Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light On

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Abstract: The pharmaceutical industry, in its marketing efforts, often turns to "key opinion leaders" or "KOLs" to disseminate scientific information. Drawing on the author's fieldwork, this article documents and examines the use of KOLs in pharmaceutical companies' marketing efforts. Partly due to the use of KOLs, a small number of companies with well-defined and narrow interests have inordinate influence over how medical knowledge is produced, circulated, and consumed. The issue here, as in many other cases of institutional corruption, is that a few actors have accumulated the power to shape the information on which many others base their decisions. Efforts to address this corruption should focus on correcting large imbalances in the current political economy of medical knowledge. A sequestration of pharmaceutical research and development on one hand from pharmaceutical marketing on the other, though difficult to achieve, would address this and many other problems.

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In 2010, in connection with the Patient Protection and Affordable Care Act (Obamacare), the United States Congress passed the Physician Payment Sunshine Act.[1] This legislation requires pharmaceutical companies, medical device companies, and other manufacturers of medical supplies to collect information on their payments to physicians, beginning on August 1, 2013, and to annually report this information to the Centers for Medicare and Medicaid Services (CMS), beginning on March 31, 2014. All payments of over $10 are to be reported and aggregate payments of more than $100 to a single physician in a single year must also be reported.[2]

While it makes little sense to attribute to Congress a unified set of intentions, the Sunshine Act is framed in terms of transparency to the public at large; thus, the Final Rule implementing the Act puts its provisions in the context of exposing potential conflicts of interest to the public.[3] That is also how the Act is being portrayed by CMS and by the popular media. Dr. Peter Budetti, a CMS administrator, says: "You should know when your doctor has a financial relationship with the companies that manufacture or supply the medicines or medical devices you may need…. Disclosure of these relationships allows patients to have more informed discussions with their doctors."[4] A *New York Times* editorial, "Finding out who pays your doctor," describes the Act in the

same terms: “This information will allow patients and their families to check whether their own doctors are receiving payments and to see if those financial connections affect a doctor’s recommendation for a particular treatment or device.”[5] The Sunshine Act, then, seems to be one in a family of regulations targeting the ability of manufacturers to influence physicians, through gifts and similar inducements, to prescribe particular drugs or use particular products. By exposing conflicts of interest, the Act might lessen their impact or at least allow informed patients to understand them.

The Sunshine Act may lead to some exposure of and responses to conflicts of interest, but we can see many of these payments to physicians through a very different lens, which reveals a very different set of issues. The larger payments, at least, that pharmaceutical and medical device companies make to physicians are primarily intended not to affect their prescriptions, but rather to purchase their influence on other physicians’ prescriptions; the same is true of payments to researchers. In other words, companies hope to lead medical opinion in their preferred directions through a two-step model of influence by hiring and otherwise enrolling some physicians and researchers who will, in turn, influence many others.

If past disclosures are a guide, we can expect the Sunshine Act to reveal that thousands of U.S. physicians are each paid many thousands of dollars in, for example, speaking fees. These fees make up a significant portion of the industry’s payments to physicians and I will argue below that, in pharmaceutical companies’ strategies, they are connected to other payments to physicians for consulting, travel, and research. Filed reports from only seven companies, made public as a result of legal actions, have revealed that hundreds of

U.S. physicians are paid more than $100,000 each year and that many more are paid more than $10,000.[6] Such amounts could hardly be justified by the value of the recipients' own prescriptions. Thus, while the Sunshine Act will bring to light important payments that influence prescriptions, it will do so partly by—unintentionally—bringing to light the scale of industry influence on the distribution of medical knowledge.

Transparency alone is not adequate to address the situation. Neither is guaranteeing the quality of the information that industry provides, another standard response to industry influence. Instead, we should be addressing the larger issue of the "institutional corruption"[7] of medicine; namely, that the pharmaceutical industry has a disproportionate influence on medical opinion, which weakens medicine's ability to promote individual and public health in ways that are independent of the industry. I will argue that strategies to address this problem must sequester pharmaceutical research and development (R&D) from marketing.

1. Co-option

The pharmaceutical industry, in its marketing efforts, often develops and turns to "key opinion leaders," typically referred to as "KOLs," to disseminate scientific information. The term "key opinion leader" derives from the work of sociologist Paul Lazarsfeld and his students on structures of influence in politics, fashion, culture, medicine, and other domains.[8] As suggested by the term itself and its history, pharmaceutical companies hire KOLs primarily to influence others and to lead professional opinion in the directions that the companies prefer.

In what follows, I describe the development and control of KOLs, drawing on a variety of sources including notes from three pharmaceutical industry conferences on the management of KOLs, interviews with 12 physicians who each earned more than $100,000 in speakers' fees in 2009, and some advertising and marketing brochures and websites. This article is part of a larger project drawing more fully on all of these sources.

Making KOLs

Since the early twentieth century, pharmaceutical companies have recognized the value of having respected medical experts speak and write positively about their products.[9] However, the industry didn't start thinking systematically about opinion leaders and KOLs until about the mid-1950s, when Pfizer funded a study on the spread of the prescription of tetracycline, a project that led to a number of articles and to the book *Medical Innovation*.[10]

Michael Oldani, a former pharmaceutical sales representative turned anthropologist, writes:

> A key task of a pharmaceutical rep's job is to help transform influential doctors into speakers and consultants who know the rules of the game and are quite adept at negotiating a stipend and "working the crowd" …. This can be a long process, often years in the making. The process starts with small gifts (ranging from pens to pertinent clinical articles) just to get in the door, which helps establish trust and

> rapport over time, and eventually "developing" the doctor into a speaker for a company's drugs.[11]

For 40 years or more, sales reps and medical science liaisons (pharmaceutical company employees who typically serve as connections to researchers and physicians on scientific, not sales, issues) have been identifying potential KOLs, establishing relations with them, and developing them into more effective speakers and advocates for companies. Increasingly, responsibility for identifying and managing relationships with KOLs has shifted to independent firms. The activity is worldwide, but even within the U.S. market, dozens of companies specialize in identifying potential KOLs, mapping their influence, and recruiting and managing them; others specialize in other national or regional markets. One of the larger such firms is Thought Leader Select, which advertises services such as "Thought Leader ID," "Thought Leader Impact," and "Thought Leader Engage" for, respectively, identifying, mapping, and planning engagement with KOLs.[12] Some firms tout their sophisticated use of social network analytics and others specialize in KOL relationship management and have proprietary software for planning and tracking interactions.[13] KOLs are key to successful pharmaceutical marketing, so engaging with them is big business.

The industry recognizes different kinds of KOL requiring different forms of interaction. At the bottom of the totem pole are ordinary physicians—general practitioners or specialists—who are paid to speak to other physicians. These KOLs become part of the "speakers bureaus" for particular drugs. They might address other physicians at lunchtime talks organized by sales representatives or serve as after-dinner speakers at physicians' events, also organized by sales representatives.

Higher on the totem pole (and usually better paid) are researcher KOLs—people who have a significant research profile and whose value to pharmaceutical companies might stem from any number of activities. They might be paid to speak to researchers or patient groups or at continuing medical education (CME) sessions. They might be consulted on any number of medical, marketing, or research issues. They might serve as authors of medical journal articles stemming from company-led research. Or they might contribute to research either by recruiting patients for trials or by initiating their own trials.

Pharmaceutical companies train their speakers and work with them to make them "product champions."[14] One well-paid KOL, Dr. C, although he recognizes that there is more to a good speaker than knowledge, describes his experience of speaker training in terms of the scientific knowledge he gains:

> Usually, [speaker training sessions] are two- to three-day meetings where you're sort of in meetings from about 8 o'clock in the morning to about 5 o'clock at night for a few days where you're learning about the clinical research, the FDA approval process for the medicine, get a chance to speak with some of the people that were involved in the original research, and sort of try to become more educated about the details.

The communications firm Wave Healthcare, however, frames the virtues of speakers in terms of the influence they can have. "It's vital that advocates are able to communicate and influence colleagues with clarity and conviction," the company claims on its website. "To ensure speakers are at the top of their game, we have developed a communication skills programme for clinicians."[15] KnowledgePoint360, which owns Physicians World

Speakers Bureau, offers training programs for speakers, sales representatives, and medical science liaisons alike and its promotional material appears to treat KOLs and employees in the same terms: "Whether it is for external resources, such as speakers, or internal staff, including sales representatives and medical science liaisons, a robust training program is critical to the long-term success of any pharmaceutical, biotech, or medical device company."[16] Members of a speakers bureau are seen by pharmaceutical companies as promoters of a drug, making an effective scientific case for it. This is important because, according to industry analysts, pharmaceutical companies spend 15 to 25 percent of their marketing budget on speaking events.[17]

Undoubtedly, some physician KOLs on speakers bureaus are influenced in exactly the way that the framing of the Sunshine Act envisions. Pharmaceutical company manager Mr. E, speaking at a KOL management conference, raises the specter of an investigation of a speakers bureau program: "When you say 'I need 700 to 1000 speakers in this activity,' the questions [that are] going to get pushed back to you in investigations are, 'Why do you need so many? How many is each speaker going to do? Why did you need a thousand?'"[18] Mr. E's concern is that investigators will conclude that 1000 speakers are being trained not because they are all effective communicators, but because they are important prescribers. Nonetheless, there is a continuum from KOLs employed primarily to change their own prescribing patterns to those employed primarily to change other physicians' prescribing patterns. Given how high some of the payments are, there must be many of the latter.

Controlling KOLs

We can see the pharmaceutical companies' goals in, for example, the medical marketing firm Watermeadow's claim that the term "KOL" is usually "a convenient shorthand for those people—usually eminent, usually physicians—who we co-opt into our development and marketing strategies."[19]

In the U.S., physician KOLs are generally given zero latitude in their talks, which are deemed by the Food and Drug Administration (FDA) to be "promotional" because the physicians are essentially acting as pharmaceutical company representatives. To reduce the chance of speakers saying anything that might be construed as off-label marketing, which could become fodder for lawsuits, sponsoring companies provide PowerPoint slides and instruct speakers to hew closely to the content of those slides. Salespeople monitor the talks and provide helpful suggestions on how to increase their marketing potential.[20] Dr. J, another of my sample of well-paid KOLs, says: "When you're out there actually doing a talk, you really have to follow those rules to a T. If you don't follow those rules then … you're at risk of, you know, breaking procedure and, I mean, arguably, I guess you're at risk of breaking the law."

Ideally, from a company's perspective, its relations with KOLs are part of a general "KOL management" plan. Judging from discussions at KOL management conferences, it's apparent that many smaller pharmaceutical companies fall short of having a full plan.[21] At the very least, say the experts in KOL management, interactions with KOLs

should be structured by goals. Ms. B, a senior manager of medical science liaisons at a mid-sized pharmaceutical company, says:

> When you go in, that might be your goal, your objective, is to just continue to develop that relationship. And that's okay. It's just that, at some point, you need to expand on that goal.… At the end of the day, we do want something from them.… We have needs that need to be met by KOLs, on the medical affairs side.[22]

With physician KOLs, the goals and consequent relationships are straightforward, since the physicians are simply hired to give talks. Researcher KOLs, though, are treated so that they feel more like partners—perhaps junior partners—in medical science and education. As a result, interactions with them need to be subtle. Indeed, much of their value to the companies—and this creates a real tension—stems from their independence from those companies. Mr. J, an experienced consultant who has worked both in and with the pharmaceutical industry, emphasizes that the industry needs KOLs who are willing to work closely with it, but who also wish to maintain their sense of integrity and appearance of independence. He says the number-one requirement specified by KOLs is: "Protect my reputation." He goes on to reiterate that KOLs desperately want to avoid the "appearance of . . . being an industry 'sell-out'."[23] Still, this does not stop KOL management experts from indicating over and over that KOLs can be used as important mediators for pharmaceutical companies. Here is Ms. C talking to KOL managers and medical science liaisons about good planning:

> [A] KOL point person can help you and the organization make sure that you are … identifying the right expert for the right need and able to work with them at the right place and time and be able to deliver a KOL plan that's aligned to their scientific objectives. … Particularly as you start to enter Phase One, Phase Two [trials], and, you know, these molecules are moving along, it looks to have some promise—okay there are unique aspects perhaps about the mechanism of action—it's going to be very important to help start to educate the community, the physician community, the patient community, the professional societies on this mechanism of action [and] on the disease state itself.[24]

That early education is done by researcher KOLs. Therefore, they need to be "engaged" and have their "experiences managed" so that they become parts of a "coalition," "an armamentarium of expertise external to the company," or parts of "activation networks for drugs"—a selection of descriptions that arose at one conference.[25]

As with the physician KOLs, the most important thing that researcher KOLs do for pharmaceutical companies is influence other physicians and researchers. They are paid to deliver CME content, give talks to specialists and other important physician groups, make presentations at workshops and conferences, and even give training sessions for physician KOLs. For these talks, the honoraria can be $2500 or more,[26] versus the $500 to $1000 paid to physician KOLs for their presentations.

But researcher KOLs do more than simply speak. They can smooth the path to acceptance of drugs and diseases by helping to shape the background of accepted issues and opinions

in a field; that is, by acting as the "opinion leaders" described by Lazarsfeld and others in the 1940s and 1950s.[27] For example, researchers on female sexual dysfunction acted as mediators between pharmaceutical companies, the FDA, physicians, and potential consumers.[28] They held industry-sponsored workshops and wrote position papers that solidified female sexual dysfunction as an illness, thereby positioning themselves as the very experts to whom the FDA would turn for advice on drug submissions and to whom the media would turn for interviews and information. Because of their various roles, researcher KOLs often receive consulting fees, awards for travel, and research grants on top of their speaking fees.

One particularly useful way in which researcher KOLs can help establish a favourable medical reception for a drug is to serve as (unpaid) authors on "ghost managed" manuscripts. These are manuscripts for which pharmaceutical companies control or shape multiple steps in the research, analysis, writing, and publication. Pharmaceutical companies not only fund clinical trials, they also routinely design and shape them, typically employing contract research organizations to run those trials.[29] By combining and splitting datasets, the companies propose multiple manuscripts derived from a study or group of studies.[30] Hired medical writers produce first drafts and edit papers, which publication planners expertly shepherd through the publication process.[31] Because of the commercial importance of having the right sort of author and of keeping companies' interests in the background, KOLs serve as the nominal authors of manuscripts. It can then appear as if respected independent researchers, rather than coordinated corporate teams, led the research and analysis. KOL authorship increases the perceived credibility

of an article while hiding key features of the research process. For example, even though an array of employees and contractors—company statisticians and researchers, reviewers from multiple departments, medical writers, and publication planners—often contribute more to the research and the articles than the nominal authors do, they are only rarely acknowledged in journal publications.[32]

It is difficult to evaluate the real influence and effects of KOL activities. Discussion at conferences dedicated to KOL management indicates a consensus that KOLs are increasingly important and that investment in KOLs is increasing at the expense of investment in sales forces.[33] Of course, the attendees at such a conference are committed to—and have a stake in—activities involving KOLs. Still, their views are corroborated by other sources; for example, the number of articles in the industry journal *Pharmaceutical Executive* that mention "opinion leader" roughly tripled between 2000 and 2010. The industry appears to be paying more attention to KOLs, which may reflect an increasing awareness of their potential value.

2. Institutional corruption and the politics of knowledge

Many of the standard responses to industry influence on medicine focus on transparency and information quality. Both are important, but, as I show below, the effects of acting on them are limited.

Increasing the transparency of relations between KOLs and their sponsors

There is some evidence that exposing conflicts of interest actually intensifies their effects.[34] But even setting that aside, pharmaceutical industry funding of medical education and research is so widespread that many within the medical community evaluate information with industry origins or connections in the same way that they evaluate more independent information and sometimes even value it more highly. Physicians recognize that drug representatives have interests in promoting products, but many welcome interactions with those representatives anyway. In focus groups, they justify their actions in various ways; for example, by referring to educational value: "They [sales reps] tell you about their product and you learn about it. A lot of the things I know about the new drugs, I learned from the pharmaceutical representatives."[35] Furthermore, continuing medical education is dominated by industry funding, a fact apparently accepted by the many physicians who participate.[36] And, with few exceptions, medical journals apply exactly the same procedures and standards to industry-sponsored submissions that they apply to independent ones.

The extraordinary transparency legislated by the Sunshine Act will, as I have argued above, display much more flow of money and many more interactions than those simply designed to influence the prescriptions of the physicians who receive that money. But such interactions are ubiquitous, so transparency, while it is ethically desirable and provides useful data for analysis, is of limited immediate value in changing the situation.

Guaranteeing the quality of the information that KOLs circulate

The FDA requires that all drug talks deemed "promotional" align their claims to those of the drug's label. The penalties for deviance from that label can be substantial, as can be seen from the many recent government suits against drugmakers that include complaints of off-label marketing.[37] This is one way in which regulators attempt to control the quality of pharmaceutical industry information. But we should not assume that well-educated and apparently honest physicians and researchers are routinely peddling falsehoods. Indeed, the kind of knowledge that they share conforms well to medical standards and passes many routine regulatory and scientific tests. Medical journal articles sponsored by the pharmaceutical industry score as highly on standard methodology criteria as do comparable independent articles.[38] Ghost-managed articles are cited three times as often as their independent counterparts on the same medication.[39] These facts suggest that industry science is not, on the surface, inferior to independent science. As for the human conduits of that information—the highly paid KOLs I interviewed—all insist that they believe in the drugs for which they speak. Dr. A, for example, cheerfully comments: "My mother and father are on a lot of the drugs I speak for. I think they're terrific. So, I am not putting my parents on it because I am speaking for the company—it's the best drug." Their confidence in the drugs stems not only from experience, but from evaluations of the science. Says Dr. B of giving presentations: "If I don't believe the data, I won't do it."

For all these reasons, concern about industry use of KOLs should not fixate on the possibility that industry-KOL relations are hidden or that KOLs spread incorrect or unsanctioned information. Rather, we should attempt to limit the sheer amount of

influence that pharmaceutical companies have on medical opinion. The extensive and various use of KOLs, in particular, contributes to a situation of institutional corruption. That is, the medical profession has been corrupted because a small number of companies with well-defined and narrow interests have inordinate influence over how medical knowledge is produced, circulated, and finally used by physicians to make decisions concerning their patients. As in many other cases of institutional corruption, a few actors have accumulated the power to shape the information landscapes—in this case, some very large and important landscapes—on which many others base their decisions. Pharmaceutical companies not only shape taken-for-granted medical knowledge and opinions, but have also, in many situations, naturalized their presence and roles: Most physicians see the companies as playing legitimate roles when the companies promote products in clinics, when they create and distribute medical research, and when they fund and provide continuing medical education.

The issue of how much influence pharmaceutical companies have on medical opinion is entirely independent of any issues of the truth or solidity of the knowledge they create, shape, and distribute. Even if it consisted of nothing but sound medical knowledge, its very form and availability serve the companies' interests. The questions asked and answered, the precise ways in which studies are designed and performed, the aggregation of data, the framing of analyses, and the audiences to which conclusions are communicated—all of these can be affected by companies' interests, especially when those interests are applied consistently. Pharmaceutical companies' profits are increased most by having large markets for drugs at high prices; this need can most easily be served

by increasing demand, which is a product of perceptions of illness and perceptions of the efficacy of drug treatments. In the case of drugs, increasing demand often is not in the public interest, and especially not in the interests of consumers and payers.

Unfortunately, understanding the problem in terms of large imbalances in the current political economy of medical knowledge does not lend itself to easy solutions. If pharmaceutical companies have too much power to shape medical knowledge because of their substantial resources, solutions would have to focus on reducing their resources or substantially increasing someone else's resources as a counterbalance.

A number of commentators have called for the "sequestration" of clinical trial research on drugs.[40] The idea is that this key knowledge resource is too important to be left to private industry and should therefore be controlled by governments or by independent agencies funded through taxes or fees paid by the pharmaceutical industry. Former *New England Journal of Medicine* editor-in-chief Marcia Angell, for example, proposes the establishment of an "Institute for Prescription Drug Trials" under the auspices of the National Institutes of Health, to be funded through a tax on the revenues from prescription drug sales.[41]

We can push the sequestration strategy further to address imbalances in medicine's economy of knowledge. A full sequestration of pharmaceutical research from marketing at the organizational level would much reduce the corruption of medical knowledge. Recognizing that the integration of pharmaceutical R&D and marketing does not serve

the interests of the public, governments could split companies into those units that perform R&D and those that market, like the successful separation of the generation and distribution of electricity in the United States. R&D firms would sell, in a well-regulated manner, their successful products to marketing firms. Variants of this proposal have been put forward to address other issues; in particular, the high prices of drugs in the U.S. and the pharmaceutical companies' inefficient use of their R&D resources. Harvard medical scientist Stan Finkelstein and MIT economist Peter Temin, for example, propose that a public-private entity—a "Drug Development Corporation"—buy patents from pharmaceutical R&D firms and auction them to marketing firms.[42] Their proposal would separate R&D from marketing up to the point of FDA approval, though it would allow pharmaceutical marketing companies to continue to perform Phase IV trials (those trials conducted after a drug is on the market). Because of that continued connection between R&D and marketing, the proposal would likely fail to curb some of the industry's excesses, such as the ones detailed above, in which marketing goals infuse the creation and distribution of scientific knowledge. For this reason, a strict separation of functions, rather than of R&D phases, is preferable, even though it would leave postmarketing studies to be funded through public sources.

A split between pharmaceutical R&D and pharmaceutical marketing companies would place limits on R&D and marketing only by reducing the blending of the two, but in this it would have profound effects on the structure of both. Pharmaceutical R&D firms would have little incentive to flood the medical marketplace with knowledge, because they would be selling their products to marketing firms, not to physicians and consumers.

Thus, R&D firms would likely not engage in close interactions with physicians and would have less incentive to invest resources in the ghost managing of medical research and publications. Pharmaceutical marketing firms would be free to sell products on the basis of science, but would be hampered in shaping medical science because their marketing role would be overt. The proposal thus dovetails with efforts at transparency, because the companies doing the marketing would be explicitly understood to be doing just that.

This strong sequestration proposal is radical and is unlikely to be implemented in the short run. At least, though, one could respond to the above account of KOLs with a more limited proposal, using a similar strategy but focusing on physician KOLs. There is no obvious public good served by physicians giving promotional talks. Even if there is educational value in promotional talks—a debatable point—that value could be provided just as well by sales representatives as by physicians. Thus it would make sense to ban promotional talks by physicians, leaving those talks to be given by sales representatives, whose recognized job is to promote drugs.

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41. *Id*., Angell, p. 245. Schafer's proposal is essentially the same. See, also, See, D. W. Light, J. Lexchin, J. Darrow, "Institutional Corruption of Pharmaceuticals and the Consequences for Patients" Journal of Law, Medicine and Ethics (this issue).

42. S. Finkelstein and P. Temin, *Reasonable Rx: Solving the Drug Price Crisis*. Upper Saddle River, New Jersey: Pearson Education, 2008. See also the Medical Innovation Prize Act. H.R. 417 (109th).