normal and sclerotic adult human glomeruli. J Am Soc Nephrol. 1992:3:662 (presented at the 25th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 15-18, 1992).

7. Peten EP, Yang CW, He CJ, Carome MA, Striker GE, Striker LJ. Late remodeling in glomerulosclerosis. FASEB J. 1993:7:A197 (presented at the annual FASEB meeting, March 28-April 1, 1993, New Orleans, LA).

8. Carome MA, Peten EP, Elliot SJ, Stetler-Stevenson WG, Striker GE, Striker LJ. Expression of gelatinase proteins and mRNA and TIMP-1 mRNA by intact mouse glomeruli and mesangial cells in vitro: studies in glomerulosclerosis (presented at the XIIth International Congress of Nephrology, Jerusalem, Israel, June 13-18, 1993).

9. Peten EP, Yang CW, Carome MA, Striker GE, Striker LJ. Phenotypic switch and gene activation in experimental glomerulosclerosis (presented at the XIIth International Congress of Nephrology, Jerusalem, Israel, June 13-18, 1993).

10. Yuan CM, Bohen EM, Carome MA. Induction of heat shock proteins reduces cyclosporine toxicity in LLCPK cells. Clin Res. 1994;42:221A (presented at the annual AFCR Clinical Research Meeting, Baltimore, MD, April 29-May 2, 1994).

11. Carome MA, Kang Y-H, Bohen EM, Nicholson DE, Carr FE, Yuan CM. The distribution of radiolabeled phosphorothioate oligonucleotides (ODNs) within the rat kidney following intravenous administration. J Am Soc Nephrol. 1994;5:618 (presented at the 27th annual meeting of the American Society of Nephrology, Orlando, FL, October 26-29, 1994).

12. Salzberg DJ, Carome MA, Musio F, Yuan CM. Induction of the heat shock response reduces cis-platin toxicity in cultured renal epithelial cells. J Am Soc Nephrol. 1994;5:930 (presented at the 27th annual meeting of the American Society of Nephrology, Orlando, FL, October 26-29, 1994).

13. Yuan CM, Musio F, Bohen EM, Carome MA. The protective effect of heat shock (HS) on subsequent cyclosporine A (CYA) toxicity in renal epithelial cells in vitro declines concurrently with decreasing Hsp 70 levels. J Am Soc Nephrol. 1994;5:934 (presented at the 27th annual meeting of the American Society of Nephrology, Orlando, FL, October 26-29, 1994).

14. Yuan CM, Popham SG, Musio F, Salzberg DJ, Bohen EM, Carome MA. Mannitol protects LLC-PK1 cells from cyclosporine A (CYA) toxicity without induction of heat shock protein 70 (Hsp 70) gene expression. J Am Soc Nephrol. 1994;5:934.

15. Yuan CM, Bohen E, Carome M. Betaine exposure inhibits heat shock-induced up-regulation of Hsp70 protein and subsequent tolerance to cyclosporine toxicity in LLC-PK1 cells. J Am Soc Nephrol. 1995;6:371 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).

16. Bohen EM, Yuan CM, Carome MA. Hydrogen peroxide induces Hsp70 gene expression and protects against subsequent H_2O_2 or cyclosporine (CYA) toxicity in LLC-PK1 cells. J Am Soc Nephrol. 1995;6: 974 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).

17. Pisel GA, Yuan CM, Carome MA. Induction of the heat shock response protects cultured human proximal tubular (HRPT) cells from cyclosporine A (CYA) toxicity. J Am Soc Nephrol. 1995;6:1063 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).

18. Yuan CM, Bohen EM, Carome MA. Cyclosporine (CYA) induces Hsp70 gene expression and protects against subsequent CYA toxicity in LLC-PK1 cells. J Am Soc Nephrol. 1995;6:1067 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).

19. Musio F, Carome MA, Bohen EM, Sabnis S, Yuan CM. The effect of glycine on cis-platin nephrotoxicity and heat shock protein 70 expression in the rat kidney. J Am Soc Nephrol. 1995;6:985.

20. Carome MA, Bohen EM, Yuan CM. Arachidonic acid (AA) induces Hsp70 gene expression but fails to induce tolerance to subsequent toxin exposure in LLC-PK1 cells. J Am Soc Nephrol. 1995;6:975.

21. Carome MA, Bohen EM, Yuan CM. Heat shock induces tolerance against hydrogen peroxide exposure but not against arachidonic acid toxicity in LLC-PK1 cells. J Am Soc Nephrol. 1995;6:975.

22. Staley D, Carome M, Yuan C. Effect of calcium on HSP70 gene expression after heat shock or

cyclosporine exposure in LLC-PK1 cells. J Am Soc Nephrol. 1996;7:1846 (presented at the 29th annual meeting of the American Society of Nephrology, New Orleans, LA, November 3-6, 1996).

23. Salzberg DJ, Carome MA, Yuan CM. Lazaroids block the protective effects of heat shock in LLC-PK1 cells. J Am Soc Nephrol. 1996;7:1845 (presented at the 29th annual meeting of the American Society of Nephrology, New Orleans, LA, November 3-6, 1996).

LETTERS TO THE EDITOR

1. Carome MA. Is Informed Consent Always Necessary for Randomized, Controlled Trials? N Engl J Med. 1999;341:448-449.

2. Carome MA, Wolf SM. Florbetapir-PET imaging and postmortem beta-amyloid pathology. JAMA. 2011;305:1857.

3. Carome M, Wolfe S. Rethinking clinical trials: phase 1 studies insufficient. Science. 2011;334:1346.

4. Carome MA. Hospital's response inadequate. Casper Star Tribune. March 16, 2012.

5. Carome MA, Wolf SM. As superbug spread, NIH failed in its duty to protect. The Washington Post. August 24, 2012.

6. Carome MA, Sorscher S. Compounding pharmacies can be regulated by FDA. The Washington Post. April 21, 2013.