



UNIVERSITY of  
**ROCHESTER**  
MEDICAL CENTER

# **Pharmaceutical and Device Industry Gifts and Interactions**

**URMC Policy  
Adopted June 25, 2008  
Key Points**

**PowerPoint Updated July 26, 2008**

# URMC Policy Scope

- **Applies to:**
  - **Clinical and educational relationships, not research**
  - **All URMC Divisions and Affiliates**
  - **Employees/family members**
  - **Non-employed medical staff when on URMC premises**
  - **“Industry” including pharmaceutical, biotech, device, and hospital equipment representatives**

# Recent History

- **Key Publications**
  - **NEJM 2004: Blumenthal, “Doctors and Drug Companies”**
  - **JAMA 2006: Brennan, et. al, “Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers”**
- **Model Policies from Academic Medical Centers**
  - **Michigan 2002-2003**
  - **Yale 2005**
  - **University of Pennsylvania 2006**
  - **Stanford 2006**
- **Local**
  - **Ethics Grand Rounds at Rochester Academy of Medicine 2006**
    - **Jerome Kassirer, MD, former editor of NEJM**
  - **URMC Primary Care Network – April 2007 policy**

# Key Policy Statements

- **Adherence to Highest Ethical and Legal Standards**
- **Avoiding actual or perceived conflicts of interest and improper relationships**
- **Independent Clinical Decision Making**

# URMC Policy – Topics Addressed

- **Gifts, Benefits and Samples**
- **Site access by Industry representatives**
- **Educational funds for students/trainees**
- **Support for educational/professional activities**
- **Disclosure of relationships**
- **Training**
- **Violations**

# Not Included in This Policy

- **URMC Research interactions**
- **University of Rochester Schools not within URMC**

# Fundamental policy concepts concerning gifts

- **Gifts to URMC staff from Industry vendors are prohibited**
  - **Directly provided meals or food are gifts and are prohibited**
  - **Industry vendors included are from Pharmaceutical, Biotech, Medical Device, and Hospital Equipment & Supplies Industries**
- **Rationale**
  - **Direct gifts to individuals (even minimal) introduce potential bias in clinical or administrative decisions, or the appearance of bias**
  - **Accepting gifts raises concerns of patients and purchasers**
  - **Community leaders and payers link accepting gifts and meals to use of expensive drugs and devices**
  - **Government may pursue apparent biases to levy fines & penalties**
    - **False Claims Act**
    - **Anti-Kickback Statute**

# Gift policy by site and employment status

- **Gifts may not be accepted from Industry vendors at any URMC site (including food, pens, etc.)**
- **Gifts may not be accepted from Industry vendors by URMC employees including full time faculty onsite or offsite**
- **Non-employee medical staff are required to follow these policies while at any URMC site and are encouraged to follow these policies when off-site**

# Not changed

- **Medication samples for patients are permitted**
  - **Still need to follow policies concerning record keeping**
- **Industry vendor (e.g. pharmaceutical or device representative) meetings for “detailing”**
  - **Still need to be by appointment**
- **Industry vendor “specialty technicians” participating in procedures**
  - **Permitted via hospital policy with credentials check, patient informing, & consent**
- **Education program grants**
  - **Fellowships and educational grants for trainees (e.g. residents and fellows) and students permitted through schools, centers, departments, and divisions**

# Permitted Gifts

- **Medication samples for patients**
  - **Need to follow policies concerning record keeping**
- **Gifts from patients**
  - **Minor non-monetary gifts to faculty & staff**
  - **Financial gifts to URMC and its components – should be through appropriate channels (e.g. Advancement Office)**
- **Books donated by Industry to URMC Personnel**
  - **May be donated through centers, departments, divisions, or programs, but not directly to individuals**
  - **Must be de-identified as to source**
- **Anatomical models donated by Industry to clinical sites**
  - **Permitted if under \$100**

# Pharmaceutical and Device Representative Site Access

- **May meet by appointment with clinicians**
- **With approval and invitation from URMC manager may participate in:**
  - **In-service education for approved products**
  - **Evaluations of potential new purchases**
- **May not provide gifts or meals**
- **May not attend private conferences**
- **May attend public conferences but at URMC site may not “detail” clinician attendees**

# Pharmaceutical and Device Representatives

- **Should provide information to appropriate URMC Committees**
- **May mail info via US Mail to clinicians**
- **May not directly use interoffice mail**
- **May not advocate within hospitals for non-formulary agents or disapproved devices**
- **May share information directly via departments, residency programs, divisions with prior review and approval by leader or designee**
- **May meet by appointment with clinicians**
- **Industry “specialty technicians” may participate in procedures per hospital policy when clinically necessary with credentials check, patient informing, & consent**

# Funding of URMIC-Sponsored Educational Conferences

- **Internal Conferences (e.g. noon conferences, journal clubs)**
  - **May not accept direct funding or meals from vendors**
  - **May provide meals for attendees, just not from vendors**
  - **Whether on-site or off-site**
  - **May receive funding from central pools within URMIC Components derived from industry donations**
- **Grand Rounds or other CME events organized by Centers, Departments, or Divisions without registration fee**
  - **May accept funding of outside speaker honoraria and travel expenses**
- **Continuing Medical Education (CME) Conferences organized through URMIC Office of Continuing Professional Education or URMIC Departments with registration fee**
  - **May accept funding of any expenses**

# Scholarships and Educational Funds

- **Permitted for students/trainees if:**
  - **URMC selects scholar**
  - **URMC determines program has merit**
  - **Funds not provided directly to scholar**
  - **No implied or express quid pro quo**
  - **Source of funding not disclosed to scholar whenever possible.**

# Non-URMC Events with Food

- **If registration fee roughly proportional to group value of meal, the meal would not be perceived to be a gift**
- **If no such registration fee, consider 3 elements in deciding what is allowed:**
  - **Expert speaker (e.g. faculty from URMC or other academic center) who is main focus of the event presenting important topic = bona fide educational activity**
  - **CME or equivalent education credits = compliance with standards**
  - **Hosted by educational or clinical institution (e.g. other academic center, hospital, professional org.) – not pharmaceutical or device co. rep.**
- **3 elements = OK to accept modest Industry funded food related to event.**
- **0 or 1 elements = NOT OK to accept modest funded food.**
- **2 elements = Use discretion in accepting any food.**

# Industry Funding of Travel Expenses

- **URMC Personnel may not directly accept compensation, including consultancy payments or defraying of travel costs, for simply attending a CME or other activity or conference**
- **URMC Personnel may accept honorarium or defraying of travel costs, proportional to bona fide services provided (e.g. presenting an educational talk at a conference, true consulting, etc.)**
- **URMC Personnel may accept defraying of travel cost if traveling to clinically necessary education on using a new or existing device at the direction of department or hospital leader**

# Prior Gifts & Patient Education Materials

- **Phased implementation July 08 – June 09**
  - **Evidence of gifts - Over time presence of pharmaceutical or device industry past gifts should decrease (e.g. pens, other paraphernalia)**
  - **Use of public education materials for patients when possible (e.g. from government, foundations, professional societies)**

# Disclosure

- **Required for participants in purchasing, therapeutics and new technology decision-making**
- **Must disclose:**
  - **Equity interests and compensation arrangements**
  - **Research or educational relationships**
- **Leader of decision making group will make recusal decision relying upon UR Code of Conduct and input from internal conflict of interest experts as needed.**

# Violations

- **Employees: In accordance with UR/URMC policies, including the Code of Conduct.**
- **Representatives:**
  - **First Strike: verbal warning**
  - **Second Strike: written warning**
  - **Third Strike/Flagrant Violation: access denial or restriction.**

# Time Line

- **April 2008 – Introduction and discussion of drafts**
- **May 2008 – Further review and modifications based on input from many groups (e.g. SMH & HH Clinical Councils, Board Quality of Care Committee and its Clinical Subcommittee, Medical Center Executive Team)**
- **June 2008 – Final recommendations**
- **June 25, 2008 – Adopted by Joel Seligman, UR President**

# Questions or suggestions?

- **Questions about policy compliance within URMC**
  - Contact URMC Compliance Office (275-1609)  
or the URMC Office of Counsel (758-7600) for assistance
- **Questions about policy development, implementation, or clarifications**
  - Email Robert Panzer, Associate VP, Patient Care Quality and Safety (Robert\_Panzer@urmc.rochester.edu)