



**THE GEORGE
WASHINGTON
UNIVERSITY**
WASHINGTON, DC

Responsible University Official:

Associate Dean for Faculty Affairs and
Professional Development

Responsible Office: Office of Faculty
Affairs, SMHS

Most Recent Revision: 1/2015

THE GEORGE WASHINGTON UNIVERSITY
SCHOOL OF MEDICINE AND HEALTH SCIENCES
POLICY ON CONFLICTS OF INTEREST RELATED TO CLINICAL CARE

I. POLICY STATEMENT

The George Washington University School of Medicine and Health Sciences (SMHS) adheres to the principle that the involvement of faculty, administrators, department chairs, residents, and students in the exchange of ideas and knowledge with outside organizations may help advance the science and delivery of medicine. SMHS is committed to the development of drugs, biologics, and devices for the benefit of patients. Discovery, safety, efficacy evaluations, and appropriate clinical use of products require collaboration among academic institutions, government, and industry. The objective of SMHS is to recognize the ideological differences between academia and industry, and to facilitate interactions with industry in a transparent manner that minimizes real and perceived conflicts of interest.

The SMHS Policy on Conflicts of Interest Related to Clinical Care (“SMHS Policy”) is not intended to replace or supersede the George Washington University (GW) Policy on Conflicts of Interest and Commitment for Faculty and Investigators (“University Policy”). The purpose of this Policy is to provide guidance to SMHS faculty, administrators, department chairs, residents, and medical and health sciences students regarding the acceptable parameters of provider/industry interactions as they relate to clinical care and interaction with industry, and to establish SMHS procedures for evaluating and managing clinical conflicts of interest. For purposes of this Policy, the term “Industry” shall include biomedical, pharmaceutical, medical device and other companies that make products or provide services used for the provision of health care.

II. SCOPE

- A. This Policy applies to:
1. All active status regular faculty, research faculty and University employed visiting faculty in SMHS (“Faculty”) regardless of clinical practice location;
 2. SMHS Department Chairs;
 3. SMHS administrators;
 4. Resident physicians; and
 5. Medical and Health Sciences Students (“Students”).
6. Collectively, all of the groups referenced together will be referred to as “SMHS Members.”
- B. Since SMHS Members provide clinical care at sites other than GW, it is expected that they will adhere to the conflict of interest policies at the sites where they practice, including, but not limited to GWU- Medical Faculty Associates, Children’s National Health System, Inova Fairfax Hospital, Veterans Administration facilities, Holy Cross Hospital, and others. When such policies exist, Members shall be guided by local policies as well as by this SMHS policy. If questions arise regarding any differences between this SMHS policy and conflict of interest policies at a clinical affiliate site, Members shall direct them to the Associate Dean for Faculty Affairs and Professional Development.
- C. Faculty may be employed by organizations other than the University. Faculty are expected to abide by any employment guidelines regarding outside activities and relationships with interest, even if they are more restrictive than this policy.
- D. Limited service and voluntary faculty members who are not employed by GW, are expected to provide clinical care and clinical instruction that is consistent with the Association of American Medical Colleges (AAMC) principles articulated below in Section III.

III. Guiding Principles

- A. SMHS endorses the principles published by the AAMC¹ regarding the interactions between academic medical institutions and industry as set forth below:
- The interactions should serve to enhance the public health.

¹ Industry Funding in Support of Medical Education: AAMC Task Force 2008

- The interactions should be transparent.
 - All the interactions between academic medical centers and industry must reflect high standards of medical professionalism that reach beyond applicable laws and regulations.
 - The interactions should be reciprocal, with knowledgeable parties on both sides of the interactions.
 - The interactions should support and enable the free exchange of information in appropriate settings in a manner adherent to applicable law and consistent with the standards of medical professionalism. Interactions should also be consistent with additional standards that may be established to assure that exchanges of information are evidence-based and free of bias to the maximum possible extent.
 - The interactions must serve both academic medicine and the legitimate missions of industry. Compensation structures and arrangements should be consistent with the foregoing principles.
- B. When SMHS faculty, administrators, faculty, and department chairs, interact with outside organizations, even on their own time, they shall be mindful that their faculty or administrative title is representative of GW and that they bear responsibility for maintaining integrity and professionalism associated with their faculty title.

IV. REQUIRED DISCLOSURES

- A. The Physician Payment Sunshine Act of the Patient Protection and Affordable Care Act of 2012 (“Sunshine Act”) requires industry to disclose to the public all payments and transfers of value to physicians and other providers over the sum of Ten Dollars (\$10.00).
- B. Professional online profiles maintained or publicized by a SMHS faculty member’s clinical practice organization shall include a disclosure section, listing companies or industries with whom a faculty member discloses a financial interest of the value of ten thousand dollars (\$10,000) or greater. This requirement does not apply to SMHS member personal social media accounts such as Facebook, LinkedIn, Twitter and others.
- C. Individual SMHS Members may have additional disclosure requirements imposed as part of a conflict management plan as provided for in Section VI of this Policy.

V. **CONFLICT OF INTEREST PROCEDURES**

A. For procedures described in this section “Authorized Official” shall mean the following for different types of SMHS Members:

1. Department Chair for Faculty
2. Associate Dean for Faculty Affairs and Professional Development for Department Chairs and non-faculty administrators
3. Senior Associate Dean for MD Programs for Medical Students and Residents
4. Senior Associate Dean for Health Sciences for Health Sciences Students

B. **Personal Gifts**

SMHS Members shall not accept personal gifts or entertainment (including travel), regardless of value, from Industry. Unsolicited, non-branded, and general use gifts that have an educational value and are for the benefit of patient care or health education are not considered personal gifts and may be accepted on behalf of an SMHS Department or Office by the Authorized Official. (Unsolicited general use gifts that have an educational value and are for the benefit of patient care or health education, and which are branded, may be accepted by an Authorized Official in limited circumstances depending upon the need and availability of such gifts). Examples include books, anatomic models, illustrations, and clinical diagrams, provided they are not solely for a specific individual recipient’s benefit. By contrast, a stethoscope given by an industry representative or vendor to a specific individual would be considered a personal gift and may not be accepted.

C. **Meals**

Industry-sponsored meals for SMHS Members are considered personal gifts and are prohibited. This prohibition includes, among other things, industry-donated lunches and other meals for grand rounds and other educational conferences. However, Industry representatives may donate funds centrally to a SMHS department (or division) to support a general fund for meals and/or educational activities, provided:

1. The donation is unrestricted and the Industry representative does not determine the content or presenter for any specific program; and
2. The Industry representative making the donation to a general meal fund is identified generally among all commercial sponsors of on-site educational programs and is not identified as specifically supporting any particular educational activity.

D. Industry Support for Educational Activities

All educational support from Industry must be donated centrally to the School or to a Department. Such educational support may be accepted if used for travel to scholarly or educational meetings, course work, textbooks and learning materials, or other academic activities, provided the following conditions have been satisfied:

1. Funds are unrestricted or designated for use only for broad areas of interest (i.e. “cancer prevention”, or “education in cardiovascular diseases’.) Funds cannot be designated for use by specific individuals.
2. With the approval of their Authorized Official, SMHS Members may attend industry-sponsored training programs, and may accept payment for travel and meals by industry to attend such programs, provided attendance at the program is beneficial for the SMHS Member attending the program to become credentialed to use new technologies or devices, or if travel is educationally necessary for the SMHS faculty member to improve his or her clinical practice.
3. Department Chairs or Administrators who accept donations from Industry to support education on behalf of SMHS or an SMHS department that is valued at Ten Thousand Dollars (\$10,000.00) or greater shall disclose in writing to the Associate Dean for Faculty Affairs and Professional Development the value and intended use of the gift.

E. Speaking and Honoraria

1. SMHS Members may speak at Industry-sponsored education or training activity that is not ACCME or similarly accredited, provided each of the following requirements have been satisfied:
 - a. The SMHS Member has provided his or her Authorized Official with a written summary of the nature of the speaking engagement, the remuneration, if any, and the estimated time commitment².
 - b. If the remuneration for the activity is Ten Thousand Dollars (\$10,000.00) or greater, the SMHS Member discloses the activity in writing to the SMHS Associate Dean for Faculty Affairs and Professional Development for a determination of whether a conflict management plan is warranted.

² This requirement does not apply to SMHS Members who are not university-employed faculty members unless the remuneration for any single activity is \$10,000 or greater, or the cumulative remuneration is \$10,000 or greater from any single Industry source in a single academic year.

- c. The SMHS Member's Authorized Official has approved participation in the activity in writing³.
 - d. The SMHS Member agrees to adhere to any applicable guidelines of the Food and Drug Administration (FDA) governing FDA-regulated promotional activities.
2. SMHS Members who speak at a non-University sponsored event may not present themselves as representatives of Industry.
3. All remuneration received by an SMHS Member for a speaking engagement is subject to the disclosure requirements set forth in the University Policy. The Authorized Official will monitor speaking engagements of an SMHS Member on an ongoing basis and will consult with the SMHS Associate Dean of Faculty Affairs and Professional Development as necessary for a determination of whether a conflict management plan is warranted.
4. SMHS Members may accept reasonable travel expenses as part of their compensation for speaking, but may not accept gifts of travel expenses for spouses, dependents, or domestic partners.
5. SMHS Members may speak or give presentations at bona fide academic conferences, such as grand rounds at other academic centers, scholarly meetings, ACCME-approved (or similarly accredited) educational events, etc. SMHS members may accept honoraria for these academic engagements, including payment for modest expenses for travel, lodging and meals.

F. Consulting

1. SMHS Members may engage with Industry to serve as consultants, scientific advisors, or to serve on advisory panels provided each of the following requirements have been satisfied:
 - a. The SMHS Member has provided his or her Authorized Official with a written summary of the nature of the activity, the remuneration, if any, and the estimated time commitment.
 - b. If the remuneration for the activity is Ten Thousand Dollars (\$10,000.00) or greater, the SMHS Member discloses the activity in writing to the SMHS Associate Dean for Faculty Affairs and Professional Development for a determination of whether a conflict management plan is warranted.

³ This requirement does not apply to SMHS Members who are not university-employed faculty members unless the remuneration for any single activity is \$10,000 or greater, or the cumulative remuneration is \$10,000 or greater from any single Industry source in a single academic year.

- c. The SMHS Member's Authorized Official has approved participation in the activity in writing.
2. All remuneration received by an SMHS Member for a consulting is subject to the disclosure requirements set forth in the University Policy. The Authorized Official will monitor consulting engagements of an SMHS Member on an ongoing basis, and will consult with the Associate Dean of Faculty Affairs and Professional Development as necessary for determination of whether a conflict management plan is warranted.
3. SMHS Members may accept reasonable travel expenses to the extent travel is required as part of their consulting engagements, but they may not accept gifts of travel expenses for spouses, dependents, and domestic partners.

G. Ghost Writing

SMHS Members are prohibited from publishing articles or other materials under their own names when such articles or materials are written in whole or material part, by industry representatives/vendors (ghostwriting).

H. Vendor and Industry Representative Access

SMHS faculty, Department chairs, and Administrators may meet with Industry representatives on campus, provided each of the following requirements are satisfied:

1. Meetings that are promotional in nature shall occur in a faculty office or conference room and not in a clinical area.
2. If an Industry representative will be in a clinical area, such as for technical support for their products or devices, there shall be a faculty member present.
3. Industry representatives are not permitted to meet with students or residents unless there is a faculty member present.

I. Samples

Medication and medical equipment samples may be accepted by faculty members from Industry for patient care use pursuant to the following guidelines:

1. When prescribing medications, the faculty member or resident shall choose an agent based on evidence for efficacy, side effects, tolerability, medication interactions and cost-effectiveness.
2. Samples are for bona fide patient care use only and not for use by faculty, staff, family members, trainees, or others.
3. Samples must be kept in a secure location.
4. Distribution of samples to a patient should be documented in the patient's medical record
5. Students and residents cannot sign for the receipt of samples.

J. Pharmacy and Therapeutics Committees and Purchasing Committees

SMHS Members who serve on pharmacy and therapeutics committees, or serve in a capacity where they may be in a position to influence formulary or purchasing decisions related to pharmaceuticals, medical devices, medical software, or other products and services, must recuse themselves from any decision making regarding a product or service from a company with which they have a financial interest as defined in the GW Policy on Conflicts of Interest and Commitment for Faculty and Investigators.

K. Financial interests related to medical devices

1. SMHS Members receiving compensation for scientific or clinical advising to Industry for the development of medical devices shall comply with the requirements of this Policy set forth in Section IV(F ("Consulting") above.
2. SMHS Members who develop medical devices, software, or other inventions or patents related to clinical care shall abide by the GW Policy on Patents and Scholarly Works.
3. Ownership by SMHS Members in Physician Owned Distributorships (POD) is prohibited.
4. All financial interests relating to medical devices should be disclosed in writing to patients on whom the device will be used and to the SMHS Member's Authorized Official.

VI. Procedures for Review

- A. Review and management of potential conflicts of interest for faculty and administrators will occur in accordance with the University Policy section IV.

1. For potential conflicts involving faculty who are not employed by the University, the Associate Dean for Faculty Affairs and Professional Development shall work closely and collaboratively with the Authorized Official and designated compliance officer at the employing institution for review, and if a management plan is warranted, for drafting of that plan.
 2. Resolution of disputes about conflicts or conflict management plans shall occur in accordance with the University Policy
- B. For potential conflicts involving residents or students, the Associate Dean for Faculty Affairs and Professional Development will work closely with the Authorized Official for review.

Who Needs to Know This Policy

All students, faculty, and staff of the School of Medicine and Health Sciences

Website Addresses for This Policy

<http://smhs.gwu.edu/about/policies>

Contacts

Office of Faculty Affairs: Ray Lucas 202-994-3266 rlucas@gwu.edu

Who Approved This Policy

Approved by the SMHS Faculty Assembly Executive Committee January 22, 2015