

# **Policy on Interactions with Industry**

**January 1, 2012**

**University of Wisconsin Medical Foundation, Inc.**



**Purpose of Policy:**

This policy establishes guidelines for interactions between Industry and faculty physicians employed by the University of Wisconsin-Madison ("UW"), as well as other UW- or UWMF-employed health care professionals. The UW School of Medicine and Public Health ("SMPH") has entered into a Memorandum of Understanding with UWMF, whereby UWMF is charged with implementation of this Policy on behalf of the UW and SMPH with respect to UW Faculty Physicians and other UW-employed health care professionals.

We encourage interactions and partnerships with Industry which serve the public good and promote our missions. These interactions must be appropriately conducted and monitored in order to avoid or manage conflicts of interest that can adversely affect our patients or the institution. The purpose of this policy is well summarized by the Association of American Medical Colleges: "the overarching goal for both academic medicine and Industry must be to maintain productive relationships in research, education, and patient care that contribute to the health of the public and sustain the public's trust."

**Statement of Policy:**

Interactions with Industry should be conducted so as to avoid conflicts of interest when possible, and to minimize and effectively manage these when conflicts do exist.

**Basis for Policy:**

Professionalism is a core value of UWMF and the SMPH, and forms the basis for the provision of health care. Because health care providers occupy esteemed and privileged positions in our society, we must maintain a strong relationship of confidence and trust between clinicians and their patients. Promoting the values and behaviors associated with professionalism for both current and future generations of healthcare providers is a primary responsibility of an academic health center. All health care providers must ensure that the process by which they make clinical decisions is transparent, ethical, free of undue economic influence, and reflects the highest professional standards. Patients deserve and expect well-informed, objective health care decision-making based on their best interests.

*An individual conflict of interest occurs when a person with entrusted responsibility has another interest that may conflict with the proper exercise of that responsibility.*

UWMF was chartered by the University of Wisconsin Board of Regents in 1996 to support the educational and research missions of the SMPH through the coordination and delivery of clinical care by the faculty of the school. The authority bestowed in the charter carries with it the responsibility to exercise our clinical mission with the highest standards possible. While the UW has policies that speak to conflicts of interest, such policies do not fully reflect the special covenant that exists between clinicians and patients, and do not respond to the urgency felt by academic health centers to formulate specific policy in this area. As a result, UW and the SMPH have delegated the responsibility to implement this Policy on behalf of the UW and SMPH with respect to UW Faculty Physicians and other UW-employed health care professionals

**Scope of Policy:**

This policy addresses a specific set of interactions with Industry, and purposefully excludes others. In particular, it does not address activities certified for CME credit by an ACCME-accredited organization, nor does it generally address faculty research activities, the former being addressed by the Office of Continuing Professional Development and the latter through the University of Wisconsin-Madison policies. This Policy addresses the following areas:

- I. Gifts to Individuals
- II. Gifts to UWMF
- III. Attendance at Non-CME certified events / outside activities funded by Industry
- IV. Speaking at Non-CME certified events Sponsored by Industry
- V. [Intentionally Omitted]

- VI. Consultation with Industry
- VII. Ownership and Corporate Board Membership
- VIII. Royalties
- IX. Oversight of Outside Relationships with Industry: The Industrial Interactions Review Committee (IIRC)
- X. Internal Disclosure
- XI. Disclosure to Patients
- XII. Site Access by Industry Representatives
- XIII. Industry Sponsored Scholarships and Other Educational Funds for Trainees
- XIV. Pharmaceutical Samples
- XV. "Ghostwriting" and Responsible Communications Practices
- XVI. Individual Involvement with Industry in Purchasing Decisions for UW Healthcare Entities

**Application of Policy:**

This policy applies to all UW Faculty Physicians and UW- or UWMF-employed health care professionals (defined collectively as "UW/UWMF Providers," below).

**Definitions:**

- A. **Industry or Industry Representatives:** Manufacturers, services, and other vendors of pharmaceutical, medical device, medical supply, and medical testing companies, and their employees, representatives, agents, and vendors.
- B. **UW Healthcare Entities:** Collectively, the University of Wisconsin School of Medicine & Public Health, the University of Wisconsin Hospitals & Clinics Authority, and the University of Wisconsin Medical Foundation, Inc.
- C. **IIRC:** Refers to the Industrial Interactions Review Committee. The IIRC is a committee of the UWMF Board of Directors which is charged with oversight of all UW/UWMF Providers that are within the purview of this policy.
- D. **Non-CME Events:** Events, including those held in other countries, which are not certified for continuing medical education credit by an ACCME-accredited organization.
- E. **UW/UWMF Providers:** UW Faculty Physicians and UW- or UWMF-employed physician assistants, nurse practitioners, nurses, and other health care professionals.

## **POLICY**

### **I. Gifts to Individuals**

UW/UWMF Providers may not accept from Industry anything of value for their private benefit or the benefit of their immediate family or an organization with which they are associated, for which payment or services are not provided in return. This includes, but is not limited to money, property, favor, service, food, travel, and entertainment. For the purposes of this Policy, there is no minimum value to a gift; items of little value such as pens, sticky notes, magnets, key chains, and laser pointers, are all considered gifts.

### **II. Gifts for Patient Education**

By agreement with UWHC, non-branded, non-promotional patient education materials may be received under the oversight of the UWHC Vendor Liaison Office (VLO). Such gifts for patient education should first be approved by the VLO staff, who will review the material for inappropriate promotional messaging. Gifts must be made at the Section, Divisional or Departmental level, with simultaneous notification of the Chair of the IIRC. Gifts shall not be made to or on behalf of individual faculty members.

### **III. Attendance at non-CME Events / Outside Activities Funded by Industry**

UW/UWMF Providers may attend Industry-sponsored events, such as educational programs that are not certified for CME credit, at their own discretion. Dinner programs, "roundtables," or "educational conferences" sponsored by Industry are included in this category. In such cases, the UW/UWMF Providers shall not receive any remuneration or gifts (See Section I, above) in exchange for attendance. This prohibition includes the cost of meals and reimbursement for any expenses to attend the program such as food, travel, accommodations, or registration fees. UW/UWMF Providers who attend non-CME Industry-sponsored events must pay all of their own expenses.

### **IV. Speaking at Non-CME Events Sponsored by Industry**

UW/UWMF Providers may not participate as speakers in outside activities that are promotional and funded by Industry, such as speaker's bureaus, speaker's training programs, and contracted educational programs.

With prior approval, UW/UWMF Providers may speak at non-CME events sponsored by Industry which provide unique learning opportunities.

To obtain prior approval to speak at a non-CME event, UW/UWMF Providers must complete the form located at the following location on uConnect:

<http://apps/uconnect.wisc.edu/emailforms/form.jsp?ef=78>

The uConnect form requires answers to the following questions:

#### **A. For events sponsored by pharmaceutical or biologic Industry companies:**

1. Why are the events not certified for CME by an ACCME-accredited organization?
2. Will the events comply with the current *Code on Interactions with Healthcare Professionals of the Pharmaceutical Research and Manufacturers of America (PhRMA)*?  
[Also see all questions enumerated in Section IV.C., below]

**B. For events sponsored by device manufacturer Industry companies:**

1. Will the events conform to applicable FDA regulations or guidelines?
2. Will the events comply with the current *Code of Ethics on Interactions with Health Care Professionals* of the Advanced Medical Technology Association (AdvaMed)?  
[Also see all questions enumerated in Section IV.C., below]

**C. For events sponsored by any type(s) of Industry companies:**

1. Will the events provide unique teaching/learning opportunities?
2. Do the UW/UWMF Providers involved develop and retain control over the content of presentations?
3. Are there contracts with clear deliverables?
4. Are the presentations balanced, with consideration of all relevant treatment options?
5. Are the educational materials used non-promotional

Each UW/UWMF Provider who speaks at a non-CME event sponsored by Industry must submit his or her presentations and an agenda or syllabus for the non-CME event to the IIRC. Materials may be submitted at any time prior to the non-CME event, but must be submitted no later than one month after the event. Materials must be submitted electronically to [iirc@uwmf.wisc.edu](mailto:iirc@uwmf.wisc.edu).

UW/UWMF Provider participation in any non-CME event sponsored by Industry is subject to the following conditions, which are based on provisions of the United States Department of Justice September, 2007, deferred prosecution agreements with certain device manufacturers<sup>i1</sup>:

1. Fair market value compensation in exchange for time spent in bona fide teaching activities, but in no event in excess of five hundred (\$500.00) dollars per hour.
2. Presence of a management plan for notice to and interaction with patients.
3. Presence of a written contract set in advance, establishing clear and actual deliverables, and the details of compensation.
4. Reasonable reimbursement for incurred lodging, transportation and dining expenses.

**V. [Intentionally Omitted]**

**VI. Consultation with Industry**

- A. UW/UWMF Providers may participate in non-promotional outside activities with Industry, such as providing expert consultation, serving on advisory boards, serving as medical directors or chief medical officers, serving on research advisory committees or data safety and monitoring boards for clinical trials, without prior approval but subject to the same requirements outlined in Section V. B., above, except for the compensation limit included in B.1.
- B. UW/UWMF Providers must submit to the IIRC, within one month of completing the engagement, information about the activity, with details as required by the IIRC.
- C. The IIRC will consider the following in its review:
  - Is there a need for a management plan for interactions with patients?
  - Is there a contract with clear deliverables for services provided at a fair market value?
  - Is the content of the work scientific and/or academic rather than promotional or commercial?
- D. The IIRC will review the submitted information and, if necessary, meet with the UW/UWMF Providers. If the IIRC concludes that there are problematic issues with the activity, it may require a UW/UWMF Provider to obtain pre-approval of any future consulting activities.

## **VII. Ownership and Corporate Board Membership**

UW/UWMF Providers may own equity interests in or serve in leadership roles (i.e., serving as a director on a Board of Directors) for Industry companies. These activities must be reported to the IIRC and must have a management plan for interactions with patients.

Stocks held in mutual funds are exempt from this policy.

## **VIII. Royalties**

UW/UWMF Providers may receive royalties from sales of commercial products sold by Industry; however, each of the following requirements must be satisfied:

- A. Royalty payments for commercial products sold by Industry must not include those sales that take place at any UW Healthcare Entity. UW/UWMF Providers who receive royalties are responsible for notifying the source of the royalty payment of this policy and identifying relevant UW Healthcare Entities in such notification.
- B. UW/UWMF Providers who receive royalties for commercial products must disclose this fact, in writing, to patients who are presented with the option of receiving the commercial product as part of their medical care.
- C. The monetary value of all royalties, including those distributed to UW/UWMF Providers from WARF, must be reported to the IIRC annually. In accordance with standard WARF reporting procedures, WARF royalties are reported as single lump sums and not broken down by individual company payees. SMPH and UWMF will work with WARF to attempt to create accounting mechanisms that allow categorization of royalties by individual payees.
- D. A management plan for interactions with patients is required.
- E. UW/UWMF Providers who receive royalties under this section may not participate on any pharmacy and therapeutics committee, or committee equivalent, when the product for which the royalty is received is under consideration by such committee.

## **IX. Oversight of Outside Relations With Industry: The Industrial Interactions Review Committee (IIRC)**

Oversight of all UW/UWMF Providers' activities in the purview of this policy will be under the auspices of the IIRC. The IIRC will be established by the UWMF Board of Directors and will be charged with reviewing and managing all outside interactions between Industry and UW/UWMF Providers that may affect the clinician-patient interface. The IIRC will be populated by SMPH faculty members and members of the UWMF Board of Directors, as approved by the UWMF Board of Directors on recommendation of the UWMF Executive Committee. The Executive Committee will consult with the UWMF Council of Faculty and UWMF Council of Chairs in developing its recommendations. The UWMF Board of Directors, on recommendation of the UWMF Executive Committee, will also appoint a chair of the IIRC. Administrative support to the IIRC will be provided by UWMF.

In its reviews, determinations and actions, the IIRC will carefully consider the overall context and implication of each interaction with Industry that may create a conflict of interest. Its determinations will set precedent for the consideration of subsequent situations. Activities of the IIRC will include:

- A. Working with UWMF administration and the SMPH Dean's office to create and maintain a set of procedures that are complementary to this Policy.
- B. Working with UWMF administration and the SMPH Dean's office to create and maintain a set of Frequently Asked Questions (FAQ) that address the majority of situations that will fall under this policy.

- C. Maintaining availability of the IIRC Chair, designated IIRC members, or administrative staff, through a “Hotline” mechanism, to answer questions about how specific activities might relate to the Policy.
- D. Reviewing UW/UWMF Providers’ participation in non-CME events funded by Industry to the extent that these activities are permitted by this policy. This may include review of presentation content or educational materials, creation and monitoring of management plans, or a finding that participation should not be allowed.
- E. Reviewing UW/UWMF Providers’ participation in outside relationships with Industry that are not promotional. This may include review of contracts, review of levels of remuneration, creation and monitoring of management plans, or a finding that participation should not be allowed.
- F. Reviewing UW/UWMF Providers’ individual stock or stock options, leadership roles on the boards of Industry entities, and licensing activities; instituting management plans for clinician-patient interactions which may be influenced by such relationships.
- G. Reviewing annual disclosure to IIRC by all UW/UWMF Providers of all outside income that originates from Industry.
- H. Giving final approval or disapproval of outside activities covered by this policy, subject to UW-Madison and WARF policies governing outside relationships and outside income. If the IIRC concludes that a UW/UWMF Provider’s participation in an outside activity is incompatible with provisions of this policy, it will forward its findings and conclusions to the UWMF CEO and SMPH Dean.
- I. Authorizing specific corrective or remedial action on matters subject to this policy. There is an expectation that activities disapproved by the IIRC will be discontinued on a timeline determined by the IIRC. Failure or refusal to comply with the IIRC’s determinations will result in referral to the UWMF Professional Conduct Committee, UWMF HR Department, or SMPH HR Department, as appropriate, to determine the proper consequences for non-compliance.

For UW Faculty Physicians, recommendations of the UWMF Professional Conduct Committee will be forwarded to the UWMF Executive Committee for final approval and subsequent action. Further, the appropriate SMPH Department Chair will be kept informed of all decisions in the process.

- J. The Chair of the IIRC will meet at least annually, and more often as directed, with the UWMF Board of Directors to provide requested information, to report on the IIRC activity for the preceding year, and to make recommendations from the IIRC for amendments to the Policy. The UWMF Board of Directors will act, on a yearly basis, to modify, as needed, and reapprove the Policy.
- K. The IIRC will propose transition plans for UW/UWMF Providers with existing contractual commitments that are not compatible with this policy.

## **X. Disclosure by UW/UWMF Providers**

UW/UWMF Providers with outside relationships with Industry, including participation in CME programs, must file an annual report with the IIRC, the specific content of which will be determined by the IIRC and approved by the UWMF Board of Directors. Disclosure may only include information necessary to implement the provisions of this policy. Every effort will be made to collaborate with the UW and its outside activities reporting mechanisms to avoid duplication. All information collected by the IIRC will be held confidential to the extent possible, subject to applicable disclosure rules and laws.

Required disclosure will include:

- A. A listing with each Industry company for which a relationship exists, including the name of the company or organization that provides remuneration.
- B. A description of the type of activity (e.g. educational lecture, scientific consulting, etc.), the type of the remuneration received (i.e. honorarium, stock, stock options, etc.) and whether the event was certified for CME credit.
- C. The dollar amount or monetary value (within \$1000) received from each Industry company for outside activities and the aggregate amount.

## **XI. Disclosure to Patients**

A central database of all relationships between UW/UWMF Providers and Industry will be created and updated annually. Disclosure to patients will include all of the following:

- A. UWMF will post signs in all of its clinics and provide notification on its website to advise patients that some UW/UWMF Providers have financial relationships with Industry. Patients will be invited to contact UWMF or SMPH for specific information about their clinicians' outside financial arrangements with Industry, including their monetary value. The names of those inquiring will be kept confidential.
- B. Other disclosures about UW/UWMF Providers' relationships with Industry relationships as may be required by the IIRC.

## **XII. Site Access by Industry Representatives**

### **A. Pharmaceutical Representatives**

In order to respect patients, patient care areas, and work schedules, UWMF will limit access to its facilities by pharmaceutical Industry representatives. General access is permitted only to public areas which are not designated for patient care. Meetings with UW/UWMF Providers should occur only in non-public areas, such as offices or conference rooms. No promotional activities shall be permitted to take place in clinic space, waiting rooms, patient lounges, cafeterias, or other areas where patients may be found.

1. These activities may occur in a manner which is consistent with the guidelines set forth in UWHC Policy 11.19, as overseen by the UWHC Vendor Liaison Office (VLO).
2. Meetings with pharmaceutical Industry representatives shall be permitted to take place only by invitation from UW/UWMF Provider or the UWHC Pharmacy Director (or their equivalent for non-UWHC clinics).
3. Requests for appointments with UW/UWMF Providers by pharmaceutical representatives shall be made through the VLO.

4. Alternative processes for implementing the intent of this policy may be adopted for geographically distant clinics and faculty locations.

## **B. Medical Device Representatives**

Medical device representatives are generally subject to the same rules as pharmaceutical industry representatives. Medical device Industry representatives may enter patient care areas only when all three of the following pre-conditions are met:

1. The representative is appropriately credentialed by the organization owning or operating the clinical entity.
2. The visit is requested by appointment and invitation of a UW/UWMF Provider or designated SMPH Department personnel, regarding required information on the medical device.
3. The visit to a patient care area is of direct benefit to the patient(s) currently being treated in the patient care area, or no patients are present.

Whenever possible, meetings should occur in non-patient care areas. These activities should be scheduled through the UWHC VLO (or equivalent for UWSMPH and UWMF sites). Requests for the services of device representatives in the operating room or procedure suites do not require VLO approval.

These requirements do not apply to individuals servicing medical devices which are already in place. For these individuals, credentialing and an existing service contract are required.

UWMF will require advance notice to, and consent by, the patient if a medical device Industry representative(s) may be present during any patient care interaction. Adherence to policies for consent in place by the clinical entity will satisfy this requirement.

Medical device Industry representatives who wish to interact with UWHC, UWMF, or UW clinical laboratory health care professionals may meet only with the Director of the Clinical Laboratories or his/her designee and are not permitted to promote their products or to meet directly with patients, health care providers or non-designated clinical laboratory staff.

## **XIII. Industry-Sponsored Scholarships and Other Educational Funds for Trainees**

All scholarships or other educational funds from Industry, including fellowships, must be donated centrally to the administration of one of the UW Healthcare Entities or to an SMPH Department. All scholarships and other educational funds must be freely given and not contain a *quid pro quo* of any kind.

The evaluation and selection of the individual recipients of such scholarships or educational funds are solely the responsibility of the receiving entity and are based on criteria determined by that entity, without involvement of any kind by the Industry donor, except that the Industry donor may direct the scholarship or other educational funds to a particular specialty area at the time the gift is made.

The existence of a scholarship or other educational funds from an Industry donor must be disclosed to the IIRC and to the Dean of the SMPH.

#### **XIV. Pharmaceutical Samples**

In response to safety concerns and financial inefficiencies caused by medication samples, as well as regulatory requirements, all medication samples are prohibited from all UWHC and UWMF clinics.

Specific exceptions may be made for over the counter medications and products approved by the UWHC Pharmacy and Therapeutics Committee (or equivalent for UWMF clinics and facilities). Such exceptions will be granted only when sample medications are required for the safe initiation of therapy. The policy will allow the possibility for the development of centralized sample repositories overseen by the UW Healthcare Entities.

#### **XV. “Ghostwriting” and Responsible Communications Practices**

UW/UWMF Providers shall not allow their written work to be ghostwritten by Industry representatives or by any other party. Authorship must always be assigned and acknowledged based on standard academic procedures. When making presentations, UW/UWMF Providers are responsible for the accuracy of the content of the presentations and slides prepared by others (this does not extend to material taken from peer reviewed publications).

#### **XVI. Individual Involvement with Industry in Purchasing Decisions for UW Healthcare Entities**

All costs related to meals, travel, lodging, etc. for meetings, site visits, or other activities related to a purchasing decision on behalf of a UW Healthcare Entity must be covered by such UW Healthcare Entity unit and not the Industry vendor, unless approved in advance by the IIRC.

#### **XVII. Author and Review**

<b>Sponsor:</b>	UWMF Board of Directors
<b>Author:</b>	Jeffrey E. Grossman, MD, CEO Robert N. Golden, MD, Dean, UWSMPH
<b>Initial Review / Committee Approval:</b>	UWMF Board of Directors (October 20, 2009) Council of Chairs Council of Faculty
<b>Approval of Revisions:</b>	UWMF Board of Directors (October 18, 2011) Council of Chairs (October 11, 2011) Interactions with Industry Committee (October 6, 2011)

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1. See a synopsis of the deferred prosecution agreements at:  
[http://www.usdoj.gov/opa/pr/2007/November/07\\_civ\\_873.html](http://www.usdoj.gov/opa/pr/2007/November/07_civ_873.html)

See all corporate integrity agreements at:  
[http://oig.hhs.gov/fraud/cia/cia\\_list.asp](http://oig.hhs.gov/fraud/cia/cia_list.asp)