# Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: June 14, 2017

TO: Janice M. Soreth, M.D.
Associate Commissioner for Special Medical Programs
Office of Medical Products and Tobacco
Office of the Commissioner, FDA

THROUGH: Jeffrey Anderson, MS, RAC
Director (Acting), Advisory Committee Oversight and Management Staff
Office of Special Medical Programs

FROM: Jayne E. Peterson, B.S.Pharm., J.D.
Director, Division of Advisory Committee and Consultant Management
Center for Drug Evaluation and Research

Name of Advisory Committee Member: Deborah Schrag, M.D.

Committee: Oncologic Drugs Advisory Committee Meeting

Meeting date: July 13, 2017

Description of the Particular Matter to Which the Waiver Applies:

Dr. Schrag is serving as a temporary voting member of the Oncologic Drugs Advisory Committee (ODAC). The Committee's function is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and make appropriate recommendations to the Commissioner of Food and Drugs.

On July 13, 2017, the committee will discuss biologics license application (BLA) 761028 for ABP 215, a proposed biosimilar to Genentech/Roche's AVASTIN (bevacizumab), submitted by Amgen Inc. The proposed indications/uses for this product are: (1) For the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy; (2) in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line ABP 215-containing regimen; (3) for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-

squamous, non-small cell lung cancer in combination with carboplatin and paclitaxel; (4) for the treatment of glioblastoma, as a single agent for adult patients with progressive disease following prior therapy; (5) for the treatment of metastatic renal cell carcinoma in combination with interferon alfa; and (6) in combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix. The topic of this meeting is a particular matter involving specific parties.

Type, Nature, and Magnitude of the Financial Interest:

Dr. Schrag has reported ownership of shares of (b) (6) a healthcare sector mutual fund. The current value of Dr. Schrag's interest in the healthcare sector fund is $50,000 – $150,000. The fund includes as an underlying asset shares of one firm that is a party to the matter and shares of six firms that compete with the product that is the subject of the meeting. The combined value of the underlying shares that are conflicting assets makes up approximately 23% of the holdings of the fund.

Basis for Granting the Waiver:

Regulation of biosimilar products is new and evolving through interpretation of the law and the published FDA guidance. Section 351(i) of the Public Health Service (PHS) Act defines biosimilarity to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product."[1] Evaluation of clinical pharmacology data is critical in addressing "no clinically meaningful difference in safety, purity and potency" between the biosimilar and the US-reference product. It is also essential that the advice provided by practicing medical oncologists is not limited to one or two experts, but that it represents the scope of practice covered by the many indications. A broad clinical oncology expertise is needed for this advisory committee meeting to ensure the committee has a successful and productive meeting. Dr. Schrag's expertise in research on utilization of new cancer treatment technologies at the population level will be a great asset for this meeting.

*Dr. Schrag has unique qualifications and specialized expertise needed for this particular matter.*

Dr. Schrag received her medical degree from Columbia University in New York in 1991. She subsequently completed her residency in Internal Medicine at Brigham and Women's Hospital, and her fellowship in Medical Oncology at Dana-Farber Cancer Institute (DFCI). She obtained a Master's degree in Public Health from the Harvard School of Public Health in 1998, and joined the staff of DFCI and Brigham and Women's Hospital. From 1999 through 2007, Dr. Schrag practiced medical oncology in the Division of Gastrointestinal Oncology at Memorial Sloan-Kettering Cancer Center, where she was an Associate Member and Associate Professor of Public Health and Medicine. In 2007, she returned to DFCI and Brigham and Women's Hospital, where she is a medical oncologist and clinical investigator in the Center for Gastrointestinal Oncology.

[1] Section 7002(b)(3) of the Affordable Care Act, adding section 351(i)(2) of the PHS Act

Her research focuses on utilization of new cancer treatment technologies at the population level. Dr. Schrag is currently leading a team of researchers at the Division of Population Science's Center for Outcomes and Policy Research, aimed to enhance the outcomes of interventions to prevent and treat cancer from both efficacy and cost-effectiveness perspectives. Her in-depth knowledge of medical oncology and new cancer treatment technologies is essential to the discussion at the ODAC meeting.

*There is limited expertise available and it is difficult to locate similarly qualified individuals without a disqualifying financial interest.*

There were a total of fourteen special government employees with expertise in medical oncology invited to this AC meeting, and six were unable to attend due to schedule conflicts. There are a total of eight medical oncologists attending, including Dr. Schrag. It is imperative to have several medical oncologists who bring a varied expertise and diverse experiences to this meeting for a fruitful discussion. Further, two of the approved indications are for use in colon cancer; Dr. Schrag's specific expertise is in the treatment of colon cancer, and she is qualified to represent this community's position on the adequacy of the data to support approval of a biosimilar product for this use.

*The particular matter is sensitive.*

The meeting topic is considered to be sensitive. The Agency does anticipate that the meeting is likely to receive significant public interest and (non-trade) press interest, as this will be the first biosimilar monoclonal antibody for cancer indications that will be discussed at an ODAC meeting.

*Dr. Schrag's expertise in this particular matter is necessary in the interest of public health.*

The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law on March 23, 2010, amends the PHS Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. This pathway is provided in the part of the law known as the Biologics Price Competition and Innovation Act (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product. A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety, purity and potency from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Biosimilars can provide more treatment options for patients, and possibly lower treatment costs.

Dr. Schrag is one of eight medical oncologists attending this meeting. It is necessary to have several medical oncologists participate, to strive to obtain a diversity of opinions and have a productive meeting. Dr. Schrag's participation will allow for a well-rounded discussion, as she brings specific expertise in the treatment of colon cancer that will enhance committee dialogue and analysis in the interest of public health.

*The dollar value of the potential gain or loss that may result from participation in the particular matter is small.*

As noted above, the current value of her holdings in the healthcare sector fund is $50,000 – $150,000. This sector fund concentrates its assets in the healthcare sector, which includes pharmaceutical firms that could potentially be affected by the particular matter that will be discussed during this advisory committee meeting.

*Dr. Schrag has served as Temporary Member of the ODAC effectively in the past.*

Dr. Schrag is among the medical oncologists with the most prior experience on the ODAC and understanding of regulatory policy. It is necessary to have several medical oncologists at this meeting for a fruitful discussion and diversity of opinions.

*Any potential for a conflict of interest is greatly outweighed by the strong need for Dr. Schrag's expertise in this matter.*

In the interest of public health, it is critical for the Agency to review biosimilar products shown to be highly similar to an FDA-approved biological product, and to have no clinically meaningful differences in terms of safety, purity and potency from the reference product. Biosimilar products can provide more treatment options for patients, and possibly lower treatment costs. Dr. Schrag's combination of expertise in medical oncology and colon cancer, and her previous experience on the ODAC, are critical for the assessment of the biosimilar product coming before the committee.

Accordingly, I recommend that you grant Dr. Deborah Schrag, a temporary voting member of the Oncologic Drugs Advisory Committee, a waiver from the conflict of interest prohibitions of 18 U.S.C. §208(a).

## Certification:

___X___ The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

Limitations on the Regular Government Employee's or Special Government Employee's Ability to Act:

_____ Non-voting

_____ Other (specify):

_____

_____ Denied – The individual may not participate.

Janice M. Soreth -S

Digitally signed by Janice M. Soreth -S
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6/22/2017

Janice M. Soreth, M.D. Date
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