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Conflict of Interest in the Pharmaceutical Sector: A Guide for Public Management

Marc A. Rodwin

CONFLICT OF INTEREST IN THE PHARMACEUTICAL SECTOR: A GUIDE FOR PUBLIC MANAGEMENT

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Abstract

This article outlines the key kinds of conflicts of interest that exist in the pharmaceutical sectors and shows how they affect 12 areas related to the development, marketing, and distribution of pharmaceuticals. It explains how these conflicts of interest can compromise good practice and policy. Most importantly, it sets forth a step-by-step guide for managing such conflicts of interest in the public and private sectors.

TABLE OF CONTENTS

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I. WHAT ARE CONFLICTS OF INTEREST?

The pharmaceutical sector plays a vital role in the promotion of individual health care and public health. However, the conflicts of interest in the pharmaceutical sector compromises the integrity of medical practice, appropriate prescribing, patient safety, and public health.[2] It can also lead to governments, insurers, and patients paying more for medications. Increased costs mean increased social burden that imposes an unnecessary limit on global access to essential medicines.

Conflicts of interest can compromise the integrity of key parts of the pharmaceutical sector. Policies that preclude, manage, or mitigate conflicts of interest promote the integrity of governmental decisions and decisions by medical professionals, who play strategic roles related to the use of medications. Public policies that promote transparency, like policies that target overt corruption are therefore aligned with conflicts of interest policies but distinct from them.[3] This article describes conflicts of interest in the pharmaceutical sector and ways public policy can address them.

The idea underlying conflicts of interest is simple: it is implicit in the principle that no individual can judge his or her own case because that would mix two incompatible roles, playing both the participant and the judge. A judge is supposed to be unbiased when deciding the outcome of a case. However, a judge cannot be neutral when he or she must decide a case that pits the judge—or member of the judge's family—against another party. Similarly, a judge who has strong financial ties or a close friendship with one party in a court case is also likely to be biased in that party's favor.

Other governmental officials also exercise authority that affects the public. These public servants also have obligations to make decisions fairly, to fulfill their public mission impartially despite their personal interests. Yet administrators and public servants sometimes have personal interests that can bias their decisions.

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[2] Marc A. Rodwin, *Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J. OF L. MED. & ETHICS 511, 511-22 (2012).

[3] *See generally* Guitelle Baghdadi-Sabeti et al., *Measuring Transparency in the Public Pharmaceutical Sector*, WORLD HEALTH ORGANIZATION [WHO] (2009), http://apps.who.int/medicinedocs/documents/s16732e/s16732e.pdf; *See generally* Jillian C. Kohler et al., *Corruption in the Pharmaceutical Sector: Diagnosing the Challenges*, TRANSPARENCY INTERNATIONAL UK (2016), https://www.transparency.cz/wp-content/uploads/Corruption-in-the-Pharma-Sector.pdf.

Physicians, pharmacists, and other professionals working in both the public and the private sectors also have obligations to serve the interests of designated parties or to perform certain public functions. Yet these professionals sometimes have a personal stake in matters that can cause them to favor their own interests over the interests of their patients, clients, or other parties they are supposed to serve.

A. Definitions

This article uses as its starting point the traditional legal definition used by the Organization for Economic and Cooperative Development (OECD), which focuses on conflicts of interest of public sector actors.[4] The OECD says that, "'a conflict of interest' involves a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests, which could improperly influence the performance of their official duties and responsibilities."[5]

Bear in mind that conflicts of interest do not constitute a breach of duty. Although law or ethics may require individuals to not enter into conflict-of-interest situations, this is only a measure to prevent acts considered wrong in themselves. Conflicts of interest can influence action, but they are not acts and do not constitute a breach of trust. Furthermore, conflicts of interest are distinct from conflicting interests. Multiple interests often pull people in different directions. But unless such conflicting interests compromise an individual or party's *obligations*, no conflict of interest exists.

Conflicts of interest constitute a problem for two reasons: (1) they compromise an actor's *loyalty* to her mission or the parties they are supposed to serve, and (2) they compromise the actor's *independent*

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[4] The Organization for Economic Co-operation and Development [OECD] uses the traditional legal definition. Some writers have attempted to redefine conflicts of interest with confusing results. *See* Marc A. Rodwin, *Attempts to Redefine Conflicts of Interest*, ACCOUNTABILITY IN RESEARCH 67, 67-78 (2018).

[5] OECD, *Managing Conflict of Interest in the Public Service: OECD Guidelines and Country Experiences* (2004), http://www.oecd.org/gov/ethics/48994419.pdf [hereinafter *Country Experiences*]; *See also* OECD, *Managing Conflicts of Interest in the Public Sector: A Toolkit* (2005), https://www.oecd.org/gov/ethics/49107986.pdf [hereinafter A toolkit] See also, MARC A. RODWIN, MEDICINE, MONEY AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST, 629-34 (1993); MARC A. RODWIN, CONFLICTS OF INTEREST AND THE FUTURE OF MEDICINE: THE UNITED STATES, FRANCE, AND JAPAN 15-16 (2011) [hereinafter *The Future of Medicine*].

judgment.[6] Consequently, conflicts of interest increase the risk that individuals will not perform their duties as they should, or even cause them to breach their obligations. The least serious form of breach could be professional neglect: a compromised public employee might not perform at his or her customary high level of competence, diligence, or effectiveness. In its most egregious form, public servants and publicly employed professionals may knowingly exploit their position. Extreme disloyalty obviously presents more dramatic danger but is easier to identify. Situations that compromise independence, loyalty, or judgment more subtly or even unintentionally, occur more frequently but are harder to recognize.

B. Some Distinctions

Individual Conflicts of Interest

Two main kinds of conflicts of interest exist: Financial and Divided Loyalty Conflicts

Financial conflicts of interest arise when an individual has financial interests that can affect decisions he makes when performing his duties. These personal interests might present a strong incentive to ignore public duty and bias the official towards his or her own wallet, or the wallet of friends and family. *Divided loyalty conflicts of interest* arise when an individual's loyalty is split between two parties with differing interests. An individual can engage in multiple activities that are acceptable when considered individually, yet often conflict when one individual performs them simultaneously.

Potential and Apparent Conflicts

The OECD uses the term "potential conflict of interest" for situations in which an official would have a conflict of interest if there were certain changes in their official work activities or in the individual's activities outside of work such that the individual would then have a conflict between his work duties and personal interests.[7]

The OECD reserves the term *apparent* conflict of interest for situations where it appears to many observers that a public official's private interests could improperly influence their performance of professional duties, but where in fact there is no conflict because arrangements have

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[6] MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST 8-11 (1993); Rodwin, *supra* note 4, at 15-17.

[7] *Country Experiences*, *supra* note 3, at 58.

been made for the official to stand aside from all decision-making related to the activities in which the official would have a conflict.[8]

For example, a public servant with an ownership interest in a private firm has a potential conflict of interest because the public servant has a private interest in the success of the firm that might conflict with the official's exercise of her duties. However, if the public servant works in the transportation ministry and is an investor in a pharmaceutical firm or pharmacy, the public servant's work is unlikely to affect the private firm or vice versa. If the public servant is reassigned to work in a bureau that approves the marketing of medicines or that regulates pharmacies, then the public servant's financial interest will likely create an actual conflict of interest. The test is whether the performance of public duties by the public official can influence decisions in favor of the business in which the official has financial ties.

Similarly, an individual who works in a pharmaceutical affairs bureau, and whose sister manages a pharmaceutical firm, has an apparent conflict of interest because it appears that the official's duties will conflict with his interest in helping his sister's firm. It remains an apparent conflict rather than an actual conflict of interest if arrangements have been made so that the official will not participate in any pharmaceutical bureau decisions that affect the firm in which the official's sister is a manager.

Conflicts of Interest of Professionals in the Private Sector

Professionals working in the private sector can also have conflicts of interest when they serve on government commissions or advisory boards or offer expert advice to public officials. Under these circumstances, these professionals perform public functions and therefore are expected to act as if they were performing their work as public employees. Yet these professionals might have financial interests affected by the outcome of their public decision. Consequently, they might be in a situation where they can perform their public sector functions in ways that promote their private interests.

Furthermore, there can also be conflicts of interest for professionals that work in private practice even when they do not perform any work for the public sector. For example, physicians and pharmacists have professional obligations to act in the best interests of their patients and to comply with professional norms. Since these professionals earn their living by performing their professional work, their personal financial interests can create an incentive for them to write prescriptions, offer advice, or generally

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[8] *Id.*

make decisions that promote their personal financial interests over the interests of their patients.

Institutional Conflicts of Interest

An *institutional conflict of interest* exists when an organization performs two or more roles that can conflict.[9] This typically occurs when the institution has financial interests that can cut against an institutional mission or activity. Some writers also hold that when an institution's senior official has financial interests that can affect institutional policies, that situation also creates an institutional conflict of interest.[10] However, the financial interests of senior officials in an organization can also be analyzed as reflecting their individual conflicts of interest.

In the United States, many private not-for-profit universities and hospitals have joint ventures with for-profit firms to conduct research and commercialize products derived from the research.[11] The university or hospital will share profits or royalties from pharmaceuticals or other products derived from the research. Meanwhile, these universities have a mission of promoting inquiry and public access to knowledge and obligations to oversee the integrity of university researchers and to monitor the financial conflicts of interest of researchers. In this situation, the university has a financial interest in the outcome of the research that can conflict with its mission as an educational and research institution.[12] For example, if an institution conducts research to evaluate a pharmaceutical product while earning income from the product's sale, those two activities create an institutional conflict of interest.

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[9] *Id.* at 66.

[10] *See generally* Association of American Universities, *Report on Individual and Institutional Financial Conflict of Interest* (2001), http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/misc/Ref/AAU_CoI.pdf; Bernard Lo & Marilyn J. Field, *Conflict of Interest in Medical Research, Education, and Practice*, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMICS [IOM] (2009), http://www.kumc.edu/Documents/coi/TOC.pdf.

[11] SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 27-56 (2004); *See* Mark Barnes & Patrik S. Florencio, *Financial Conflicts of Interest in Human Subjects Research: The Problem of Institutional Conflicts*, 30 J. L. MED. & ETHICS 390, 390 (2002).

[12] Ezekiel J. Emanuel & Daniel Steiner, *Institutional Conflict of Interest*, 332 NEW ENG. J. MED. 262, 262 (1995).

II. TWELVE AREAS OF CONFLICTS OF INTEREST RELATED TO PHARMACEUTICALS

Conflicts of interest compromise good pharmaceutical policy in 12 related areas. These areas occur in multiple points in the medication life cycles. These include, at the beginning of the medication life cycle, research on safety and effectiveness required prior to marketing the drugs. At the end of the medication life cycle they include monitoring drug safety after drugs are on the market. In between there are 10 additional points where decisions about medications present opportunities for conflicts of interest.

Exhibit A, below, displays these twelve areas roughly in the chronological order.

Exhibit A
Twelve Areas of Conflicts of Interest in the Medication Life Cycle

1) Safety/ Effectiveness Research	**2) Medical Publication**	**3) Registration /Marketing authorizatio n)**	**4) Reimbursement & Pricing**	**5) Mfg. & Distribution**	**6) Procurement**
7) Standard Treatment Guidelines	**8) Formulary Selection**	**9) Continuing Education**	**10) Prescribing**	**11) Dispensing**	**12) Post-Marketing Drug Safety**

Research to Test Medicines for Safety and Effectiveness

Governmental authorities require that pharmaceutical products be tested for safety and effectiveness before they authorize their sale. Typically, governments require that manufacturers submit evidence of safety and effectiveness derived from clinical trials. The results of clinical research to test medicines can therefore influence whether a medicine can be sold, for what purposes it can be marketed, the claims that manufacturers can make when marketing the medicine, and the warnings of health risks that manufacturers must provide. The information from clinical research also often affects the choices made by authorities that regulate medicine prices, the decisions of purchasers and prescribers, the medicine formularies developed by hospitals and health systems, and choices that patients make.

Many pharmaceutical researchers have conflicts of interest, including the individuals who design clinical trials or carry out the research or interpret and report the data. These researchers are supposed to provide objective evaluation of a pharmaceutical product, but pharmaceutical firms that wish to commercialize a medicine are often the ones who pay the researchers to conduct the research. Other times, pharmaceutical firms employ these researchers as consultants or offer them grants and gifts. These researchers might conduct their work in a way that promotes results favoring the interest of the pharmaceutical firms with which they have financial ties.

Medical Publication

Medical journals publish articles reporting on clinical trials that evaluate pharmaceutical products. These articles affect the decisions of physicians, pharmacists, and policymakers. The authors of medical journal articles can have financial ties with pharmaceutical firms and these ties can bias their publications. Medical journal peer reviewers can also have financial ties with pharmaceutical firms, and these ties can bias their evaluation. For example, both authors of journal articles as well as peer reviewers might depend on pharmaceutical firms for employment, consulting income or grants and gifts. In addition, medical journals often depend on revenue from pharmaceutical firms' advertising for and purchasing of article reprints.

Registration of Pharmaceuticals (authorization to market, approved uses, labeling)

National authorities typically regulate the marketing of medicines by setting rules for registration and sale of pharmaceutical products. These rules are intended to protect the public. If the public officials working in these agencies have financial interests in the pharmaceutical firms they regulate, then these public officials have conflicts of interest that can bias their decisions regarding the sale of pharmaceuticals.

Frequently, public authorities ask experts in the private sector to advise them regarding the registration of pharmaceutical products. When these experts earn income from pharmaceutical firms, then in turn offer advice to public authorities on sale of the pharmaceutical firm's products, the experts have a conflict of interest.

Regulation of Reimbursement and Pricing

Many nations regulate the price of pharmaceutical products. If decision makers have financial ties with pharmaceutical firms then conflicts of interest are created that can affect governmental pricing decisions.

Pharmaceutical Manufacturing, Distribution, and Oversight of Pharmacies

Governments oversee the pharmaceutical manufacturing process by setting standards for quality controls and good manufacturing practices. The public employees who oversee these processes have conflicts of interest when they receive gifts or have other financial ties with these firms. National authorities typically inspect pharmaceutical manufacturing facilities. Governments oversee the process of distributing pharmaceuticals through controls on imports and rules for storage, transportation, and delivery. The public employees who oversee this process have conflicts of interest when they receive gifts or have other financial ties with the firms involved in the distribution process. National authorities also often inspect pharmacies and other pharmaceutical facilities. Inspectors with financial ties to the firms they regulate have conflicts of interest that compromise their work.

Procurement

Public authorities, private insurers, hospitals, and other parties often procure medicines. When choosing among various products and deciding what price to pay, these parties are supposed to act in the interest of the entities they serve. However, these individuals and organizations sometimes have financial ties with pharmaceutical firms or intermediary organizations; these relationships create conflicts of interest that can bias their procurement choices.

Standard Treatment or Practice Guidelines

Standard treatment guidelines draw on existing medical knowledge to establish recommendations for good medical practice. These guidelines shape physician prescribing and clinical choices. In some countries (e.g., France) governmental authorities set practice guidelines. Other nations adapt WHO's standard treatment guidelines (e.g., Ghana). In many other countries, medical specialty societies and insurers develop medical practice guidelines, including guidelines for medicine therapy. The professionals who serve on committees that draft guidelines sometimes have financial ties to companies that can bias their decisions in drafting the guidelines.

Formulary Selection Committees (*by government, private insurers, and hospitals*)

Hospitals and insurers typically develop formularies that restrict which pharmaceutical products physicians can prescribe or affect the co-payments that patients pay. Individuals who serve on formulary committees and have financial ties with pharmaceutical firms have conflicts of interest that can bias the formulary choices.

Continuing Professional Education Related to Pharmaceuticals

Continuing medical education (CME) shapes the knowledge and perceptions of professionals on clinical issues, including the appropriate use of pharmaceutical products. Organizations that develop CME programs and the CME speakers themselves can have conflicts of interest due to their reliance on grants from pharmaceutical firms to finance the program or from pharmaceutical firms paying for the CME speaker's fees or from speakers and CME providers with other financial ties to drug firms. These conflicts can bias the information that physicians receive and influence their prescribing.

In most countries, pharmaceutical firms play a major role in financing CME, often providing discretionary grants on topics they choose. They can thereby promote programs on topics related to their products. CME funders sometimes can also affect the choice of speakers at CME events and oversee the written materials used by speakers. This kind of pharmaceutical firm influence affects the content of materials presented. In some countries, drug firms also reimburse travel expenses of attending physicians; financial support that creates opportunities to influence physicians.

Pharmaceutical Prescribing

In most countries, many pharmaceuticals are restricted to patients with a prescription from a designated professional. Physicians and other practitioners are supposed to prescribe medicines for the benefit of their patients. Yet, drug firms seek to influence prescribers. Drug firms often offer grants and gifts to prescribers or employ them as consultants to influence their prescribing choices.

Pharmaceutical Dispensing

In some countries, physicians and other prescribers can also dispense medicines, own pharmacies, or have ties with pharmacies (or facilities that dispense medicines). When prescribers earn income from dispensing medicines or from having financial ties to organizations that dispense medicines, this creates a conflict of interest. Under those circumstances, the dispensing professional can increase his income by changing his prescribing choices. For example, the professional might prescribe more medicines than necessary, or select one medicine over another to boost his own income.

Post-Marketing Drug Safety

Most countries rely on manufacturers to conduct post-marketing evaluation of their products and to report information on adverse reactions to national registration authorities. However, the incentives of manufacturers are often at odds with the interests of public safety. That conflict may cause them to invest insufficient resources to monitoring drug safety, to delay reports on adverse reactions and risks and to bias their analysis of risks.[13]

III. STRATEGIES TO ADDRESS CONFLICTS OF INTEREST

There are three main strategies used to address or cope with conflicts of interest (See Exhibit B: Conflicts of Interest: Intervention Points).[14] For the purpose of illustration, we will assume the individual with a conflict of interest is a government employee or public servant. However, this also applies to other individuals who have conflicts of interest and are employed in the private sector.

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[13] Marc A. Rodwin, *Five Un-Easy Pieces of Pharmaceutical Policy Reform*, 41 J. L. MED. & ETHICS 581, 584-85 (2013).

[14] *See The Future of Medicine*, *supra* note 3, at 207.

Exhibit B
Conflicts of Interest: Intervention Points

PREVENTION **-Before** public servant acts	**REGULATION** **-During** public servant acts	**SANCTIONS/RESTITUTION** **-After** public servant acts
Prohibit public servants from entering into situations with conflicts of interest **Disclose** conflicts of interest	**Supervise** conduct of public servants and limit their discretion	**Penalize** public servants for violations of trust **Compensate** those harmed if public servants abuse their trust

The first strategy is to *prevent the conflict of interest from occurring* or to *eliminate the conflict when it arises*. This can be done by organizing the work of government authorities in ways that preclude key actors from entering into situations in which they would have a conflict of interest. Alternatively, when individuals have a conflict of interest, the individual or their employer can eliminate the conflict.

The second strategy is to *regulate the conduct of key actors who have conflicts of interest*. This requires identifying key actors with conflicts of interest, then supervising their conduct. Overseeing the conduct of a conflicted actor can sometimes mitigate conflicts of interest. Reducing the discretion of key actors can decrease the risk that they will act in ways that are biased or breach their trust. Furthermore, if public authorities monitor the conduct of conflicted actors and suspect they have acted inappropriately, the authorities can overrule their decisions.

The third strategy is *to allow individuals to have conflicts of interest but to impose sanctions or provide restitution when public servants or publicly employed professionals have breached their duties*. This approach assumes that the risk of being sanctioned will deter individuals from breaching their obligations and that in any event, sanctions and restitution will provide adequate remedies when public employees breach their trust.

The advantage of policies that preclude conflicts of interest from occurring is that this approach avoids the risks that conflicts of interest create. However, rules that preclude conflicts of interest usually restrict many activities, some of which are beneficial. For example, a rule that prohibits public employees from engaging in any outside remunerative activity will preclude many conflicts of interest. However, it might also preclude governmental employees from supplementing their income from activities that do not create conflicts of interest. A public employee in the pharmaceutical affairs department will not have conflicts of interest when she spends her weekends writing magazine articles on films and popular culture.

A more nuanced approach is to eliminate conflicts of interest only after they arise. This approach restricts activities only when they are necessary to resolve the conflict. For example, an employee who reviews applications to market new medicines has a potential conflict of interest if they have a relative that works for Wonderpharma. When Wonderpharma submits an application to market a new medicine and the application is one the employee would normally review, the employee's potential conflict of interest becomes an actual conflict of interest. The disadvantage of waiting until a conflict actually arises is that such strategy relies on the ability to identify the conflict and take appropriate action. However, such conflict of interest might not be identified if administrators cannot monitor the financial interests of employees and the manner in which their work activities might affect their financial interests.

The advantage of employing policies that oversee conflicted actors is that these policies would not preclude potentially beneficial activities that might give rise to conflicts of interest. However, overseeing the activities of conflicted actors usually requires the use of significant resources, and it is difficult to properly execute.

The advantage of policies that rely on sanctions and restitution is that they avoid preclusion of wide categories of activities as a preventive measure. It also avoids expending resources to monitor the conduct of conflicted actors. However, the disadvantage is that it is often difficult to identify breaches of trust, and sanctions often fail to provide an adequate remedy. Moreover, while sanctions can provide a remedy for breach of trust, they cannot provide remedies when the effect of a conflict of interest is biased governmental decisions.

IV. SIX STEPS PUBLIC MANAGERS SHOULD TAKE TO COPE WITH CONFLICTS OF INTEREST

Step 1: Develop a Framework to Govern the Conduct of Public Employees and Private Sector Experts Who Advise the Government.

The first step is to develop policies and a legal framework that will govern the conduct of public employees and elected or appointed public officials. Such rules should apply to all public employees, not only those whose work concerns pharmaceuticals. It is possible, however, to have distinct rules for employees working in ministries concerned with pharmaceuticals.

Typically, after there is agreement on the basic policy, implementing the policy will require enacting legislation and/or the promulgation of administrative rules. These rules should set standards for the conduct of public employees and for private sector individuals who perform public functions, such as advising public officials or serving on government commissions. These rules can be part of civil service laws or separate laws that regulate the conduct of public employees and government officials.

These rules should set standards for the conduct of employees and therefore include provisions that are broader than merely setting standards for conflicts of interest. These rules should include legal requirements and codes of conduct or ethics that supplement legal requirements. These rules should include anti-corruption measures (such as prohibitions on accepting or paying kickbacks or bribes or other breaches of public trust) and should specify prohibited activities because they are incompatible with certain public employment and public service. For example, the rules should restrict public employees from accepting gifts from parties affected by their work; they should also preclude employees from operating a business enterprise that contracts with the government. These rules might also prohibit public employees from exercising leadership positions in a political party or in an organization that seeks to change government policy on matters related to the employee's work.

Rules for public employment should restrict employees from participating in activities that create conflicts of interest. The rules *should prohibit* public officials from engaging in certain conduct and from having certain financial ties that create conflicts of interest. Other parts of this article provide examples of the kinds of activities that can be restricted (See Box 1: Sources of Conflicts of Interest for Public Employees). It is unlikely that public employment rules will preclude all conflicts of interest. Therefore, policies are needed to address conflicts of interest as they arise. Furthermore, rules are needed to govern the conduct of individuals employed in the private sector who serve on governmental advisory boards or who perform other public functions.

A public servant's post-employment work can create conflicts of interest in three ways. First, public employees can provide favors to a regulated firm or to the industry more generally and in return receive a highly paid position in that industry after the employee leaves government service. An explicit offer of employment after leaving public office in return for a favor from a government official violates many public corruption laws. However, public officials do not have to make an explicit agreement; they might offer favorable treatment to pharmaceutical firms in expectation that the favor will be returned after they leave government service. Second, public officials often obtain confidential information that is valuable to the regulated industry and use that information to obtain lucrative post-public sector employment that relies on their knowledge of such confidential information. Third, public employees often develop personal relations with other officials, and a wide range of contacts with decision-makers. These employees can sometimes use these contacts and relationships after leaving government service to help regulated parties influence policy decisions. To address these problems many nations regulate certain activities of individuals after they leave public employment.

Step 2: Develop Measures to Implement and Enforce Conflict of Interest Policy.

Public authorities need a mechanism to *implement conflict-of-interest policies* because they do not implement themselves. These mechanisms should include programs to educate and train public employees regarding legal standards, compliance, and how to resolve conflict-of-interest problems.

Policies that lack enforcement mechanisms have little value. There need to be public officials who are responsible for enforcing the conflict-of-interest rules. If responsibility for overseeing conflicts of interest is delegated to government officials with numerous responsibilities, these officials will often focus their attention on other matters and neglect conflicts of interest. Therefore, it is preferable that the public officials charged with this task make implementing and enforcing conflict of interest policies their sole or primary responsibility.

There must be consequences when government officials (or private sector actors who perform some other public function) violate conflict-of-interest policies. First, there must be means to challenge and rescind governmental decisions when the responsible actors failed to comply with conflict-of-interest rules. If a governmental commission included members who violated conflict of interest rules, then the decision of the commission should be deemed to lack legal authority.

Disciplinary consequences are also required for public officials who fail to declare their financial interests or who report false information. These consequences can include negative employment evaluations, restrictions on promotions, removal from public employment or office, monetary fines, or criminal penalties. There also must be a means to discipline individuals employed in the private sector who violate conflict of interest rules when serving on governmental commissions or advisory boards.

Step 3: Develop Measures to Promote Ethical Conduct and Voluntary Compliance.

There should be codes of conduct and other measures to promote compliance with policies that require employees to report their personal financial interests and to avoid activities that are incompatible with their government position. Voluntary compliance is not a substitute for a system of legal and administrative rules to enforce these standards, but it is a useful supplement. An ethical culture is an important component in making conflict-of-interest policy effective because there are limits on what the law can achieve without most employees making good faith efforts to comply.

For this reason, governmental authorities should create an organizational culture that promotes these values.[15] As part of this effort, employers could develop codes of conduct or ethical codes for employees and train employees on how to comply. There also need to be laws that protect whistleblowers, individuals who report unlawful, dishonest, or corrupt governmental activity. Without such protection, many employees will be not report misconduct because they fear that powerful government officials will retaliate and jeopardize their careers.

Step 4: Require Key Actors to Declare their Financial Interests.

In order to manage conflicts of interest, it is necessary to identify them and that requires information about the work that public employees perform, their personal financial interests, and their activities outside of

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[15] WHO, *Good Governance for Medicines: A Model Framework* (2014), http://apps.who.int/medicinedocs/documents/s21548en/s21548en.pdf.

their employment that can create conflicts of interest.[16] Therefore, public policy should *require* that certain employees report to authorities on a regular basis, information on their financial interests, and activities that could conflict with their work duties. Bear in mind, disclosing financial interests does not eliminate or cure any conflict. Declarations of interest are not an end in themselves, but they are necessary to identify and manage conflicts of interest.[17]

All public employees who exercise administrative, managerial, or policymaking responsibilities, or who perform professional roles, should report certain interests using a standard form. The forms should enumerate the specific categories of interests that employees must declare. These interests should include both the interests of the public employee and also those of their immediate family members.[18] Individuals should file declarations of interest on an annual basis and, in addition, whenever they assume major new job responsibilities, or their personal financial interests undergo a significant change. (See Box 2: Declarations of Interests.)

Governments should also require declarations of interest by private sector employees who serve on government commissions or advisory boards or who advise the government in other contexts. These individuals should complete declaration forms developed by public authorities that report the same information from public employees.

Employees should disclose financial interests: income, gifts over a nominal value, investments, and ownership interests. Income should include money, in-kind benefits, and other items of economic value. Employees should also declare activities outside of government employment that could conflict with their work duties. These activities could include certain uncompensated working relationships such as serving on boards of corporations or not-for-profit organizations, and significant work for political parties.[19]

Some conflict-of-interest policies only require employees to declare interests that directly relate to their employment duties or the activities of the ministry in which they work. The rationale is that interests not directly

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[16] *See, e.g.,* U.S. Department of Health and Human Services, *Financial Disclosure by Clinical Investigators* (February 2013), https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf.

[17] *A Toolkit*, *supra* note 3, at 27.

[18] 18 U.S.C. § 208 (a) (2012).

[19] 5 C.F.R. § 2635.502 (a)(2)(b)(1)(iv)-(v) (1992); 5 C.F.R. § 2635.502 (a)(2)(b)(1)(iv)-(v) (2017).

related to an individual's work duties are irrelevant and cannot create a conflict of interest. Such policies effectually reduce the information required to be disclosed and protect employee privacy.

However, merely asking employees to decide whether a personal interest is relevant to their work entails risk. Employees often fail to see the relevance of a financial interest that is apparent to officials charged with overseeing conflicts of interest. Moreover, declarations of interests sometimes reveal a potential conflict of interest that can later become an actual conflict. Unless the potential conflict of interest is identified it cannot be managed. Most important, when individuals do not report personal interests because they consider them irrelevant, that precludes an objective review of whether a conflict of interest exists. Therefore, it is preferable to require declarations of all interests. It is the responsibility of governmental authorities, not the employee who files the declaration, to determine whether an employee has a conflict of interest, and how it should be managed.

Step 5: Identify Individual and Institutional Conflicts of Interest.

Individual Conflicts of Interest

Designated officials need to analyze declarations of interest filed by employees in order to identify potential and actual conflicts of interest. The officials who review these declarations should be trained to identify conflicts of interest. These officials can include an attorney working in the government's office of legal affairs, a compliance officer, or an official designated to oversee the ethics of governmental personnel. The reviewers should distinguish between financial interests that are related to the employee's work and those that are not. Some governments prohibit all outside employment or remunerative activity while others allow employees to engage in certain limited outside employment (See Box 3: Analyzing Conflicts of Interest Check List).[20]

Identifying conflicts of interest requires examining the individual's work responsibilities in relation to their personal interests and outside activities. The first step is to identify the employee's duties and the activities of the ministry in which the employee works. Employees can have

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[20] 5 U.S.C. § 502 (2011); Jack Maskell, *Outside Employment, "Moonlighting," by Federal Executive Branch Employees*, CONGRESSIONAL RESEARCH SERVICE (December 12, 2012), https://fas.org/sgp/crs/misc/R42857.pdf.

conflicts of interest when they are involved in government decisions such as setting general policies, granting authorization to market pharmaceutical products, approving the conduct of pharmaceutical firms through inspection of manufacturing, or participating in the awarding of contracts and licenses or permits. Employees can also have conflicts of interest when they have access to confidential information.

It is important to examine the scope of an employee's duties. Certain high and middle-level employees can affect government policy on a wide range of matters. They might also be able to exercise power or influence over other employees. When these employees have conflicting outside interests, it can affect a broad scope of government activity. In contrast, other employees often have a narrowly defined scope of responsibility and authority and can affect governmental decisions only on limited matters. They have fewer opportunities for conflicts of interest than when an employee exercises broad authority.

After identifying the kinds of decisions that the employee can influence, responsible officials should examine the employee's declarations of interest to learn whether the employee has personal financial interests or engages in outside activities that might give rise to a conflict of interest. (See, Box 1: Sources of Conflicts of Interest for Public Employees.) Responsible officials should look at the individual's: 1) Personal financial interests; 2) Financial interests and activities of family: including their spouse, betrothed, or individual with whom they cohabit; their parents; siblings and children; 3) Gifts; 4) Employment outside of public service; 5) Appointments outside of governmental work; 6) Employment after leaving government service.

Declarations of interest can reveal financial ties arising from ownership and investment that can create conflicts of interest. Employees who earn income from ownership, investment, royalties, or patents related to pharmaceuticals cannot play a neutral role in making decisions related to the enterprises that generate that income. The issue that reviewers then need to ask is whether the employee participates in work that could affect those private enterprises and whether the employee's interest in the private enterprise can affect their public employment activities.

Declarations of interest might reveal that the employee has a conflict of interest arising from the interest of a family member of the employee. The public employee's loyalty to their family might bias the public employee to favor the interests of a relative.

Declarations of interest can also reveal that employees have received gifts or grants from businesses related to the employees' work or from individuals employed in those businesses. Some governments prohibit public employees from accepting any gifts. When public policy does not prohibit all gifts, they typically require their disclosure so responsible officials can respond appropriately.

Most nations prohibit public employees from accepting gifts of any value from individuals or firms engaged in activities related to the employees' work.[21] However, some nations allow certain kinds of gifts or grants to support publicly employed physicians, researchers, or other employees. For example France allows pharmaceutical firms to pay for transportation and lodging for physicians to attend professional meetings and CME so long as the physician and pharmaceutical firm disclose the financing and they follow certain rules.[22] Typically, the funds must be used to finance the cost of participating in professional activities, such as attending professional meetings or training, or to finance research. Some nations allow public employees to accept business hospitality, such as a meal, if the value falls below a certain threshold.

Some governments prohibit public employees from engaging in any remunerated outside employment. When government employees are permitted to engage in limited outside employment, certain work can create conflicts of interest. For example, working part-time for a pharmaceutical firm will typically create a conflict of interest for employees in government ministries that oversee pharmaceutical policy. It could bias the employee to favor the pharmaceutical firm when he or she makes governmental decisions. In contrast, working part-time for an enterprise outside the pharmaceutical sector would typically be unrelated to the employee's work and would not conflict.

In some situations, it will be necessary to examine the outside employment closely to determine if there is a conflict of interest. When an employee works part-time for a law firm or consulting organization, that

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[21] *See* Eric Raile, *Managing Conflicts of Interest in The Americas: A Comparative Review*, UNITED STATES OFFICE OF GOVERNMENT ETHICS (April 15, 2004), https://www2.oge.gov/web/oge.nsf/0/63AFE8A872F928F285257EA6006557B4/$FILE/36d75c57a708473ca786a10c264797783.pdf; OECD, *Managing Conflict of Interest: Frameworks, Tools, and Instruments for Preventing, Detecting and Managing Conflict of Interest* (2008), https://www.oecd.org/site/adboecdanti-corruptioninitiative/40838870.pdf; *The Future of Medicine*, *supra* note 3, at 11-16.

[22] Marc A. Rodwin, *Reforming Pharmaceutical Industry-Physician Financial Relationships: Lessons from the United States, France, and Japan*, 39 J. L. MED. & ETHICS 662, 663 (2011).

work does not necessarily concern pharmaceutical matters related to the employee's government employment. However, if the law or consulting work concerns pharmaceutical issues, then there might be a link. Reviewers need to probe which firms and types of businesses the law or consulting firms serves and the matters on which the employee worked.

Declarations of interest might also reveal certain unremunerated activities that create conflicts of interest. For example, a government employee who serves on the board of a firm or not-for-profit organization can develop relationships with those private sector entities that could lead the employee to favor that organization. This typically creates a conflict of interest if the ministry in which the employee works regulates the private sector organization with which the government employee is affiliated.

Responsible governmental authorities also need to review the post-employment activities of certain government employees to determine if they comply with conflict of interest rules. These reviews are not, strictly speaking, a review of declarations of interest in the same sense as public employees. More often it will be a statement indicating the former employee's current employment, their work responsibilities, and a statement that they have complied with rules on post-government employment. For example, governments often restrict employees for a designated number of years from representing any private sector actor in matters before the agency in which the former employee worked.

Institutional Conflicts of Interest

These are the five steps needed to identify an institutional conflict of interest: 1) Specify the organization's mission and its activities; 2) List the organization's financial interests and its source of funds (including all revenue, grants, royalties, and ownership interests; 3) List the organization's affiliations with other organizations; 4) Review the institution's mission, activities, financial interests, and affiliations to see if there are potential conflicts among them; 5) Finally, ask whether combining these activities could compromise performance of any one of them. Also ask whether the institution's financial interests could bias the performance of its activities or pursuit of its mission.

Step 6: Resolve or Manage Conflicts of Interest

Assess the Significance of a Conflict of Interest

Conflicts of interest are widespread; their potential impact is sometimes difficult to assess. Some are minor and can be ignored without much risk of harm. But there is no simple way to determine to what degree a conflict of interest compromises an individual's loyalty, judgment, and fulfillment of their obligations. In each case, we must review the facts and context to reach a conclusion. When a declaration of interests reveals a potential or actual conflict of interest, then officials have the responsibility to assess the significance of the conflict and decide what action to take.

Some financial conflicts of interest are more serious than others. We can reasonably expect that the risk posed by compromising financial ties increases as the amount of money involved increases. As a practical matter, public policy often accepts the presence of certain small financial conflicts of interest in order to focus on more significant conflicts. However, research shows that even small gifts and financial ties often create feelings of gratitude and generate reciprocity.[23] Hence, there are also grounds to restrict the existence of small ties.

We need to ask several questions. How strong or direct are the conflicts? What is the probability of inappropriate behavior? What kinds of risk are posed? How serious might the consequences be? What effect would measures to eliminate or manage the conflict have on other goals?

Some employees might play such an important role in decision-making that it is prudent to manage even their *potential* conflicts of interest in order to avoid likely problems if an actual conflict of interest arises. However, not all potential and actual conflicts of interest are of the same importance. In some cases, the responsible official might conclude that the conflict of interest is so small that no action needs to be taken aside from disclosing the conflict in the name of transparency.

When a significant conflict of interest arises, however, public officials need to take action to either resolve or manage the conflict. It is often tempting for responsible officials to assume that rules on conflicts of interest should be waived because the government employee or private sector expert is essential and there is no way to resolve or manage the conflict of interest. In most cases, this is not true. There should be few if any waivers of rules and when they occur, the basis for the decision should be justified in writing and made public.

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[23] *See* Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 J. AM. MED. ASSOC. 252, 254 (2003); Dennis T. Regan, *Effects of a Favor and Liking on Compliance*, 7 J. OF EXPERIMENTAL SOC. PSYCHOL. 627, 631 (1971); Hershey H. Friedman & Ahmed Rahman, *Gifts-Upon-Entry and Appreciatory Comments: Reciprocity Effects in Retailing*, 3 INT'L J. OF MARKETING STUD. 161, 163 (2011).

Resolve Individual Conflicts of interest

Two main strategies can be employed to resolve a conflict of interest: A) change the compromised employee's relationship to the private interest; B) change the compromised employee's work activities.

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

- Divest the private ownership interest

The employee can sell their ownership or investment interest in the private entity. Severing the financial ties eliminates the conflict of interest.

- Terminate the relationship with the private entity.

The employee can resign from the board or cease other relationships with the private entity in order to end the conflict.

- Place the employee's investment interests in a blind trust

The employee's stock or other investment can be placed in a blind trust managed by an independent party that has no contact with the public official. This will prevent the government official from controlling their investments while the official is in a position to make decisions that can affect those investments. The trustee has authority to manage the investment portfolio through sales and purchases but cannot consult with the public official. This option is typically used for high-level public officials who own stock in publicly traded firms.

B) Change The Compromised Employee's Work Activities

- Resign: The official can end his public employment and thereby end the conflict.
- Recusal: The public official can withdraw from participating in any governmental decisions that can affect her private financial interest.[24]
- Reassign work duties: The employee's duties can be changed so that the official does not work on activities that can affect her private

[24] Recusal are an effective tool when the conflict of interest will occur very infrequently.

interests. The employee can be reassigned to work in a different division or her work duties can be modified in other ways.

- Restrict access to information: The government can limit the employee's access to information that might be used to advance her private interests. Typically, when government officials work on general policy and regulatory matters it makes sense to preclude their conflicts of interest. The reason is that it is difficult to separate particular work activities and decisions that can affect the official's private interests from work activities that do not. It is therefore not administratively feasible to cope with the conflict by restricting only discrete employment activities. Resolving the conflict requires severing the employee's financial tie to the pharmaceutical firm or changing the employee's work responsibilities.

In contrast, when public employees do not work on general policy matters but work on making discrete decisions that only concern particular firms, it is often possible to distinguish *potential* from *actual* conflicts of interest. This makes it feasible to change the employee's work responsibilities in order to preclude a potential conflict of interest from becoming an actual conflict of interest.

Sometimes government policies restrict public employees who work in a regulatory capacity from having any financial ties with a regulated industry to preclude even potential conflicts of interest. Alternatively, governments could minimize restrictions and permit financial ties that create potential conflicts of interest if it is possible to separate the employee's activities that can affect the firms with which they have a financial tie from activities that will not affect the firm.

Resolve Institutional Conflicts of interest

Institutional Conflicts of interest can be resolved in the following ways:

- Change the intuition's responsibilities to eliminate conflicting roles;
- Terminate the institution's financial ties that create a conflict of interest.

Manage Conflicts of Interest

When it is not feasible to resolve conflicts of interest, they can be managed to reduce the risk of bias or misconduct. There are two main ways to do so.

1) Oversee the Work of Conflicted Public Employees

One option is to oversee or supervise the conflicted employee to reduce the risk that the employee will abuse the public's trust. The employee's supervisor can check on her performance and modify her decisions if the employee acts inappropriately. It is worth noting that this kind of supervision is costly, burdensome, and difficult to do well. There is a significant risk that the planned oversight will be done ineffectively.[25] Furthermore, written plans for supervision can create the appearance that the conflict of interest is being effectively managed when in fact it is not. Supervision as a safeguard is used with varying degrees of success in two contexts outside of public employment.

First, American universities oversee the conflicts of interest of clinical researchers who have financial interests in the research.[26] The preferred practice is to bar individuals who have financial interests in a particular medicine or method of therapy from conducting research to evaluate the therapy. However, sometimes the university allows the individual to participate in the research subject to certain restrictions. For example, the conflicted researcher might be allowed to play a role in the research but not be allowed to direct the project. Alternatively, the university might set up a committee to monitor the research and data produced.[27] If the conflict of interest can affect the enrollment of human research subjects the university might require the presence of a patient representative to monitor the process of enrolling research subjects and obtaining their consent. However, the effectiveness of these practices remains unevaluated and there is significant reason to believe that they often are not effective.[28]

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[25] *See* Joel Lexchin & Orla O'Donovan, *Prohibiting or Managing Conflict of Interest? A Review of Policies and Procedures in Three European Drug Regulation Agencies*, 70 SOC. SCI. & MED. 643, 643-47 (2010).

[26] Marc A. Rodwin, Conflicts of Interest in Human Subject Research, HUMAN RESEARCH ETHICS AND THE DECLARATION OF HELSINKI (forthcoming 2019); Susan H. Ehringhaus et al., *Responses of Medical Schools to Institutional Conflicts of Interest*, 299 J. AM. MED. ASSOC. 665, 667 (2008).

[27] Bernard Lo & Marilyn J. Field, *Conflict of Interest in Medical Research, Education, and Practice*, IOM (2009), http://www.kumc.edu/Documents/coi/TOC.pdf.

[28] *See Id.*; Leslie Z. Benet, Presentation to the Institute of Medicine Committee on Conflict of Interest in Medical Research, Education, and Practice: Perspectives on Financial Relationships and Conflicts of Interest in Basic and Early Stage Translational Research: Reflections on 28 years of Organized COI Experience at UCSF (May 22, 2008).

A second example of managing conflicts of interest arises in the case of American insurers. Physicians paid fee-for-service often have a conflict of interest because they have a financial incentive to prescribe the services that they provide. In response to this common situation, American insurers created or adopted practice guidelines. The health insurers then appoint utilization reviewers to determine whether physicians have prescribed services or medications that do not conform to practice guidelines. The insurers typically have the authority to overrule the clinical choices of these physicians or to refuse payment for services deemed medically unnecessary according to medical practice guidelines.[29]

The system of utilization review by private health insurers described above is rarely used outside the United States. Instead, many countries have adopted WHO standard treatment guidelines for therapeutic use of medications.[30] Many nations use these standard treatment guidelines to restrict the use of medications through pharmaceutical formularies in public hospitals and national health insurance systems.

2) Minimize the Role of Conflicted Actors

If a conflicted individual participates in a group that makes a decision, the conflicted individual's influence decreases as the number of people who participate in the decision increases. Consider, for example, a conflicted expert who serves on a commission to recommend whether to approve marketing of a medicine. The conflicted expert's vote will have greater weight if five rather than twelve individuals serve on the commission. Reducing the number of conflicted experts that serve on a commission decreases the risk that bias will determine the results. Nevertheless, the conflicted expert can also influence the outcome by convincing others who serve on the commission to adopt her point of view, so conflicted individuals have more influence than their vote alone.

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[29] Marc A. Rodwin, *Conflicts in Managed Care,* 332 NEW ENG. J. MED. 604, 604-05 (1995); *See* Marc A. Rodwin, Physicians' Conflicts of Interest in HMOs and Hospitals, CONFLICTS OF INTEREST IN CLINICAL PRACTICE AND RESEARCH 197, 198 (1996).

[30] *See, e.g.,* Standard Treatment Guidelines and Essential Medicines Lists, *at* http://siapsprogram.org/approach/pharmaceutical-services/essential-medicines-lists/;

See generally WHO, *The Selection and Use of Essential Medicines: Report of the WHO Expert Committee* (2015), http://apps.who.int/medicinedocs/documents/s22190en/s22190en.pdf.

Manage Institutional Conflicts of Interest

Institutional conflicts of interest are more difficult to manage than individual conflicts of interest because organizational leaders often have their own professional interests aligned with the institution's short-run interests. They are therefore likely to find it challenging to take actions that restrict organizational activities that create the institutional conflicts of interest. Institutional leaders can try to address this problem by appointing managers without conflicts of interest to manage the institution's conflicts of interest. They may employ the following strategies:

- Create firewalls that separate the functions of different parts of the organization that have conflicting functions or financial interests;
- Limit contact between individuals who work in different divisions of the organizations that have conflicting interests and financial interests.

CONCLUSION

This article outlined twelve areas in which conflicts of interest compromise pharmaceutical policy and practice and six steps policymakers should take to identify, eliminate, or manage such conflicts. Many conflicts of interest can be eliminated or managed when they are identified. However, effectively coping with conflicts of interest requires the existence of a legal framework, institutions to oversee conflicts of interest, a clear strategy, and resources to implement these public policies.

Appendix:

Conflicts of Expert Advisors in the Private Sector

Frequently, governments seek the help of experts who are not public employees to advise them on various issues, including: 1) whether to approve the registration, marketing, and sale of a new pharmaceutical product (and if so on what terms); 2) whether to add a pharmaceutical product to a list of essential medicines or a formulary list that determines which medicines will be available at public hospitals and clinics; or 3) the level of reimbursement the government should pay for purchase of a pharmaceutical product. The government will often appoint these individuals to serve on governmental commissions or advisory boards. When these individuals advise the government, they perform a public function and are supposed to act on behalf of the public. However, because they work in the private sector, they might have financial ties with pharmaceutical firms that create a conflict of interest. These financial ties can include employment or consulting with a pharmaceutical firm, receipt of research grants, or gifts from a pharmaceutical firm or from a foundation affiliated with a pharmaceutical firm.

To avoid conflicts of interest, rules should restrict who can serve on advisory boards. The rules should exclude employees of a firm that manufactures, sells or markets pharmaceutical products as well as individuals who have financial ties with a firm whose products might be affected by decisions of the advisory board.

When a government advisory board meets to determine whether a firm should be allowed to market a new medicine, the board should not include any former employee of that firm. Similarly, the board most likely should not include any individual who has worked for a firm that markets a medicine or that competes with the firm seeking to market the new medicine. When developing a list of products to be included in a medicine formulary or list of essential medicines, the government commission should not include experts who have worked for a firm whose products might be included on the list. When a commission makes recommendations on reimbursement for the sale of a medicine, the best practice is for the commission to exclude individuals who have worked for the firm that manufactures that product, or who have worked on a competing medicine.

Government officials sometimes seek to waive rules that exclude conflicted actors because the actors have special qualifications that are difficult to find and because they believe the conflict of interest is small and will not have any effect on the actor's conduct. Certainly, having a large financial interest in a matter presents a greater risk than a small one. Therefore, it often makes sense to establish a financial threshold below which income from a pharmaceutical firm will not preclude an expert serving on a commission. Likewise, rules might ignore financial ties from work many years in the past on the grounds that they will not have any effect on the individual's conduct.

Nevertheless, studies on the effects of gifts and other financial incentives reveal that they can create bias even when they are small. Furthermore, individuals with an existing working relationship with a pharmaceutical firm (even if the work only generated modest revenue and occurred several years ago) might want to avoid taking action that could damage that relationship and jeopardize future consulting income. Therefore, it is preferable to bar individuals with conflicts unless there is no alternative.

Sometimes administrators believe that they cannot find individuals without conflicts of interest to advise them. This is rarely, if ever, true. For example, the kind of expertise needed to serve on an advisory board that evaluates whether to approve the marketing of a new medicine, does not require expertise in the medicine or the disease it treats, although that might be helpful. Typically, what is required is the ability to evaluate medical studies and literature, and to critically evaluate claims of the medicine sponsor. Many more individuals will have that expertise than specialized knowledge in a particular medicine or illness. Furthermore, if unconflicted experts do not reside in the locality, it is possible to engage the services of an expert who lives outside the nation.

BOX 1: CONFLICTS OF INTEREST OF PUBLIC EMPLOYEES

1) *Personal Financial Interests, Investment and Ownership Interests*
    - The employee's investment and ownership interest or other financial interests that conflict with work duties can be a source of conflicts of interest. There is a risk that an official who invests in or owns an entity that can be affected by her work will use her work position to favor their investment interest.
2) *Family Members' Financial Interests And Activities*
    - The employee's family members' financial interests and affiliations can be a source of conflicts of interest.
3) *Gifts and other Benefits from Private Interests*

- Public officials who receive gifts, grants, favors, or other benefits from private entities might act to help those private entities.

4) *Supplemental Private Employment*

- Sometimes the law allows public employees to engage in part-time employment or other remunerative activity in the private sector. Some of these private remunerative activities can interfere in the official's performance of her public duties.

5) *Private Sector Appointment and Performing Unpaid Work for Private Entities*

- Public officials might serve on a board or advise a private entity without compensation on matters that concern their work activity. There is a risk that the officials will use their access to government information to favor one entity over another or that in performing their public duties the public official will favor the entity with which they have an affiliation.

6) *Post-Governmental Employment*

- Employment after leaving government service can create a conflict of interest in two ways. First, while working in the public sector, the official might try to secure a job in the private sector by granting special favors to a regulated firm. Second, after leaving public service, the public official might use confidential information obtained while publicly employed to benefit the private firm.

BOX 2: DECLARATIONS OF INTERESTS

The declaration forms should ask employees to disclose for themselves and their family the following interests. The employee answer should indicate the purpose of the private entity and its activities. The form should specify any activities that are related to the employee's work, namely work on pharmaceutical matters.

Ownership and Investment Interests

- Real estate (excluding family home)
- Ownership or shares in private companies (sole proprietorships, partnerships, limited partnerships, stock ownership, other investments interests)
- Patents

Income generated through work or contracts with firms in private sector

- Part-time employment
- Consulting
- Royalties
- Corporate distributions
- Serving on boards
- Honoraria
- Fees for speaking
- Contracts that have generated or can generate other income

Loans from entities other than banks, credit unions

- Loans from private firms

Gifts from firms or individuals employed by a business related to the employee's work

- Cash
- Goods or objects worth more than $20
- Meals worth more than $20
- Transportation provided by private entities or travel expenses reimbursed greater than $20
- Other business hospitality and entertainment

Affiliations with Firms and Not-For-Profit Organizations

- Directorships
- Appointments
- Leadership positions

Family Members (Spouse or domestic partner, parents, siblings, children)

- Employment or business activity of immediate family members. For purposes of disclosure, family members should include individuals to whom they are betrothed or with whom they cohabit.

BOX 3: A CHECK LIST TO ANALYZE CONFLICTS OF INTEREST

I) Is there a conflict of interest?

1) Who is the actor and what is his/her designated role?
2) To whom does the actor owe a legal or ethical duty?
3) What is the nature of that duty or obligation?
4) Does the actor have a financial tie, a secondary activity or a secondary role that creates a risk that the actor will not fulfill her duty?
5) When the actor exercises professional discretion, can the actor promote his/her own financial interest or the financial interest of a third party?

II) How significant is the conflict of interest?

1) Is the financial incentive for the actor so strong that it may cause him to behave in ways that promote his/ her own self-interest or that of a third party?
2) How much discretion does the actor have in making professional decisions?
3) What are the potential risks/ harms that can result if the actor is biased in exercising his/ her discretion or the actor violates his/ her duties?

III) What policy options exist to eliminate, mitigate, or help manage the conflict of interest?

Consider at least these kinds of options:
1) Changes in the organization and financing of medical care;
2) Separation of professional roles or activities;
3) Restrictions on having certain financial ties or relationships;
4) Oversight of professional activity to reduce discretion or monitor performance;
5) Disclosure of financial ties to allow patients and other parties to protect themselves or to facilitate monitoring and management of professionals with CI;
6) Remedies after a breach of duties (such as restitution to individuals harmed an penalties for individuals who violate their duties).