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September 10, 2014

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

We are writing to express serious concern regarding the Food and Drug Administration's (FDA's) policy that allows an expert who serves as a temporary voting member of an FDA advisory committee on a recurring basis to move back and forth through a revolving door and assume the role of paid speaker, on behalf of a sponsor, at a meeting of that same advisory committee.

For example, at the March 27, 2014, meeting of the FDA's Cardiovascular and Renal Drugs Advisory Committee (CRDAC), which convened to discuss and make recommendations regarding the new drug application for serelaxin for the proposed indication of treatment of acute heart failure, Dr. Milton Packer, an eminent cardiologist and specialist in heart failure, was a paid speaker on behalf of the sponsor, Novartis Pharmaceuticals.

In his opening statement before the CRDAC at its March 27 meeting, Dr. Packer disclosed that his time and travel had been compensated by Novartis. Because of his simultaneous status as a "special government employee," he noted that he had asked for and "received permission" from the FDA to participate as a paid speaker for Novartis at the meeting.[1] This permission was granted despite the fact that Dr. Packer served as a temporary voting member of the CRDAC less than two months prior to his paid speaking role before his colleagues on the same committee.[2]

[1] Food and Drug Administration. Transcript of the March 27, 2014, meeting of the Cardiovascular and Renal Drugs Advisory Committee. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM404041.pdf. Accessed August 22, 2014.
[2] Food and Drug Administration. Draft Roster of the February 12, 2014, meeting of the Cardiovascular and Renal Drugs Advisory Committee.

Episodes such as this are concerning as they create, at least, the appearance of a conflict of interest and may bias committee members' view of a product advocated for by one of their recent or current committee colleagues. Such a revolving door thus threatens to undermine the objectivity of the FDA's advisory committee process, which typically plays a singularly important role in influencing agency decisions regarding drug and medical device approvals and withdrawals.

Dr. Packer's 17-year advisory committee tenure

Dr. Packer's participation on behalf of the company is especially troubling because he has served as a member of the CRDAC over a period of at least 17 years, first as a "core" voting member[3] and chair from 1997 to 2001; then as a temporary voting member on three occasions over the past four years, including two more stints as acting chair.[4]

To our knowledge, Dr. Packer's March 27 appearance represents the sixth time, since he first presided as CRDAC chair on October 23, 1997, that he has spoken on behalf of and/or served as a (presumably) paid consultant to sponsors whose products were being considered at these CRDAC meetings. The previous occurrences were as follows:

- As a speaker for Bristol-Myers Squibb at the July 19, 2002, CRDAC meeting discussing the new drug application for omapatrilat (Vanlev) for the treatment of hypertension;[5]
- As a consultant and speaker (which included giving concluding remarks) on behalf of GlaxoSmithKline at the January 7, 2003, CRDAC meeting in its presentation of the new drug application for carvedilol (Coreg);[6]
- As a speaker for NitroMed at the June 16, 2005, CRDAC meeting to discuss the company's new drug application for the isosorbide dinitrate/hydralazine (BiDil) combination therapy for heart failure;[7]

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http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM385230.pdf. Accessed August 20, 2014.

[3] "Core" voting members of each FDA advisory committee are those appointed to preside at every committee meeting held during their appointed terms. See the following FDA Guidance for Industry: Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997. October 1998. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079765.pdf. Accessed August 27, 2014.

[4] See Appendix for a complete list, going back to 1997 (the most recent year for which advisory committee archives are publicly available), of Dr. Packer's FDA advisory committee involvement, including CRDAC, either as a committee member/FDA consultant or as an industry expert/consultant.

[5] Food and Drug Administration. July 19, 2002, meeting of the Cardiovascular and Renal Drugs Advisory Committee. www.fda.gov/ohrms/dockets/ac/02/transcripts/3877T2.doc; and http://www.fda.gov/ohrms/dockets/ac/02/slides/3877s2.htm. Accessed August 11, 2014.

[6] Food and Drug Administration. January 7, 2003, meeting of the Cardiovascular and Renal Drugs Advisory Committee. Listed as a speaker in the Final Agenda at http://www.fda.gov/ohrms/dockets/ac/03/agenda/3920A2_Final.pdf; and listed as a "consultant" in the presentation "Introduction, Dr. Clare Kahn, PhD, GlaxoSmithKline" at http://www.fda.gov/ohrms/dockets/ac/03/slides/3920s2.htm. Accessed August 11, 2014.

- As a speaker for Sanofi at the March 18, 2009, CRDAC meeting discussing the company's new drug application for the atrial fibrillation drug dronedarone (Multaq);[8] and
- As a consultant for Pfizer at the July 29, 2010, CRDAC meeting concerning a clinical trial involving sildenafil (Revatio) for the treatment of pediatric pulmonary arterial hypertension.[9]

Dr. Packer's presence as an FDA advisory committee member at hearings extends beyond the CRDAC, as he has also participated in at least three meetings of the Arthritis Advisory Committee[10,11,12] and served at least once on the Endocrinologic and Metabolic Drugs Advisory Committee[13] since 2005.

We note with concern that, as with his revolving-door tenure at CRDAC, Dr. Packer has similarly worked with industry in the following capacities at non-CRDAC advisory committees while intermittently serving as a recurring member of some of these same committees:

- As a consultant to Centocor for its presentation on infliximab (Remicade) to the March 4, 2003, meeting of the Arthritis Advisory Committee;[14]

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[7] Food and Drug Administration. Summary Minutes of the June 16, 2005, meeting of the Cardiovascular and Renal Drugs Advisory Committee. http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4145M2.pdf. Accessed August 11, 2014.

[8] Food and Drug Administration. Transcript of the March 18, 2009, meeting of the Cardiovascular and Renal Drugs Advisory Committee. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM151343.pdf. Accessed August 26, 2014.

[9] Food and Drug Administration. Transcript of the July 29, 2010, meeting of the Cardiovascular and Renal Drugs Advisory Committee. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM223580.pdf. Accessed August 26, 2014.

[10] Food and Drug Administration. February 18, 2005, joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. http://www.fda.gov/ohrms/dockets/ac/05/agenda/2005-4090A1_Final.pdf; and http://www.fda.gov/ohrms/dockets/ac/05/roster/2005-4090R1_03_Consultants-Guests.pdf. Accessed August 15, 2014.

[11] Food and Drug Administration. November 24, 2008, meeting of the Arthritis Advisory Committee. http://www.fda.gov/ohrms/dockets/ac/08/roster/2008-4387r1-meeting-final.pdf; and http://www.fda.gov/ohrms/dockets/ac/08/agenda/2008-4387a1-final.pdf. Accessed August 14, 2014.

[12] Food and Drug Administration. Final Roster for the June 16, 2009, meeting of the Arthritis Advisory Committee. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM165707.pdf. Accessed August 20, 2014.

[13] Food and Drug Administration. Roster for the December 12, 2013, meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM390650.pdf. Accessed August 26, 2014.

[14] Food and Drug Administration. March 4, 2003, meeting of the Arthritis Advisory Committee. See "Remicade® (Infliximab), Centocor" presentation. http://www.fda.gov/ohrms/dockets/ac/03/slides/3930s1.htm. Accessed August 15, 2014.

- As an "external expert" cited by GlaxoSmithKline at the July 30, 2007, joint meeting of the Endocrinologic and Metabolic Drugs and Drug Safety and Risk Management Advisory Committees to discuss the cardiac ischemic risks of the thiazolidinedione diabetes drugs, with a focus on rosiglitazone (Avandia);[15] and
- As a consultant to Boehringer Ingelheim for its presentation concerning the drug tiotropium (Spiriva HandiHaler), made before the November 19, 2009, meeting of the Pulmonary-Allergy Drugs Advisory Committee.[16]

Please refer to the Appendix for a complete list of FDA advisory committees, in which Dr. Packer has participated, either as a committee member/FDA consultant or as an industry expert/consultant.

The FDA's contrasting policies on conflict-of-interest waivers and revolving-door episodes

The FDA's laxity regarding the advisory committee revolving door contrasts sharply with its commendable recent shift in policy concerning conflict-of-interest waivers for committee members. We note that, of the 16 times that Dr. Packer served as chair of the CRDAC between 1997 and 2001, he received a conflict-of-interest waiver to participate as a voting member of the committee six times, despite having an unspecified financial conflict of interest related to the products and/or companies that were the focus of these meetings (he also participated as a member in two other meetings debating the approval of nesiritide, despite having been involved in the early development of the drug; see Appendix).

Such waivers have become much less common since that time, largely in response to bad publicity[17,18] that spurred the passage of a provision within the 2007 Food and Drug Administration Amendments Act capping the number of conflict-of-interest waivers the FDA could grant in any given year (though this cap was, inappropriately in our view, rescinded in the 2012 Food and Drug Administration Safety and Innovation Act).[19] It is precisely because of its belatedly improved handling of members' conflicts of interest at committee meetings that the

[15] Food and Drug Administration. July 30, 2007, joint meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. http://www.fda.gov/ohrms/dockets/ac/07/slides/2007-4308s1-04-gsk-krall.pdf. Accessed August 25, 2014.
[16] Food and Drug Administration. November 19, 2009, Meeting of the Pulmonary-Allergy Drugs Advisory Committee. Boehringer Ingelheim- Spiriva HandiHaler (tiotropium inhalation powder) Core Presentation. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM194083.pdf. Accessed August 11, 2014.
[17] Kondro W. Conflicts cause FDA to review advisory committees. CMAJ. 2006;175(1):23. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1482745/. Accessed August 11, 2014.
[18] Lurie P, Almeida CM, Stine N, Stine AR, Wolfe SM. Financial conflict of interest disclosure and voting patterns at Food and Drug Administration Drug Advisory Committee meetings. JAMA. 2006;295(16):1921-8. http://jama.jamanetwork.com/article.aspx?articleid=202754. Accessed August 11, 2014.
[19] Wood SF, Mador JK. Science and regulation. Uncapping conflict of interest? Science. 2013;340(6137):1172-3.

agency's policy allowing current and former members to speak on behalf of drug sponsors at subsequent meetings seems so misguided.

Apparent absence of a revolving-door policy raises troubling questions

The revolving-door episodes outlined in this letter are potentially damaging to, and risk compromising the integrity of, the important FDA advisory committee process. In particular, a sponsor's use of an individual who serves, or has recently served, as a voting member of an FDA advisory committee to present its case before that member's colleagues on the committee takes advantage of the special collegiality existing among members in order to improve a company's chances of a favorable vote. Furthermore, such a revolving door raises concerns about the objectivity of committee members who accept such paid arrangements, with FDA's approval, at future hearings involving the same or a rival company.

Several questions thus arise regarding, and related to, Dr. Packer's multiple speaking and consulting roles for industry during his 17-year tenure as a recurring member of various FDA advisory committees:

> (1) During the March 27 meeting of the CRDAC, Dr. Packer mentioned receiving "permission" from the FDA to act as a paid speaker for the company while still considered a special government employee. On what basis did the FDA grant permission to Dr. Packer to speak for the company at this meeting? Where are the FDA documents that reflect granting this permission? Did the FDA grant this permission before or after the February 12, 2014, CRDAC meeting at which Dr. Packer served as a voting member?
>
> (2) Have there been other instances, beyond those listed in this letter, in which Dr. Packer or any other temporary or core advisory committee voting members have been permitted to serve as paid speakers or consultants on behalf of a presenting sponsor to their own or another FDA advisory committee while they were still listed on the FDA rolls as special government employees? If so, please provide us with a complete list of such occurrences, including all dates on which they acted as paid speakers or consultants and the previous or subsequent dates on which they acted as members of the advisory committee, as well as all documents concerning the granting of permission by the FDA.
>
> (3) Does the FDA have any written policy about temporary or core advisory committee members speaking to, or serving as consultants before, committees (either their own or another) on behalf of sponsors during or following their service? If so, please provide a copy of that policy. As a former member of the FDA's Drug Safety and Risk Management Advisory Committee from 2008 to 2012, one of us, Dr. Sidney M. Wolfe, does not remember reading any documents or being briefed concerning such a policy.

Urgent need for a rigorous revolving-door policy

It is imperative that the FDA develop, articulate, and implement a written policy applicable to all voting advisory committee members that restricts these revolving-door arrangements, which undermine public confidence in FDA advisory committees and in the agency itself. We urge the FDA to issue a guidance document outlining clear restrictions on current, former, and prospective committee members' speaking and consulting arrangements on behalf of sponsors before FDA advisory committees. Specifically, the guidance should:

a) prohibit such arrangements for core committee members during their appointed terms;

b) require a "cooling-off period" for core members who have completed their terms and for temporary voting members, such that a sufficient and reasonable amount of time elapses between an individual's service as a voting member on an FDA advisory committee and that individual's taking any speaking or consulting roles on behalf of a sponsor before any future committee meeting; and

c) amend the FDA's 2008 advisory committee conflict-of-interest guidance ("Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees") such that a previous paid speaking or consulting arrangement on behalf of a sponsor at an FDA advisory committee may be considered a "disqualifying financial interest" for the purposes of determining eligibility for participation in an upcoming committee meeting if the arrangement occurred within a reasonably recent period of time.[20]

In its 2008 guidance clarifying its approach toward conflict-of-interest restrictions for advisory committee members, the FDA recognized the importance of its advisory committee process relative to that of other federal agencies: "[W]hile many conflict of interest laws and regulations apply to advisory committees across the federal government, the public has a particular interest in and high expectations for FDA's process."[21] Indeed, FDA advisory committees exert a pivotal influence over the agency's drug and medical-device approval decisions that, in turn, critically affect the public health. It is for this reason that the FDA chose in 2008 "to implement a more

[20] Food and Drug Administration. Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees. August 2008. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf. Accessed August 26, 2014. The guidance's definition of "disqualifying financial interests" is restricted to interests that are "currently held". Presumably, a speaking or consulting arrangement for which compensation is no longer being received at the time of consideration for participation in an upcoming committee meeting would not be covered under this definition. Note that we are not asking that a recent paid speaking or consulting role, on its own, necessarily disqualify a prospective committee member, only that such a prior arrangement serve as one of several factors determining eligibility for a future committee appointment.

[21] *Ibid.*

stringent policy for considering eligibility for participation [in FDA advisory committees] than is required under the current legal framework" governing special government employees' conflicts of interest.[22]

We agree with the reasoning behind this approach and implore the FDA to again go beyond the minimal — and, in our view, grossly insufficient — legislative requirements governing the revolving door for federal special government employees.[23] It is crucial that FDA advisory committee decisions be based on an objective evaluation of the risks and benefits of a drug or medical device. The bias introduced by committee members acting as paid spokespeople or consultants before their current or former colleagues threatens to undermine the objectivity with which committee experts approach their work. Only a ban on paid speaking and consulting roles for current core FDA advisory committee members and an appropriately lengthy "cooling-off" period for former core and recurrent temporary voting members will mitigate such undue influence over the vital committee process.

We look forward to a timely response.

Sincerely,

Sammy J. Almashat, M.D., M.P.H.
Researcher

Sidney M. Wolfe, M.D.
Founder and Senior Adviser

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

[22] *Ibid*.

[23] See e.g. 18 U.S. Code § 207 where former special government employees are prohibited from lobbying their former colleagues only on "particular matters" (presumably, in this case, with regard to a particular drug or medical device) in which they were personally involved or for which they were responsible, while employed by the federal government. Only "senior" and "very senior" executive branch officials are prohibited from lobbying on more "general matters" for any period following their employment. See also 5 CFR 2635.807, which outlines broad restrictions on compensated teaching, speaking, or writing engagements for current federal employees, but does not apply — except with regard to "particular matters" — to special government employees who have not served for more than 60 days during any one-year period of their employment (most, if not all FDA advisory committee members serve fewer than 60 days in any given year).

Appendix: Dr. Milton Packer's involvement with FDA advisory committees since 1997 (the most recent year for which advisory committee archives are publicly available).

Cardiovascular and Renal Drugs Advisory Committee (in chronological order)

As drug sponsor's "representative" for the meeting:

- February 27, 1997 (SmithKlineBeecham) http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3264T1.PDF.

As chair*:*

- October 23, 1997. http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3338t1.pdf.
- October 24, 1997. http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3338t2.pdf.
    - full waiver received for reported conflict of interest
- January 27, 1998 [sic]. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3368t1.pdf.
    - full waiver received for reported conflict of interest
- January 28, 1998. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3368t2.pdf.
- April 9, 1998. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3421t1.pdf.
- April 10, 1998. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3421t2.pdf.
    - waiver received for reported conflict of interest
- July 9, 1998. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3439t1.pdf.
- October 22, 1998. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3462t1.pdf.
- October 23, 1998. http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3462t2.pdf.
    - full waiver received for reported conflict of interest
- January 29, 1999. http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3490t2.pdf.
    - Dr. Packer did not require a waiver to participate in this meeting. However, he was allowed to participate despite having been, more than two years previously, a consultant and a Phase II investigator (though he did not participate in subject recruitment or data analysis) in the early development of the hypertension drug nesiritide (Natrecor), the approval of which, for the short-term treatment of congestive heart failure, was the focus of this meeting.
- April 29, 1999. http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3511t1a.pdf.
    - waiver received for reported conflict of interest
- April 30, 1999. http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3511t2a.pdf.
- October 14, 1999. http://www.fda.gov/ohrms/dockets/ac/99/transcpt/3555t1a.pdf.
- May 2, 2000. http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3612t2a.pdf.
    - full waiver received for reported conflict of interest

- October 20, 2000. http://www.fda.gov/ohrms/dockets/ac/00/transcripts/3656t2a.pdf.
- May 25, 2001. http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3749t2_01.pdf.
    - As with the January 29, 1999 meeting, Dr. Packer was allowed to participate in this second meeting focusing on the potential approval of nesiritide for the treatment of acute heart failure.

As drug sponsor's speaker and/or consultant:

- July 19, 2002 (Speaker, Bristol-Myers Squibb) www.fda.gov/ohrms/dockets/ac/02/transcripts/3877T2.doc.
- January 7, 2003 (Speaker, GlaxoSmithKline) http://www.fda.gov/ohrms/dockets/ac/03/agenda/3920A2_Final.pdf.
- June 16, 2005 (Speaker, NitroMed) http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4145M2.pdf.
- March 18, 2009 (Speaker, Sanofi) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM151343.pdf.
- July 29, 2010 (Consultant, Pfizer) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM223580.pdf.

As temporary voting member and/or acting chair*:*

- December 8, 2010 (Acting Chair) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM241788.pdf.
- May 2, 2011 (Acting Chair) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM254384.pdf.
- February 12, 2014 (Temporary voting member) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM385230.pdf.

As drug sponsor's speaker:

- March 27, 2014 (Novartis) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM392153.pdf.

Other Advisory Committees (in chronological order)

As drug sponsor's consultant (Arthritis Advisory Committee):

- March 4, 2003 (Centocor) http://www.fda.gov/ohrms/dockets/ac/03/slides/3930s1.htm.

As non-voting FDA consultant (Joint meeting of the Arthritis and the Drug Safety and Risk Management Advisory Committees)*:*

- February 16, 2005 http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T1.pdf.

As "external expert" for sponsor (Joint meeting of the Endocrinologic and Metabolic Drugs and the Drug Safety and Risk Management Advisory Committees):

- July 30, 2007 (GlaxoSmithKline) http://www.fda.gov/ohrms/dockets/ac/07/slides/2007-4308s1-04-gsk-krall.pdf.

As temporary voting member or non-voting FDA consultant (Arthritis Advisory Committee)*:*

- November 24, 2008 (Temporary non-voting member) http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4387t-01-part1.pdf.
- June 16, 2009 (Temporary voting member) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM174953.pdf.

As drug sponsor's consultant (Pulmonary-Allergy Drugs Advisory Committee):

- November 19, 2009 (Boehringer Ingelheim) http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM194083.pdf.

As temporary voting member (Endocrinologic and Metabolic Drugs Advisory Committee)*:*

- December 12, 2013 http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM388936.pdf.