Conflict of Interest and Professional Integrity in Medicine
Training for Medical Students, Residents, and Fellows
Learning Objectives

• Learn about industry interactions with physicians

• Learn the definition of conflict of interest

• Review ethical principles underlying the concept of professionalism and better understand your role

• Learn about the Feinberg School of Medicine Office for Regulatory Affairs and the Feinberg Professional Integrity and Disclosure Policy
Industry Interactions with Physicians
Industry

• Throughout this training, the term “industry” includes the following:
  – Pharmaceutical Industry – discovers, develops, produces, and markets drugs for use as medications.
  – Medical Device Industry - discovers, develops, produces, and markets instruments, apparatus, implements, machines, contrivances, implants, in vitro reagents, or other similar or related articles,

  • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  • intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Source: Federal Drug Administration www.fda.gov
Industry Contributions

Industry makes important and costly contributions to health care. These contributions include:

• Research and development of new pharmaceuticals and devices
• Funding of clinical trials and other research
• Support of continuing medical education and other training and educational opportunities
Significant Resources are Spent on Marketing and Research Activities

Source: GlobalData
Balancing Interests

• Medicine and industry are interrelated
  – Society wants effective new treatments
  – Academia wants to translate basic science discoveries into new treatments
  – Industry wants to develop new products
• Manage potential conflicts by promoting a culture of transparency
Current External Environment

“There's a lot of skepticism about financial relationships between doctors and drug companies. Disclosure of those ties would help to build confidence that there's nothing to hide. Requiring disclosure is a common sense reform based on the public dollars and public trust at stake in medical training, medical research and the practice of medicine.”
-- Senator Charles Grassley
Federal Oversight: Sunshine Act

• Part of the Affordable Care Act
• Requires that applicable manufacturers and group purchasing organizations provide CMS with the details of any direct or indirect payments they made to physicians and teaching hospitals
• Provides the public with access to information about the financial relationships their health care providers may have with industry
Key Take-Away Points

• Pharmaceutical and medical device companies discovery of innovative treatments has evolved significantly.
• Effective marketing helps pharmaceutical and medical device companies achieve their mission.
• Industry marketing is sophisticated, influential, and has the potential to impact healthcare professionals’ decision making.
• There is a major trend toward transparency regarding physician and researcher relationships with industry.
Defining Conflict of Interest
It is Important to Understand Conflict of Interest (COI) Definitions:

- **Conflicts of Interest** occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised.

- **Financial Conflicts of Interest** occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain.

  Brennan et al. 2006.
How Does Feinberg Define a “Conflict of Interest?”

• Per the Feinberg School of Medicine Professional Integrity and Disclosure Policy: A "conflict of interest" exists when there is a divergence between a faculty member's private interests and his/her professional obligations, such that an independent observer might reasonably question whether the faculty member's professional actions or decisions are determined by any consideration other than the best interests of the school, his/her students/trainees, or his/her patients.

• Link to Feinberg’s Policy:
Key Take-Away Point

It is important to manage potential and actual conflicts of interests to avoid compromising research, the academic community and the public’s trust.
Basic Ethical Principles – Your Role/Professionalism
Fiduciary Characteristics

- A fiduciary is one who:
  - Holds a specialized knowledge or expertise
  - Holds the trust of others
  - Is held to high standards of conduct
  - Avoids conflicts of interest
  - Does not seek personal gain
  - Is objective
  - Is accountable or obligated (ethically and legally)

How many of these characteristics apply to physicians?
All of the characteristics should apply to a physician. Therefore, a physician is, in effect, a fiduciary, and should avoid conflicts that could undermine patient care.
Why Is This Important?

- Patients place their trust and well-being in the hands of physicians
- Physicians are responsible for the welfare of patients
- Physicians respond to patients’ actual (vs. perceived) needs
- Physicians are responsible for controlling patient/third-party payor expenses for medications and other medical services
Physicians and Conflicts of Interest

• A conflict of interest may exist if a professional judgment concerning a primary interest stands to be unduly influenced by a secondary interest.

• Because of the fiduciary nature of the patient/physician relationship, it is generally expected that physicians should avoid conflicts of interest that may undermine patient care.

• For actual or perceived conflicts that cannot be avoided, disclosure may function as the primary mechanism to reduce the effect of the conflict.
Examples of Potential Conflicts

• Example 1 – Ownership Interest/Service on Board of Directors/Involvement in Purchasing Decisions
  - Dr. Peter Martin, faculty member and researcher
  - President of Board of Directors, and owner of Laboratory Solutions, Inc. (LSI)
  - Dr. Martin’s research group purchases scientific supplies and equipment from LSI

• Example 2 – Ownership/Investment Interest in Research Sub-Contractor
  - The University was awarded a federal grant on which Dr. John Samuel serves as the PI
  - He sub-contracted a portion of the work to a vendor named Opticware for installation of eye-movement analysis software
  - Dr. Samuel has an equity interest in this vendor
Examples of Potential Conflicts (cont’d)

• Example 3 – External Consultant for Research Sponsor
  - Professor Marsha Jones, faculty member and researcher
  - Consultant/speaker for National Device Company (she earned $55,000 last year)
  - NDC wants to sponsor University research to evaluate new technologies
  - Professor Jones wants to be Principal Investigator (PI) on the study

• Example 4 – Royalty Payments/Inventor Share and Equity Interest Involvement/Sponsored Research
  - Dr. Katie Snow developed a new method for collecting adult stem cells, which was patented by the University; she receives royalties for this intellectual property (IP) through the University
  - The technology is licensed to Cell Colonies, Inc., a non-public company
  - She holds equity in the company
  - Dr. Snow is conducting federally sponsored research to further evaluate the technology
Key Take-Away Points

- Physicians should ensure that interactions with industry are free of any conflicts of interest that could compromise or appear to compromise their judgment.
- Many financial arrangements with industry should be reviewed with qualified legal counsel to verify that they conform to ethical guidelines and the law.
- The consequence of unprofessional behavior is an erosion of public trust.
- The presence of a potential conflict does not mean the relationship with industry is prohibited.
- Conflicts can be managed by addressing them and imposing a plan to manage, reduce, or eliminate the conflicts.
Feinberg Office for Regulatory Affairs and Feinberg Policies
Feinberg’s Disclosure and Professional Integrity Policy

It is important to read and understand the Feinberg Disclosure and Professional Integrity Policy available via:


Many of the sections within this policy impact you, including:
• Faculty Use of Students/Trainees in Outside Professional Activities
• Professional Integrity – Gifts and Business Courtesies
• Ghost Writing
• Student/Trainee Contractual Arrangements
• Attendance at Educational Programs
• Training and Education Regarding the Use of Medical Devices
• Meals
• Industry-Sponsored Scholarships and Fellowships
• Educational Grants and Donations
• Access by Industry Representatives
Policy Highlights

• **Faculty – Student Agreement:** Any student/trainee engagement in faculty enterprises must be pre-approved and requires a signed agreement available via this link:
  - [http://www.northwestern.edu/coi/policy/student_faculty_agreement.docx](http://www.northwestern.edu/coi/policy/student_faculty_agreement.docx)

• **Gift and Business Courtesies:** Students may not solicit or accept gifts or business courtesies of any value from Industry.

• **Ghost Writing:** Ghost writing is prohibited.

• **Student-Trainee Contractual Arrangements:** These arrangements are prohibited unless written permission is received from the Vice Dean for Regulatory Affairs.

• **Attendance at Educational Programs:** Attendance at educational programs is acceptable only if specific criterion are met; see the policy for more detail.

• **Training and Education Regarding the Use of Medical Devices:** This activities are acceptable only if specific criterion are met; see the policy for more detail.
Policy Highlights (cont’d)

• **Meals:** Meals are acceptable only if specific criteria are met; see the policy for more detail.

• **Industry-Sponsored Scholarships and Fellowships:** All offers from Industry must be submitted for review/approval by the Vice Dean for Regulatory Affairs.

• **Educational Grants and Donations:** These are acceptable only if specific criteria are met; see the policy for more detail.

• **Access by Industry Representatives:** This is generally restricted to non-patient care areas and requires an appointment or invitation of the faculty member. Involvement of students/trainees should occur only for educational purposes and under the direct supervision of the faculty member. The [vendor access policies](#) of our affiliated hospitals and practice groups must also be followed.
Joint Affiliates Annual Disclosure Survey

• The Joint Affiliates consist of the following entities:
  - Northwestern University Feinberg School of Medicine
  - Northwestern Memorial HealthCare and its subsidiaries
  - Children’s Hospital of Chicago Medical Center
  - Rehabilitation Institute of Chicago

• The Joint Affiliates partner to conduct an annual disclosure survey that addresses their conflict of interest, conflict of commitment and business integrity policies.

• Faculty are required, at a minimum, to disclose annually their external relationships to Feinberg and their clinical practice group.

• The information disclosed in this annual survey is posted publicly to NU faculty profiles
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Please contact us if you have any compliance, conflict of interest, or disclosure questions or concerns.
Affirmation of Training Completion
Completion of Required Training:

- By checking the box next to the attestation text and clicking “Submit” you are acknowledging that you have read and understand what is expected of you.

- **NOTE:** Completion is required by McGaw and Feinberg policies.