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PEER-REVIEWED CME ARTICLE

Medicine's Valuing of "Normal" Cognitive Ability

Julie M.G. Rogers, PhD, C. Christopher Hook, MD, and Rachel D. Havyer, MD

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Functionalists describe the role of medicine as maintaining the "normal" functioning of individuals and society [1]. Definitions of normal functioning, however, are subjective, determined by cultural and personal values. Medicine's values and the resulting explanatory model of disease do, in fact, promulgate a definition of normal functioning and, by extension, a version of "the good life." However, medicine's version of "the good life" may not reflect that of many of those it serves, causing a conflict that remains largely unrecognized. Herein we discuss how one of the most prominent values of the medical profession—intellectual ability [2]—contributes to that conflict. This valuing of intellectual ability constructs and projects onto patients an often misguided notion of "the good life," with far-reaching and unfortunate implications for those with cognitive or intellectual disabilities. We conclude with practical suggestions for how medical students, faculty, and practitioners can challenge biases that may be harming patients who have a different notion of "the good life."

Intellectual Ability and "The Good Life"

We surveyed two consecutive classes of first-year students at Mayo Medical School and asked them: "Would you be able to live a fulfilling life if you had a severe physical disability [or] severe cognitive disability?" Ninety-three of 95 students (98 percent) responded. Forty-nine students (53 percent) thought they could have a fulfilling life with a severe physical disability, but only 24 students (26 percent) thought they could have a fulfilling life with a severe cognitive disability (unpublished survey). In the resulting classroom discussion, the students recognized that their personal success and identity had been linked to their intellectual ability, making a cognitive impairment much more of a threat to their identities. They wondered if a similar survey of athletes would yield the opposite results.

Physicians are educated for many years and are rewarded for their intellect. It is not surprising that intellectual ability is a primary value held by academic physicians [2].

However, the notion that intellectual ability is an essential element of “the good life” is not necessarily congruent with the capably expressed [3] perceptions of the approximately 25 million people living with cognitive disabilities, intellectual disabilities, or both in the United States [4, 5]. While there is considerable diversity in findings of life satisfaction [6, 7] for people with cognitive and intellectual disabilities, some from sampled populations have expressed a high level of life satisfaction. For example, a national survey [8] reported that “99 percent of people with Down syndrome indicated that they were happy with their lives [and] 97 percent liked who they are” [9], a result that did not correlate with reported degree of learning difficulty [8]. Also, a recent survey of people with dementia found no correlation between a person’s level of cognitive impairment and reported quality of life [LINK: <http://journalofethics.ama-assn.org/2006/05/jdsc1-0605.html>] [10]. In fact, several clinical trials have shown significant increases in cognitive function in patients with dementia without changes in reported quality of life [11-14].

In studies showing that some people with a cognitive impairment experience a lower quality of life than those without cognitive impairments, the reasons cited for diminished quality of life more often include conditions like depression [15] or social factors like employment and relationship problems [6, 16, 17] than the cognitive impairment itself.

Historically, persons with cognitive and intellectual disabilities have lived with severe social stigma [18]. As they begin living in communities instead of institutions and obstacles to employment [19] and education [20] are addressed, social attitudes are also improving [21]. While this trend is also seen among medical professionals [22], change in medicine’s perception of intellectual and cognitive disability lags behind change in other professions’ attitudes. A study comparing members of four different helping professions who regularly interact with people with intellectual disabilities—physicians, psychologists, social workers, and special education teachers—found that physicians had significantly lower expectations and more pessimistic prognoses than surveyed members of all other professions [23].

Consequences of Medicine’s Valuing of Intellectual Ability

Medicine’s definition of normal intelligence is an intellectual quotient above 70. Similarly, a mental status exam score consistently below 26 suggests dementia [24]. Such measures of function are important to medicine because they are used to determine the need for and potential impact of interventions. Measures of life satisfaction or quality of life, on the other hand, are rarely considered. Of the numerous clinical trials that have investigated medical interventions for dementia, only a small percentage has included any measurements of patient life satisfaction [25]. As a direct consequence of the narrow design of this research, the targets of interventions are sometimes more controversial among patients and their families than those immersed in medical culture realize. For example, when parents of people with Down syndrome in Canada were asked

if they felt researchers should be trying to find a cure for Down syndrome, only 43 percent said “yes” [26]. Some research advancements hailed by the media as possible “cures” might be met by resistance from some parents of those with Down syndrome, a phenomenon described by one journalist as “Down syndrome soul searching” [27].

Many clinical ethical dilemmas arise from the intersection of intellectual and cognitive disability and medicine’s valuing of intellectual ability. For example, the medical literature discusses a “window of *opportunity*” to withdraw life-sustaining treatment for someone who is likely to survive an acute event with an intellectual or cognitive disability [28]—the term “opportunity” implying that death might be a preferable outcome. The medical literature contains few studies on the long-term quality of life of the people who survive acute events with disabilities (e.g., neonates who survive an intraventricular hemorrhage) [17, 29, 30]. Skotko, Levine, and Goldstein’s survey of people with Down syndrome found that 99 percent of those surveyed were happy with their lives [8], which would indicate that the assumption that a person’s interest is better served by dying than living with disability may be erroneous. And many of these respondents were born before the passage of the Baby Doe Law [31], when it was thought compassionate to allow a newborn with Down syndrome to die.

Such attitudes have real health consequences. People with intellectual disabilities meet most of the federal criteria for a “medically underserved population.” Two Surgeon General’s reports [32, 33] and a report from the National Council on Disabilities [34] describe decreased access and poorer-quality health care for people with intellectual disabilities. People in this population are less likely to receive preventive care [32], treatment for acute conditions [35], or desired care at the end of life [36]. The disparities have been partially attributed to overly negative attitudes on the part of clinicians [LINK: <http://journalofethics.ama-assn.org/2015/06/nlit2-1506.html>] [37, 38] about quality of life with a disability, which greatly influence proposed treatment plans [39, 40]. For example, it has been suggested that physicians undertake fewer smoking cessation discussions with patients who have intellectual disabilities than with patients who do not, because physicians assume that smoking provides some enjoyment in an otherwise unhappy life [41].

Not only is the health care provided to individuals with disabilities subpar, but their very self-concepts and their families’ perceptions of them can be affected. For example, a study found that people who were newly injured and interacting closely with medical staff absorbed negative attitudes about themselves [42]. Similarly, parents’ fear and anxiety were increased if medical staff chose to present what parents later perceived to be overly negative information at the time their children were diagnosed with intellectual disabilities [43]. This phenomenon is dangerous to a population that is overcoming social stigma and has only recently been afforded the same rights as other citizens [44]. Although pessimistic attitudes towards people with intellectual and cognitive disabilities

are prevalent in medicine, the impact of the problem on health is so great that it has been suggested that anyone prejudiced in this way should be excluded from the profession [38].

Suggestions for Current Medical Students, Medical Faculty, and Practitioners

Medicine's valuing of intellectual ability has negatively affected the care provided to people with intellectual and cognitive disabilities. But patients' accounts of their own experience show that the entire range of cognitive abilities, even those that fall well below a medically defined "normal," are compatible with a high or acceptable quality of life. To better serve patients with intellectual or cognitive disabilities, it is imperative that medicine challenge its own biases and recognize the harmful effect of imposing recommendations based on medicine's version of the "good life" on those who may hold different personal values. We provide a brief list of suggestions to move toward this goal.

1. *Teach about disability in medical school.* A national survey of medical students found that 81 percent were not receiving any clinical instruction on intellectual disabilities and 66 percent did not believe they received sufficient classroom instruction [45]. Furthermore, there are very few medical schools that have curricula addressing the lived experience of people with intellectual and cognitive disabilities, even though such curricula have the potential to improve attitudes toward these populations [46].
 - a. Individuals who have intellectual or cognitive disabilities should be involved in the design and implementation of this training [47, 48]. Their involvement would help challenge notions of "the good life" derived exclusively from medical culture and communicate the actual experiences of patients.
 - b. Make the value medicine places on intellect visible and a topic for discussion. Allow for reflection about how this value might manifest itself in the students' own decision making and potentially impact patient care.
 - c. Encourage premedical and medical students to gain experience working with people who have intellectual and cognitive disabilities through either volunteer or classroom activities. People who have relationships with people who have intellectual and cognitive disabilities are more likely to understand them [22, 49]. Discussion of student experiences with disability should be encouraged.

2. *Increase diversity* [LINK: <http://journalofethics.ama-assn.org/2015/04/msoc1-1504.html>] *in medical schools and, therefore, the medical profession.* Admit applicants who have disabilities and work toward improving their education. *Unnecessary barriers* [LINK: <http://journalofethics.ama-assn.org/2015/02/pfor2-1502.html>], such as overly rigid technical standards for admission and lack of the

accommodations that should be available according to the Americans with Disabilities Act, exist for medical school applicants who have disabilities [50]. Furthermore, there are notable discrepancies in medical education outcomes. Students without disabilities perform significantly better on the US Medical License Exam (USMLE) Steps 1 and 2 Clinical Knowledge, even with comparable academic and clinical performance [51], as well as on the Medical College Admissions Test (MCAT) [52]. The reasons for this discrepancy are poorly understood, and a failure to examine this problem perpetuates the stigma surrounding disability and the belief that intellectual “normalcy” is necessary for “the good life.”

3. *Treat the patient, not the impairment.*

- a. The dangers of adhering to “the golden rule,” or “treat others as you would like to be treated,” in a clinical setting have been described [53]. Physicians must recognize their own values and that these might be very different from those of their patients.
- b. Accordingly, if increasing cognitive function is an option, it should be discussed with the patient, but clinicians should not assume that increasing cognitive function is a goal.
- c. Clinicians should not assume that cognitive impairments necessarily decrease quality of life for every patient.
- d. If the patient describes a low quality of life, clinicians should not assume cognitive impairment is the cause but should explore depression and other mood disorders as well as social contributors to quality of life, like relationships and employment.

4. *Research the patient, not the impairment.*

- a. Interventions can only be useful to patients if they are in line with their own perception of “the good life.” Researchers should not assume that increased cognition is the only end goal that matters. Quality of life and social factors affecting people with intellectual and cognitive disabilities should also be studied [54].
- b. A good way to achieve this goal is to develop the aims of research programs with help from the community intended to benefit from the research.

We are urging a cultural change: not devaluing intelligence in medical professionals, but increasing awareness of medical culture and values and how they may differ from those of patients. All cultural change takes time and is challenging, but medical culture has been described as particularly difficult to change [55]. It is not impossible, however, and it is important that medicine does not, through its own unexplored values, perpetuate

inequalities for people with cognitive and/or intellectual disabilities as they attempt to overcome substantial historical stigma.

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FROM THE EDITOR

Medicine and the Market

Unlike in countries with nationalized or restrictively regulated health care systems, the United States' system is embedded in and based on a capitalist, market-based model. Market forces, including the profit motives of corporate interests such as insurance and pharmaceutical companies, have a significant role in shaping the provision of medicine in the United States. They have significant effects on individual practitioners—in their medical education years and in their practice years—and on patients—in their ability to access, afford, and choose care—as well as policy, through industry lobbying efforts. Our contributors examine and elucidate these effects in the August 2015 issue of the *AMA Journal of Ethics*.

Corporate interests begin shaping physicians' practice as soon as they begin their education. In a case commentary, Ashvini K. Reddy, MD, explores the effect of donated surgical equipment on the future business practices of medical students, who can form a lifelong preference for and loyalty to the systems they train on. Recognizing the early appearance of business issues in medicine, the Bander Center for Medical Business Ethics works to instill in students ethical business decision making. As Erin L. Bakanas, MD, and Tyler A. Zahrli explain, its most recent endeavor in that direction is its new casebook, available for free on the Bander Center website.

Once physicians get into practice, pharmaceutical companies vie for their business; though much of the wining, dining, and gifting that were once standard is now prohibited, companies still seek to pitch to and form relationships with physicians. David F. Essi, MA, contributes a piece on commonplace violations of Food and Drug Administration guidelines for pharmaceutical speaker programming at restaurants. In his case commentary, Shahram Ahmadi Nasab Emran, MD, MA, gives readers guidance about meeting with pharmaceutical company representatives and parsing the information they present.

Pharmaceutical companies affect not only physicians' prescribing practices, but also which drugs are developed, how much they cost, and their availability in ways influenced by financial motives. Taeho Greg Rhee, AM, gives an overview of the Orphan Drug Act's incentive for companies to develop treatments for rare diseases and what progress still needs to be made. I review a statement on the high and increasing prices of drugs for chronic myeloid leukemia, which the authors, experts in the field, strongly object to. Tobin Klusty explains the recent court case *State of New York v Actavis*, which determined that the practice of "product hopping," or introducing a new formulation of a patented

drug just before its patent expires, thereby restarting the patent “clock” and preventing generic competition, is anticompetitive.

Insurers, too, of course, have their own bottom lines to consider. The Affordable Care Act (ACA) has done much to curtail insurer business practices that harm patients. Sandy H. Ahn, JD, LLM, reviews the new regulations of insurer business practices that the ACA put in place to promote access to care, affordability, and adequate insurance coverage.

Concerns about the bottom line also affect what hospitals charge patients and their insurers and how they collect those fees. Erin C. Fuse Brown, JD, MPH, discusses the gaps in current legislation that fail to prevent for-profit hospitals from engaging in predatory billing and bill-collection practices; she suggests making the preventive restrictions apply not only to nonprofit hospitals but to all hospitals that participate in Medicare. In the podcast, interviewee Peter A. Ubel, MD, discusses factors contributing to the high cost of health care and the compatibility of cost containment and profit seeking.

Another way of protecting patients from unpayable hospital and health system prices is discussed by Gerard Anderson, PhD, and Bradley Herring, PhD: all-payer rate setting, in which all insurers pay the same price for each individual service or treatment, rather than each paying different rates. This would reduce costs by drastically reducing the complexity and administrative needs of the system, give insurers the bargaining power to keep prices lower, improve access to care, and make costs more transparent to patients.

Several situations in which physicians’ own bottom lines may create conflicts of interest—dispensing of products in the clinic and self-referral—are discussed in this month’s code excerpt. In his piece, Eli Y. Adashi, MD, MS, takes a big-picture look at the relationship between financial gain and healing throughout the ages.

The fact that our health care system is market based is the background against which all medical ethics issues play out in the United States. Too often this leads us to take market-based ethical problems for granted. We hope that this issue of the *AMA Journal of Ethics* will spur readers to consider them anew.

Hannah L. Kushnick, MA

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ETHICS CASE

Assessing Information from Pharmaceutical Company Representatives

Commentary by Shahram Ahmadi Nasab Emran, MD, MA

"Just five minutes of your time, doc!"

Dr. Herman turns to see a brilliantly white, winning smile aimed her way. This is the third drug company detail rep who's come looking for her this week.

Newly finished with her residency training, Dr. Herman has joined an outpatient practice group. Her residency program had a policy requiring that interactions with pharmaceutical representatives be pre-approved by the program director, that no gifts or freebies be accepted, and that the scheduled time be used only for the group of residents to discuss peer-reviewed publications and indications for FDA-approved uses with the rep; the guidelines for the interactions were very clear. Not so now.

Dr. Herman actually does have a few minutes before her next appointment, but she turned away the last pharmaceutical rep because she was busy when he came by. *I need an actual plan for this*, she thinks to herself. Should she make a habit of talking to these representatives? Just accept their samples—every doctor she knows seems to do that, but is it a good idea? Send them away? In her new position, she is realizing, it's up to her to set the rules, the times, and the tone for these interactions.

Commentary

The questions Dr. Herman is dealing with are not in any way peculiar to her. Almost all practitioners of medicine will face the same questions sooner or later in their careers. The answers given thus far [1, 2] by medicine's professional organizations reflect the major concern: unjustifiable influence resulting from [physicians' relationships with drug representatives](#). There is ample evidence [3, 4] indicating that drug reps unduly influence physicians' prescription behavior. Current codes of ethics and guidelines [1, 2] emphasize the financial side of the relationship and the resulting conflicts of interest and changes in physicians' prescription and professional behavior. Hence, the general theme in [almost all of the guidelines](#) is to keep the level of [gifts](#) and financial incentives that physicians are allowed to accept from drug representatives to a minimum.

There is an important information-transfer side of the relationship that is not touched upon by these guidelines. The information about new drugs and technologies presented by drug reps is convenient and inexpensive [5], and many physicians rely on drug reps as

a source of this information [6, 7]. However, there is strong evidence that the quality of information physicians receive from drug reps is poor and biased in favor of the drugs that are being promoted: drug information communicated by reps has been found to be inaccurate and often lacking data on drug safety, side effects, and contraindications [8-10]. Furthermore, physicians in general are unable to recognize the inaccuracies and biases in the information they receive from drug reps [3]. The question then arises: why are physicians unable to tell when they are receiving biased information from drug reps?

Using Evidence

A useful way of characterizing the problem is to consider physicians' reliance on drug reps for information as an example of the bigger problem medical professionals have in handling and interpreting medical and scientific information [11]. It means that the problem in physician-pharmaceutical industry interactions should rightly be considered a problem in physicians' information management strategies. New knowledge is constantly produced and published in the language of research, using methods and concepts from epidemiology and statistics. In order to do their jobs, physicians need to constantly update their knowledge by reviewing medical and scientific literature, interpret the implications of research findings for clinical practice, and incorporate relevant information into their daily practice. This process is what we mean by evidence-based medicine.

The basic idea in evidence-based medicine is to identify the best medical treatment that fits the needs and values of the individual patient based on the best available scientific evidence. This way of practicing medicine requires a critical appraisal of the published data on a given subject to choose the option that best benefits the interests and respects the values of the individual patient [12]. Since medical evidence is expressed in the language of numbers, statistics, and probability, the epistemic virtue of being able to understand and use the results of research is inseparable from the practice of evidence-based medicine.

Since a large number of studies published in the medical literature have clinical applications, and since proper understanding of these studies and their potential impact on clinical practice is crucial to being a good practitioner, physicians need to develop certain capabilities and information management strategies for handling the volume of new information that they constantly receive from various sources. A number of intellectual competencies, which are necessary "to understand the quantitative aspects of clinical medicine, [and] original research" [13]—generally referred to as "physician numeracy" skills [13]—are indispensable for the practice of modern medicine. Examples of such skills include the ability to interpret standard deviation, relative risk, confidence interval and statistical significance, and *p* value; recognize power, sample size, and bias; and determine strength of evidence for risk factors [14]. However, the fact is that many physicians do not have the necessary competencies for understanding the results of

scientific research and appraising medical literature [14-16]. In addition, most physicians seem to lack a clear information management strategy to process the information, distinguish between high- and low-quality information, and integrate high-quality information into patient care [17, 18].

We can now look at Dr. Herman's dilemma from the perspective of information evaluation rather than financial conflicts of interest.

Assessing Pharmaceutical Relationships and Information

Regarding the question of whether she should talk to reps at all, Dr. Herman needs to be fully aware of the fact that the purpose of the encounter for the rep is to communicate information about a new drug, and the information the rep presents is probably biased in favor of the drug that is being promoted. Since drug reps are not a reliable source of good quality information about new drugs and devices, meeting with a drug rep should not be given fixed space in a physician's schedule. The duration of such meetings should be kept at a minimum. A physician needs to spend her nonpatient time on reviewing more reliable sources of information, such as scholarly journals.

In addition, to avoid problems in her interactions with pharmaceutical reps, Dr. Herman needs, first and foremost, to have a solid information management strategy and to cultivate the necessary competencies. All information needs to be critically evaluated and appraised before being applicable to practice, and the information received from drug reps is not an exception. Dr. Herman needs to be able to evaluate the validity of research studies, including their design. She therefore should be good at finding biases in research. She also needs to cultivate the necessary numeracy skills that are indispensable for the thorough understanding of scientific data.

Having appraised the general quality of drug reps' information and developed her critical and numeracy competencies and approach to interacting with drug reps, Dr. Herman does not necessarily need to avoid speaking with them. A drug rep might bring a new drug to Dr. Herman's attention. Instead of being considered the final word on the subject, a conversation with a drug rep can be the starting point of an information-seeking process about a new drug or new use. In this way, communication with a drug rep can help the physician and, ultimately, improve her patient care.

She should, however, avoid forming personal relationships with drug reps. A personal relationship might blunt the critical attitude that is necessary for a robust and responsible assessment of the information the drug rep presents. And without this critical attitude, Dr. Herman might become blind to the flaws in the drug reps' information.

Whether to avoid drug reps altogether depends on the doctor and the level and quality of new information the drug rep provides. A busy doctor who does not have enough time to constantly update his or her knowledge of new drugs might benefit himself and his patients by speaking with a drug rep about a new drug or medical technology if it becomes the starting point of an inquiry into more reliable sources of information. However, for those physicians who already have access to reliable sources of information, such as professional journals and textbooks, meeting with a drug rep should never be a central part of their information-seeking strategies.

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ETHICS CASE

Donations of Expensive Equipment for Resident Training

Commentary by Ashvini K. Reddy, MD

As the newly appointed director of a retina fellowship at an academic center, Dr. Bayes took his educational responsibilities most seriously, advocating for trainees to have access to interesting cases and the newest technology.

One afternoon, Dr. Bayes received a phone call from Mr. Clements, a surgical device representative for VitreSure, a company specializing in surgical retina platforms and equipment. Dr. Bayes agreed to speak with Mr. Clements about the possibility of purchasing the VitreSure surgical machine for the residency training program.

As agreed, the two met one week later. Dr. Bayes explained to Mr. Clements that, while his institution did have a surgical machine already, it was an older model, and getting approval for funds to purchase a new system could be difficult. There was need for a new system, and only one machine would be needed. "I'm thrilled that you are considering our device, Dr. Bayes," said Mr. Clements enthusiastically. "The VitreSure offers state-of-the-art surgical support, and we are excited to be introducing it to surgeons in training in the United States. In fact, because we are confident that young surgeons who have the opportunity to use the VitreSure system in training will choose our equipment once they graduate, we are willing to donate it to your institution."

Dr. Bayes hesitated. His trainees had access to an existing surgical system, but it was getting older and a new machine was warranted. He wanted his trainees to have access to as many types of technology as possible and he believed that the VitreSure was a fine system to use and become acquainted with, but VitreSure's donation of the equipment as an investment in the trainees' future gave him pause.

Commentary

The unsettling feeling that Dr. Bayes has about accepting an expensive but useful piece of surgical equipment stems from the understanding that the goal of the donation is to generate a favorable bias among his trainees toward the equipment and the company donating it. Is Dr. Bayes right to be skeptical?

The donation of new surgical equipment to the department stands to benefit trainees as well as patients, but how should this be balanced against the introduction of bias by the company? Dr. Bayes essentially has three options: (1) accept the donation of the system

and the bias toward the company and its products that might be generated because of it, (2) decline the donation and raise money for the purchase of the VitreSure or another manufacturer's device, or (3) decline the donation and continue using the department's current equipment.

Dr. Bayes's dilemma is clear: if the offered equipment is better than what the academic program currently has, but not what it would buy if it had its choice and money were not an object, he might feel disposed to accept the donation—and ethically unsure about that course of action.

Think of the Patients

One might argue that, because patients benefit from newer surgical equipment, the donation of a system is analogous to pharmaceutical companies' donating "free samples" for patient care. Many academic medical institutions now ban the [donation of free samples](#) for patient care because the sample medications are often more expensive than other alternatives, including generics, and patients can develop brand loyalty on the basis of the sample and may be reluctant to switch away from a medication that they feel benefits them [1]. This brand loyalty can lead to escalation of costs for the patient in the long term. Furthermore, both young and established physicians have a tendency to develop a "pattern of prescription," meaning that they tend to prescribe certain medications more than others. Samples can introduce expensive prescription habits that affect patients who might not even receive the samples themselves [2, 3]. In the same way that some people may always feel more comfortable driving the brand of car they learned to drive originally, surgeons may, over the course of their careers, prefer the brand of surgical equipment they trained on and be uncomfortable switching to new systems. And in surgical subspecialties, the bias towards one device can impact thousands of lives.

In the United States, drugs and medical devices are regulated by distinct divisions of the US Food and Drug Administration (FDA). While both drugs and medical devices are used in the diagnosis, treatment, and prevention of disease and must comply with federal regulations regarding labeling, advertising, production, and postmarketing surveillance, there are differences in the FDA premarket review and approval processes for the two types of products [4]. In FDA regulation, the level of premarket scrutiny is related not only to the level of clinical evidence available, but also to standards for quality of the product. FDA regulation of devices is different than regulation of drugs: the clearance of a device does not necessarily mean that safety and efficacy have been shown for the product, or even that clinical trials have been conducted [5]. Because oversight of medical devices may be less robust, the consequences to patients of bias generated toward surgical devices may be greater than those of bias in prescribing drugs. The possible effect of bias on patients argues against Dr. Bayes's accepting the donation unless it is the device he would choose to buy if the program had funds to buy the "best."

When it comes to donations of free samples, educational seminars and materials, and [gadgets such as pens](#) from pharmaceutical companies, the American College of Physicians has published statements to guide us [1]. This guidance indicates that, although industry information fills an important need, studies suggest that [it is often biased](#) [6-8]. Since providers of graduate and continuing medical education are obligated to present objective and balanced information to their participants, they should not accept any funds that are contingent on a sponsor's ability to shape programming. Medical educators need to evaluate and control the planning, content, and delivery of education and should disclose industry sponsorship to students and faculty. Where pharmaceuticals are concerned, medical educators have largely adopted explicit organizational policies about acceptable and unacceptable interactions with industry in the interest of promoting independent judgment and professionalism.

There is, however, a paucity of guidance about donations of larger medical devices. Surgical equipment donation isn't featured in the general press as often as pharmaceutical donations, but there are professional guidelines on accepting gifts. The *AMA Code of Medical Ethics'* opinion 8.061 [9] states that "gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients." The opinion further states that physicians should decline any gifts for which reciprocity is expected or implied.

Take the Long Road

Is the department obligated to expose trainees to multiple surgical systems? No. In fact, most subspecialties use only one system with good reason. Multiple systems can make teaching and learning more difficult—it is generally easier to choose one system that works for the group. One of Dr. Bayes's options is to delay acquisition of a surgical system until the department can afford one. There are two consequences of this action: (1) current trainees and patients will have to work with older equipment until newer equipment can be purchased, and (2) since only one surgical device is needed, indeed, preferable for training, all those in the fellowship program will be influenced in favor of the existing device.

Thus, Dr. Bayes's thinking should be along these lines: if the device offered is the one the program would purchase if it had funds to buy the best, there is stronger ethical justification for accepting the donation. If it is not the device the program would purchase if it had funds to buy the best, justifying acceptance of the donation is a greater ethical challenge.

It seems, then, that Dr. Bayes may have good reasons for "going with his gut" and declining the donation of the VitreSure surgical system. The more rigorous FDA approval and marketing process for drugs than medical devices and the long-term consequences

for patients and trainees of a capital investment in surgical equipment are both key to thinking critically about the potential for bias generated by the surgical device industry's donations.

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THE CODE SAYS

The AMA *Code of Medical Ethics'* Opinions on Physicians' Financial Interests

Opinion 8.0321 - Physicians' Self-Referral

Business arrangements among physicians in the health care marketplace have the potential to benefit patients by enhancing quality of care and access to health care services. However, these arrangements can also be ethically challenging when they create opportunities for self-referral in which patients' medical interests can be in tension with physicians' financial interests. Such arrangements can undermine a robust commitment to professionalism in medicine as well as trust in the profession.

In general, physicians should not refer patients to a health care facility that is outside their office practice and at which they do not directly provide care or services when they have a financial interest in that facility. Physicians who enter into legally permissible contractual relationships—including acquisition of ownership or investment interests in health facilities, products, or equipment; or contracts for service in group practices—are expected to uphold their responsibilities to patients first. When physicians enter into arrangements that provide opportunities for self-referral they must:

- (1) Ensure that referrals are based on objective, medically relevant criteria.
- (2) Ensure that the arrangement:
 - (a) is structured to enhance access to appropriate, high quality health care services or products; and
 - (b) within the constraints of applicable law:
 - (i) does not require physician-owners/investors to make referrals to the entity or otherwise generate revenues as a condition of participation;
 - (ii) does not prohibit physician-owners/investors from participating in or referring patients to competing facilities or services; and
 - (iii) adheres to fair business practices vis-à-vis the medical professional community—for example, by ensuring that the arrangement does not prohibit investment by nonreferring physicians.

(3) Take steps to mitigate conflicts of interest, including:

(a) ensuring that financial benefit is not dependent on the physician-owner/investor's volume of referrals for services or sales of products;

(b) establishing mechanisms for utilization review to monitor referral practices; and

(c) identifying or if possible making alternate arrangements for care of the patient when conflicts cannot be appropriately managed/mitigated.

(4) Disclose their financial interest in the facility, product, or equipment to patients; inform them of available alternatives for referral; and assure them that their ongoing care is not conditioned on accepting the recommended referral.

Issued June 2009 based on the report "Physicians' Self-Referral," adopted November 2008.

Opinion 8.063 - Sale of Health-Related Products from Physicians' Offices

"Health-related products" are any products that, according to the manufacturer or distributor, benefit health. "Selling" refers to the activity of dispensing items that are provided from the physician's office in exchange for money and also includes the activity of endorsing a product that the patient may order or purchase elsewhere that results in direct remuneration for the physician. This Opinion does not apply to the sale of prescription items which is already addressed in Opinion 8.06, "Prescribing and Dispensing Drugs and Devices."

Physicians who engage in in-office sales practices should be aware of the related guidelines presented in Opinion 8.062, "Sale of Non-Health-Related Goods from Physicians' Offices;" Opinion 8.06, "Prescribing and Dispensing Drugs and Devices;" Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician;" Opinion 3.01, "Nonscientific Practitioners;" Opinion 8.20, "Invalid Medical Treatment;" as well as the reports from which these opinions are extracted.

In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.

(1) Physicians who choose to sell health-related products from their offices should not sell any health-related products whose claims of benefit lack scientific validity. When judging the efficacy of a product, physicians should rely on peer-reviewed literature and

other unbiased scientific sources that review evidence in a sound, systematic, and reliable fashion.

(2) Because of the risk of patient exploitation and the potential to demean the profession of medicine, physicians who choose to sell health-related products from their offices must take steps to minimize their financial conflicts of interest. The following guidelines apply:

(a) In general, physicians should limit sales to products that serve the immediate and pressing needs of their patients. For example, if traveling to the closest pharmacy would in some way jeopardize the welfare of the patient (e.g., forcing a patient with a broken leg to travel to a local pharmacy for crutches), then it may be appropriate to provide the product from the physician's office. These conditions are explained in more detail in the Council's Opinion 8.06, "Prescribing and Dispensing Drugs and Devices," and are analogous to situations that constitute exceptions to the permissibility of self-referral.

(b) Physicians may distribute other health-related products to their patients free of charge or at cost, in order to make useful products readily available to their patients. When health-related products are offered free or at cost, it helps to ensure removal of the elements of personal gain and financial conflicts of interest that may interfere, or appear to interfere, with the physician's independent medical judgment.

(3) Physicians must disclose fully the nature of their financial arrangement with a manufacturer or supplier to sell health-related products. Disclosure includes informing patients of financial interests as well as about the availability of the product or other equivalent products elsewhere. Disclosure can be accomplished through face-to-face communication or by posting an easily understandable written notification in a prominent location that is accessible by all patients in the office. In addition, physicians should, upon request, provide patients with understandable literature that relies on scientific standards in addressing the risks, benefits, and limits of knowledge regarding the health-related product.

(4) Physicians should not participate in exclusive distributorships of health-related products which are available only through physicians' offices. Physicians should encourage manufacturers to make products of established benefit more fairly and more widely accessible to patients than exclusive distribution mechanisms allow.

Issued December 1999 based on the report "Sale of Health-Related Products from Physicians' Offices," adopted June 1999.

Clarification of Opinion 8.063

Do the guidelines discussing the sale of health-related products (E-8.063) and the sale of non-health-related goods (E-8.062) apply to physicians' practice websites?

Yes. The physician who provides or sells products to patients must follow the above guidelines regardless of whether the products are provided in the physician's office or through a practice website.

Adopted December 2000 as "Addendum III: Council on Ethical and Judicial Affairs Clarification on Sale of Products from Physicians' Offices (E-8.062 and E-8.063)."

Opinion 8.062 - Sale of Non-Health-Related Goods from Physicians' Offices

The sale of non-health-related goods by physicians presents a conflict of interest and threatens to erode the primary obligation of physicians to serve the interests of their patients before their own. Furthermore, this activity risks placing undue pressure on the patient and risks demeaning the practice of medicine.

Physicians should not sell non-health-related goods from their offices or other treatment settings, with the exception noted below.

Physicians may sell low-cost non-health-related goods from their offices for the benefit of community organizations, provided that (1) the goods in question are low-cost; (2) the physician takes no share in profit from their sale; (3) such sales are not a regular part of the physician's business; (4) sales are conducted in a dignified manner; and (5) sales are conducted in such a way as to assure that patients are not pressured into making purchases.

Issued June 1998 based on the report "Sale of Non-Health-Related Goods from Physicians' Offices," adopted December 1997.

Clarification of Opinion 8.062

Do the guidelines discussing the sale of health-related products (E-8.063) and the sale of non-health-related goods (E-8.062) apply to physicians' practice websites?

Yes. The physician who provides or sells products to patients must follow the above guidelines regardless of whether the products are provided in the physician's office or through a practice website.

Adopted December 2000 as "Addendum III: Council on Ethical and Judicial Affairs Clarification on Sale of Products from Physician Office (E-8.062 and E-8.063)."

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[The American Medical Association *Code of Medical Ethics*' Opinions on the Physician as Businessperson](#), February 2013

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MEDICAL EDUCATION

Teaching Medical Business Ethics: An Introduction to the Bander Center's Casebook

Erin L. Bakanas, MD, and Tyler A. Zahrli

Introduction

The [Bander Center for Medical Business Ethics](#) was established in 2007 at Saint Louis University with an endowment from the BF Charitable Foundation to promote "ethical business practices in medical care and research through the development of training and investigation responsibilities for medical students, residents and physicians in practice" [1]. The center defines medical business ethics (MBE) as "the ethical engagement of the financial dimension of medical practice and research" [1]. Many of physicians' decisions related to clinical practice or medical research have a business component. In the market context of medicine in the United States, issues in MBE "such as conflicts of interest (COI), Medicare fraud and abuse, and the structure and functioning of reimbursement systems" affect the integrity of medical practice and research [2]. Preserving trust in the institution of medicine as it operates in an increasingly complex environment is challenging. To better prepare practitioners for this challenge, the Bander Center has published a freely available online case-based curriculum in medical business ethics. *Exploring Integrity in Medicine: The Bander Center for Medical Business Ethics Casebook* [3] serves as a comprehensive teaching instrument, highlighting pertinent variables in MBE decisions by exploring their effects on medical practice and research and reflecting on the values and motives that influence the behavior of health care professionals.

The Challenge

Major professional organizations such as the Institute of Medicine [4] and the Association of American Medical Colleges [5, 6], as well as government bodies such as the Office of the Inspector General [7], have produced reports and guidelines to encourage physician self-regulation and impose rules to limit physician relationships with for-profit entities. In addition, the Accreditation Council for Graduate Medical Education lists both professionalism (which includes ethics) and systems-based practice (which includes "awareness of the larger context and system of health care" and its resources) among their six core competencies [8]. Nevertheless, no published curricula exist in the area of MBE.

In 2013 the Bander Center surveyed medical students and residents at two academic medical centers in Missouri on "their awareness of major MBE guidance documents, knowledge of key MBE research, beliefs about the goals of an education in MBE, and the

areas of MBE they were most interested in learning more about" [2]. The results revealed that "medical students and residents had little awareness of recent and major reports on MBE topics and had minimal knowledge of basic MBE facts" [2], such as what percentage of academic physicians have a financial relationship with industry. However, "both groups showed significant interest in learning more about MBE topics...such as 'the business aspects of medicine' and 'health care delivery systems'" [2].

Topic Identification

Bander Center-affiliated faculty and staff conducted a Delphi consensus panel project "to establish priorities for curricula in business ethics in medical practice and research" [1]. The Delphi process, a structured communication technique in which a group of experts are polled and their responses used to generate further polls for them to respond to, is used to establish a consensus among experts on topics that involve subjective judgments rather than analytical problem solving, such as policy priorities or educational curricula [9]. A heterogeneous panel of 26 expert participants representing a diverse group of stakeholders in medical practice and research was selected using non-probability sampling and split into two groups, one focusing on medical practice (14 panelists) and one on research (12 panelists). Prospective panelists were identified via a web-based search by areas of expertise. Medical practice panelists had "expertise in medical practice, medical education, medical ethics, medical sociology, health care administration, health economics, health law, outcomes research, and government oversight" [1]. Medical research panelists had "expertise in medical research, research training, research ethics, social science, research administration, health economics, research regulations, and government oversight" [1]. Invitation to participate on the panels was done by e-mail, and all participants freely consented to be members of the panels.

The Delphi panels were surveyed in two phases. The first phase focused on data collection by giving participants open-ended prompts like "Please list up to 10 topics that you consider most important to address within educational programs for physicians-in-training in the domain of business ethics in medical practice" [1]. The medical practice panel produced 103 responses, which the researchers grouped into 14 distinct topics. The research-focused panel produced 97 responses, which the researchers reduced to ten distinct topics. The Bander Center team analyzed the responses to create a list for the second phase, in which the panelists ranked the importance of the list items to a curriculum on medical business ethics on a scale from 1 (not at all important) to 5 (essential).

Eleven topics were rated as "very important" or "essential" by general agreement among the participants [1]. Five topics related to medical practice and included problems that can arise from conflicts of interest, general health care organization and systems, and fostering patient care quality and safety. The remaining six topics related to medical

research and included the ideals of the medical research profession, strategies for managing conflicts of interest in research, and challenges of playing the roles of both physician and researcher.

Structure and Intended Uses of the Casebook

The casebook is designed for facilitating educational discussions among health care professionals about hypothetical case scenarios. The book includes fourteen case scenarios, each ending with a question about what the professional should do to remedy the situation. These vignettes are meant to help discussion participants understand their role as professionals in a given situation. The casebook includes a guide that outlines eight steps to facilitating a good group discussion and case notes to help structure it: in the facilitator's version, each scenario includes information about pertinent stakeholders, medical facts, ethical norms, legal norms, options for addressing the situation, and reflection questions to spark further discussion. Indices are included to help the facilitators choose the appropriate case for highlighting particular issues in medical practice or medical research.

The educational experience of analyzing case scenarios is entirely dependent on a dynamic and productive discussion. Prior to presenting the case, the facilitator should become familiar with the relevant background information (described below). The key to a good discussion is asking questions, specifically open-ended questions to engage the audience in problem solving by examining decisions and mental processes used to arrive at them. The discourse is most effective when small discussion groups are provided with handouts of the case. The facilitator should allow time for a case introduction, debate, discussion, and conclusion—one or two cases can be covered in less than an hour.

SFNO Method of Case Analysis

The casebook utilizes the "so far no objections" (SFNO) approach [10]. The acronym SFNO also stands for stakeholders, facts, norms, and options—four components that medical decisions must take into account.

Stakeholders. Stakeholders are those significantly affected by the decision(s) being made. There is great variability in the impact experienced by the stakeholders; for example, a patient has a direct, significant stake in his or her health and the medical care received, while society has a lesser stake in patient protection and cost related to health care in that single case.

Medical facts. The casebook includes both quantitative and qualitative medical information relevant to the case discussion drawn from medicine, public health, economics, business management, and other fields. Including this medical information is important for both the facilitator and participants because of the improbability that any one person has all this information readily available.

Ethical and legal norms. Norms are the ethical principles or values relevant to the case at hand, including mid-level principles of bioethics, the American Medical Association's (AMA) Principles of Medical Ethics [11], and legal norms focused on federal law and principles of state and tort laws. When presenting norms relevant to each case, the editors employed a standardized approach. First, the mid-level principles of biomedical ethics as described by Beauchamp and Childress [12] are examined in relation to the given case. The relevant sections of the AMA's Principles of Medical Ethics are then identified and their application to each section of the case explained. The last group of norms considered is legal—federal and state legislation, regulation, and common law—presented not to offer legal advice or end the case discussion but rather to supplement the ethical norms described. Good ethical deliberation of a case scenario requires the facilitator and participants to discuss the interplay of all these norms to arrive at a decision in the patient's best interest.

Options and reflection. The reflection questions and options included for each case are intended to aid discussion by eliciting the participants' thoughts about the case presentation and the balancing of ethical and legal norms. The reflection questions draw out the differing opinions of the audience, which may lead the group to recognize a variety of options for remedying the situation. The response options included highlight those actions the editors consider plausible. The intention is for the case discussion to explore the nuances of the options with the goal of reaching the best possible conclusion among them. The options list also enables the facilitator to continue the discussion after the group has reached a decision, allowing for additional deliberation.

Conclusion

Exploring Integrity in Medicine: The Bander Center for Medical Business Ethics Casebook serves as an educational tool for facilitated discussion of important topics in medical business ethics related to clinical practice and medical research using a well-described model of case analysis, the SFNO approach. To date, the casebook has been used in teaching doctoral students in health care ethics, senior medical students in a medical business ethics capstone course, and first- and second-year medical students in business and ethics interest groups. It has also been presented to educators at the Academy for Professionalism in Health Care Annual Meeting [13], at the International Conference on Clinical Ethics [14], and at the annual Health Law Professors Conference [15]. By including an array of information pertinent to each case, the casebook educates health care professionals on the wide spectrum of information pertinent to decision making in medical business ethics. The materials included in the casebook make it possible for professionals not formally educated in the areas relevant to the case information to serve as discussion facilitators.

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IN THE LITERATURE

Pricing Cancer Drugs: When Does Pricing Become Profiteering?

Hannah L. Kushnick, MA

Experts in chronic myeloid leukemia. The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts. *Blood*. 2013;121(22):4439-4442.

The 100-plus authors of “The Price of Drugs for Chronic Myeloid Leukemia (CML) is a Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts” [1] include a telling example of [cancer drug pricing](#): imatinib (trade name Gleevec), a tyrosine kinase inhibitor (TKI) used to treat CML, was “initially priced at nearly \$30,000 per year when it was released in 2001... Its price [was] \$92,000 in 2012, despite the fact that (1) all research costs were accounted for in the original proposed price”—and therefore increases were not needed to recoup costs—“(2) new indications were developed and FDA approved”—meaning that many more potential consumers now exist than when the drug was first approved—and therefore “(3) the prevalence of the CML population continuing to take imatinib was dramatically increasing,” taking revenue upward with it [2].

Examples like this call into question the idea that the high prices of drugs, particularly cancer drugs, are necessary to recoup development costs and to provide a sufficient incentive to pharmaceutical companies to develop them.

How Are Drugs Priced?

The authors explain that, despite “the many complex factors involved, price often seems to follow a simple formula” [3]: a 10-20 percent increase over the price of the most recently released similar drug, citing a Novartis executive’s account of the development of imatinib [4].

Is this magnitude of increase required in order for drug companies to recoup the high cost of developing such drugs? The 100-plus authors put forth the generous estimate of \$1 billion (pointing out that some experts think the real cost may be 10-40 percent lower) to cover “the cost of development of the new (successful) drug and all other drugs that failed during development, and ancillary expenses including the cost of conducting the clinical trials required for approval, bonuses, salaries, infrastructures, and advertising among others. In other words, once a company sells about a billion dollars-worth of a drug, most of the rest is profit” [3]. Thus the tripling of imatinib’s price over a decade was

not needed for Novartis to cover the costs of developing it—according to the Novartis executive’s account, it was believed that the original price would allow those costs to be recouped within *two* years if market penetration were high enough. The authors also review prices for cancer drugs in different geographic areas and nations, finding a wide range, including an enormous gulf (a difference of roughly 100 percent) between the prices of TKIs in European countries with national health services and the United States. This, they argue, “supports the notion that drug prices reflect geopolitical and socioeconomic dynamics unrelated to the cost of drug development” [2].

The authors then respond to the argument that extant prices are, by definition, what the market will bear and that competition can be counted on to lower prices sufficiently, by questioning whether the US market for cancer drugs is really a “free” one, functioning as it should. Without pointing any fingers, the authors calmly explain that “a new branch of economics, called game theory, details how collusive behavior can tacitly maintain high prices over extended periods of time, despite competitive markets, thus representing a form of ‘collective monopoly’” [5]. Supporting the idea that prices in the US drug market may be distorted by such collusive behavior, the authors mention that “market competition may have worked well” in South Korea, where TKI prices are a mere 20-30 percent of US prices, “perhaps because of the approval by the Korean health authorities of radotinib (annual price \$21,500), a locally discovered and developed TKI” [5]. All this would seem to indicate that, while some markets may be functioning optimally and, therefore, some prices are appropriate, ours in the US are not.

Three Ethical Issues

The authors identify three key moral concerns about TKI pricing: that it obstructs patients’ access to treatment for chronic myeloid leukemia; heavily burdens patients who can access it; and threatens the sustainability of our overall health care systems, potentially harming many other people.

Obstructing access. High prices can deter patients from gaining access to the drugs in the first place. The authors believe this may be occurring in the US, based on the higher estimated market penetration in Sweden, which has universal health coverage, than in the US, which does not. The higher prices in the US are partly encouraged by the patent system, which allows branded drugs a period of 20 years to be the only version of a given drug on the market before allowing entry of generic competitors, the presence of which often lowers the price [6]. Strategies for delaying the entry of generic competitors—including “pay for delay,” in which a company selling a brand-name drug pays its competitors to delay releasing generic versions, and “[product hopping](#),” in which a company introduces new (and therefore patented) variants of a drug, thereby restarting the patent “clock”—often prolong these periods far past the designated endpoint. The expiration of the patent on Gleevec was initially pushed back from 2013 to January 2015 and now generic competition has been pushed back another seven months

through a pay-for-delay agreement, which will delay the release of generic versions until February 2016 [7].

Burdening patients. As the authors put it, “grateful patients may have become the ‘financial victims’ of the treatment success, having to pay the high price annually to stay alive” [2]. This dependence is particularly acute with a highly effective drug for a condition like CML, which has effectively been transformed into a chronic condition requiring nonstop long-term treatment. The authors also subtly raise the question of whether, in countries without universal health coverage, like the US, the financial stresses of paying for extremely expensive long-term treatments may themselves have effects on health.

Creating unsustainability. Much has been written about the ballooning costs of the US health care system, which, the authors point out, have not yielded markedly better health outcomes for its populace. They identify two American beliefs as contributors to widespread reluctance to consider value in making treatment decisions: faith in the free market and discomfort with the idea of “putting a price” on a human life. Although individual physicians and medical organizations are moving toward considering a treatment’s value-for-cost—the Sloan-Kettering Cancer Center recently made a public statement that it will not be prescribing the \$11,000-a-month Zaltrap, a more expensive but, according to high-ranking physician staff members, no more effective alternative to Avastin [8]—the practice has not been embraced at the social or policymaking level. High prices and anticompetitive measures like pay-for-delay in cancer drugs, the authors say, are contributing to this unsustainable rate of health care spending.

Proposals and Arguments

The authors propose that the value we assign a drug “should be proportional to the benefit to patients in objective measures, such as survival prolongation, degree of tumor shrinkage, or improved quality of life [3].... For CML, and for other cancers,...drug prices should reflect objective measures of benefit, but also should not exceed [amounts] that harm our patients and societies” [5].

They end with a “win-win” argument: “Lowering the prices of TKIs will improve treatment penetration, increase compliance and adherence to treatment, expand the population of patients with CML who live longer and continue on TKI therapy, and (paradoxically) increase revenues to pharmaceutical companies from sales of TKIs” [5].

The authors’ focus is practical, proposing meetings and actions for physicians and framing price reduction as beneficial to both patients and industry, but the question lurking beneath the surface is, as the authors themselves ask, “what determines a morally justifiable ‘just price’ for a cancer drug? A reasonable drug price should maintain healthy pharmaceutical company profits without being viewed as ‘profiteering’ (making

profit by unethical methods, like raising commodity prices after natural disasters)" [2]. This raises the further question: how do we decide what constitutes profiteering, and who gets to have a say in that determination? Ultimately, these are not questions that can be solved without value judgments. While the authors' invocation of a system in which pharmaceutical companies' self-interest aligns neatly with patients' is hopeful, a conflict may lie therein that can only be resolved in favor of one side or the other. It would appear that our current system favors the interests of the pharmaceutical companies.

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HEALTH LAW

The Affordable Care Act and Insurer Business Practices

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Health insurer business practices are regulated at both the federal and state level. State law plays a role in regulating business practices such as the types of coverage offered and payment of claims [1]. For example, states can mandate coverage for certain medical treatments or conditions like [autism](#) [2]. State law also regulates how quickly insurers have to pay claims for health care services, referred to as prompt pay laws [3]. Federal law, most notably the [Affordable Care Act](#) (ACA), has brought about market reforms to make health insurance [more accessible](#), affordable, and adequate [4]. While the ACA sets forth market reform requirements that apply to private health insurance, these requirements are not applicable to all types of plans. Some requirements only apply to the nongroup (i.e., individual) and small group markets, whereas others apply across the board to the nongroup, small group, and large group markets [5]. “Group health plans” refers to employer-sponsored insurance, with the number of employees defining the type of market [6].

Major ACA provisions related to health insurance practices are summarized below.

Access to Health Insurance Coverage

- Health insurance plans must accept every applicant who agrees to the terms and conditions of the insurance (e.g., paying the monthly premiums); such plans are referred to as “guaranteed issue” [7, 8]. Health plans may not discriminate on the basis of pre-existing health conditions or health factors [9].
- Health plans cannot place annual or lifetime dollar limits on essential health benefits [10].
- If insurers offer coverage to dependents, then they must make that coverage available to them until they are 26 years old [11].
- Health plans cannot cancel coverage after an enrollee incurs medical expenses unless that enrollee has engaged in fraud or intentional misrepresentation [12].

Affordable Health Insurance Coverage

- Insurers must make sure that enrollees’ out-of-pocket costs do not exceed a certain amount each year. “Out-of-pocket cost” refers to expenses that enrollees must pay while they have coverage (see table 1) before the insurance plan begins

paying 100 percent of costs for covered services. Once an enrollee reaches his or her maximum out-of-pocket amount (MOOP), an insurer must pay 100 percent of further costs for covered services that are provided within the network. For 2015, the maximum out-of-pocket cost is \$6,600 for self-only coverage and \$13,200 for family coverage; these costs increase slightly to \$6,850 and \$13,700 in 2016. After 2016, the individual cost-sharing limits apply to all consumers, whether they are on a self-only or family plan: if the out-of-pocket maximum for a family plan is \$13,700, each covered family member's out-of-pocket costs only have to reach \$6,850 before the insurer has to pay 100 percent of further costs for covered in-network services for the individual [13].

Table 1. Typical out-of-pocket health care costs for insured patients in the US

Deductible: an amount an enrollee must pay before benefits “kick in.” For example, a plan might entail that enrollees pay \$1,500 out-of-pocket for health care services before it begins to cover costs. In general, consumers are billed by clinicians for deductible amounts.

Co-pay: a fixed amount that an enrollee pays every time for a given type of covered health care service at the time of service. For example, a plan could require a \$10 co-pay for each prescription and a \$20 co-pay for a doctor's visit. Health plans can also set higher co-pays for specialists.

Co-insurance: a fixed percentage of costs an enrollee pays for covered services. For example, 20 percent co-insurance means the health plan will pay 80 percent of costs for a covered service. In general, consumers are billed for co-insurance amounts by the organization where they receive care.

- Large group health plans must be affordable, meaning that an employee's premium contribution for self-only coverage for the lowest-cost plan offered cannot exceed 9.56 percent of his or her household income [14, 15].

Adequate Health Insurance Coverage

- Individual and small-group health plans must provide coverage for the following benefits, referred to as essential health benefits (EHB): ambulatory patient services (outpatient care); emergency services; hospitalization; maternity and newborn care; mental and behavioral health and substance use disorder services; prescription drugs; [rehabilitative and habilitative](#) services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services including oral and vision care [16, 17]. While the ACA requires health plans in the individual and small-group

markets to provide these *categories* of services, states have the discretion to pick a benchmark plan that sets out lists of specific services that must be included within each category [16].

- Large group health plans must meet or exceed the [minimum value](#) set by the federal government, currently defined as paying for at least 60 percent of medical expenses on average for a standard population [17, 18]. Federal guidance states that hospital and inpatient services must be substantially covered for the plan to count as providing this minimum value [19].
- Health plans cannot impose cost sharing, such as co-pays or co-insurance, for preventive services (except for plans in existence prior to March 10, 2010 that have not had substantive changes since that date, referred to as “grandfathered plans” [20]). Various federal entities make evidence-based recommendations about what should be in this category [21-23]. For example, federal agencies recently clarified that the anesthesia accompanying a preventive colonoscopy falls within the scope of a preventive service and must be covered without cost sharing [24].
- Health plans cannot prohibit enrollees from participating in federally approved clinical trials and must pay routine costs associated with a clinical trial, including drugs, procedures, and services that the health plan would normally cover [25].
- Health plans are prohibited from requiring referrals for obstetrical or gynecological (OB/GYN) care [26, 27].
- Health plans are prohibited from requiring prior authorization for emergency services, regardless of whether the clinician is in or out of network. Health plans must pay for out-of-network emergency services at either the in-network amount, the amount for other out-of-network services, or the amount that Medicare pays [26, 27].
- Health plans (except grandfathered plans) are required to allow enrollees to designate a primary care provider (PCP). Health plans can still designate a PCP but must allow the enrollee to change that designation. This includes allowing parents to choose in-network pediatricians for their children [26, 27].

Other Consumer Protections

The ACA establishes other consumer protections that regulate how insurers operate. For example, under the medical loss ratio (MLR) requirement, an insurer must spend a certain percentage of premium revenues on health care claims and quality improvement expenses or rebate the difference between those costs and their premium charges to enrollees. For individual and small-group plans, insurance companies must spend 80 percent of premium revenues on medical care; for large-group plans, the amount is 85 percent [28].

The ACA also requires all health plans to have an appeals process that allows consumers to appeal insurer decisions—for example, to deny a medical claim to pay for a service. Under the ACA, the appeals process must involve both an internal and external review (e.g., by an independent third party), and health plans must follow certain timeframes for decisions in general and in special circumstances (e.g., urgent care) [29]. While the ACA establishes a federal minimum for appeals, states may have processes that are more protective of consumers [30].

Conclusion

Five years after the passage of the ACA, there has been a 35 percent reduction in the number of uninsured people in the US; there are approximately 16.4 million newly insured people [31]. The ACA is making health insurance much more accessible and affordable. As implementation of the law continues, the question of whether existing coverage is adequate is likely to be raised, particularly as the newly insured begin using their coverage and insurer business practices continue to evolve. Subsequently, how well the ACA protects consumers and what gaps exist will become more evident.

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HEALTH LAW

A Legal Test for the Pharmaceutical Company Practice of “Product Hopping”

Tobin Klusty

In September 2014, the New York Attorney General filed a claim in federal court alleging that the pharmaceutical company Actavis was violating federal and state antitrust laws by preventing competition through a practice known as “product hopping.” Product hopping occurs when a pharmaceutical company discontinues an old formulation of a drug whose patent expiration date has passed or is approaching in an attempt to force consumers to change to the drug’s new—and newly patented—formulation. Patents protect pharmaceutical companies from generic drug manufacturing competition for 20 years, assuming the patent is not extended [1]. After the patent’s expiration, competitors are free to use the drug’s formula to manufacture generic versions as a cheaper option. Fearing large profit losses with the availability of generic versions, some pharmaceutical companies seek separate patents for new formulations of the patented drug. Minor changes, like the switch from a two-a-day to a one-a-day pill, can qualify for a new drug patent [2]. Following patent approval, the pharmaceutical company makes a push for use of the new formulation.

Patients are more likely to be reliant on a drug when few drugs are available for their particular ailment. Under such circumstances, discontinuation of an old formulation effectively forces people to use the new formulation. By the time the patent for the old formulation of the drug expires and generic versions become available, users often have become reliant on the new formulation of the drug. If the new formulation has a different dosage, strength, or delivery mechanism than the old formulation, most state drug substitution laws prevent pharmacists from replacing the new formulation with generic versions of the old formulation [3]. Thus a successful “product hop” can extend a pharmaceutical company’s monopoly for a drug for another 20 years—effectively stifling competition—and companies can hop several times within a single drug line.

New York v. Actavis addresses Actavis’s use of product hopping for the prescription drug Namenda [3]. Actavis, through its subsidiary Forest Laboratories LLC, marketed and sold Namenda IR, a twice-daily prescription drug used to treat Alzheimer’s disease [3]. Namenda is Actavis’s largest revenue generator, and it is the only memantine drug approved by the FDA to treat Alzheimer’s disease [4]. With Namenda IR’s patent set to expire in July 2015, Actavis released a once-daily version named Namenda XR and attempted to persuade consumers to switch from Namenda IR to Namenda XR by offering rebates and discounted rates for Namenda XR and heavily promoting the switch

to the healthcare community [5]. Due to concerns that patients would not switch to Namenda XR if IR was still available, Actavis announced that it would no longer produce Namenda IR, forcing consumers to switch to the once-daily Namenda XR because generic versions of Namenda IR had not yet hit the market [5]. Due to state drug substitution laws, pharmacists in most states will be unable to automatically switch patients from the once-daily Namenda XR to generic versions of the twice-daily Namenda IR, effectively prolonging Actavis's monopoly on memantine treatments for Alzheimer's disease until Namenda XR's patent expires in 2029 [3]. Actavis's marketing strategy led New York's Attorney General to bring suit in the United States District Court for the Southern District of New York.

New York's attorney general claimed that Actavis violated federal and state antitrust laws by preventing generic competition through product hopping [3]. The claim included a preliminary injunction, which requested that the federal court prevent Actavis from stopping the production and sale of Namenda IR (the older formulation). The district court granted New York's request for the preliminary injunction, requiring Actavis to continue production of Namenda IR until one month after generic versions entered the market. Actavis filed an expedited appeal with the United States Court of Appeals for the Second Circuit, which affirmed the district court's ruling [3].

The Second Circuit's ruling was unusual for a few reasons. First, the injunction forces Actavis to continue producing Namenda IR and dictates that its terms of sale cannot be changed. Antitrust law, under the Sherman Antitrust Act [6], does not normally require companies to assist competitors in the market, but the Second Circuit found that Actavis's product hopping strategy disallowed fair competition. The ruling referred to public comments from Actavis's CEO indicating that Actavis's purpose was to thwart competition rather than promote competitive technology: "We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity" [7] and "what we're trying to do is make a cliff disappear and rather have a long—a prolonged decline. And we believe that by potentially doing a forced switch, we will hold on to a large share of our base users" [8]. The only way to prevent irreparable harm to both competition and consumers, according to the district court and the Second Circuit, was to reverse Actavis's product-hopping strategy.

Secondly, the decision did not give weight to the potential benefits Namenda XR offered to consumers that Namenda IR did not. The Second Circuit did not quantify the strength of Namenda XR's benefits because Actavis's market strategy coercively forced patients and doctors to use XR without being able to weigh the benefits themselves [9]. In other words, Actavis's purposeful restriction of fair competition prevented it from arguing that Namenda XR's benefit to consumers warranted the removal of Namenda IR from the market.

While the Second Circuit's ruling forbids the use of product hopping as an anticompetitive and coercive marketing strategy, the conflict between preventing anticompetitive practices and encouraging innovation is still left murky, especially since most district courts are handling the issue without guidance from the higher courts. With the lack of precedent, more circuit courts are likely to decide the legality of product hopping. In the interim, Actavis is expected to appeal the Second Circuit's decision to enforce production of Namenda IR. A decision forcing production of a discontinued drug is unprecedented and may warrant the US Supreme Court to agree to review the decision per Actavis's appeal. For now, all that can be concluded is that the product hopping strategy is forbidden by the Second Circuit if there is evidence that the strategy is coercive and used to restrict fair competition.

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HEALTH LAW

IRS Rules Will Not Stop Unfair Hospital Billing and Collection Practices

Erin C. Fuse Brown, JD, MPH

When Keith Herie could not afford the \$14,000 bill for his wife Katie's emergency appendectomy, the debt collector for Heartland Regional Medical Center sued him and garnished his wages [1]. Herie is not alone—hospitals throughout the country have sued tens of thousands of patients for unpaid medical bills [2]. Unmanageable medical bills push millions of Americans into financial distress, ranging from damaged credit to bankruptcy [3].

On December 31, 2014, the Internal Revenue Service (IRS) issued final rules for tax-exempt hospitals that ostensibly limit these harsh hospital billing practices [4]. The IRS rules implement additional requirements for a hospital's maintenance of federal tax exemption status enacted by the 2010 [Patient Protection and Affordable Care Act](#) and codified in section 501(r) of the Internal Revenue Code [5]. These IRS rules, however, provide inadequate and unpredictable protection for many patients, leaving them vulnerable to financial and health-related consequences of hospital billing abuses.

Unfair Hospital Prices and Harsh Debt Collection Practices

The IRS rules for tax-exempt (generally speaking, nonprofit) hospitals address the twin problems of [unfair hospital prices](#) and harsh debt collection practices. Hospitals routinely charge uninsured patients undiscounted "chargemaster" prices, the "rack rates" or list prices of the health care industry, while government and commercial payers receive substantial discounts of 50 percent or more of the chargemaster prices for their members [6]. Increasingly, insured patients are also paying inflated prices for out-of-network care, that is, care from hospitals or physicians who are not part of an insurer's network and therefore have not negotiated discounts with those insurers [7]. Even if the patient's health plan pays for part of the care, the patient is often billed for the difference between the amount paid by the insurer and the hospital's or clinician's full charges. The proliferation of narrow-network health plans with few in-network hospitals, clinics, and physicians makes it more likely that patients will find themselves unwittingly out of the network with high out-of-pocket bills.

The problem of [unmanageable hospital bills](#) is exacerbated by harsh debt collection practices [8]. These practices include assigning the debt to collection agencies [9], suing patients [2], seeking foreclosure or liens on patients' homes [10], garnishing wages [1], charging high interest rates [11], requiring upfront payment before providing additional

care [12], and even seeking arrest for failing to appear in court for a debt collection hearing [13].

Aggressive hospital debt collection practices inflict significant financial, emotional, and health-related hardship upon patients. Patients may lose their wages, homes, or creditworthiness or be pushed into bankruptcy. Unmanageable medical debt has been associated with higher levels of stress and anxiety and poorer health [14]. Indebted patients may have difficulty securing future health care because hospitals and clinicians may not serve those with outstanding medical debt [3]. Further deleterious health problems may ensue as patients [self-ration](#) medically necessary care, prescription drugs, or other necessities like food or shelter to pay their medical bills.

Although the IRS rules aim to protect vulnerable patients from unfair hospital billing and collection practices, the rules are distressingly underinclusive and create unjustifiable gaps in protection.

The IRS's Billing and Collection Rules for Tax-Exempt Hospitals

The IRS rules prescribe fair billing and collection requirements for tax-exempt hospitals. First, hospitals must maintain and widely publicize financial assistance policies, including eligibility criteria. Second, hospitals must limit the amounts charged to patients who are eligible for financial assistance to “amounts generally billed” to insured patients for emergency or medically necessary care. Hospitals may not charge such patients their undiscounted chargemaster rates. Third, the rules bar hospitals from using “extraordinary collection actions” unless the hospital has made reasonable efforts to determine whether the patient is eligible for financial assistance [4].

There are two main gaps in the IRS rules' protections. First, they do not apply to for-profit or government-run hospitals, which make up more than 40 percent of all hospitals in the US [15]. Second, the rules give hospitals complete discretion to determine eligibility for financial assistance, which is the trigger for the rules' protections. Under the rules, for example, a hospital could adopt a narrow financial assistance policy with very restrictive income requirements, exclude all patients with any form of insurance regardless of out-of-pocket expenses, or make applying for financial assistance so onerous that few are able to complete the process.

Although a growing number of hospitals are for-profit, ownership or tax status is difficult for patients to discover. Of a sample of 140 hospitals across fourteen states, I discovered that more than half did not have information on ownership or tax status readily available on their websites. If a hospital was for-profit, it was significantly less likely to provide ownership information on its website than if it was nonprofit or government-run. Moreover, for-profit hospitals were also less likely to post financial assistance

information. With a few exceptions, for-profit hospitals do not appear to have voluntarily adopted the financial assistance, billing, and collection policies required of nonprofits.

Furthermore, hospital financial assistance policies vary significantly in terms of generosity and terms. Among the sample of financial assistance policies from 140 hospitals, eligibility cutoffs for financial assistance ranged from an income of 100 percent of the federal poverty level (FPL) to 600 percent of the FPL. Many hospitals with financial assistance policies offered free care to those with incomes up to 100–200 percent of the FPL and sliding scale discounts above that threshold. However, some hospitals did not offer any free care and only offered moderate discounts even to the poorest patients. Of the hospitals in the sample that provided eligibility information based on insurance status, a quarter excluded those with insurance from their financial assistance policies altogether.

Hospitals' debt collection practices also vary significantly. One investigation compared the number of medical debt collection lawsuits filed in 2013 by the two dominant nonprofit health systems in Springfield, Missouri [16]. CoxHealth or its assignee debt collector had filed 701 lawsuits, while Mercy or its assignee had filed only 40 in the same period. Many of the patients sued were ineligible for financial assistance as defined by the two health systems and thus were unprotected by the IRS requirements. These data were published because investigators from ProPublica compiled and analyzed court records for all medical debt lawsuits in the state [16], but information about most hospitals' debt collection practices is not generally available.

Even if information about a hospital's tax status, financial assistance, or bill collection practices were readily ascertainable, the uneven protections of the IRS rules remain problematic because these factors do not drive a patient's choice of hospital. Most patients choose their hospitals based on their physicians' referral or because it is the closest in an emergency [17]. This means that whether or not a patient is protected by the IRS's fair billing and collection rules is a matter of luck and fiat. Although the financial consequences for the patient may be dire, the current rules requiring fair prices and collection practices of some hospitals and not others creates a system of financial roulette.

A Better Approach: Fair Hospital Pricing and Collection for All

There is no good reason to limit fair pricing and collection requirements to tax-exempt hospitals. Requiring hospitals to charge fair prices to patients paying out of pocket and to refrain from the most onerous debt collection practices is not mandating that they engage in charitable acts—nothing is being given away for free or at a loss—and, therefore, the requirements could be appropriately applied to for-profit hospitals. Hospitals are still able to charge a fair market rate (i.e., the rate they generally charge

insured patients) with commercially reasonable expectations of getting paid for services rendered.

The model for broadening these protections to all hospitals regardless of tax status already exists in various state fair pricing and collection laws: at least ten states have passed laws that limit the amount hospitals may charge to patients who fall below defined income levels and restrict hospital collection practices for these patients [18-27]. The strongest example is California's Hospital Fair Pricing Act, which limits how much California hospitals may charge uninsured patients who earn less than 350 percent of the FPL or insured patients whose medical bills exceed 10 percent of household income [18]. The California law also substantially restricts hospitals' collection activities against these patients. It has leveled the field for financial assistance for patients. California's experience with its fair pricing and collection law has been positive; it has not resulted in widespread financial strain on hospitals. Indeed, most hospitals have voluntarily adopted policies that go beyond the requirements of the law [28].

Taking laws like California's as a model, a better national approach would be to decouple fair pricing and collection rules from hospital tax status and make compliance with these rules a condition of participation in Medicare. (Nearly all hospitals [participate in Medicare](#) as a financial necessity.) This proposal would require all Medicare-participating hospitals to limit the amounts charged to self-pay patients with incomes less than a defined threshold, say 350 percent or 400 percent of the FPL, as well as any patients whose out-of-pocket medical bills exceed 10 percent of their annual household income. The protections would thus extend not only to uninsured patients but also to insured patients with high out-of-pocket expenses. By defining the income and affordability thresholds, the policy would replace hospitals' discretion in determining eligibility for fair billing and collection with level and predictable standards across all hospitals. Hospitals could receive further financial enhancements to their Medicare payments if they offered, for example, free emergency and medically necessary care to all self-pay patients with incomes less than 200 percent of the FPL. As with California's laws, there could be some flexibility in the requirements as applied to rural or critical access hospitals that might struggle to comply with the general rule.

The proposal would also expand debt collection protections. Under the current IRS rules, hospitals may continue to use aggressive debt collection practices as long as they have made "reasonable efforts" (e.g., providing notice and time for the patient to apply for financial assistance) to determine the patient's eligibility for financial assistance. Again, state laws [18-27] provide a more rigorous model for fair debt collection practices. First, the hospital would have to offer eligible patients an option for an extended payment plan with no or limited interest. Second, a hospital pursuing debt collection would be prohibited from attaching a lien to or forcing the sale of a person's primary residence while it is occupied by the patient, his or her spouse, or any dependent. Third, the

hospital would be prohibited from seeking wage garnishment while a person is making a good-faith effort to pay the debt. Fourth, the hospital would be allowed to assign a debt to a collection agency and report nonpayment to a credit reporting agency only if the patient has stopped making any payments for a defined period of time (e.g., 90 or 120 days past due), the hospital has made reasonable efforts to contact the patient, and the collection agency agrees to the same limits on collection to which the hospital is subject under the law.

Conclusion

The IRS rules for tax-exempt hospitals took a step toward ensuring fairness in hospital billing and debt collection, but the rules' gaps—allowing hospitals to determine eligibility for financial assistance and excluding for-profit hospitals—create a harsh system of financial roulette for patients. Patients ought to be treated fairly by all hospitals, which have a duty to avoid inflicting not only physical harms on their patients but also unjustifiable financial harms. It is time to broaden the protections of fair hospital billing and collection practices to all hospitals and financially vulnerable patients.

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Disclosure

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POLICY FORUM

The All-Payer Rate Setting Model for Pricing Medical Services and Drugs

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In theory, the price set by a competitive market-oriented health care system should result in efficient (and presumably ethical) rates for hospitals, physicians, drugs, and other health care services. In practice, however, price efficiency does not generally occur for many health services. Because of health insurance, most patients are less sensitive to prices than they would be if they paid the full price. In addition, in some geographic areas, health systems with significant market power can negotiate very high prices, while in other areas, one or two dominant private health insurers have great power to set relatively low prices [1, 2]. As a result, prices paid by individuals for the same service can vary by a factor of 10 at some hospitals [3]. Moreover, a side effect of all these negotiations is that the private insurers and health systems spend millions of dollars negotiating and carrying out unique deals with each other—dollars that could be better spent delivering care [4].

At the same time, the public Medicare and Medicaid programs in the US have set payment rates using a totally different approach from that of the private insurers. The Medicare program has used a diagnosis-based prospective payment system for hospitals since 1984 and the [Resource-Based Relative Value Scale](#) (RBRVS) payment system for physicians since 1992. Both attempt to estimate the underlying costs of providing a given service, resulting in a distinct amount for each of about 750 different hospital services [5] and 16,000 different physician services [6]. There is, however, wide variation in payment rates among state Medicaid programs; the average Medicaid payment rates are comparable to Medicare for hospitals but about one-third lower than Medicare for physicians [7-9].

Consequences of Price Inefficiency in Health Care

The result of the wide variations in payment rates and methods among private and public insurers can lead to access problems. When the payment rate of one insurer is much lower than that of other insurers, patients have access to a restricted number of participating hospitals and clinicians. And when the premium rates of some insurers are much higher than those of other insurers, people have difficulty paying for health insurance. Moreover, as noted above, the complexity of numerous insurer payment methods means that health systems have to negotiate payment rates with various insurers and hire many people to keep track of these different payment methods, leading to higher administrative costs embedded in these prices. The end result is that prices in

the US are typically [much higher](#) than they are for similar services in other industrialized countries, or, as one of us wrote years ago, “It’s the prices, stupid” [10]. In addition, when the payment methods differ from one insurer to another, hospitals and clinicians are given mixed messages about exactly what services to provide and whether to emphasize quality, price, or satisfaction.

Are there alternatives?

Alternate Model: The Common Payment Method

One option is for all insurers—public and private—to use the same method for paying hospitals, but not necessarily the same rates. This would reduce the administrative costs associated with each insurer’s developing and maintaining its own payment methodology and each health system’s learning each new methodology. A common payment system (but not necessarily the same payment rates) could be adopted voluntarily or imposed through legislation.

The US has developed a variant of this approach already: the RBRVS payment system for physicians used by Medicare since 1992 [11]. Subsequently, nearly all private insurers have chosen to adopt Medicare’s relative value units as the starting point for negotiating payment rates to physicians [11]. Although most private insurers pay higher rates than Medicare does and some pay less, nearly all insurers use relative value units as the basis for starting the negotiation.

Advantages. The advantage of a common payment method is that it simplifies the system for both insurers and physicians. As noted above, it reduces the administrative burden on insurers (who would not have to develop and maintain their own payment systems) and health systems, simplifies the negotiation between them (since the negotiation is simply over the price and not also the payment method), and improves price transparency for patients because only one number is needed to compare prices when all insurers are using the same payment system.

Disadvantages. One potential disadvantage of a common payment method is that it presumes that a regulated process will generate a better payment method than the market-oriented approach. Yet, most analysts believe Medicare’s current volume-based fee-for-service payment method is inherently inefficient. There is a growing consensus that a value-based common payment system that takes into account care quality and cost is a more desirable approach, and both the public and private insurers have endorsed it [12]. Another issue not addressed by a common payment method is that the negotiations over rates may still yield different payment amounts for the same services based on the amount of market concentration for insurers and health systems and clinicians.

Alternate Model: All-Payer Rate Setting

A significant step beyond the common payment method approach is “all-payer rate setting.” In this approach, there is both a uniform payment method and a single rate that all private and public insurers pay for a service [13]. In some variants, all hospitals and physicians are paid the same rate, while in other variants each hospital and clinician has a unique rate. An international example of all-payer rate setting is the German system [14]. In Germany, all insurers sit on one side of the proverbial table and representatives for the hospitals and physicians sit on the other side. Their objective is to negotiate a single payment rate for each service that all health insurers and all health systems will accept. The rates are binding on all insurers and all hospitals and clinicians. There are no special deals for a dominant organization in a local market.

The US attempted a number of state-specific all-payer rate setting programs beginning in the 1970s [15]. One program that has remained operational is Maryland’s, which was fully implemented in 1977. Until 2014, the state used prospective diagnosis-based payments for each admission, a method similar to the Medicare hospital payment system [16]. The Maryland program was able to reduce significantly the rate of increase in spending per hospital admission below the national rate of increase in the US [17]. However, because the admission rate increased, the program was less successful in controlling overall hospital spending. This necessitated a revision to the payment system. Since 2014, Maryland has used a prospective annual global budget that requires each hospital to monitor both the number of admissions and the cost per admission [17].

The Maryland program has a number of features that differentiate it from other all-payer rate setting programs. Whereas the payment rates in Germany result from a negotiation between payers and hospitals and physicians, the payment rates in Maryland are established singlehandedly by a quasigovernmental agency called the Health Services Cost Review Commission (HSCRC). Moreover, all payers in Maryland—large private insurers, small private insurers, the Medicare program, and the Medicaid program—essentially pay a given hospital the same rate for the same service. Unlike the Germany system, however, each hospital negotiates its own rates.

The Maryland program has a Medicare waiver that allows it to set Medicare payment rates [17]. Much of the attention paid to the HSCRC’s all-payer hospital rate revolves around this waiver and what Maryland must do to maintain it. Historically, the waiver test focused on the growth in hospital payments per admission, while the current waiver test focuses on the growth in hospital spending per capita [17]. This change is more in line with the overall change in payment philosophy that now emphasizes value and per-capita spending [12].

Advantages. In addition to the benefits of adopting a common payment method—reduced administrative burden on insurers, simplified negotiations between insurers and

health systems, and improved price transparency for patients—an additional potential advantage of all-payer systems is improved access to care. With a common payment method, but not common payment rates, low-paying insurers can create access problems for those they cover. All-payer price regulation can eliminate variation in payments, thereby improving access. All-payer rate setting has other potential benefits; for example, Maryland’s hospital rates included surcharges to support an “uncompensated care pool” for the uninsured and a public plan for residents with chronic health conditions [17].

Disadvantages. The potential disadvantages of an all-payer rate setting approach are similar to those of a single payment methodology. First, it presumes that payment method and rates can be developed that are better than the multiplicity of rates and methods in the current system. Second, the reduced administrative costs incurred by insurers and health systems are partially replaced by additional regulatory expenses, although they are smaller. Third, the uniform prices do not reward higher-quality care, a situation that can be rectified with pay for performance, transparent quality metrics, and other value-enhancing payment systems that can be more easily introduced when all insurers are on the same payment system. Finally, there is the possibility of what’s referred to in the economics literature as “regulatory capture,” which occurs when regulators, such as the Environmental Protection Agency, Food and Drug Administration, or Securities and Exchange Commission, focus less on protecting the public and more on protecting the commercial interests of the industry being regulated. This does not seem to have occurred in Maryland, however.

Conclusion

These models have numerous advantages and have worked relatively well in Maryland and in other countries. However, all-payer rate setting could be difficult to sell elsewhere in the US, inasmuch as many insurers, hospitals, and clinicians believe they live in Lake Wobegon and receive above-average rates that give them a competitive advantage. This makes them less willing to accept a regulated system that would eliminate this competitive advantage, which means that the US will continue to pay higher prices than other countries and will restrict access to health care for some Americans.

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POLICY FORUM

Policymaking for Orphan Drugs and Its Challenges

Taeho Greg Rhee, AM

In the United States, rare diseases (e.g., cystic fibrosis and leukemia) are defined by the Food and Drug Administration (FDA) as diseases that affect fewer than 200,000 people [1]. The roughly 6,000-8,000 diseases defined as rare collectively affect approximately 25 million US citizens [2]. About 80 percent of rare diseases are genetic in origin (e.g., caused by defects in a single gene or mutations in several genes) [2]. Because rare diseases are “life-threatening and/or chronically debilitating” and many people “die before reaching adulthood,” treating patients with rare diseases should be a significant public health concern [3].

Before the advent of the Orphan Drug Act (ODA) of 1983 [4], biotechnology and pharmaceutical companies did not invest much in developing drugs and biologics (hereafter referred to as drugs) for rare diseases or conditions because “there [was] no reasonable expectation [that] the sales of the drug[s] would] recover the costs” [5]. Such drugs are often referred to as orphan drugs because they were neglected. Only 10 drugs were available to treat rare diseases in the 1970s before the enactment of the ODA [1].

Due to the rarity of the conditions and limited demand for treatments, biotechnology and pharmaceutical companies were unlikely to develop orphan drugs without government intervention [6]. As a result of advocacy from public and special interest groups (e.g., the National Organization of Rare Disorders) in the late 1970s, the Orphan Drug Act (ODA) of 1983 was signed into law to provide several incentives to encourage biotechnology and pharmaceutical companies to develop orphan drugs. Through subsequent amendments to the act, incentives include: (1) seven years of market exclusivity for any unpatented drugs designated as treatments for rare conditions; (2) tax credits for certain research and development costs; (3) elimination or reduction of procedural fees; (4) fast-tracking of FDA review and approval of applications pertaining to orphan drugs; and (5) federal and state grants for drug development (e.g., research grants from the National Institutes of Health) [2, 7].

Successes of the ODA

Since the enactment of the ODA, the FDA has granted approval for marketing to more than 400 orphan drugs [1]. Considering that only ten orphan drugs were available between 1973 and 1983, this is great progress. Stimulating rare disease research through the ODA not only led to scientific breakthroughs but also “permit[ted] enough

freedom of movement for sponsors [(e.g., biotechnology and pharmaceutical companies)] to recycle [or re-purpose] previously discontinued products" [8]. Moreover, through the ODA and its amendments, orphan products became more diverse. For example, they include not only traditional (i.e., chemically based) drugs, but also biologics (e.g., "natural sources such as human cells or microorganisms") and medical devices [9].

The increase in availability of orphan drugs had a positive impact on health. Approved orphan drugs are shown to reduce premature mortality rates in patients with rare diseases [10]. Using longitudinal, disease-specific data from 1996-2006, for example, Lichtenberg found that the cumulative number of orphan drugs approved three to four years earlier was significantly inversely associated with premature mortality rates in patients with rare diseases (e.g., rare cancers, Huntington disease, Tourette syndrome, and Lou Gehrig's disease) [10, 11]. While a relationship between mortality and cumulative number of drugs approved up to two years earlier was not found, this may be because "most patients probably do not have access to a drug until several years after it has been launched" [12].

Problems Remaining after the ODA

Despite recent successes in developing orphan drugs, less than 10 percent of patients with rare diseases are treated today [2]. While the ODA had some benefits, there are major problems it did not address.

Medications are available, but they may not be always accessible due to high costs. Several studies indicate that orphan drugs are very expensive and that their accessibility can be a huge concern [13]. For example, cerzyme was developed by Genzyme to treat Gaucher disease. There are about 2,000 patients with Gaucher disease in the US [13], and the medication costs as much as \$400,000 every year for an adult patient [14]. There is a concern that pharmaceutical companies can create a [monopoly](#) market [6], precluding payers' ability to negotiate prices, by "splitting up a disease into several sub-diseases that qualify as rare diseases (a practice called 'disease sub-setting,' 'salami-slicing' or disease stratification)" [15]. Furthermore, drug manufacturers are "free to set their own introductory prices" [16], and "establishing a price that maximizes its profit is legal" [17]. Such high medication costs can be burdensome to payers and, especially but not only if reimbursement is denied, to patients.

The incentives may not be doing enough. Some researchers also raise the question of whether, even when given incentives to focus on rare diseases, the pharmaceutical industry concentrates only on commercially lucrative areas. At least 95 of the aforementioned 400-plus orphan drugs were for cancer treatment; orphan drugs used to treat rare cancer are the [most profitable](#) [13, 18-20]. Haffner and colleagues ask, does the "development [of orphan drugs] actually take place for the truly rare diseases, or only for the more common ones" within the rare group, like the rare cancers [21]?

Wellman-Labadie and Zhou question whether these “oncology products should qualify for orphan drug designation and whether so many cancers should be considered as rare diseases” [22].

Conclusion

To improve the accessibility of orphan drugs for patients with rare diseases, relevant policies should be altered in ways that promote fairness and equity. As Côté and Keating state, fairness requires “a positive action by the state [or government] when the market does not provide a good match between investments and health [care] needs. Finally, fairness requires that the barriers to access should be morally justifiable” [23].

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MEDICINE AND SOCIETY

Money and Medicine: Indivisible and Irreconcilable

Eli Y. Adashi, MD, MS

First there was barter. A well-cooked meal for a lanced boil. Cords of wood for a home visit. A chimney sweep for a gash treated. And then there was commodity money such as tobacco, not to mention wampum. However, with specie and paper money on the rise in the New World colonies, barter was increasingly being relegated to a historic footnote. The outright innocence of it all notwithstanding, the ethics of barter and medicine in days of yore was most likely just as challenging as ethics is at present with contemporary monetary counterparts. The constancy of the fundamentals of human nature would have seen to that. Still, medicine was simply not all that present in most people's lives. Few users. Few providers. This constrained transactional scope all but precluded the notion of medicine as a business on a grand scale. Interestingly, this steady state of "cash for care" had held sway through centuries during which physicians occupied a lofty perch. The twentieth century changed all that. This commentary explores the potential ethical fallout from the contemporary juxtaposition of money and medicine in the practice, business, and industry arenas.

The Rise of Fee for Service

Ironically, it was the advent of the employer-sponsored health insurance paradigm [1] and its "fee-for-service" payment system [2] that ushered in the contemporary business of medicine and the ethical challenges thereof [3]. Under this system, patients were kept in the dark about the going rates for health care services. Details of the latter were the proprietary domain of physicians and payers. Confidentially negotiated agreements saw to that. What is more, patients were not assigned the responsibility of paying the bills for medical services rendered, the accountability for which had been assumed by their employers. Having been taken off the proverbial financial hook, patients broadly embraced the newly inaugurated third-party insurance universe, wherein the conspicuous provision and consumption of health care services became the new normal. For their part, physicians did their very best to accommodate the growing demand. Aided and abetted by fee-for-service payment policies, the new world order now linked physician reimbursement to the volume of units of service rendered, thereby establishing medicine as a retail business. Happily uninformed—indeed blissfully oblivious—patients offered no resistance and did little to douse the flames of overconsumption. A culture antithetical to "choosing wisely" ensued [4], wherein the need to "bend the cost curve" became increasingly urgent [5-7]. It will be some time

before current efforts at reform reestablish measures of accountability and discernment [8].

Money and Medicine in the Practice Arena

Stripped to its core, medicine is a service industry, the product of which is health care. As such, the practice of medicine, not unlike the provision of any other service, is deserving of professional remuneration. Viewed in this light, medicine and money are sensibly interrelated and by extension indivisible. Less clarity exists, however, about the question of whether medicine should be a conduit to wealth accumulation. To its proponents, the notion of medicine as the road to personal wealth constitutes just another example of free-market economics. Medicine, after all, is but another form of business, and conflicts of interest never enter the equation, given a self-regulated, unswerving clinical decision-making process. To its detractors, the notion of self-enrichment from the practice of medicine represents an example of capitalism gone awry. According to this outlook, striving for riches in the healing professions is rife with financial conflicts of interest, with clouded clinical judgments, and with a compromised professional posture. Examined in this light, medicine and money appear irreconcilable [9]. Cautionary sentiments along these lines have reverberated over the ages. The twelfth-century Physician Oath of Maimonides offers the hope “may neither avarice, nor miserliness...engage my mind” [10]. The fifteenth-century Oath of Vaidya, intended for Hindu physicians, offers the admonition “You must put behind you...greed” [11]. The sixteenth-century Rules of Enjuin lay out a comparable line of reasoning wherein Japanese physicians are counselled against “avarice” [12]. The above notwithstanding, several other physician oaths and pledges make no mention of the subject. Notable examples include but are not limited to the Hippocratic Oath [13], the Physician’s Oath (The Declaration of Geneva) [14], and the Oath of Asaph [15]. Whether or not the authors of the latter three attestations deemed money and medicine to be reconcilable is unknowable.

As a matter of course, the practice of medicine comprises both specialty and primary care disciplines. In general, the former, especially the surgical varieties, are more remunerative than the latter. It follows that greater financial returns from the practice of medicine are more likely in the specialties than they are in the primary care arena. This conclusion appears to be particularly applicable to the “cash-only” segment of medicine exemplified by the subspecialties of plastic surgery and cosmetic dermatology and some subspecialties of assisted reproductive care, to name a few. As such, it is hardly surprising that a body of peer-reviewed contributions highlights the role of debt in the career choices made by medical school graduates [16, 17]. It follows that decisions at the earliest stages of a medical career may be guided not only by professional preferences but also by the need to address financial realities and goals.

Money and Medicine in the Business Arena

Medicine and money become further entangled when the role of the [physician-entrepreneur](#) is considered. Herein, the focus is on the business rather than on the practice of medicine [18, 19]. The literature is largely mum on the pervasiveness of this preoccupation among actively practicing physicians, although the fraud and abuse literature suggests that only a vanishingly small fraction is involved [20]. Still, physician ownership of health care businesses constitutes a growing reality deserving of mention. As it stands, physicians are invested in pharmacies, distributorships, toxicology laboratories, pathology laboratories, surgery centers, imaging centers, radiation therapy centers, physical therapy centers, and sperm or egg banks to name a few health care enterprises [21, 22]. Physicians also invest in and own hospitals and group purchasing organizations.

As going business concerns owned and operated by nonphysicians, the aforementioned enterprises raise little or no concern. In contrast, physician-owned and -operated health care enterprises have been the subject of federal scrutiny for the better part of three decades [23, 24]. In most if not all cases, concerns have revolved around the practice of [self-referral](#) and the possibility of an attendant financial conflict of interest [21, 25-28]. Restrictive covenants followed. The Stark Laws ("Physicians Ownership of and Referral to Health Care Entities") of 1989 and 1993 targeted self-referrals to physician-owned outpatient facilities [29]. More recently, section 6001 of the Affordable Care Act ("Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals") set its sights on physician-owned hospitals [30]. To proponents of medicine as a business, physician-entrepreneurs are merely a sign of the times. Viewed in this light, physician self-referral represents a patient-centered care-enhancing proposition. To its detractors, self-referral is ethically challenging, possibly unnecessary, and potentially harmful. On this plane, never the twain shall meet, let alone reconcile.

Money and Medicine in the Industry Arena

Another frontier whereon medicine and money have been vying for a *modus vivendi* is the interface between medicine and its industry partners. Herein, concerns revolve around the possibility that clinical decision making will be influenced by financial ties to manufacturers of drugs, devices, biologics, and medical supplies. Payment categories in this context may include but need not be limited to royalty, licensing, promotional speaking, consulting, and research. Physician ownership and investments in industrial concerns have also come to the attention of regulators. Importantly, this intersection of money and medicine has, not unlike the self-referral phenomenon, been the subject of substantial federal scrutiny. Long-standing drives to enumerate and report the financial transactions between physicians and industry have finally been consummated with the implementation of section 6002 ("Transparency Reports and Reporting of Physician Ownership or Investment Interests") of the Affordable Care Act, also known as the "Physician Payments Sunshine Act" [31]. As a result, physician-industry financial

interactions are now largely transparent and publicly listed [32]. What is more, significant tightening of the financial conflict-of-interest rules associated with [industry-funded continuing medical education](#) [33] has further attenuated the financial dimension of the medicine–industry interface. The same appears to hold true for the all-out exclusion of [pharmaceutical sales representatives](#) from most physician offices and health care facilities [34]. Finally, author disclosure requirements of industry support have been introduced in an effort to assure the integrity of the peer-reviewed literature [35]. These policies are presently undergoing reevaluation [36, 37].

In a 1992 editorial, the late Arnold S. Relman, MD, then editor of the *New England Journal of Medicine*, singled out physician self-referral [25] as a prime example of the “growing encroachment of commercialism on medical practice” [38], which he termed the “medical-industrial complex” [39]. A highly influential thesis, this far-reaching observation has withstood the test of time. However, its impact on the commercialization of medicine and on the attendant ethical fallout remains debatable. Consider the matter of self-referral. The detrimental consequences of self-referral are well documented [21, 22, 27–29, 40–44]. However, opinions as to its value and its ethical implications remain as irreconcilable as ever [45].

Going forward, physician reimbursement will be altered by the anticipated dismantling of the “fee-for-volume” payment system and its substitution with “fee-for-value” alternatives [46]. Whether or not a momentous alteration of the economic ground rules on this scale will in effect change hearts and minds remains doubtful. More than likely, money and medicine will remain both indivisible and irreconcilable for some time to come. Few expect otherwise.

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SECOND THOUGHTS

Mixing Dinner and Drugs—Is It Ethically Contraindicated?

David F. Essi, MA

Introduction

Over the past 50 years, the medical literature has documented concern about the influence of the pharmaceutical industry on the behavior of health care professionals [1-4]. One area of industry-clinician interaction that requires attention is pharmaceutical speaker programming at restaurants. The current speaker program model is flawed because, while third-party companies are often contracted to oversee compliance with Food and Drug Administration (FDA) guidelines for these events, the responsibility for creating some documentation used to assess whether the pharmaceutical company has complied is delegated to restaurants. Restaurant employees, as directed by pharmaceutical representatives, can manipulate the itemized dinner receipt to mask violations of guidelines before the receipt is sent off to compliance companies. The loopholes in the requirements for industry-clinician interactions, as well as other incentives and disincentives, do not support ethical conduct.

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals provides guidelines for the pharmaceutical industry's interactions with clinicians [5]. Adopted in 2002 amidst the Vioxx controversy (the high-profile drug company-FDA conflict that resulted in market withdrawal of a highly potent analgesic after it was determined to be associated with cardiovascular sequelae, including death), the code articulated minimum standards of conduct that would prevent violations of the federal Anti-Kickback Statute—a criminal prohibition against payments, in any form, made to induce or reward the referral of patients covered by federal health insurance. The code arrived just before the Office of the Inspector General released Compliance Program Guidance for Pharmaceutical Manufacturers in 2003 [6] and was superseded in 2009 to reflect even more stringent requirements, some of which were specific to entertainment and meals provided to clinicians [7].

The PhRMA code defines speaker programs as promotional programs that involve hiring a speaker to educate health care professionals about the benefits, risks, and appropriate uses of a company's medicines [5]. In light of the revised code's assertion that pharmaceutical companies are responsible for the active monitoring of their speaker programs for FDA compliance [7], third-party compliance companies are commonly hired to assist in the planning and documentation of these programs. The aim is to provide an added layer of watchfulness over compliance with regulations. However, this layer of

oversight is circumvented when a restaurant alters dinner service documentation, as directed by pharmaceutical sales representatives.

Planning

In planning the programs, third-party coordinators communicate to prospective restaurants that certain standards must be met to ensure compliance with the PhRMA code [7] and the federal Anti-Kickback Statute. Contracts that detail the regulations are sent to restaurants, which may choose not to sign them but are nonetheless expected to follow the guidelines strictly. Examples of dinner service-related guidelines are:

- no cocktail service
- wine and beer served only during dinner service; no after-dinner drinks
- no specialty coffees
- no “to go” orders, including desserts (though attendees may take leftover or uneaten portions of their meals with them)
- Wine may not exceed an average of \$9.00 per glass or \$36.00 per bottle.
- Spending per health care provider (HCP), including tax and gratuity, cannot exceed \$125.

The creation of highly specific dinner-related guidelines is driven by the desire to avoid the perception that HCPs are being treated extravagantly, as was the case in the recent past.

Documentation

Third-party compliance companies rely on the final itemized restaurant bill to document compliance with regulatory standards. The bill indicates whether prohibited items like hard liquor were sold and whether dinner costs were congruent with attendance. This method of identifying noncompliance is ineffective, however, because the restaurant can alter the receipt to mask noncompliant activities, allowing behaviors that violate federal law to occur without any repercussions.

Changing the number of meals. The purpose of manipulating the number of meals is to conceal the attendance of individuals not allowed by the code. The code states that the “inclusion of a healthcare professional’s spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate” [8]. Their presence at speaker programs is ethically inappropriate because the events are intended as educational sessions for health care professionals and the inclusion of nonrelevant guests reintroduces the opportunity for [gift giving](#) into the interaction. This gift giving may generate conflicts of interest (e.g., with obligation to patients or objectivity in research) due to psychosocial norms of reciprocation [9]. Some of the most profound changes that occurred with adoption of the PhRMA code in 2002 involved these very gift-giving practices, the effects of which are bountifully described in the literature [3].

Having worked in the restaurant industry, I can say that it is not unusual to see siblings or spouses of HCPs attending speaker programs. One physician told me that he accompanied a fellow physician to a speaker event only because he wanted to try the restaurant; the drug being presented was irrelevant to his practice specialty. As such, his attendance was not as a physician qua physician, but rather as a physician qua guest.

In situations in which a pharmaceutical representative allows a nonrelevant person to attend a speaker program, he or she risks being caught if the number of meals on the itemized bill is in excess of the number of appropriate attendees documented elsewhere. Concealing this discrepancy can be achieved by asking the restaurant workers to delete a meal from the receipt and allocate the cost associated with that meal to “non-person-specific” charges (i.e., beverages, room fee, etc.). In this way, compliance companies will not be able to detect that extra people attended the speaker program.

Changing the types of drinks served. Another common violation related to hosting pharmaceutical speaker programs at restaurants occurs when attendees order liquor-based drinks. Although servers are often aware that liquor-based drinks may not be served to attendees (because of standards communicated by compliance companies to restaurants), they may get verbal permission from pharmaceutical sales representatives to do so because they feel uncomfortable refusing this otherwise normal request for a liquor-based drink. At the end of the event, the cost associated with liquor-based drinks is converted to wine and beer sales (which *are* permitted beverages) for inclusion in the final bill. Both restaurant and pharmaceutical representatives get what they want: the restaurant increases its sales by attending to guest requests, and the pharmaceutical representatives get to deliver on what their attendees desire at the speaker program (in this case, liquor). During my work in the restaurant industry, one compliance company representative told me that she recognized that guidelines were not always followed and, if evidence of a violation did appear, I should remove the inappropriate charges as directed by the pharmaceutical representative.

Discussion

Ultimately, violations of guidelines can occur because some institutions within American health care are strongly profit-driven and willing to assume risks associated with noncompliance in order to attain both short- and long-term sales goals. In the context of compliance-related interactions among restaurants, compliance companies, and pharmaceutical representatives, the ability to manipulate restaurant compliance documentation inevitably diminishes the riskiness of participating in noncompliant behavior. The ways that companies can fail to comply are innumerable, given the organic development of businesses and business practices.

Sometimes, noncompliance is exposed through the actions of whistleblowers. This was the case in April 2013, when the United States government filed a complaint against

Novartis, a Swiss pharmaceutical company, for violations of both the False Claims Act and the Anti-Kickback Statute specifically related to speaker programs:

From January 2002 through at least November 2011...Novartis systematically paid doctors to speak about certain of its drugs, including its cardiovascular drugs Lotrel and Valtorna and its diabetes drug Starlix, at events that were often little more than social occasions for the doctors.... In practice, Novartis held thousands of speaker programs all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drug at issue. Instead, Novartis simply wined and dined the doctors at high-end restaurants with astronomical costs, as well as in sports bars, on fishing trips, and at other venues not conducive to an educational program. Novartis's own internal analyses showed that speaker programs had a high return on investment in terms of the additional prescriptions for its drugs written by the doctors who participated in the programs, both as speakers and attendees [10].

This case demonstrates that the safeguards put in place to prevent kickbacks and other undue influences on the prescribing habits of HCPs are insufficient. In fact, they are so insufficient in preventing violations that the aforementioned lawsuit considers almost a decade of noncompliance.

Physician attendance of pharmaceutical speakers programs has repeatedly been shown to effect [change in their behavior](#). Not only has attendance been linked with an increased likelihood of formulary requests for new drugs [11, 12], but the provision of meals to physicians has also been positively correlated with frequency of prescribing a given medication [13-18]. Given the substantial evidence that sales techniques can influence physicians to favor a particular medicine [1-3], it is intuitive from a business perspective that a pharmaceutical company would want to make use of such tactics, especially if there is a mechanism by which illegal and ethically problematic activities could be concealed.

Without following speaker event guidelines, pharmaceutical companies can employ sales techniques that are common in other business sectors. Certain of these, such as kickbacks, are not ethically permissible in the realm of medicine due to the conflicts of interest that they can create. The social action of gift giving is a basic interaction between humans that functions as one method of generating reciprocal obligations, conscious and unconscious. There is no way to know with certainty whether a given medical decision is made on the basis of a conscious or subconscious sense of needing to return the drug company's gift. Without a way to directly assess or verify that a conscious or subconscious bias may conflict with the best interest of a specific patient in

a specific instance, it may be justifiable to say that even the mere perception of the existence of a conflict of interest is enough to oblige disclosure and removing of oneself from a decision in the case at hand. Perceptions alone can create distrust of individual physicians and the health care system as a whole.

There is no strong incentive for compliance companies to ensure that guidelines are being followed. In fact, their interest appears to lie in maximizing a pharmaceutical company's return on investment/marketing costs (i.e., the speaker program): many compliance companies offer other business products that aim to generate returns on investment by using various methods, such as developing "key opinion leaders" [19]. If allowing prohibited sales techniques—kickbacks—can bolster a pharmaceutical company's ability to maximize prescriptions and, hence, profits, and restaurants can whitewash the documentation of noncompliant behavior, compliance companies can allow noncompliance to continue without having any evidence that shows they knew otherwise. Conceivably, any compliance company that deviated from the current standards of monitoring compliance by, for example, implementing more scrupulous oversight measures with on-site personnel or video recording, would disadvantage itself in competing for future clients in the marketplace and maintaining its current business relationships.

Like pharmaceutical and compliance companies, restaurants also lack a substantial interest in following or ensuring compliance with guidelines in accordance with the duties prescribed for them in speaker program contracts. This should not come as a surprise. Restaurants' primary interest is increasing their sales, and thus they may be willing to manipulate itemized receipts as long as they are paid what is due. Restaurants lack both the authority and expertise to ensure any form of meaningful adherence to guidelines, and the culture of the service industry is based on the notion of pleasing customers. In this context, the restaurant's role as an enabler of noncompliance is a particularly interesting component of the ethics of pharmaceutical speaker programs. Speaker programs often occur at mid- to high-end restaurants, which may be more likely to have private rooms where they can take place. At such restaurants, the standard of service requires that virtually every reasonable guest request be fulfilled. Servers have been conditioned to focus on meeting guest expectations by training and gratuity-based compensation. Even if a certain gratuity is guaranteed, as is often the case with speaker programs, the culture of the restaurant industry makes it especially difficult for workers to go against established norms of the service industry in general. In other words, adhering to two-drink maximums—and no cocktail service—is culturally discordant for restaurant workers and impossible once a pharmaceutical representative has given staff an "okay" to meet the request. Restaurant workers are interested in serving not only the attendees of the pharmaceutical speaker program, but also the pharmaceutical representative, who is likewise a guest. The culture of the service industry renders the compliance company's reliance on it to provide oversight of dinner-related stipulations

useless.

Conclusion

Noncompliant activities undoubtedly occur at speaker programs held at restaurants. Some of the methods used to identify potential regulatory violations can be disguised by a simple and effective means of manipulating content on itemized receipts. At best, pharmaceutical speaker programs operate within a poorly designed framework that fails to meet the goal of eliminating excessive spending and gift giving. At worst, the existing structure provides an invitation to circumvent both legal and industry standards. Finally, asking restaurants to participate in enforcement and documentation of guest behavior is contradictory to the goals and norms of the service industry.

Restaurants should play neither a moral nor a legal role in the regulation of the pharmaceutical industry; no legitimate basis for such a role exists. For the most part, restaurants and their staff are unaware of the larger industrial-regulatory framework for HCP-pharmaceutical company interactions, yet they have been charged with documenting and carrying out certain activities related to compliance. This makes their exploitation by pharmaceutical representatives even more egregious. The burden of documentation and oversight should not fall in any way upon restaurant workers, regardless of whether they could effectively monitor for noncompliant activities.

Since the pharmaceutical companies, compliance companies, and restaurants do not have incentives that strongly encourage adherence to pharmaceutical speaker program compliance guidelines, any solution to this problem must involve rethinking the current system's incentives and disincentives. One obvious remedy would entail banning industry-provided meals at speaker programs altogether. Such a ban was enacted statewide in Massachusetts in 2008 [20]. Four years later, however, the ban was repealed after lobbying from pharmaceutical and medical-device companies and restaurateurs, leaving Vermont the only state that currently prohibits industry-provided meals at speaker programs [20].

Other solutions might reimagine pharmacotherapy education altogether, delegating the responsibility to pharmacists or brown-bag sessions. Some clinicians may consider pharmaceutical speaker programs necessary for disseminating information on new drug therapies [21]. This opinion is erroneous, however; major medical centers have already evolved to address educational "gaps" that opened up after the prohibition of sales representatives in hospitals or satellites. Given health care systems' ability to address these educational gaps, the pharmaceutical speaker program marketing tool cannot play an exclusive role in educating physicians and other HCPs about new pharmaceuticals or indications. Rather, a much stronger justification would have to be made in order to allow the current system of speaker programming to continue.

This article has described a system that facilitates the masking of noncompliant activities at pharmaceutical speaker programs held at restaurants, contributing to the body of literature showing that industry-HCP relationships are an ongoing [area of concern](#) for the American medical system. Making use of innovative solutions for addressing the conflicts of interest that flow from industry-HCP relationships is an ethical requirement to avoid harm to patients and to help improve the quality of pharmaceutical education. Strategies have been described for eliminating industry influence in practice at both large academic medical centers and family practice settings [22], sometimes termed being “pharma-free” [21]. With the advent of the patient-centered medical home, other options may begin to make more cultural sense, such as increasing utilization of the only medication experts in health care—pharmacists—in novel ways.

The ongoing debate over industry-practitioner interactions is important and may at times seem too large to fix. The apparent insurmountability of these challenges, however, does nothing to lessen the importance of the ethical claims about conflicts of interest and the primacy of our obligations to patients. Digging deeper into the intricacies and hidden aspects of the pharmaceutical industry’s marketing practices may help to further clarify what kind of ethical reformation is needed.

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Suggested Readings and Resources

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