Managing Conflicts of Interest in the Pharmaceutical Sector

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Analogy to Judging One’s Own Case

• Can a person objectively judge themselves?

• Is it prudent policy to allow individuals to judge themselves?
Analogy to a Judge

• Should a judge/arbitrator be paid by only one of the disputing parties?

• Should a judge/arbitrator decide case where one party is a close relative or friend or business associate?

• Should physicians and other professionals be held to similar standards?
Corruption and Conflicts of interest (CI)

• Classic Corruption (kickbacks, bribes, fraud) is generally illegal and considered abnormal.

• But CIs are sometimes tolerated.

• Legal systems 1st target corruption and later address CI.
BUT often parties that pay kickbacks and bribes can recast financial payments as legal arrangements that create a financial CI, while producing similar effects.

Examples:

• 1: Instead of paying a bribe to change a government official’s conduct, you can: (a) offer a gift or favor or (b) create a business financial relationship that influences their conduct.

• E.g., the pharmaceutical firm can hire the official as an advisor or finance an educational program for the official’s ministry.
1) CI regulation can be a means to control *disguised* corruption.

2) CI regulation can also be a means to control *bias* that may influence a person’s judgment but that is different from classic corruption.
Conflicts of Interest (CI)

Definition from Law

CI exists when individuals have defined duties and:

(1) *(Financial CI)* Individuals have financial incentive to breach their obligations;

OR

(2) *(Divided Loyalties CI)* When the person’s loyalty is divided between their defined duties and loyalty to other goals or to serving other parties.
Conflicts of Interest

(1) Compromise loyalty;

(2) Compromise independent judgment;
Create bias.
Some Examples

Financial CI
• Public official with financial interest in industry they regulate.
• Medical expert consulted by government with financial ties to parties affected by her advice.
• Physician who dispenses medicine.

Divided Loyalty CI
• A public official responsible for attracting investment from drug firms while also responsible for regulating the safety of medicines.
• A researcher who develops new medicines and with a patent on it while also evaluating for registration authority whether the medicine is safe and effective.
CI are Not the Same as a Breach of Loyalty or Other Misconduct

• A CI is a situation that creates bias and increases risk of misconduct, not a particular decision or action.

• It is possible to have a CI and fulfill one’s obligations.

• Policy and good management try to remove or manage CIs to reduce risk of bias and misconduct.
What a CI is Not

• A breach of duty or misconduct;

• Conflicting interests;

• A hard value choice between two competing objectives;

• Conflicts between competing interest groups;

• A bad decision or policy.
## Conflicts of Interest:

<table>
<thead>
<tr>
<th>PREVENTION</th>
<th>REGULATION</th>
<th>SANCTIONS/RESTITUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before</strong> person acts</td>
<td><strong>While</strong> person acts</td>
<td><strong>After</strong> person acts</td>
</tr>
<tr>
<td>Prohibit</td>
<td>Supervise/ Manage</td>
<td>Penalize</td>
</tr>
<tr>
<td>Individuals from entering into situations with CI</td>
<td>Conduct of individuals and limit their discretion</td>
<td>Individuals for violation of trust</td>
</tr>
<tr>
<td>Disclose</td>
<td></td>
<td>Restitution</td>
</tr>
<tr>
<td>Financial Ties</td>
<td></td>
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Summary of Key Strategies to Resolve or Manage Conflicts of interest
Ways to Resolve Individual Conflicts of interest

A) Change The Compromised Employee’s Relationship to the Private Interest

• Divest the private ownership interest

• Terminate the relationship with the private entity.

• Place the employee’s investment interests in a blind trust
How to Resolve Individual Conflicts of interest

• *B) Change The Compromised Employee’s Work Activities*

• **Resign**

• **Recusal**

• **Reassign work duties**

• **Restrict access to information**
Manage Conflicts that cannot be resolved

• Oversee the Work of Conflicted Public Employees
  – Reduce the actor’s discretion and their scope of work

• Minimize the Role of Conflicted Actors
  – Reduce number of conflicted actors on government advisory committees
Management of Cls: Two Phases

(1) STRUCTURAL RESPONSES
   – Change pharmaceutical sector and government to preclude/avoid Cl.
   – Legislation/ regulation of public service, private economy to preclude/avoid Cl.
   – Financing of activities in ways that avoid Cl.

(2) OVERSIGHT OF CONDUCT
   – Oversight of government personnel to ensure legal compliance.
   – Policies to identify and oversee Cl.
   – Management of particular activities and transactions.
   – Supervision of conflicted personnel when the Cl can’t be avoided.
Examples of Structural Responses

• Prohibitions on civil servants:
  – having financial ties with regulated industry
  – receiving gifts or grants from industry

• Prohibitions on civil servants engaging in remunerative work with regulated industry.

• Post-employment restrictions on government personnel working in regulated industry.

• Separation of prescribing from dispensing.

• Independent funding for continuing medical education/professional medical activities.
CI of Public Servants

1) From Previous employment.

2) During government employment.

3) After leaving government service.

A Government Agency Supervises the Ethics of Employees:

• Implement CI policies;

• Education, training and advice, and advisory opinions;

• Investigations.
Some CIs of Public Servants 1

- Representing or advising private parties regarding matters before public authorities;
- Employment with entities regulated by the state;
- Simultaneously serving in certain government positions;
- Participating in decision-making when the official or a relative, or business associate has an interest in the matter;
Some CIs of Public Servants 2

• Engaging in business, or other financial relationships with private parties that are regulated by the government;

• Misuse of information gained through government position;

• Misuse of public functions to benefit a political organization or campaign;

• Appointing relatives to government positions;

• Influence peddling.
CI During Public Employment 1

- Restrictions on outside employment;
- Restrictions in certain outside investments;
- Restrictions on using government information for private purposes;
CI During Public Employment 2

• **Recusal** from decision-making in matters that can affect the employees personal financial interest or interest of their family;

  — The employee is not allowed to participate in matters if the employee or family have investment or other financial ties in firms affected by governmental decisions.
CI from Previous Employment in Private Sector

When an individual is recruited from private sector for a high-level government position, the individual may have investments that could be affected by government decisions.

3 Options

1. Preclude the individual from certain public service;

2. Require the individual to divest ownership in firms that could be affected by their government employment;

3. Require the individual to place all their stock into a blind trust that is managed by an independent trustee. The trustee can sell the stock and invest it in other areas. The trustee can’t communicate with the public servant.
CI: Post-Government Employment Restrictions

Public officials have information and contacts that can help private parties. To reduce the risk that public servants will inappropriately use their position for private gain after leaving public service, legislation can restrict certain post-government employment in the regulated industry.

- E.g., Preclude individuals from representing private interests before government agency in which they worked for 2 years after they leave government service.
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Managing CIs:

Removing the CI

Set threshold on amount regulated;

• Ban on conflicting relationships;

• Recusal of conflicted individuals:
  – From voting or other decision-making in affected matter;
  – From participating in meeting (discussion, offering of opinions).

Oversight of the Conflicted Individual

• Supervision of the conflicted individual.
The Role of Disclosure

*Medicines Agency*

“Conflicts Disclosed, Conflicts Disposed (and forgotten)”
How Disclosure of CI Might Help

• Allow administrators to take management action:
  – Removal of conflicted actor from position;
  – Recusal of conflicted actor;
  – Supervise conflicted actor.

• Allow third parties to review conflicted behavior or action.

• Allow press and public to mobilize politically to seek changes.

• Allow affected parties to make informed choice to avoid conflicted actors or to protect themselves.
Limits of Disclosing CI

• The CI and bias *are not* eliminated.

• Often there is no ability to effectively manage the CI.

• Often there is no increased choice for affected public.

• Disclosure might create false confidence or trust rather than warn of risk.

• Disclosure might give license to conflicted individuals to act in their own interest.
What Should Be Disclosed?

Disclosure of own interest or those of family member:

• Ownership of firm;
• Investment in firm; stock ownership;
• Patent/ other intellectual property;
• Consulting relationship;
• Grants or gifts or receipt of equipment, goods, or in-kind services;
• Any other financial ties, e.g.,
  – Honoraria;
  – Expert testimony payment;
  – Reimbursement of travel;
  – Reimbursement of fees to participate in professional meetings or continuing medical education.
How to disclose and to whom?

• Need for managers to review financial disclosure forms;

• Need to act on information received;

• Public access to disclosed information to hold government agencies accountable.
CI of Private Sector Actors

• Experts that perform public functions or advise government;

• Experts writing on pharma issues;

• Professionals prescribing or dispensing drugs;

• University faculty/ researchers;

• Clinical researchers.
Expert Serving on
Government Advisory Board 1

Management Options:
• Do not employ experts with financial ties to industry;
• Recuse experts with CI related to particular matters;
• Do not permit conflicted experts to vote;
• Staff advisory board so majority lack CIs;
• Require written reports justifying basis for advice and have reports peer reviewed before vote;
• Disclosure of CI to implement measures listed above.
Clinicians Paid by Drug Sponsor to Report Patient Response to Drug for Phase IV Study

• Have study conducted by individuals with no relation to prescribing physicians.

• Regulate studies to ensure they are needed and to minimize probability they will be used to pay doctors to prescribe drugs.

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