Industry Relationships & Conflicts of Interest

Benefits

- Physicians are uniquely qualified to inform product developments that can lead to advancements in patient care and improved clinical outcomes

Risks

1) Industry financial relationships can:
   - Unduly shape physician beliefs and behaviors
   - Promulgate non-evidence based clinical care that negatively impacts patient safety and drives up medical costs

2) Improper and exorbitant payments from industry violate anti-kickback laws and can lead to criminal prosecution

3) Industry financial relationships can undermine public trust in the medical profession and research integrity
Industry Relationships & Conflicts of Interest

Media Exposure

- “Is Your Doctor Tied to Drug Makers?”
  NY Times (7/2/2007)

- “Senate Panel Looks Into Medtronic, Physician Consultants”
  WSJ (6/22/2011)

- “Hidden Drug Payments To Three Prominent Psychiatrists at Harvard”
  NY Times (6/10/2008)

- “Pfizer, Merck, Glaxo pay local doctors over $1 million”
  St. Louis Business J (4/15/2011)

- Institute of Medicine Calls For Doctors to Stop Taking Gifts From Drug Makers”
  NY Times (4/29/2009)
ACA Sunshine Provision

- Many pharma companies are already voluntarily disclosing physician payments on their company web sites (Lilly, Merck, Glaxo-SmithKLine, etc)

- ACA includes a “Sunshine” provision that, effective August 1, 2013, requires all drug and device manufacturers to report annually any payment or transfers of value to individual physicians and teaching hospitals that exceed $10.

- Fines for noncompliance:
  - $10,000 per incident up to $150,000 maximum for unknowing oversight
  - $10,000 to $100,000 per incident up to $1M for knowingly failing to report

- Physician payment Information will be posted on CMS public web site on September 1, 2014

- Physicians can review and dispute information to be posted before it becomes public by registering on the CMS “Open Payments” web site In July
Policy Goal Is To Achieve the Right Balance

Recognize the importance of academic-industry collaboration in medical discovery and scientific advancement

while

Ensuring professional integrity & preserving public trust
Academic-Industry Collaboration

*Putting It Into “Human Terms”*
WUSM Clinical Conflict of Interest Policy

Key Elements

1) Faculty must annually disclose to University all financial relationships with industry regardless of amount of payment, i.e. zero dollar threshold

2) Faculty compensation must be based on tangible services:
   ✓ Consulting services, advisory board activities related to product design
   ✓ Licensing agreement or royalties for inventions
   ✓ Educational lectures and associated preparation and travel time

3) Compensation must be at “fair market value” for rendered services
Assessing “Fair Market Value”

Consulting Agreements & Educational Lectures

• Benchmark against MGMA compensation data for academic physicians by subspecialty – *maximum of $500 per hour*
  • $3,000 maximum flat fee per educational lecture

Royalties

• Is there a patent or patent pending?

• If not, manufacturer must provide:
  - Detailed written description of process used to certify that faculty member made a significant and valuable contribution of IP to the design or development of the royalty-bearing product, AND
  - An Attestation that royalty rate is c/w fair market value of IP
Key Elements

4) Relationships with commercial companies must be codified in writing and clearly specify the scope of services to be provided and related payments for those services.

5) Consulting and Royalty arrangements must be documented in separate written agreements, i.e. not co-mingled in the same agreement.

6) Faculty must maintain detailed records of compensation received and services provided, including time and effort.
Unacceptable Payments

1) Payments cannot be based on the use of a particular device, implant or drug in a patient

2) Faculty may not collect royalties based on the use of their product in Washington University patients

3) Faculty may not accept gifts from commercial companies including but not limited to:
   - Cash payments
   - Free goods or meals
   - Free travel and accommodations
   - Payment of meeting registrations
   - Payment for participation in on-line CME programs
Unacceptable Payments & Contract Terms

4) Faculty cannot accept payments from a commercial company for writing peer review publications related to that company’s products.

5) Faculty cannot agree to industry contracts that include language:
   - Requiring company approval of the faculty member’s publications or presentations
   - Preventing criticism of a company’s products and services

6) Faculty cannot accept payments from industry for allowing visiting physicians to observe the faculty member perform procedures on WU patients that may be billed to third party payers.
WUSM Clinical Conflict of Interest Policy

Industry-Supported Educational Lectures

1) All financial support by industry must be fully disclosed by the meeting sponsor.

2) Speakers must provide a fair and balanced assessment of therapeutic options and promote objective scientific and educational discourse.

3) Speakers must have **final editorial discretion** as to lecture content and materials:
   - *The only exception is where compliance with FDA or other regulatory agency guidelines is required*
   - *Presentations that provide information related to non-FDA approved uses for drug products and/or devices must clearly acknowledge the unlabeled indications or investigational nature of their proposed uses to the audience*

5) Speakers should make it clear that content reflects their individual views and not the views of WUSM or its affiliated teaching hospitals.

6) PowerPoint presentations, slides, handouts, brochures, flyers and mail and email announcements of industry-sponsored lectures cannot be co-branded using Washington University symbols, logos, trademarks or images.
• 42 pharma companies have accepted WUSM’s speaker’s bureau language requirements regarding editorial control of lecture content and materials:

- Genentech (6)
- Lilly (4)
- Amgen (3)
- DePuy (3)
- Dfine (2)
- Merck (2)
- Stryker (2)
- Abiomed (1)
- Astellas (1)
- Atricure (1)
- Baxter (1)
- Bayer (1)
- Boehringer Ingelheim (1)
- Boston Scientific (1)
- Celgene / Abraxis (1)
- Covidien (1)
- Cubist (1)
- EV3 (1)
- GSK (1)
- Johnson & Johnson (1)
- Life Cell (1)
- Medtronic (1)
- Pfizer (1)
- Prostraken (1)
- Regeneron (1)
- Alcon
- American Regent
- Cephalon
- CSL Behring
- Ethicon
- Gilead
- Globus Medical
- Hospira
- Kimberly-Clark
- Lantheus
- Novartis
- Siemens
- UCB
- Vertex
- Zimmer
- ZymoGenetics

• 14 companies have rejected WUSM’s speaker’s bureau language requirements:
  - Abbott, Abbvie, Alergan, Alexion, Amylin, AstraZenica, Bristol Meyer Squibb, EMD Serono, Genzyme, Otsuka, Salix, Sanofi Aventis, Teva and Therakos

• WUSM faculty are in discussion with Caris, Novo Nordisk and Takeda

(x) = number of faculty relationships >$10K
Speaker’s Bureau and Consulting Contract Language Requirements

Speaker’s Bureau Agreements are required to include the following language:

“As speaker or panelist, (speaker) will have control over his/her own comments and content, except where compliance with FDA or other regulatory agency guidelines requires speakers to adhere to content that meets the agency’s guidelines or proscriptions.”

Consulting Agreements are required to include the following language:

“Notwithstanding anything herein to the contrary, Company agrees that CONSULTANT serves Company under this Agreement in his individual capacity, as an independent contractor, and not as an agent or representative of Washington University (“Institution”), that Institution exercises no authority or control over CONSULTANT while acting in such capacity, that Institution receives no benefit from such activity, that CONSULTANT and/or Company cannot and will not make use of Institution resources or Institution managed funding in acting in such capacity, that Institution is not a party to this Agreement, and that Institution makes no representations or warranties under this Agreement and assumes no liability or obligation in connection with any such work or service undertaken by CONSULTANT. Company further agrees that any breach, error, or omission by CONSULTANT acting in such capacity or otherwise under this Agreement, shall not be imputed or otherwise attributed to Institution. Moreover, nothing in this Agreement shall be read or understood to encumber, in any way, any intellectual property that Institution claims ownership of through the Institution’s Intellectual Property Policy as such may be amended from time to time.”
Oversight of Potential Conflicts of Interest

Process

1) **Disclosure** by faculty of all industry financial relationships

2) **Review and Determination** if a material COI exists

3) **Management** of the COI

4) **Monitoring** of COI management strategy for faculty compliance
Faculty Disclosure Process

• All faculty members must annually complete a confidential web-based *Financial Disclosure Statement* to the University
  
  - *Financial Disclosure Statements must also be updated immediately upon entering a new or revised financial relationship*

• The disclosure statement encompasses:
  
  - *Faculty research and clinical relationships with industry*
  - *Personal investments in free-standing ambulatory facilities providing technical services*

• “*Financial relationships*” are defined as any relationship involving a faculty member or his/her immediate family including spouses, children, domestic partners and in-laws
WUSM Clinical Conflict of Interest Policy

Threshold Triggering Institutional Review & Patient Disclosure

Industry relationships are defined as “Material” if a faculty member:

a) Earns >$10,000 per year from a company related to any of the following activities:
   • Consulting agreements
   • Board of Director or Advisory Board activities
   • Company-sponsored lectures
   • Licensing or product development agreements

b) Has equity in a health care-related commercial company, including:
   • Stock and/or stock options earned for rendered services
   • >5% ownership position
Patient Disclosure

Faculty physicians who have a material relationship requiring patient disclosure are notified by the Associate Vice Chancellor for Clinical Affairs and advised to:

- Disclose their financial relationship to patients when prescribing a medication or using a medical device manufactured by that company

- Provide the patient with a **WUSM Patient Disclosure Statement** approved by the Office of the Associate Vice Chancellor for Clinical Affairs:
  - When using an implantable or invasive device, the patient must sign the Disclosure Statement as part of the informed consent process
  - A copy of the Patient Disclosure Statement is given to the patient and a second copy retained in the patient’s **ambulatory** electronic medical record (Touchworks)

- Patient disclosure is waived in emergent situations (ex: *ED admission or hospital transfer where patient is taken directly to the OR, Cath Lab, etc for a procedure*)
Sample COI Patient Disclosure Statement

As part of your treatment, Dr. ____ is prescribing a medication manufactured by *Eli Lilly*. In the interest of full disclosure, Dr. XXX wants to make you aware that he is paid to serve on a Medical Advisory Board for *Eli Lilly*. In this role, Dr. ____ provides medical advice about the development of new products.

In addition, Dr. ____ is periodically paid by *Eli Lilly* to give educational lectures and provide training for other physicians about the management and treatment of certain medical conditions.

Dr. ____ wants to assure you that the medication prescribed as part of your care is based only on what he believes is best for you, not on which pharmaceutical company manufactures this medication.

If you would prefer, for any reason, that a medication manufactured by *Eli Lilly* not be used in your treatment, please feel free to let Dr. ____ or his staff know and they will be happy to discuss alternative medications and treatments that may be available.
Public Disclosure of Clinical Conflict of Interests

1) Commercial company financial relationships are disclosed on the Faculty Practice Plan public web site if a faculty member:

- earns >$10k/year or receives stock or stock options for rendered services
- has >5% ownership position in a health care-related commercial company

2) Public disclosure required even if the faculty member does not prescribe or use the commercial company’s products

3) Disclosure appears on the faculty member’s individual profile page just before the section listing selected journal articles and book chapters

3) The basis for any industry payments is noted (ex: consulting, royalties, etc)

4) The amount of industry earnings for the prior calendar year is displayed in the following dollar ranges:

- $ 10,001 - 25,000
- $ 25,001 - 50,000
- $ 50,001 - 100,000
- $100,001 - 200,000
- >$200,000
Dr. __________ reported the following earned financial interests during calendar year 2011:

<table>
<thead>
<tr>
<th>Company</th>
<th>Royalties</th>
<th>Equity</th>
<th>Consulting &amp; Advisory Boards</th>
<th>Educational Speaker Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Johnson &amp; Johnson</td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Merck</td>
<td></td>
<td></td>
<td>$25,001-$50,000</td>
<td></td>
</tr>
<tr>
<td>Pfizer</td>
<td>&gt;$100,000</td>
<td></td>
<td></td>
<td>$10,001-$25,000</td>
</tr>
<tr>
<td>Zimmer</td>
<td></td>
<td></td>
<td>$10,001-25,000</td>
<td></td>
</tr>
</tbody>
</table>

To learn more about Washington University’s policies on collaboration with industry click here
WUSM Clinical Conflict of Interest Policy

Other Management Strategies & Issues

1) Restructure industry consulting and/or royalty agreements to comply with WUSM Clinical COI Policy
2) Reduce consulting agreement payments to be consistent with fair market value benchmarks
3) Reduce hours devoted to outside consulting activities (Conflict of Commitment)

Compliance & Enforcement

1) OGC review of all faculty-industry contracts
2) Regular audits of patient electronic medical records to ensure compliance
3) Sanctions for non-compliance:
   - Suspend faculty member’s clinical privileges
   - Withdraw professional liability insurance coverage for faculty member
   - Reduce the faculty member’s salary or bonus
   - Other actions as appropriate
Clinical COI Faculty Disclosures
FY14 to date (as of June 25, 2014)

YTD, 9% (117/1,306) of the faculty have disclosed industry relationships requiring management:

• 43 (3.3%) faculty earning >$10k/yr were required to disclose their financial relationship to patients when prescribing/using that company’s products:
  ✓ 25 faculty have pharmaceutical company relationships
  ✓ 18 faculty have medical device company relationships

• 46 (3.5%) faculty earned >$10k/yr, have equity or receive royalties but do not use the company’s products - these individuals are only required to disclose their industry relationship on the FPP web site

• 19 (1.5%) faculty earned >$10k/yr but voluntarily decided to reduce future earnings to <$10k/yr rather than have to disclose their financial relationship to patients

• 9 (0.9%) faculty elected to terminate an industry relationship
### WUSM Faculty with Material Industry Financial Relationships

<table>
<thead>
<tr>
<th>Earnings</th>
<th>Speaking</th>
<th>Consulting / Advisory Board</th>
<th>Royalties</th>
<th>Equity (Stock, Options, Company Position)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$10,001-$25K</td>
<td>14 (50%)</td>
<td>26 (67%)</td>
<td>3 (23%)</td>
<td></td>
</tr>
<tr>
<td>$25,001-$50K</td>
<td>10 (36%)</td>
<td>6 (15%)</td>
<td>2 (15%)</td>
<td></td>
</tr>
<tr>
<td>$50,001-$100K</td>
<td>3 (11%)</td>
<td>5 (13%)</td>
<td>3 (23%)</td>
<td></td>
</tr>
<tr>
<td>$100,001-$200K</td>
<td>1 (4%)</td>
<td>1 (3%)</td>
<td>1 (8%)</td>
<td></td>
</tr>
<tr>
<td>&gt;$200K</td>
<td>0 (0%)</td>
<td>1 (3%)</td>
<td>4 (31%)</td>
<td></td>
</tr>
<tr>
<td><strong>Total Faculty</strong></td>
<td>28</td>
<td>39</td>
<td>13</td>
<td>5*</td>
</tr>
</tbody>
</table>

* Excludes 17 additional faculty who have equity relationships but do not utilize the company’s products.
Physician-Industry Relationships

Patients entrust their health and their lives to the physicians who care for them and have a right to expect the most efficacious, safest and most cost-effective, based on sound medical judgment unbiased by extraneous factors or inducements.

Key Principles

1) Professionalism
2) Integrity
3) Transparency - i.e. disclosure
QUESTIONS & COMMENTS