Fair Market Value Issues in Financial Arrangements with Research Physicians

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Robert A. Wade, Esq.
Krieg DeVault LLP
4101 Edison Lakes Parkway,
Ste. 100
Mishawaka, IN 46545
Phone: 574-485-2002
Email: bwade@kdlegal.com

Kari K. Loeser, Esq.
Jazz Pharmaceuticals plc
3180 Porter Drive
Palo Alto, CA 94304
Phone: 650.496.3002
Email: kari.loeser@jazzpharma.com

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Why Is Documenting Fair Market Value and Commercial Reasonableness Important?

- Fines and Penalties, including 3 times the amount paid by Medicare/Medicaid for service, $10,000 fine per payment, etc.
- Exclusion from Medicare/Medicaid Programs.
- Intermediate Sanctions.
- Damage to reputation.
- Corporate Integrity Agreements/Deferred Prosecution Agreements.
- Shareholder lawsuits
- Imprisonment.

This really will not happen to me, will it?

The government has better things to worry about than one contract between a manufacturer and physician, right?
Tell That to the Parties Involved in the Following Recent Cases:

- DePuy Orthopaedics
- Biomet
- Caremark
- Smith & Nephew
- Stryker Orthopaedics
- Bristol-Myers Squibb
- Astra Zeneca
- Pharmacia
- Merck-Medco
- Pfizer
- Schering-Plough
- Advance PCS
- MedTronic
- Novartis Nutrition

2007 Settlements with Orthopedic Device Companies

- 5 Companies, $311M – Largest Settlement was $169.5M
- Monitor Expense – $28 - $52M
- Information is being gathered
- Focus will switch to physician consultants – See March 22, 2008 article “New Focus of Inquiry Into Bribes: Doctors” attached as Exhibit A.
“If you don’t focus on doctors, this is a problem that will never end.”

Lewis Morris, Chief Counsel to the Office of Inspector General

2009-2010
Orthopedic Physician Settlements

- OIG alleged physicians sought and received “consulting payments” in exchange for using devices.
  - 10/20/09: Robert Diaz, M.D. $65,000 and excluded for 3 years
  - 2/16/10: Harvey Montijo, M.D. $650,000
  - 10/21/10: Steven Lancaster, M.D. $101,000
ANTI-KICKBACK STATUTE
(42 U.S.C. § 1320a-7b)

It is illegal to knowingly or willfully:

- Offer, pay, solicit, or receive remuneration;
- Directly or indirectly;
- In cash or in kind;
- In exchange for:
  - Referring an individual; or
  - Furnishing or arranging for a good or service; and
- Payment may be made by Medicare or Medicaid.

UNITED STATES V. GREBER

THE “ONE PURPOSE” RULE

*If one purpose of the remuneration is to induce referrals, the statute is violated, even if the payment was also intended to compensate for professional services.*
THREE NECESSARY ELEMENTS

- Intentional Act
- Direct or Indirect Payment of Remuneration
- To Induce the Referral of Patients or Business

WHAT IS REMUNERATION?

- Extremely Broad Scope, whether in cash or in kind, and whether made directly or indirectly, including:
  - Above or below market credit arrangements;
  - Above or below market rent or lease payments;
  - Above market consulting fees;
  - Bribes;
  - Discounts;
  - Furnishing of supplies, services or equipment either free, above or below market;
  - Kickbacks;
  - Gifts;
  - Rebates; and
  - Waivers of payments due.
**CAUTION**

Almost Any Benefit
By and Between
Pharma/Device
Manufacturers and
Medical Providers Can
Be Considered
Remuneration

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**ANTI-KICKBACK STATUTE**

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS

- Written Agreement signed by parties
- Term of at least one year
- Agreement must specify *aggregate payment* and such payment must be *set in advance*
- Compensation must be *reasonable, fair market value* and determined through *arms’ length negotiations*
- Must set exact services required to be performed
ANTI-KICKBACK STATUTE

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS, cont’d

- Compensation must not be determined in a manner that takes into account volume or value of referrals
- All arrangements must be in one contract.
- The arrangement must serve a commercially reasonable business purpose.

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS, cont’d

If the Agreement does not contemplate full-time services, it must also specify:
- The exact schedule of intervals;
- Their precise length; and
- The exact charge for such intervals.

Note: Many consulting arrangements may not have exact schedules.
SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS

Most Research and Consulting Arrangements will not be Safe-Harbor protected because:

1. Aggregate compensation set in advance, and
2. Exact schedule of services.

EMPLOYMENT SAFE HARBOR

Payments made by employer to employee under bona fide employment relationship with employer for employment in furnishing of any item or service for which payment may be made under Medicare or Medicaid are excepted from the Anti-Kickback Statutes’ prohibitions.
ANTI-KICKBACK STATUTE

EMPLOYMENT SAFE HARBOR, cont’d

If payments under employment arrangements are not fair market value, payments above fair market value could be construed to be outside of employment compensation.

ANTI-KICKBACK STATUTE

SAFE HARBOR FOR RENTAL OF OFFICE SPACE

- Written Agreement
- 1 Year
- *Fair Market Value*
- Identify space used
ANTI-KICKBACK STATUTE

SAFE HARBOR FOR EQUIPMENT RENTAL

- Written Agreement
- Identify Specific Equipment
- Schedule of Usage
- 1 Year Term
- Fair Market Value

WHAT IS FAIR MARKET VALUE?

*Fair market value* is “the value in arm’s-length transactions, consistent with the general market value.”
WHAT IS FAIR MARKET VALUE?

“General Market Value” means the price that an asset would bring as a result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as a result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

42 C.F.R. § 411.351

ROLE OF FAIR MARKET VALUE

- Critical in Pharma for any fee or honoraria paid
- Broad Reaching
  - Promotional Speaker Programs
  - Advisory Boards
  - Consulting / Fee for Service
  - Investigator Meetings
  - Clinical Research
- Reporting Requirements
  - State Laws
  - Federal Sunshine Act (final rule published 2/1/13)
In the healthcare context, there are essentially 3 basic views on the meaning of FMV:
- “Person on the street” perspective
- Professional appraisal perspective
- Legal/regulatory perspective

Unfortunately, these 3 basic views frequently conflict.
Parties can get “dazed and confused” when these 3 competing views meet to complete a transaction.

“What everyone is getting paid in the market”
“What the hospital down the street is paying”
“Incremental cost plus a profit margin”
“What’s in a survey book”
“What it’s worth to one party to the transaction”
Professional Appraisal View of FMV

• Based on the “hypothetical-typical” buyer concept
• FMV contrasts with investment value or strategic value
• Determination of FMV is based on 3 approaches to value:
  ➢ Cost
  ➢ Income
  ➢ Market
• Formal body of knowledge and professional standards governing the appraisal practice for real estate and business valuation (“BV”)
• No current body of knowledge or standards for compensation valuation (“CV”)

Legal/Regulatory View of FMV

• Stark regulations state that the definition of FMV “is qualified in ways that do not necessarily comport with the usage of the term in standard valuation techniques and methodologies.”
  Stark example: Exclusion of market comparables between parties in position to refer.
  Stark example: FMV can be established by “any method that is commercially reasonable.”
• OIG Anti-kickback statute example: Footnote 5 to Advisory Opinion 09-09 cautioning the use of the Discounted Cash Flow (DCF) method for an ASC valuation
Avoid the FMV Definition Pitfall

- The “Street” perspective of FMV is generally not reliable for healthcare regulatory purposes but may provide useful information.
- Regulatory definition of FMV may limit or qualify FMV methods used in professional appraisal practice.
- FMV as determined under professional appraisal standards may be more rigorous than the regulatory requirements.

Avoid the FMV Definition Pitfall

- Learn to identify and navigate through the different views of FMV as they arise in negotiating transactions and compliance reviews.
- Recognize that appraisal professionals do not give regulatory advice, but only their opinion as to the determination of FMV, which may or may not take into account regulatory considerations.
WHAT IS FAIR MARKET VALUE?

Key points:

- Referrals between the parties cannot be considered.
- Fair market value is determined upon the sale or when the service agreement is executed.
- Local market conditions are factors (i.e., lack of a specialty in the market, depressed real estate market).
- Proximity of real estate to the lessor (hospital) cannot be considered, but costs of developing or improving real estate should be considered.
- Expertise of physician for personal services.

DOCUMENTATION OF FAIR MARKET VALUE/COMMERCIAL REASONABLENESS

For every physician contract, fair market value/commercial reasonableness is the biggest issue.
Types of Arrangements in Device/Pharma Industry where FMV is Important:

- Consulting agreements
- Royalty agreements
- Product development agreements
- Service agreements
- Teaching or education agreements
- CME (continuing medical education) agreements
- Promotional agreements (speaker agreements)
- Marketing agreements
- Fellowships or payments to fellows

Types of Arrangements in Device/Pharma Industry where FMV is Important (Continued):

- Preceptorship agreements
- Grants
- Honoraria
- Charitable contributions
- Speaking engagements
- Clinical trials
- Clinical data collection
- Lease agreements with HCPs
- Author for hire agreements
THE SUNSHINE ACT

- Begin collecting data: August 1, 2013
- First Report of data to CMS: March 31, 2014
- “Any payment(s) or other transfer of value” (abbrev. list)
  - Consulting fees
  - Compensation
  - Honoraria
  - Gifts
  - Entertainment
  - Food / Meals
  - Travel
  - Education

FAIR MARKET VALUE

All Device/Pharma Arrangements can fit into one of the following three categories:

- Employment Agreements
- Consulting/Independent Contractor Services
- Royalty Payments
GENERAL FMV PRINCIPALS

Market Data:
1. Determine what competitors are paying (anti-trust risks)
2. Opinion letter from compensation analyst
3. Third party surveys
4. National experts

GENERAL FMV PRINCIPALS

Although there are exceptions, most compensation arrangements should be evaluated by:
- Hours worked
- Compensation per hour
**NOTE:** In Orthopedic device Settlements, ALL arrangements needed to be substantuated based upon hourly rate and no compensation above $500 per hour.

Typical third party surveys include:

- **Sullivan, Cotter & Associates, Inc.** - Physician Compensation and Productivity Survey;
- **HayGroup** - Physicians Compensation Survey;
- **Hospital and Healthcare Compensation Service** - Physician Salary Survey Report;
- **Medical Group Management Association** - Physician Compensation and Productivity Survey;
- **ECS Watson Wyatt** - Hospital and Health Care Management Compensation Report
- **William M. Mercer** - Integrated Health Networks Compensation Survey
Summarized below is the market survey data establishing the fair market value of pay for Family Practice Physician (without OB). This market data has been obtained from independent third party compensation surveys.

**SURVEY DATA**

**FAMILY PRACTICE (WITHOUT OB)**

<table>
<thead>
<tr>
<th>Survey</th>
<th>Survey Match</th>
<th>Region</th>
<th>Total Cash Compensation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>25th %tile</td>
</tr>
<tr>
<td>Saline</td>
<td>Family Practice without OB</td>
<td>National</td>
<td>$152,264</td>
</tr>
<tr>
<td>Key</td>
<td>Family Practice</td>
<td>National</td>
<td>$175,467</td>
</tr>
<tr>
<td>Eng</td>
<td>Family Practice</td>
<td>Regional</td>
<td>$120,856</td>
</tr>
<tr>
<td>MDA</td>
<td>Family Practice without OB</td>
<td>National</td>
<td>$116,877</td>
</tr>
</tbody>
</table>

**Average**

$157,786 $152,236 $135,178 $142,879

Additional information:
A 3% to 5% premium can be applied to total cash to be at the benefit. A 3% person applied to the 50th percentile would equal approximately:

- $19,840 per year
- $10 per hour
- $30 per day

**Sources:**
Krieger Health Care Compensation Survey - 2021 Physician Survey Report
Medical Group Development Survey - Physician Compensation and Production Survey 2020

**EXHIBIT B**
### GENERAL FMV PRINCIPALS

#### Key Concepts with Exhibit B:

1. Range established (25%, 50%, and 75%)
2. Specialty is matched
3. Hourly rate is determined by percentile
4. Surveys are averaged to negate disparity
5. Premium added to base in lieu of benefits (assuming physician is independent contractor)

### KEY FACTORS IN APPLICATION OF PERCENTILE

How does Physician compare with other physicians in same specialty?

- National/Regional reputation
- Articles published
- Speeches presented
- Productivity (worked RVUs)
- Opportunity Costs
- Supply v. Demand
- Unique Specialty/Subspecialty
- Experience
National Experts/Thought Leaders

- Evidence of above-normal compensation
- Established fee schedule
- Frequency of above-normal compensation
- Unique skills/experience
- Speaking/writing/research experience
- Highly specialized services

Research Arrangement Example

FACTS
Orthopedic Device Company seeks to engage nationally recognized orthopedic surgeon to evaluate new hip replacement device. Company seeks physician to perform physical review of device and use of device in ten patient hip replacements with monitoring and evaluation of device post-surgery for one year. Because the device has not been approved by the FDA, the surgical procedures in which the device is used cannot be paid for by Medicare or other third party payors. Company believes that the following number of hours will be committed by orthopedic surgeon to perform evaluations and to provide written feedback:
Research Arrangement Example

<table>
<thead>
<tr>
<th>Service</th>
<th>Estimated Number of Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device evaluation</td>
<td>20 hours</td>
</tr>
<tr>
<td>Pre-surgical evaluation of 4 hours/patient, including obtaining patient informed consent</td>
<td>40 hours</td>
</tr>
<tr>
<td>4 hours per surgery</td>
<td>40 hours</td>
</tr>
<tr>
<td>4 hours per patient post-surgical evaluation</td>
<td>40 hours</td>
</tr>
<tr>
<td>Written report with detailed analysis</td>
<td>20 hours</td>
</tr>
<tr>
<td>TOTAL NUMBER OF HOURS ESTIMATED</td>
<td>160 hours</td>
</tr>
</tbody>
</table>

Benchmark Data

<table>
<thead>
<tr>
<th></th>
<th>25th</th>
<th>50th</th>
<th>75th</th>
<th>90th</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Cash Compensation(^1)</td>
<td>$372,437</td>
<td>$497,088</td>
<td>$658,842</td>
<td>$825,044</td>
</tr>
<tr>
<td>Hourly Rate (+ 2,000 hours)</td>
<td>$186.22</td>
<td>$248.54</td>
<td>$329.42</td>
<td>$412.52</td>
</tr>
<tr>
<td>Hourly Rate + 25% for expenses and benefits</td>
<td>$232.78</td>
<td>$310.68</td>
<td>$411.78</td>
<td>$515.63</td>
</tr>
</tbody>
</table>

\(^1\)2011 Medical Group Management Association Physician Compensation and Productivity Survey.
Orthopedic surgeon is considered to be a thought leader because surgeon has published numerous articles regarding hip implant specifications and has spoken at numerous national conferences on the subject. Surgeon has stated that he is typically paid $600 per hour.

If Orthopedic surgeon and device manufacturer concur that $600 per hour is reasonable and a monthly stipend is desired, then monthly stipend can be calculated as follows:

160 hours x $600 = $96,000 ÷ 12 = $8,000
RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

1. Hourly payment (with maximum number of hours in contract)

2. Annual payment (determined by projected number of hours multiplied by Fair Market Value hourly rate)

If Annual Payment method is used, need to track hours to make sure consistent with contract.
RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

Duties and Responsibilities:

Require physician to complete a time card, (written statement of services rendered and amount of time dedicated to such services).

Actual consulting services should be performed.

Good:

- Analyze drug/device and provide written analysis to Company.
- Give speech on behalf of Company.
- Review and develop written reports/analysis
- Write articles for Company.
RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

Questionable:

- Compensation paid just to sign up patient in clinical trial not tied to or evaluated based upon time.
- Paid “consulting fee” to sit in an audience to listen about a new product/service.
- Pay physician to participate on large panel (15 members+) when fewer members would be reasonable (i.e., 5 members).
- Pay physician to “shadow” when there is no legitimate business need for shadowing.

ROYALTY PAYMENTS

- Appraisals
- Focus on Actual Sales
- Aggregate payment should not exceed a specified percentage of actual sales
ROYALTY PAYMENTS

Questionable Arrangements:
- Flat fee or Guaranteed fee
- Royalties paid beyond patents
- Royalties paid even though no product sold

RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

One Example:
Company desires to train 30 physicians of various specialties who will provide research services about a particular disease state or device or drug. Training to occur at central location (i.e., Chicago).
Example FMV Questions:

Q. How many physicians are reasonably needed?
Q. How are physicians selected?
Q. What does Company pay each physician to attend training session?
Q. What does Company pay the trainer?
Q. What expenses can the Company pay for?

EXAMPLE
HOW MANY?

- Why is this a FMV issue?
- Needs Assessment
  - Project need
  - Amount of research services reasonably anticipated
  - Flexibility of physicians selected
  - Demand for research services
  - Supply of physicians with requisite skills
**EXAMPLE**

**HOW ARE PHYSICIAN’S SELECTED?**

- Reputation
- Past Interaction
- Past Research Projects
- Flexible Schedule
- Specialist in Disease State
- Geographic Diversity
- Specialty
- Familiar with Company’s Products
- Past Speeches/Articles

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**EXAMPLE**

**WHAT DOES COMPANY PAY?**

- Fixed amount for each physician
- Varied amount based on specialty
- Individually negotiated amount
- Determine time that is compensable
  - Travel
  - Preparation
  - Training Time
EXAMPLE
WHAT DOES COMPANY PAY?

Bottom Line: Company MUST have documented reason for compensation decisions that are DEFENSIBLE!

Bad Rationale: Because that is what everyone is doing.

EXAMPLE
WHAT DOES COMPANY PAY?

Reasonable Documentation:
- Time sheets
- Sign-in sheets
- Invoice from Physician
- Benchmark data
- Rationalize payment based upon hourly rate
EXAMPLE
PAID EXPENSES

Good:
- Reasonable coach airfare
- Midsize rental car
- Reasonable hotel
- Reasonable meals/per diem
- Modest social events – Focus on networking

Bad or Questionable:
- Spouse’s expenses paid
- First class airfare
- Luxury rentals/limousines
- Expensive resort
- Luxury restaurants
- Spa or golf payment/reimbursement

DOCUMENTATION GUIDELINES

Pharma/Device companies should establish a structured approval and documentation process for all physician contracts.
Sample Pharmaceutical Company FMV Methodology

**METHODOLOGY OPTIONS**

- Standardized Rate
  - Set Rate for all speakers based on 2 or 3 tiers
  - Predictability, Minimal variance

- Variable Hourly Rate
  - Based on Hourly Rate for each individual Speaker
  - Flexibility, Tailored

- All rates must have a methodology
  - Based on data and HCP specialty
    - Compensation and Salary, US BLS
  - Business Unit / Franchise specific
## Sample Methodology Components

<table>
<thead>
<tr>
<th>KOL Tier</th>
<th>Local vs. Travel</th>
<th>Single vs. Multiple</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Live vs. Web</th>
<th>Program length &amp; Prep time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ex: Regional KOL, MD OB-GYN, Travel, Single Live Program = $2,000  
National KOL MD OB-GYN, Travel, Single Live Program = $1,500

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## Sample Rate Card
(For internal use at company)
DOCUMENTATION GUIDELINES

One example is using the Board of Trustees, or a committee of the Board of Trustees (i.e., Executive Committee).

Documentation submitted for approval can include:

1. Fair Market Value/Commercially Reasonableness Documentation (Survey, Checklist, Competing Offers)
2. Proof of Legal Review
3. Officer’s Certificate (see Exhibit D)
4. Copy of contract (or contract review memo disclosing the material components of the contract.)

CONTRACT APPROVAL

Officer’s Certificate

Exhibit D

* Can be signed by CEO, VP or President.
**PHYSICIAN CONTRACT REVIEW MEMO**

**Name of Physician or Group with whom contract is being sought:**

**Type of contract (i.e., Medical Director, Employment Agreement, Practice Location Agreement):**

**Specialty:**

**Contracting Entity (check all that apply):**

**List of Entities**

**Name and Title of Administrator completing Physician Contract Review Memo:**

**Signature of above administrator:**

**Date:**

**Pursuant to the terms of the proposed contract, the physician/group will do the following:**

**Terms:** The contract will commence and end on the date of service provided.

**Required terms, if any, are as follows:**

**Describe in detail the contract’s Fair Market Value and its method of compensation. Offer very detailed, including calculations, to have the actual compensation reviewed. For example: If this Remuneration Fair Market Value is determined to be $100,000, and the physician is being offered a $110,000 salary, this should be explained in detail.**

**In addition to the above, fair market value documents, including Physician Recruitment Criteria if appropriate.**

**In addition to the above, fair market value documentation if appropriate. If not, please explain why:**

**Administrator responsible for monitoring performance of all aspects of contract by physician/group: (could include, but not limited to the following: CEO, CFO, CFO, VP):**

**Contract Review Memo (Page 2)**

**STATE why the Contract is needed (including those needs that further charitable purpose):**

**Billing:** Does the contract cover professional patient care services to be performed by the physician?  
Yes  
No  
If Yes, will the physician directly bill or will it bill through a contracted billing company?  
Yes  
No

**In addition to the above, is this contract needed to further the charitable purposes of the hospital?  
Yes  
No  
If Yes, what charitable purpose does the contract further? (check all that apply):**

**[Legal staff to complete the following portions of this memo]**

Has the Contract been reviewed and approved by legal counsel?  
Yes  
No

**Stock exception upon which contract is based: (legal staff must initial this):**

**Room file, employment relationship**

**Personal services arrangement**

**Rental of office space**

**Rental of equipment**

**Other:**

**If the contract was reviewed by in-house counsel, the signature that follows is a representation that: (legal staff must initial this):**

In-house counsel believes that the contract complies with all applicable laws governing such relationships;

**[Signature of]**

**Has an Officer’s Certificate been executed and delivered to the legal office? (legal staff must initial this):**

Yes  
No

**If not, please explain why:**

**[Chief Financial Officer, or designee, to complete the remaining portion of this memo]**

Has the Contract been reviewed and approved by Finance?  
Yes  
No

**[Initials]**

**[Date]**

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**Page 37**
Because of the inherent risk with physician contracts, the Company should establish a Committee that should i) be involved in the approval process, and ii) oversee process for approval of physician contracts.

For every contract, the following documents should be maintained in a central file:

- **Executed** and copy of contract
- Fair market **current** value/commercial reasonableness documentation that formed the basis for the contract
- Documentation of legal review
- Officer's Certificate (see Exhibit D)
DOCUMENTATION GUIDELINES

- Time Report for actual and commercially reasonable services performed
- Payment records consistent with:
  - Time worked
  - FMV hourly rate
- W-2/1099 reflects all compensation paid

BOTTOM LINE:

It is all about the Money (and documentation)!
Case Example: Industry-Sponsored Research

Assume University of Erehwon physician to do investigator initiated research (IIR), sponsored by Pharma Company. Part of research proposal process includes submitting a detailed, line item budget.

<table>
<thead>
<tr>
<th>Item</th>
<th>Permissible?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct costs (staff time, res. Assistant, lab equipment)</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient-related costs (for this study only)</td>
<td>Yes, only if not part of standard patient care</td>
</tr>
<tr>
<td>Computer equipment, printer, software</td>
<td>Yes, only if needed and used for this particular study</td>
</tr>
<tr>
<td>Fringe Benefits (vacation time, staff benefits)</td>
<td>Typically no. Cannot pay for costs that a Univ would otherwise pay for (if no sponsored research occurred)</td>
</tr>
<tr>
<td>Indirect costs (flat % for &quot;overhead&quot;)</td>
<td>Depends; typical limit of 50%</td>
</tr>
</tbody>
</table>

Case Example: Comparison Point

<table>
<thead>
<tr>
<th>Acceptable Budget</th>
<th>Problematic Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Item</td>
</tr>
<tr>
<td>Cost x Unit</td>
<td>Unit x Cost</td>
</tr>
<tr>
<td>Total</td>
<td>Total</td>
</tr>
<tr>
<td>Salary PI $190 x 100 hr $19,000</td>
<td>Salary PI $400 x 100 hr $40,000</td>
</tr>
<tr>
<td>Res. Asst $50 x 200 hr $10,000</td>
<td>Res. Asst $40 x 1000 hr $40,000</td>
</tr>
<tr>
<td>Pt. Costs None --</td>
<td>Pt. Costs $100 per pt. x 100 pts. $10,000</td>
</tr>
<tr>
<td>Supplies (computer, hard drive, storage disks for data) $5000 $5,000</td>
<td>Supplies (computer, hard drive, storage disks for data) $3 x $5000 $19,500</td>
</tr>
<tr>
<td>Mandatory res. Phone call f/up $1000 $1,000</td>
<td>Mandatory % staff salary set aside 10% x $80000 $8,000</td>
</tr>
<tr>
<td>Research Facility Use $25,000 $25,000</td>
<td>Other Indirect Costs 70% x Total study budget $82,250</td>
</tr>
<tr>
<td>Other Indirect Costs $18,000 (30% of total study budget) $19,000</td>
<td>TOTAL $177500+$82250 $259,750</td>
</tr>
<tr>
<td>TOTAL $60000+$18000 $78,000</td>
<td>TOTAL $259,750</td>
</tr>
</tbody>
</table>
Industry-Sponsored Research: Final Points

• Budget clarification
  ➢ Signed MOU with NIH, NCI, etc. is irrelevant for IIR
  ➢ Line-item & specify all direct costs when possible

• Typically, 2 stages to protocol review & approval
  ➢ Concept Review
  ➢ Detailed Protocol Review

• Letter of Agreement (contract) outlines all specifics, including milestone payments and financial accruals
  ➢ Never will pay full research grant at onset

• Termination of Research
  ➢ Slow or no patient enrollment
  ➢ Study drug no longer available
  ➢ Major changed circumstances or factors

Questions