Drug Reps Off Campus! Promoting Professional Purity by Suppressing Commercial Speech

Lance K. Stell

In purity and holiness I will guard my life and my art.[1]

Every physician-patient encounter is a conflict of interest. Every physician-payer encounter is also a conflict of interest.[2]

Wide-spread criticism of the pharmaceutical industry's extravagant marketing practices[3] and some doctors' undignified, even appalling eagerness to stuff themselves, their pockets and their offices with the industry's "stuff,"[4] prompted physician groups,[5] the drug and device industry itself (albeit synergized by the federal government's ominous shadow[6]) to institute reforms designed better to limit industry influence on physicians.[7]

But according to Troyen Brennan and his co-authors,[8] the reforms, while reducing some of the most egregious instances of industry influence peddling and physicians' self-debasement, were doomed fundamentally, for three reasons. First, they were based on common sense but incorrect assumptions about the mechanism of industry influence and on myths about the efficacy of disclosure as an ethical disinfectant. Second, they relied on voluntary adherence and so failed to pinpoint responsibility for monitoring compliance and enforcement. Third, they overestimated physicians' powers of self-control but underestimated their venality. The evidence shows that physicians are meeting more frequently with industry reps than they were only seven years ago.[9]

On the Brennan group's pessimistic assessment, physicians really would sell their souls for a pen.[10] Perhaps each attendee at noon conference or Grand Rounds should suspect that those sitting on either side may have done so already.

In light of the great danger the Brennan group saw, tepid reforms virtually guaranteed that the medical profession's conflicts with industry, "arguably, the most challenging and extensive" of those the profession faces, would continue to jeopardize the medical profession's standing with the public and to pose chronic, serious threats to medical professionalism.[11]

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Because academic medical centers do and should provide professional leadership, are in position to instill long-lasting practice behaviors in the nation's future doctors, and are in position to take immediate action, the Brennan group proposed, and several medical centers quickly agreed, to form a vanguard to institute more aggressive reforms.[12]

- Prohibit faculty from listing themselves as authors of ghost-written publications;
- Prohibit "no strings attached" grants or gifts; and
- Make available on a publicly available website all grants, gifts, and industry ties by faculty.

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Purge, Ban, and Suppress Commercial Speech[13]

Among the aggressive, potentially very effective reforms the Brennan group does not propose or even discuss is abolishing the medical profession's prescribing privilege. That legal monopoly explains the pharmaceutical industry's physician-focused marketing in the U.S. Many countries (e.g., Mexico) do not legalize a practitioner monopoly over access to pharmaceuticals. And its doctors escape the numerous and associated conflicts.

Less dramatically, by comparison, the Brennan group proposes an across-the-board reduction in physicians' on-campus exposure to the pharmaceutical industry's commercial speech, including:

- Zero-tolerance[14] for industry detailers ("drug reps") on campus;[15]
- Zero-tolerance for gifts of any kind; [16]
- No drug samples directly to physicians;
- Ban from the pharmacy and therapeutics committee (aka the "formulary committee") any physician (or any other health care professional) who has a financial relationship with any drug manufacturer, including any that receives any gift, inducement, grant, or contract;
- Prohibit any pharmaceutical industry company from sponsoring a specific continuing medical education (CME) event;
- Prohibit industry funding for individual physician travel (including resident physicians);
- Prohibit faculty-physician or faculty-researcher service on industry speakers bureaus;

The Association of American Medical Colleges (AAMC) has recently proposed measures mirroring the above, but that go even farther, prohibiting *off-campus* any behavior, relationship, or situation that is prohibited on campus.[17]

It appears that a cadre of medicine's thought-leaders has provoked a competition in public hand washing and bright-line drawing.[18]

I will argue that this ethics-revival movement, undertaken in the name of "restoring" professionalism, is misguided, creates counter-productive incentives, is based on faulty premises, and will fail the duty to prepare future physicians for constructive, ethical engagement with their commercial partners in health care.

Industry's Investment in Commercial Speech

IMS, the go-to source for data on drug and device industry spending, estimated that in 2004, $27 billion went to product promotion while slightly more ($29 billion) went to research and development.[19] Aggregating firm-level accounting surveys to arrive at a two-figure industry-wide budget summary not only impresses with large numbers, it invites us to imagine ourselves as an ethically astute accountant, on raised eyebrow alert, auditing big Phrma's value-revealing trade off: promotional spending *versus* research and development (R&D). But Phrma is not OPEC. No such industry-wide trade off "decision" is ever made.

The eye brow raising exercise invited by juxtaposing aggregate expenditures on marketing and R&D rests on a two assumptions: (1) that what counts as marketing and what counts as R&D is not a matter of serious dispute among fair-minded, objective people

(e.g., should post-approval, Stage IV Studies count as an R&D expenditure, or are they better regarded as "seeding trials," therefore marketing/product promotion?) and (2) that expenditures on marketing are ethically dubious while those on R&D are legitimate. These assumptions provoke a tendentious question: does the pharmaceutical industry *really* focus on innovative research in pursuit of life-saving interventions (productive, good), or is it primarily market-driven by greed and profiteering (wasteful, bad)?

The Brennan group reveals its assumption that marketing lacks fundamental legitimacy by omission when it opines, "As part of the health care industry, pharmaceutical and medical device manufacturers promote the welfare of patients through their commitment to research and product development. Their investments in discovering, developing, and distributing new pharmaceutical agents and medical devices have benefited countless patients."[20]

Omitting to mention marketing among the activities that promote patient welfare is more than an oversight, it is rhetorically advantageous. It allows the Brennan group to insinuate, without actually claiming or even implying, that promotional spending does not promote patient welfare. Yet, isn't it obvious that an FDA-approved product can promote patient welfare *only if* prescribing doctors know about it, learn to use it properly, and timely begin offering patients access to it?

With newly FDA-approved devices, for example, physicians and surgeons often must be shown (not merely told) how to use them safely. Someone with product-development experience (e.g., a consulting physician or surgeon) must do this. But this fact jeopardizes preserving a bright line between education and product promotion. Showing a procedure-performing physician how to use a newly approved device, helping her to become comfortable with it, will tend to promote both successful patient outcomes and product allegiance. Favorable clinical experience with the device will lead to her teaching her procedure-performing colleagues how to use it. *See one, do one, teach one*.

By the Brennan group's moralistic accounting principles, all industry-sponsored educational speech is camouflaged *commercial speech*. Its purported educational purpose should be discounted as sheer propaganda. Ban it! But banning commercial speech on campus will tend to increase what the translational science movement calls "T1" and "T2" errors.[21] Dismissively stigmatized as mere "product promotion," industry-sponsored "how-to" demonstration seminars on campus must be forbidden. This diminishes faculty incentive to avoid T1 errors (by continuously updating their theoretical knowledge base) because the commercial-speech ban prohibits learning the clinical applications from tainted promotional sources. The AAMC's proposal to ban all off-campus interactions that are banned on campus closes the off-campus "loophole." If so, proponents of an ideologically-drawn bright line between educational speech and commercial speech seriously jeopardize the translational science initiative.

Strict enforcement of the distinction between education and product promotion will pose an unhappy choice for academic medical center faculty who are committed to innovation and translational science:

Effective educational speech tends to have motivational effects, especially in a science-using art, like medicine: product demonstration promotes technical proficiency promotes familiarity promotes comfort promotes successful patient outcome promotes product loyalty. For some practitioners, product loyalty borders on the evangelical, industry rewarded or not.

(1) adhere to the Brennan/AAMC marketing bans; (2) depart the medical center for an environment less devoted to the desultory task of maintaining a high wall of separation between educational and commercial speech; or (3) mutter in private with other disgruntled realists about being cut off from the cutting edge.

A compelling interest in innovation, translational science and putting patient safety first says that medical centers must make an exception to allow device education (with inescapable promotional effects) on campus. Breaching the bright line between education and promotion for medical devices will escape no one's notice.

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Thinking that brand loyalty is an irrational preference instilled by marketing might prompt a medical center to defeat it by preventing procedure-performing physicians from special ordering their preferred instrumentation. This would be consistent with the principle of P&T Committee ("Pharmacy & Therapeutics Committe" aka the "Formulary Committee") autonomy favored by the Brennan group. Procedure-packs might be prepared in-house to contain the P&T Committee's annual (semi-annual, quarterly?) choice of FDA-approved instruments it had determined suitable for a scheduled procedure. Complicating this strategy in product-loyalty prevention: FDA-approved instruments, despite being tried and generally abandoned by practitioners, do not thereby lose their "approved" status. Squelching ever-evolving product loyalty in medical devices might adversely affect patient safety or actually retard post-approval discovery and reporting of problematic instruments.

Valuing innovation and translational science is in tension, if not at odds with, maintaining a bright line between educational speech (good) and commercial speech (unsavory). A physician charged to supervise and discipline his colleagues' adherence to the bright line will make value judgments that must appear arbitrary to some observers. To practical-minded clinicians, the arbitrariness will become increasingly obvious. Then, either the enforcement teeth demanded by the Brennan group will tend to bite less hard, less often and/or vacillate haphazardly between hard bites/gentle nips. Worse, from a moral point of view, insisting on physician adherence to bright-line ideology will war with their clinical common sense — a recipe for cynicism and moral distress, not an upgrade in medical integrity.

Of course, we should notice in passing that medical centers also market themselves. They tout their awards, their national rankings, their technology, the excellence of their nursing and medical staffs, their high rankings in patient satisfaction surveys, their celebrity-patient endorsements. Residency training programs tout their curricula, their award-winning faculty, their work conditions, the number of house staff poster sessions at regional and national meetings, their clinical training opportunities, their board scores, and their fellowship placement rates. These commercials educate, but they also are meant to be *influential and promotional*. Medical center marketing departments evaluate these materials prior to "roll out" — the photos for gender and racial balance, and the wording and text-placement for "tone" and "impact."

Of course, an academic medical center's promotional materials do not "tell the whole story." No footnote disclaimer discloses unvarnished M&M (morbidity and mortality) statistics, or recounts the tragedies that are (and should be) embedded in every medical center's institutional memory. On the contrary, these glossy commercials emphasize the positive. And there is nothing wrong with that.

To counterbalance up-beat, promotional efforts, American society also has a large and growing "expose" and compliance industry. This industry markets its undercover services and precaution-laden products to public and private consumers eager to correct for over-the-top product promotion.

Marketing and Clinical Inertia

Despite its many imperfections, misleading promotional graphs, questionable tactics or its deep or ultimate purpose ("all about sales"), industry marketing addresses but insufficiently offsets another chronic problem in medicine: "clinical inertia." "Strong evidence now indicates that therapy for hypertension, dyslipedemia, and diabetes can prevent or delay complications. The goals of management are well defined, effective therapies are widely available, and practice guidelines for each of these diseases have been disseminated extensively. Despite these advances, health care providers often do not initiate or intensify therapy appropriately during visits of patients with these problems. We define such behavior as clinical inertia — recognition of the problem, but failure to act."[22] It has been estimated that clinical inertia may account for 80% of cardiovascular events, suggesting not only that this failure to act should be a focus of quality improvement, but possibly for public reporting as well.[23]

Not everyone fears clinical inertia. Some commentators fear that the momentrum of translation science too often outpaces risk discovery. They have proposed "black triangle" warnings and two-year post-approval bans on directive-to-consumer advertising (DTC).[24] These are well-intended prophylaxis against real cases of danger discovered post-approval.

However, these measures would delay acceptance of interventions that might have provided more patients earlier benefit. They would reduce the value of FDA approval, and effectively shorten post-approval, patent-protected marketing time. The threat of a stigmatizing novel products with a black triangle reduces the incentive to bring genuinely novel and potentially superior products to market, but increases the incentive to pursue more "me-too" drugs and/or to resurrect the commercial value of off-patent drugs with novel dosing technologies. Both tactics are predictable industry responses to an environment that increasingly emphasizes regulation, precaution, and risk reduction.

De-legitimizing Commercial Speech While Entrenching Market Leverage

The Brennan group's proposed commercial-speech restrictions will have predictable and unequal distributional effects. The largest drug and device companies already enjoy substantial market leverage in virtue of brand-name recognition alone. In descriptive-ethical terms, these companies enjoy and have fought hard to secure "status trust."[25] Leave aside whether they deserve "trusted brand" status. They have it. And it's very valuable.

Across-the-board restrictions on access to academic medical centers will further entrench the advantage trusted brands enjoy, but handicap companies less well known to academic physicians. Companies with products marketable by DTC advertising will have an incentive to emphasize such products even more. With promotional efforts in academic medical centers prohibited, all pharmaceutical companies will have an increased incentive to shift their R&D expenditures towards DTC marketable products. Highly likely, the distribution of R&D investments will be affected by restrictions on products that would be better marketed to physicians.

"Ask your doctor" DTC prompts office visits. The influence exerted on physician decision making by motivated patients exceeds the subtle "reminders" planted by logo-bearing pens and pads. A recent study investigated the extent to which patient expectations were fulfilled at an office visit. It found that 75% of patients received the drug they visited their physicians to obtain. Only 22% reported that their physicians attempted to counsel an alternative.[26]

Does Industry Pose the Greatest Threat to "Putting the Interests of Patient First"?

The Brennan group claims that conflicted commercial relationships with drug and device makers "arguably" pose the greatest challenge to physicians' commitment to putting the interests of patients first. No data support this claim. No study has compared industry's *commercial influence* with the influence of reimbursement models on physician decision making *using patient outcome as a measure*. Operationalizing the ethical principle "putting the interests of patients first" would seem to require this outcome measure rather than a surrogate with only a tenuous, speculative relationship with patient outcome. Yet, Wazana's review of the industry-influence literature, on which the Brennan group relies, while finding mostly negative effects of physician-industry interactions and only one positive ("improved ability to identify the treatment for complicated illnesses"), states bluntly, "*no study used patient outcome measures.*"[27]

If none of the studies she reviewed used patient outcome measures, what basis is there for claiming that physician interactions with industry *cause* patient harm? Studies have found that reimbursement models are associated with and apparently influence utilization of elective procedures.[28] Other studies have found that physicians practice defensive medicine. [29]

No doubt, marginal increases in needless tests and procedures prompted by reimbursement rules and physician self-defense produce some unfortunate increases in false positives and some needless iatrogenic injury, but defensive medicine produces some patient benefit as well. Moreover, no studies have compared the influence of financial conflicts with non-financial conflicts. Yet at least one commentator acknowledges that non-financial conflicts probably exert greater influence on decision making in research.[30]

What Is a Fiduciary Relationship?

A fiduciary relationship is one of confidence and trust. *Inequality* (of expertise and experience) is a common characteristic of many fiduciary relationships, (e.g., attorney-client, doctor-patient, accountant-client) but not an essential feature. Indeed, the most cited law case elaborating the "uncompromising rigidity" of fiduciary loyalty concerned alleged acts of betrayal by a business partner in a commercial joint-venture.[31]

Fiduciary loyalty problems arise in an agency relationship because the beneficiary cannot easily supervise his agent's diligence. Nor can a disappointed beneficiary readily discern whether an untoward outcome resulted from the fiduciary's betrayal of trust in exercising his discretionary authority or from exogenous factors not reasonably under the agent's control.

In principle, any opportunity, any incentive an agent has to gain personally from the relationship, or to shirk in services owed under the terms of the trust constitutes a conflict of interest because it poses *some risk* of detriment for the beneficiary. Magnitude and probability of harm must be provided to arrive at a risk-estimate.

However, incentives are not acts, nor wrongs, nor harms. A conflicted relationship or situation with associated advantage-taking incentives will typically have faith-keeping, loyalty-strengthening incentives as well. Conflicted fiduciaries tend to have multiple conflicts. The associated incentives reinforce or counter, offset, or outweigh each other in complex ways. Incentives that work somewhat toward the beneficiary's detriment may *at the very same time, and even more strongly* work to his benefit. Fee-for-service physician reimbursement has this feature. Capitated care reim-

bursement may, too, but for unclear reasons, Americans seem less confident that "less can be more."

The Definition of Conflict of Interest

"Conflict of interest is the problem that gives a profession its defining characteristic."[32] Remarkably, *there is no generally accepted definition of conflict of interest*. Some definitions distinguish conflicts between the agent's (selfish) interests and the ethical duties owed to *the* principal versus conflicts between obligations the agent owes to multiple principals. Others distinguish between "the appearance" of conflict and "actual" or real conflict. Some see conflict of interest arising from and grounded in the agent's *motives* when faced with *temptation,* others focus on "misaligned" incentives irrespective of the agent's motives (on the assumption that more closely aligned incentives are always better) while still others define conflicts of interest in terms of "undue influence," a qualitative criterion suggesting that aggregating influences pose no conflict until tripping the trigger at the "undue" threshold.[33]

Hindsight bias makes the diagnosis of "undue influence" all but irresistible when a conflicted fiduciary actually does wrong or a bad outcome makes the conflict salient.[34] If a conflicted fiduciary regularly does what he should, obviously we do not invoke the conflict to explain his diligence. Yet, by hypothesis, he is *conflicted*, every day. Why isn't it a heuristic bias for us to invoke the conflict only as an explanation of his doing wrong? A physician under fee-for-service reimbursement has an incentive to maximize utilization. Defensive medicine reinforces the bias. These incentives put pressure on the duty of patient loyalty by subjecting his/her time and resources to needless capture. Capitated care carries an incentive to economize on utilization, putting pressure on patient loyalty, but in a different direction. A comparatively benign malpractice environment reduces that source of utilization bias.

If we say "but for" the economizing bias in capitated care, the patient would have received a life-saving cardiac catheterization. Mustn't we also say that but-for the utilization bias associated with fee-for-service, an iatrogenic death in the cath lab would not have occurred?[35]

The Brennan Group's Definition

"Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician's roles are or will be compromised." Will this serve as a practically useful guide to ethical decision making?

A person's *motives* are unobservable. Motives are *attributed*, based on evidence of some sort. The Brennan group fails to specify the *standard of evidence* required for making an *objectively reasonable* attribution of a preponderant, malignant, role-compromising motive.

Suppose reasonable observers disagree whether preponderant, malignant, role-compromising motives should be attributed to a physician. How should this dispute be resolved? Must "he who alleges the existence of preponderant malignant conflict" bear the burden of proof, and if so, to what standard? Should those who affirm the presence of a malignant motive bear the burden of proof (by a preponderance of the evidence or by clear and convincing evidence)?

No, not according to the Brennan group. If (some) reasonable observers have diagnosed a malignant motive or situation, then their conclusion prevails against all reasonable opinion to the contrary. Why? Because some have thus concluded meets the standard "could conclude."

"Reasonable observers" invokes the perspective of the layperson rather than the expert or professional. This is consistent with the Brennan group's insistence that the medical profession's standing rests on public trust. Postulating a lay-perspective for diagnosing malignant motives and situations also conveys their judgment that physicians' perceptions of their relations with industry should not be credited because of chronic self-deception and because "physicians differ about what they consider a conflict." Internist Robert Goodman[36] and family physician Howard Brody[37] have compared medical professionals' insight-deficit to that of the motivated false belief of a self-deceived drug addict.

However, the Brennan group ignores the contrary evidence that "reasonable person" fact-finding naturally seeks. That evidence says that the lay-public does not attribute trust-destructive malignant conflicts to physicians.

In four recent polls conducted between 1998 and 2006, The Harris Poll consistently found physicians ranking at the top or near the top for trustworthiness. In 2006, they ranked first, with 85% of adults agreeing that doctors generally can be trusted to tell the truth. By comparison, journalists, members of Congress and (ironically) pollsters ranked well down the list with only 39%, 35% and 34% respectively agreeing.[38] A 2005 national survey by Research!America found that 73% of respondents think that government, universities, and the pharmaceutical industry do not work together to develop new treatments; 95% think that they should.[39]

An erosion of public confidence in physicians is very hard to document.[40] One study claimed to find a long-term decline in confidence in the medical profession among the lay public. Interestingly, the investigator found an even greater decline in confidence among political elites.[41]

The Dirt on Coming Clean[42]

The long-standing, persistent, and comparatively high levels of status-trust enjoyed by the nation's physicians would not reassure the Brennan group. On the contrary, the data showing that physicians apparently enjoy a bullet-proof trust-rating with the public only serves to confirm their theory predicting that public disclosure of physicians' extensive conflicts of interest with industry will fail to trigger the appropriate degree of trust-discounting.

For this remarkable conclusion, the Brennan group relies on research using college students who played an ingenious game for purposes of determining whether disclosing conflicts of interest would result in the right amount of trust-discounting.

Here's a bare-bones description of the experiment. Estimators attempted to guess the dollar value of coins in a jar. They were awarded for accuracy. Advisors provided Estimators with advice about how many coins there were in the jar. The Advisors had more (but not perfectly accurate) information of the likely value of the jar's contents than had the Estimators and this was known to the Estimators. Multiple rounds of the game were played with Estimators and Advisors changing roles.

In one scenario, Advisors were rewarded by how accurate their Estimator's guess was. Estimators were told that their Advisor's incentive was aligned in this way immediately after the Advisor had given his advice but before giving their guess.

There were two conflicted-Advisor scenarios. In both, Advisors were rewarded for getting their Estimators to over-estimate the value of the jar's contents, the higher the over-estimate, the greater the Advisor's reward. In the "undisclosed conflict" scenario, the Advisor's incentive to prompt exaggeration was not revealed to the Estimators. In the "disclosed conflict" scenario, the Advisor's conflict was revealed to the Estimator immediately after the Advisor's advice was given but before the Estimator guessed.

In the "incentives-aligned" scenario, Estimators tended to underestimate. In the conflict scenarios, Advisors distorted their advice in the predicted direction. However, surprisingly, the "mean absolute estimator error [was] significantly greater with disclosure than without disclosure…[in other words] estimators were less accurate with disclosure than without it."

It is not clear what generalizations this study supports about physicians. For one thing, physicians and patients do not reverse roles (professional courtesy may be an exception). The study had a built-in "right answer" (the amount of money in the jar) against which to measure Estimator and Advisor performance. The study investigators clearly assume that disclosure in the setting of misaligned incentives should trigger a trust-discount. And that's what they found, but not as large a discount as they thought should have been given.

How big a trust-discount, if any, should a disclosure have in the physician-patient setting? Suppose a patient suffers from aortic insufficiency. His medical doctor recommends medical management. His surgeon recommends valve replacement. The medical doctor discloses that he has consulted extensively with almost all the makers of cardiovascular medications and was the principal investigator on the study for the medicines he's recommending. The surgeon discloses that he helped design the prosthetic valve he uses, is on the company's board that makes it, and that he has installed it in more than 100 of his patients with good success. Each doctor recommends second opinions and each offers to arrange for them. What is the dirt on coming clean in this hypothetical? What discount, if any, should the patient apply to these opinions?

George Bernard Shaw once quipped, "If you pay a man to cut, he will cut." Shaw's ridicule of fee-for-service surgery might warn our patient to discount the surgeon's advice. But it might also encourage him if he wants valve replacement and if the reimbursement setting better assures him that his surgeon will be willing, and not reluctant, and if the surgeon is a personally invested believer in the instrumentation he uses.

We do not know what effects a disclosure in medicine *should* have. Imagine that a capitated care reimbursed doctor discloses: "I have an incentive to pull the plug earlier than an FFS reimbursed doctor. And the consequence of my acting on that incentive will be a shorter ICU stay for you and likely, an earlier death." His endstage cancer patient responds: "Good!"

The dirt-on-coming-clean study investigators speculate that "physicians will prefer disclosing gifts from pharmaceutical companies (or disclosing payments for referring patients to clinical trials) to actually eschewing such benefits."

They cite no behavioral (or survey) study to support that physicians actually have this preference. After all, many physicians have taken and adhere to the "no free lunch" pledge. We have evidence that patients want physicians to disclose financial incentives that would cause a compromise in their care.[43] But we also have evidence that physicians dislike discussing reimburse-

ment issues with patients and prefer to offer assurance of their trustworthiness in all circumstances.[44]

In Praise of the Conflicted Fiduciary

"Conflict" has an unfortunately negative connotation, suggesting that all conflicts of interest are inherently malignant and role-compromising. Thus one treatise-writer opines that a conflicted fiduciary is "placed under temptation" and will allow "selfishness" to trump the duty to serve the beneficiary. And why is that? Because "[i]t is *not possible* for any person to act fairly in the same transaction on behalf of himself and in the interest of the trust beneficiary."[45]

Common sense and more advanced scholarly understanding of human motivation has abandoned the selfish/altruistic dichotomy in favor of more nuanced theories.[46] As Allen Buchanan has pointed out, "a growing awareness that the basic models of economic rationality do not require the assumption that human motivation is exclusively or even primarily self-interested…[and] to assume that (rational) individuals maximize expected utility is not in itself to assume that every individual's or even most individuals' utility functions include only self-regarding interests."[47]

Thomas P. Stossel emphasizes that the cooperative (albeit conflicted) relationships between the medical profession and the pharmaceutical industry have generated overwhelmingly positive benefits on an unprecedented scale — advancing scientific knowledge, enriching drug and device makers and their stockholders, vastly expanding the treatment and diagnostic armamentarium, but mostly importantly to the advantage of patients.

Dr. Stossel does not deny, ignore, or discount that egregious abuses have occurred. He acknowledges that academic biomedical researchers have not proved immune to bad judgment, bad luck and disagreeable behavior, but he cautions that zealousness to make impossible a recurrence of well-vetted abuses creates an insidious, but serious over-deterrence risk that threatens and disadvantages everyone.[48]

Managing the Conflicted Fiduciary Problem

In his critique of trust law's over-deterring the conflicted fiduciary, legal scholar John Langbein observes, "The very term 'conflict' is an epithet that prejudices our understanding that some overlaps of interest are either harmless or positively value enhancing for all affected parties."[49]

Our discounting modifiers ("apparent" conflict, "potential" conflict) perpetuate rather than fully expose the built-in bias against conflicts. "Benign conflicts" and "conflicts positively value-enhancing for all affected parties" remain not only underappreciated, but empty categories.

"To be sure, [writes Langbein], some conflicts of interest may harbor incentives so perverse, yet so hard to detect and deter, that categoric prohibition, as under the sole interest rule, is the cost-effective way to deal with the danger."[50] And in estate-trust law, "self-dealing" has traditionally been placed in that category, but even there, not absolutely.

A trustee who wishes to purchase assets from the trust he administers, e.g., at an auction he arranges, may do so provided that he obtains prior permission from a court which must be convinced that a proposed conflicted transaction (because, the trustee has an obvious incentive to avoid timely recruiting aggressive, competitive bidders) may yet be best for the trust's beneficiaries, all things considered.

If it is axiomatic that big gifts buy big influence, then its corollary says that *de minimis* gifts buy no material influence. The theory would deny that gifting a politician with a $2 pen or $5 coffee mug will buy disproportionately great influence, far in excess of their monetary value.

Traditionally, physicians have been "self-dealers," at liberty rather than prohibited to offer treatment for conditions they diagnose. Indeed, as Plato noticed 2500 years ago, physicians practice two arts (medicine and getting fees) despite *professing* to practice only medicine. Plato points out that it's the fee-getting art that prompts progressive medicalization of human distress, the invention of new illnesses, and provides an incentive to enroll and keep one's patients on a clinical schedule of perpetual subordination so long as the patient's life and money hold out.[51]

The drafters of the American Medical Association's (AMA) First Code showed awareness of the conflicted fiduciary problem when they cautioned, "…unnecessary visits are to be avoided, as they give useless anxiety to the patient, tend to diminish the authority of the physician, and render him liable to be suspected of interested motives."[52]

Most conflicts are not malignant. Langbein recommends that trust law recognize the fact by abandoning the "sole interest" criterion of fiduciary duty and switch over to a "best interest" criterion instead. The argument is simple. A beneficiary may do better when his fiduciary follows the "best interest" criterion in a transaction than with what the "sole interest" criterion would direct. When this is the case, the concept of fiduciary loyalty recommends that the fiduciary ought to do what's best for the beneficiary, despite that the fiduciary will be conflicted when so acting.

A gratuitous fiduciary who owes his loyalty to only one beneficiary will find it easy to adhere to the "sole interest" criterion for judging his transactions. However, the beneficiary might do much better being served by a professional fiduciary, who bills fee-for-service and owes loyalty to many clients. While the latter fiduciary cannot satisfy the rigoristic "sole interest" criterion, he will find it entirely manageable to measure up to the "best interest" criterion.

A proper reform of trust law, in Langbein's view, would recognize that the conflicted fiduciary is not *per se* worse for his beneficiaries but often is better. Thus, he proposes that trust law recognize a new defense against an allegation that a fiduciary has acted disloyally — that the fiduciary acted prudently and in the best interests of the beneficiary. Interestingly, Langbein's proposal is substantially similar to the criterion published by the AMA's CEJA in 1991 — that a physician's interactions with industry should primarily entail a benefit to patients.[53]

Gifting and Influence

Common sense says that a gift's biasing effect on a recipient's judgment is proportional to its value. On this theory, the value of a money-gift and its buying power takes no expert explanation. It's all-too-obvious that substantial influence has been put up for sale when a hidden video shows a congressman stuffing his pockets with tens of thousands of dollars at a clandestine meeting in a cheap motel.

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The Influence Mechanism: Gifting > Reciprocation?

The Brennan group rejects common sense gifting theory for a more sophisticated, but counter-intuitive theory. It explains the well-documented association between doctor-exposure to marketing and product-favorable prescribing by an indebtedness mechanism triggered by acceptance of small gifts. Former drug reps disclose that they were trained to take advantage of and reinforce doctors' feelings of entitlement by giving gifts. Gift-acceptance triggers *a subconscious reciprocation reflex* disproportionally generous to the gift.[54]

Social psychologist and compliance theorist, Robert Cialdini elaborates: "An obligation to receive reduces our ability to choose those to whom we wish to be indebted and puts the power in the hands of others… A person who violates the reciprocity rule by accepting without attempting to return the good acts of others is disliked by the social group."[55] The mechanism triggered by gifting-exchange potentially threatens to undermine the physician's fiduciary duty to the patient to preserve his *independent* medical judgment.

But gift-exchange theory provides only an explanatory sketch of industry rep/physician interaction. Assuming that physicians *perceive* pens, pads, and pizza as "gifts," it remains to be explained why the psychological law of reciprocation compels the physician to return larger-scale good acts in the form of prescription writing for the product manufactured by the drug reps employer. It is also a puzzle why doctors' supposed "entitlement mentality" that explains gift-acceptance doesn't actually cut off reciprocation rather than prompt it. Moral logic says receiving *undeserved gratuities* should trigger reciprocation, but with respect to gifts to which one is only enititled after all, moral logic prescribes "thank you," not reciprocation.

How does the threatened social group sanction for non-reciprocation work? Are there data that physicians regard drug reps as members of their social group? Or perhaps it's not social-group membership but rather friendliness — an artful blend of the personal with respectful subordination…"Dr. Jones") — some flattery, a pen, or mug that in aggregate create expectations of reciprocation. At next week's visit, the smiling rep will return knowing whether one has reciprocated with a script. Script writing prophylaxes anticipatory guilt. Plausible, at least for some people.

Michael Oldani, nine years a drug rep, but now a college professor at the University of Wisconsin at Whitewater, emphasizes that the successful drug rep uses rhetorical jujitsu on client-physicians, deflecting and redirecting their skeptical aggressive-seeming questions into momentum for a sale. The drug rep talks the talk of improved patient outcome, but his sales targets and economic interests motivate his every word and gesture. In the hands of a skilled, well-trained drug rep, the inquisitorial physician is flipped, becoming a compliant, high-prescriber of the company's products.[56]

Robert Cialdini agrees and thinks its past obvious that medical consultants play tit for tat with their expert advice. He says, "Take the case of the medical controversy surrounding the safety of calcium-channel blockers [CCBs], a class of drugs for heart disease. One study discovered that 100 percent of the scientists who found and published results supportive of the drugs had received prior support (free trips, research funding, or employment) from pharmaceutical companies: but only 37 percent of those critical of the drugs had received any such prior support."[57]

But Dr. Stossel points out an important omission from this indictment. Cardiovascular consultants to makers of other cardiac drugs (but who did not make CCBs) were as likely to endorse the comparative safety of CCBs as the consultants retained by the CCB makers. In other words, supporters of CCBs were as likely to have received funding from a CCB competitor as from the maker of a CCB.

Stossel speculates (tongue-in-cheek) that perhaps all the consultants to the cardiovascular drug makers have a predominant convergent interest prompting reflexive support for any cardiovascular drug, no matter who makes it. This hypothesis would predict that they would form up in lock-step to find CCBs not more dangerous than other cardiac drugs.

Stossel prefers a simpler explanation: the consultants retained by the makers of cardiovascular drugs are simply well-informed experts; his hypothesis is supported by a preponderant, successful, long-term experience with CCBs. So, on further review, it seems less clear that cardiovascular consultants just played tit for tat.

Besides, if we really should suspect that all the supporters of CCBs were playing tit for tat, wouldn't parity of suspicion say that the 37% who were critical of CCB's safety but not paid had been eating sour grapes before they rendered their "unbiased" opinions? If we must suspect some consultants for susceptibility to loyalty-reciprocity, mustn't we suspect others of retributive spite or envy? And if we do succumb to the wicked pleasure of diagnosing consultants' motivational pathologies, so what? Competitiveness, venality, glory seeking, and arrogance do not preclude loyalty, diligence, brilliance, and ingenious achievement with resulting tangible welfare gains for everybody, not all them denominated in money.

Professor Cialdini prescription for addressing the conflicts posed by industry sales tactics is cognitive. Analysis and reintepretation are key to achieving defensive, autonomous control over the gift-exchange mechanism. "Once we have determined that the initial [gift] was not a favor but a compliance tactic, we need only react to it accordingly to be free from its influence. As long as we perceive and define the action as a compliance device instead of a favor, the giver no longer has the reciprocation rule as an ally."

Conclusion

In my view, "just say no" and pulling up the draw bridge to the medical center is not an educational philosophy for professional engagement with the pharmaceutical industry. Let the reps come, but under terms like those already in place at many medical centers (Carolina Health Care System's policy is appended in the reference section). But also bring on campus former drug reps to give resident conferences disclosing how they were trained, the compliance tricks they perfected and used successfully.[58] Former drugs are often entertaining and instructive.

Cialdini points the better way for academic medical centers to train the next generation of physicians. Learn and teach good cognitively active self-defense techniques. Physicians practice in a commercial environment. They see the industry's "ask your doctor" DTC on their own televisions and in their popular magazines. They will see in the offices patients motivated by it. As learned intermediaries, physicians owe it to their patients to critically engage profession-targeted marketing in the medical center. If the information offered them by industry is objectionably biased, doctors should demand better materials. After all, physicians are the target-consumers of drug rep marketing. Its educational quality will not improve until physicians demand better.

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3. IMS, a firm that specializes in gathering and analyzing data on the pharmaceutical market and disseminating it for a fee, is commonly regarded as "the authority" on the industry's promotional expenditures. Relying on IMS data, the U.S. GAO concluded that, in aggregate, pharmaceutical companies spend more on research and development than on marketing – US$29.6 billion on R& D versus US$27.7 billion for promotion. However, a reanalysis by Gagnon and Lexchin that included data from CAM (Cegedim, a global company that audits promotional activity worldwide as well as in the U.S.) estimated that promotional spending by the industry in the U.S. was more than twice as high as the IMS estimate for 2004, the latest year for which data was available. *PLoS Medicine* 5, no. 1 (2008).
4. C. Elliott, "The Drug Pushers," *The Atlantic Monthly* (April 2006): 82-93. A physicians group known to the author (LKS) and composed of 6 practitioners of general internal medicine,

decided to inventory and then purge from their office drug company-logo-bearing stuff. Among the items inventoried for discard were: 5 clocks, 11 tissue boxes, 31 refrigerator magnets, 39 mugs/cups, 44 pieces of office equipment such as calculators and staplers, 119 paper pads, 257 pens, and 1609 patient handouts/brochures/drug discount coupons.

5. S. L. Coyle, "Physician-Industry Relations, Part 1: Individual Physicians," *Annals of Internal Medicine* 136, no. 5 (2002): 396-402; S. L. Coyle, "Physician-Industry Relations, Part 2: Organizational Issues," *Annals of Internal Medicine* 136, no. 5 (2002): 396-402.
6. D. M. Studert, M. M. Mello, and T. A. Brennan, "Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry – Self-Regulation in the Shadow of Federal Prosecution," *New England Journal of Medicine* 351 (2004): 1891-1900.
7. For example, PhRMA's 2002 Code on Interactions with Healthcare Professionals affirmed the basic principle "...that a health care professionals care of patients should be based, and should be perceived as being based, solely on each patient's needs and the health care professional's medical knowledge and experience." The Code interpreted this principle as ruling out free tickets to entertainment and recreational events. Free golf balls and sports bags were prohibited because they were not primarily of benefit to patients. Free gas fill-ups were excluded on similar grounds. *De minimis* items ($100 or less) intended primarily for patient benefit were OK. Stethoscopes and medical textbooks were OK. Logo-bearing notepads, pens, and "reminder" items are OK. Continuing the practice of providing occasional meals is OK, provided that they are "modest by local standards," occur in a venue conducive to communication of scientific or educational value, and no spouses allowed. (No more "dine and dash," no more dropping off food for the office). Gift certificates given as premiums for attending drug talks is prohibited. Reimbursement for meeting travel expenses? No longer allowed. Payments to compensate physicians for bona fide services, such as speaker fees, was still OK. PhrMA's Revised Code (effective January 1, 2009) prohibits all reminder items, as well as stethoscopes and medical textbooks).
8. T. A. Brennan, D. J. Rothman, and L. Blank et al., "Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers," *JAMA* 295, no. 4 (2006): 429-433.
9. E. G. Campbell et al., "A National Survey of Physician-Industry Relationships," *New England Journal of Medicine* 356, no. 17 (2007): 1742-1750. The study asked 3167 physicians in six specialties whether, in the past year, they had received: food or beverages in the workplace; free drug samples; honoraria for consulting; payment for service on scientific advisory boards or on boards of directors; payment in excess of costs for enrolling patients in industry-sponsored trials; costs of travel, time, meals, lodging, or other personal expenses for attending meetings; gifts received as a result of prescribing practices; free tickets to cultural or sporting events; free or subsidized admission to meetings or conferences for continuing medical education (CME) credits. 94% of physician-respondents reported some type of industry relationship within the last year. 83% reported getting food in the workplace. 78% reported getting drug samples. 35% got reimbursement for attending professional meetings or continuing medical education. 18% got paid for consulting, 16% for giving lectures, 9% for serving on advisory boards, 3% for enrolling patients as research subjects in clinical trials. 7% reported getting free tickets to cultural or sporting events. Family medicine doctors met more frequently with industry reps than physicians in other specialties and were more likely to get drug samples, or reimbursements than pediatricians and anesthesiologists. Hospital- or clinic-based physicians met with reps less frequently than doctors in solo or group practice. Cardiologists were more than twice as likely to get paid for consulting or giving lectures than pediatricians, anesthesiologists, or surgeons. Industry has an incentive to target its marketing resources on physicians perceived as influencing the prescribing behavior of other physicians. The survey's results were consistent with that prediction. Overall, all specialties except anesthesiology seem to be meeting more frequently with industry reps than they did only seven years ago.
10. A. N. DeMaria, "Your Soul for a Pen?" *Journal of the American College of Cardiology* 49, no. 11 (2007): 1220-1222. While acknowledging the pervasiveness of industry influence, Dr. Pointing expresses concern about over-deterrence and points out that the very venue in which the Brennan group proposed its ban, the *Journal of the American Medical Association*, contains substantial industry advertising.
11. If the sheer number of physicians' interactions with industry is the right outcome measure for judging the reforms' effectiveness, a recent study found that physicians are meeting more frequently with industry representatives than ever. A 2007 survey of 3167 physicians in six specialties found that all specialties except anesthesiology were meeting more frequently with industry than they did only seven years ago. It should be noted however, that only 7% reported receiving personal items as "gifts" from industry. See *Campbell*, supra note 9.
12. Stanford, Yale, the University of Michigan, and the University of Pennsylvania have announced their commitment to comply with the Brennan group's recommendations. The University of California at Davis joined their ranks in the summer of 2008.
13. The commercial speech doctrine traces to *Valentine v. Chrestensen,* 316 U.S. 52 (1942) which sustained a ban on the distribution of handbill advertisements soliciting customers to pay admission to tour a submarine. The Court viewed the ban as a *regulation of business activity* rather than an infringement of First Amendment protected speech. Later cases made it clear, however, that speech does not lose 1A protection simply because of a commercial context. The doctrine is vexed, complicated and somewhat arbitrary in application. I cannot give it a fair analysis here, so I leave the idea of "commercial speech" intuitive but vague.
14. "Zero Tolerance," a form of ethical absolutism, has become an unfortunately popular surrogate for "ethical seriousness." It manifests in pronouncements of state medical boards. Thus the North Carolina Medical Board's position statement on "The Physician-Patient Relationship provides, 'Patient trust ...requires that: there be no conflict of interest between the patient and the physician or third parties.'" *NCMB Forum* 4, no. 1 (2007): 12.
15. For example, at Carolinas Medical Center, where the author holds a part-time teaching position in the Department of Internal Medicine, the following restrictions have been in place since 2001:

    Brief Policy Summary:
    - Pharmaceutical sales representatives must display approved identification while on CHS campuses.
    - Pharmaceutical sales representatives must check in at the approved area in each facility to receive the approved identification and have appointments verified.
    - Pharmaceutical sales representatives will not have access to CHS campuses without prearranged appointments.
    - Pharmaceutical sales representatives must receive prior approval from the Pharmacy Department to access all professional lounges and the lab.
    - Detailing of pharmaceuticals is limited to designated areas.
    - Pharmaceutical detailing will be limited to formulary products and approved indications unless otherwise approved.
    - Pharmaceutical sales representatives will not access patient information, view procedures or make rounds in any patient care area.
    - Pharmaceutical industry sponsored educational offerings held on CHS campuses must have prior approval and be advertised only in designated areas.
    - Samples, when accepted, will be delivered only to the Pharmacy Department.

    Identification Violations:

• No Identification badge
• Outdated identification badge
Location Violations:
• Found on campus with no appointment
• Found in a restricted area
• Found after approved hours without prior approval
Detailing Violations:
• Detailing non-formulary agents or dosage forms
• Detailing non-formulary indications or usage
• Using inappropriate detail material
• Detailing in a restricted area
• Leaving samples in unapproved areas
Promotional Violations:
• Providing unapproved educational offerings on campus
• Posting notices for unapproved educational offerings
• Posting or leaving *any promotional material in* unapproved areas
Violations Guidelines:
• First Violation Received – Pharmacy Department will issue a *written warning* to the pharmaceutical sales representative and a copy will be sent to the company regional manager
• Second Violation Received – Pharmacy Department will issue a second written notice to the pharmaceutical sales representative indicating that he/she are banned for three months from all facilities named in the CHS Pharmaceutical Sales Representative policy. The pharmaceutical company's regional manager, will receive a copy of the written notice.
• Third Violation Received – Pharmacy Department will issue the third and final written noticeto the pharmaceutical sales representative indicating that he/she are banned permanently from all facilities named in the CHS Pharmaceutical Sales Representative policy. The pharmaceutical company's regional manager, will receive a copy of the written notice.

16. The American Medical Association's Council on Ethical and Judicial Affairs provides: "Any gifts accepted by physicians individually should primarilyentail a benefit to patients and should not be of substantial value." R. J. McMurray et al., "Gifts to Physicians from Industry," *JAMA* 261, no. 4 (1991): 501.
17. G. Harris, "Group Urges Ban on Medical Giveaways," *New York Times*, April 28, 2008.
18. The AMA's Council on Ethical and Judicial Affairs proposed amendments to its Constitution and Bylaws that include the following: "Individual physicians and institutions of medicine, such as medical schools, teaching hospitals, and professional organizations (including state and medical specialty societies) must not accept industry funding to support professional education activities." *Report 1 of the Council on Ethical and Judicial Affairs (A-08): Industry Support of Professional Education in Medicine.*
19. M. A. Gagnon and J. Lexchin, "The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States," *PLoS Medicine* 5, no. 1 (2008). Gagnon and Lexchin express skepticism about the accuracy of the IMS data. IMS relies on surveys. This fails to rule out that companies may systematically underestimate their promotional spending for public image reasons. IMS does not count the cost of meetings and sponsored talks featuring speakers bureau members. IMS does not count spending on phase IV "seeding" trials. These are designed to promote prescribing of new drugs rather than to generate scientific data. And, since almost 75% of these trials are managed solely by the commercial, as opposed to the clinical, division of biopharmaceutical companies, Gagnon and Lexchin infer that the vast majority of these trials are promotional. Their revised estimate for promotional spending in the U.S. is twice as high as IMS.
20. T. A. Brennan et al., "Health Industry Practices That Create Conflicts of Interest: A Policy for Academic Medical Centers," *JAMA* 295, no. 4 (2006): 429-433, at 429.
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31. *Meinhard v. Salmon*, 164 N.E. 545 (N.Y. 1928).
32. G. C. Hazard, "Conflict of Interest in the Classic Professions," in R. G. Spece, D. S. Shimm, and A. E. Buchanan, *Conflict of Interest in Clinical Practice and Research* (New York: Oxford University Press, 1996): 85-104, at 85.
33. See, E. L. Erde, "Conflicts of Interest in Medicine: A Philosophical and Ethical Morphology," in R. G. Spece, D. S. Shimm, and A. E. Buchanan, *Conflicts of Interest in Clinical Practice and Research* (New York: Oxford University Press, 1996): 12-41.
34. See *Neade v. Portes,* 193 Ill.2d 433 (2000). Despite that the Court agreed with Dr. Portes that his motive in denying decedent a referral for cardiac catheterization was irrelevant to the question whether his doing so constituted malpractice, the case narrative makes it very hard to resist the inference that the incentives Dr. Portes faced motivated the denial. We aren't told how many times Dr. Portes authorized referrals despite the incentive to deny them. Since the incentive to deny referral was always present, obviously it cannot explain the referrals he authorized.
35. See *Neade v. Portes*, 193 Ill.2d 433 (2000) for a case focused on fiduciary duty and incentives to disloyalty. The Court rejected inquiry into Dr. Portes incentive-prompted motives and insisted that the cause of action be framed in malpractice — namely, that the doctor's duty should be determined by reference to what a reasonable doctor would have done in the circumstances.
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