Managing conflicts of interest and commitment: academic medicine and the physician's progress

Norman J Kachuck

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The policy changes governing the relations between the pharmaceutical, medical device and service industries ('the commercial sector') and academic clinical research physicians, recommended by the Institute of Medicine,[1] the American Academy of Medical Colleges,[2] and much discussed in the media and on our campuses, aim to create some protective ethical firewalls. However, some potentially critical consequences of these steps are missed if we do not acknowledge what else is on the table, and who is sitting at it.

By only reacting defensively to the juggernaut of righteous indignation over the loss of purity in a faculty physician's approach to medical problem solving, we are allowing the process to blind us to the difficulties in establishing fair and equitable management of all of the potential conflicts of commitment and conflicts of interest we incur, not only as faculty members, but also as departments and academic medical centres (AMC). Critically, this involves all sources of revenue—private, commercial and public—that support our professional and institutional commitments as well as our personal finances.[i] To counter the present crackdown on inappropriate financial relationships effectively, we will need to reframe the questions, and convince all stakeholders to the process that there is more to this crisis than can be resolved through our public confessions of commercial largesse obliged.

The Phrma Code guidelines[3] have resulted in what is believed to be a defensible, if as yet legally untested, compartmentalisation of the commercial sector's marketing, medical education and research sponsorship activities. We at the AMC are a long way from understanding how those same missions, as they emanate from our multifarious commitments, can be isolated and individually managed. Defining the parameters for establishing institutional conflicts of interest and commitment are beyond our essay's scope, but with the very public emphasis on capitalist subversion of the decision-making abilities of the academic clinical research physician, we have had opportunities aplenty to deconstruct the hapless physician at the output end of the therapy—production 'food chain'.[4–11] Along with an increased understanding of our role in the financial structure of the modern AMC, a deeper crisis looms. Many believe, as I do, that this controversy arises out of our failure to maintain society's confidence and trust in the moral authority of the physician as healer and educator.This larger context for this discussion will need to await a future forum for its full extrapolation.

STEPPING BACK WHILE DRILLING DOWN: A QUICK PRIMER ON CONFLICTS OF INTEREST AND COMMITMENT

All professionals in our society, including physicians, have a primary interest—the goal of their profession, but that primary interest is divisible into commitments that may or may not be equally weighted at all times and all places. Table 1 shows a way to visualise these primary and secondary interests. Ethical issues often arise in the relationships between primary and between secondary interests. A conflict of commitment occurs when primary interests are discordant, and when we assume roles that may have overlapping, but not identical, primary interests. A conflict of interest occurs when a secondary interest compromises the integrity of judgements related to primary interests. It is also important to note that secondary interests can be non-financial. We are not worried solely about the effect of money. Power, glory, and the other secondary interests can also compromise judgements related to the primary interests. History has hopefully made it clear that zealotry, even in the ostensibly virtuous pursuit of the good and the right, may be more dangerous to our wellbeing than wealth, or even power.[ii]

No one of us is without these potential conflicts of interest/commitment; they come with the territory and are an inherent—and necessary—part of our lives as academic clinical research professionals. They cannot be totally eliminated, and no amount of evidence-based expertise is going to expunge them from the ethical equation calculating their probity. The goal is to manage them, rationally and ethically.[3]

THE CONSEQUENCES OF ALL OF OUR COMPENSABLE ACTS

What are the risks to our patients and ourselves when we do not perform due diligence on conflicts of interest/commitment? The dangers are clear and present, and there is no doubt that they need to be identified and managed on both individual and collective bases, but are these issues really exclusive to this relationship of academia with the commercial sector? Is it possible that we brought similar attitudes and behaviours to other relationships in which there are possible conflicts of interest/commitment?

Widening the focus on relationships between physicians, AMC and our revenue sources, an as-yet-unnamed critically important player comes into view—the government. At our medical school, one does not have to delve very far into the economics of the institution to identify potential conflicts of interest/commitment, and perceive a possible double standard as regards the way that the institution values and prioritises revenue streams that support infrastructure and clinical faculty salaries.

The money that drives the economic engine of the modern AMC is generated

Correspondence to Dr Norman J Kachuck, University of Southern California Keck School of Medicine, 1520 San Pablo Street, Suite 3000, Los Angeles, CA 90033, USA; nkachuck@usc.edu

[i]There is more to being a physician than being the delivery end of the government—industrial medical complex. This argument for the consideration of what constitutes the requisite and unique sources and justification of the moral authority of physicians will be discussed in further contributions to this journal, and is the subject of an editorial by the author, from which some of the material for this commentary is redacted.[12]

[ii]I am indebted to Ezekiel Emanuel, MD, PhD, for his permission to modify his presentation on this subject for this publication.

Table 1 Conflicts of commitment and conflicts of interest in academic medicine

	Conflicts of interest		
	Role	**Primary interest & commitments**	**Secondary interest**
Conflicts of commitment	Physician Academician	Health of patients Train and educate Conduct research Serve the Service/Department/ Institutional Mission	► Intellectual ► Emotional ► Financial ► Psychological ► Spiritual ► Recreational
	Researcher	Increase generalized knowledge of field	► Family ► Sociopolitical and community priorities
	Clinical researcher	Safety/Protection of subjects Enforce Common Rule: respect, beneficence, justice	► Validate research design ► Conduct meaningful research ensuring data integrity ► Ensure proper dissemination of results

from diverse sources: federal, state and municipal grants; tuitions; contracts for hospital and clinic staffing; private and government insurers, health plans; discretionary accounts derived from charitable endowments, grants, bequests and awards. These revenue streams are often cobbled together faculty member by faculty member, programme by programme, year to year, to create salaries and infrastructure development and maintenance.

These sources are often deemed 'internal' or 'external' to the parent institution, apparently to differentiate the non-vitiating from the vitiating. Making that distinction appears more and more arbitrary as finer levels of detail are sought. To the outside observer, it can seem that the more hands such revenue goes through, and the more 'laundered' and disconnected that revenue's provenance is from its ultimate use, the more 'internal' a funding source seems to become. Money trickles through the system, and in a process that apparently cleanses it of any ethical opprobrium, becomes the operating capital of the institution, the budget of the departments, and the salaries of the faculty.

To the extent that federal research funds are awarded to the institution and not to individual faculty members, they are given 'internal' status. This is often also true for many charitable donations and endowment sources. So far, practically all of the controversy about relations between academic physicians and the commercial sector arises from 'external' sources. The implicit supposition being made by the institution, the media, concerned medical students, and congressional interrogators, is that the less 'internal' a source is, the more likely it is to be associated with a conflict of interest/commitment.

Is this really a valid argument? I believe we can disprove its premise; but first, a note of caution, as philosopher Baruch Spinoza would demand when following an argument to its logical conclusion.In painting our sources of support with such a broad brush, we are potentially invoking a 'plague on all of our houses'. There is some wisdom to being careful for what you wish; opening this Pandora's jar to examine the propriety of our funding sources may reveal problems that, until resolved, may jeopardise our academic mission. If money corrupts, then, to be transparent about when recusals and mea culpas are called for, we should be asking for disclosure of any and all sources of a faculty salary, because any of them might theoretically incur bias. Money is money, fungible asset; it comes from somewhere, and it is being rained down on grateful academicians by people and institutions with mission statements, organisational goals and expectations for best use of their contributed assets. As important to our thesis, those with power, and the capacity to influence the politics of academic medicine that control the way we spend our time and resources, have identifiable conflicts of interest and commitment that may have a profound influence on our capacity to fulfil our personal and institutional goals ethically. It has been argued that equating compensation with conflict of interest inappropriately conflates these issues, and I agree that there is a 'Cromwellian' (more Oliver than Thomas) reformist aspect to the damning of any influence, especially an influence as fungible as money. On the other hand, there is some truth in even the most radical position, and we can learn about where that truth may benefit us by applying the extreme values to the variables and see where the model stops being useful.

DRILLING DOWN, AND HITTING… SLUDGE

We are assailed by headlines, media feeding frenzies, astonished AMC administrators and shamed doctors. The efforts of the US Senate Finance Committee, among others, have been admirable in ferreting out conflicts of interest occurring in our relationships with commercial sectors' marketing and drug and device development teams, but it has not been as interesting, evidently, or as easy, to identify the conflicts of interest/commitment when the money is funnelled through the institution in support of services, infrastructure and salaries. This is at least partially due to AMC not developing definitions of, or mechanisms of, disclosure for what constitutes institutional conflict of interest, which are integrated with the faculty conflict disclosure process. When promulgated, such policy is likely to cover ownership or rights to products or intellectual property developed by faculty, and not concern itself with how the institution's revenue streams could inappropriately influence its faculty's medical work.

Establishing the potential for ethical unsoundness of the 'internal' support is made difficult by the complexity of their paper trail through the AMC, from an origin in a general asset account to the point at which it pays some bill, as opposed to the relative simplicity associating an identified cheque written using 'external' funding. These sources are usually granted and registered by name to individual faculty members or programmes, and thus can be clearly associated more directly with support of an entity that, unlike the institution, may come under scrutiny by watchdogs and earnest congressional committees for violations of conflicts of interest regulations.

We see the consequences of this facile, erroneous simplification at its most onerous when sums are reported as having been 'paid' to a hapless faculty member from a commercial sector source. In truth, although deposited in that person's name, the 'direct' funds and, less easily seen, the 'indirect' budgeted amounts, are actually residing in the institution's accounts, and the institution's governors control both. Based on available funds and time-to-time budgeting requirements, these can be doled out to pay for a variety of programmatic and infrastructure costs, perhaps having nothing to do with the ostensible line items established for the intended programme until some accounting makes it all right… or never quite gets around to doing it. Audits able to trace a dollar's budgeted intent to its actual use may never be done or

scrutinised for ethical soundness in or out of the institution.

How do we establish how and if that dollar ostensibly for health research, be it from commercial, charitable or, as we will now explore, the government financing sources, impacts on the ethical aspects of the doctor–patient relationship? Federal and state-funded projects are filtered through review committees, and it is the time-honoured expectation that even controversial new ways of seeing the world and validating some new paradigm will survive the winnowing-out process, over and above petty issues of personality and allegiance to some theory, personality, or world view. Competition that favours some and not others is expected, and it can be freely admitted that faculty cannot all do what they desire, even if it would pass scientific and ethical litmus tests of acceptability.

On the receiving end, conflicts may arise in faculty members' institutions' need for infrastructure support, maintenance of reputation, ongoing membership in alliances such as the oncology consortiums of the National Cancer Institute, and the goals of their departments and department chairs. Researchers may be asked to contribute some percentage of faculty effort as a condition of employment, furthering a goal of a superior's or institutional mission. Hammering out compromises like these is part of the expected negotiations defining a faculty position, a process of quid pro quo that everyone recognises as coming with the territory of academic life. It would be of only passing interest, but now it assumes import beyond its monetary value, and becomes a variable in the ethical equation of those faculties' potential conflicts of interest/commitment.

There is a larger, and more opaque, background to all of this beating of chests. It is something of which we might dare not speak, as casting aspersions on it potentially jeopardises a critical, not-so-secret area of success for AMC. It lies in the emphasis on federal funding as a benchmark for success for the institution on the national stage. At our institution, we have seen recent missives from the medical school's dean about our research effort, including a 'Top Research Universities' offprint showing our ranking highlighted. Federal-funded research has been allowed completely to eclipse all other clinical research activities that operate on campus to the benefit of our patients and community. There is no mention in these self-congratulatory publications of the work done by faculty that is supported by non-governmental funding sources.

There are plenty of good reasons, and some very bad reasons, for this being the case. It is pointing to a precedent, established in the postwar expansion of federal support of clinical research, of the use of government funding as the preeminent measure used to establish the prestige of the institution among its peers, especially in the competitive marketplace of academic fundraising.

Unfortunately, we seem to have been unable to evolve our benchmarks of success with the subsequent expansion of the academic–commercial sector relationship, which were given the imprimatur of the good housekeeping seal of political approval with the passage of the Bayh–Dole Act of 1980. That legislation encouraged universities and medical schools to commercialise their research conducted with government funds, and created new incentives for scientists, clinicians and academic institutions to partner with the commercial sector in entrepreneurial enterprises.

Notwithstanding Francis Collins' vision of what the new National Institutes of Health will support, the translational research critical to bringing a new therapy to market has not been within that institution's mandate. The American way is that the commercial and medical evaluations of the efficacy and safety of new products for health care are in the main organised and financed by the commercial sector. It should be emphasised to all concerned that this process places academic clinical medicine between the two primary players in this project: Basic science and preliminary work on a new therapy may take place in the medical school or other laboratory or clinical context; and when it is being brought to registration, there should be no question that the optimal performance of patient-centered experimental care takes place in the hands of an academic medicine specialist in a centre of excellence. That this is increasingly not perceived to be the case is a direct result of this inconsistency we have in establishing fair and appropriate relations between all of the parties involved in these developing therapies.

Unfortunately, not only inertia in medical school politics can be blamed for this state of affairs. The priority given to federal dollars in academic medical institutions can be perceived as having been established in the pursuit of financial gain by the institution, and may represent a profound conflict of interest in the support it gives for the advancement of our work as physicians, educators and researchers. These are monetary and public relations-related reasons that benefit the institution directly, and have the potential to move resources away from needed areas from the standpoint of priorities of our outreach to our communities as physicians, centres of excellence in health care and research and academic departments, and towards goals that the institution creates to meet financial benchmarks both internally and externally mandated.

Although there are many ways that conflicts of commitment can occur, it is critical that we recognise that such diversions of resources might be related to the difference in the higher so-called 'indirect costs' paid to the institution for government work (often more than 60% for basic science, less for clinical work, which is another story) compared with that paid by the commercial sector (usually in the 10–25% range of total research costs), not to mention the value of the virtuous appearance the school can show—see, no filthy lucre!—to potential donors from the community for support of the institutional mission.

At the very least, we should recognise the failure of deterrence for unethical decision-making that can arise from the present system of government science funding of academic work, and a failure of disclosure of how this funding may compromise our capacity to manage personal and institutional conflicts of interest and commitment. Even if it is paid for using tax dollars, there is no free lunch, and all revenue accruing to anyone or any institution, from any company or government programme, comes with strings attached. Critically, in our actions in response to their process, we in turn can be biased or suborned by how our time, resources and interests are focused through the lens of governmental and institutional priorities. Even manna from heaven came with expectations of certain returns on the deity's investment, and, in our more profane context, with a loss of autonomy on the part of the recipient.[10] In this process conflicting commitments and interests must be considered for all parties concerned.

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