

Who Else Is Paying Your Doctor?

What to ask your neurologist about his or her relationship to industry.

BY ORLY AVITZUR, M.D., M.B.A.



When Maran Wolston was asked to enroll in a clinical drug trial for multiple sclerosis (MS) by her neurologist—who admitted to being compensated for running the trial—her initial concerns about any conflict of interest were trumped by the sense that she was lucky to have a neurologist on the front lines of MS research. She understood that if physicians were not compensated for conducting research, far fewer treatments would be available.

But the request was the first in a series of events—including feel-

ing pressured to take certain medications that she was unsure were in her best interest—that eroded her trust in that physician's judgment, which she feared was colored by financial relationships with drug companies that manufacture and market medicines for MS.

So Wolston, a doctoral candidate in philosophy at the University of Minnesota, looked up her doctor in a database ([bit.ly/OapAJR](#)) provided by the Minnesota Board of Pharmacy. She found out he had received more than \$300,000 from drug companies. One company had sponsored the clinical trial in

“I have no idea whether my neurologist’s advice and judgment were affected by **his relationships** with the drug industry. But it would have been foolish of me not to **consider the possibility** that the relationships were affecting my care.”

—MARAN WOLSTON

which she had been enrolled, and another had manufactured the drug he ultimately prescribed. The money he received included compensation for “speaker fees” and for “promotional and marketing consulting services.” She chronicled her experience in “An MS Patient Loses Trust When She Finds Out Her Doctor Is Paid by Drug Companies,” a story published in *Health Affairs* this past December (bit.ly/Oap5j3).

“In fact,” Wolston wrote in her article, “I have no idea whether my neurologist’s advice and judgment were affected by his relationships with the drug industry.” In addition, the database failed to specify whether all of the payments were for promotional activity as opposed to, say, research—and over what period of time the money was received. “But because I was his patient,” Wolston continued, “the effect of those relationships was not a theoretical question. It would have been foolish of me not to consider the possibility that the relationships were affecting my care.”

Minnesota, Vermont, and Massachusetts (1.usa.gov/M7Mst3) have mandatory marketing disclosure laws, which require the reporting of physician payments such as those to Wolston’s doctor. These reports, along with those released by more than 250 pharmaceutical and device companies, are accessible through an online database called PharmaShine (pharmashine.com). Anyone can also access Dollars for Docs (bit.ly/cZzi9A), a free ProPublica database that allows individuals to search by physician in order to find disclosed payments made by 12 pharmaceutical companies to health-care practitioners. Some patients are already using this resource.

By 2013, the implementation of the Physician Payment Sunshine Provision of the Affordable Care Act will allow anyone to look into the financial relationship between a physician and pharmaceutical or medical device manufacturers, as all these companies will be required to collect, track, and report this information. The accumulated data will ultimately populate a national physician payment database open to the public. But the final implementation regulations from the Centers for Medicare & Medicaid Services (CMS) are not complete, and many physicians are concerned about the accuracy and manner in which the tool will display information.

DATA: THE RAW AND THE COOKED

As chair of the conflict-of-interest steering committee that oversees the ethics integrity process at Dartmouth-Hitchcock Medical Center, neurologist and Fellow of the American Academy of Neurology (AAN) James L. Bernat, M.D., has concerns about how relationships between doctors and industry are being lumped together when they are displayed on some of these websites. “The data are raw, and the sites don’t appear to distinguish between funds received from speaker’s bureaus, consulting, or research grants,” he says. For example, one of his

colleagues was listed as having received \$18,000 from a company, but an investigation revealed that the funds went to support a research grant for a doctor that his colleague mentored.

Some experts are also concerned about whether the legislation will achieve its intended goals or cause additional problems. Supporters of transparency believe such a national database is sorely needed because the information will permit patients to consider their physicians’ potential conflicts of interest. But others argue that it may discourage physicians from working with industry, a relationship many believe is necessary for fostering innovation and improving care.

“If you are going to inquire if your neurologist has received compensation from industry, you need to understand which aspects of that relationship are constructive and potentially helpful, and which parts are not constructive and potentially harmful to the trust that you need to have in your physician,” advises James A. Russell, D.O., the current vice-chair of the AAN joint Ethics, Law and Humanities Committee, and the vice-chair of the department of neurology at the Lahey Clinic at in Burlington, MA, where he is a member of the ethics section.

Patients Concerned About Pharma Influence

In a nationally representative survey by *Consumer Reports* of 1,250 adults in 2010, more than three-fourths said they would be “very” or “somewhat” concerned about getting the best treatment or advice if their doctor were accepting drug-company money (bit.ly/ajXOqg). And 70 percent said doctors should tell their patients about such payments if they are going to prescribe drugs from one of those companies. Other findings include:

- ▶ **58 PERCENT** thought it was “very” or “somewhat” common for drug companies to pay doctors to give speeches or presentations to other doctors about the effectiveness of their drugs.
- ▶ **40 PERCENT** said they would not feel comfortable asking if their doctors had accepted payments from the company that makes a drug they prescribe.
- ▶ **51 PERCENT** said even a payment of \$500 or less from a drug company would make them concerned that a “doctor’s judgment might be influenced by the dollars.”

Source: ProPublica: bit.ly/cMcdnP

“There are many **legitimate relationships** with industry. The key is for the public to **encourage scrutiny**, and for physicians not to sell their souls.”

—JOHN R. CORBOY, M.D.

“You need to be fully informed, not partially informed,” Dr. Russell stresses. “For example, a patient may hear that his doctor has listened to lectures sponsored by a pharmaceutical company and accepted a free lunch and therefore assume that his doctor must be biased. But those lectures may have been supported by an unrestricted grant to an organization like the AAN to use at its discretion, so while at first glance it may appear to pose a conflict of interest, often it is not.” Dr. Russell fears that without such sponsored educational opportunities, physicians—particularly those geographically disadvantaged—may be unable to remain up-to-date in a wide variety of neurology fields.

What’s more, conversations about disclosure may take up time better devoted to discussion about the patient’s care, according to Dr. Russell. “If we go off on a tangent, we may be less likely to solve their problem,” he suggests.

Deciding whether or not your doctor’s relationship to industry represents a conflict of interest can be tricky. So what are some of the potential situations that may arise due to your neurologist’s relationship with industry, and what questions will help you arrive at the best decision about your care?

PRESCRIPTIONS

If you find it intimidating to ask your doctor directly if he/she has a relationship with the drug’s manufacturer, it may help to consider the following:

- ▶ **Were you prescribed a therapy but not offered any explanation or scientific data as to support why it is superior to others?**
Were you not provided with any information about alternative medications or treatments?
- ▶ **Were you given free samples from the office to get you started? Although many doctors provide free samples in order to help patients with financial limitations, these patients may end up paying for a more expensive drug down the line.**
- ▶ **Did you see drug company logos on pens, mugs, pads, or reflex hammers in the office or exam room, or on print materials in the waiting room?**

None of these necessarily indicate bias, but if they are accompanied by a sense of coercion, listen to your gut; it’s time for a second opinion. “Free samples may seem like a good idea at the time, but they are only available for the newer—and often more expensive—brand name medications, not for generic drugs,” says John Santa, M.D., M.P.H., director of the Consumer Reports Health Ratings Center (bit.ly/LrUjHc), cautioning that when you fill your prescription, they will typically cost more money. “For the purposes of detecting conflict of interest, they do provide a

clue that the manufacturer’s drug rep has visited and probably spoken with your doctor—ditto for the tell-tale logo-embossed freebies that may catch your eye, or the waiting room pamphlets and educational brochures,” he adds.

PUBLIC SPEAKERS

If you have a neurologic condition or are a caregiver, you may have received an invitation or seen a flyer promoting a local talk on that condition. “In my experience, speakers at these kinds of events run the gamut from providing accurate, balanced information on the one hand, to really pushing the product on the other,” observes Dr. Bernat. “There should be clear disclosure at the beginning of talks, especially to patients, because they may assume that the speaker is providing unbiased information. If it’s sponsored by industry, the audience should be told upfront that the speaker is being paid by a manufacturer,” he says.

Dr. Russell adds that attendees should consider whether the competitors’ drugs were presented. For example, were the hand-outs provided exclusively for the sponsoring pharmaceutical company’s drugs? And does it appear that the presence of pharmaceutical sponsor reps in the room could be placing pressure on the speaker?

CLINICAL TRIALS

John R. Corboy, M.D., professor of neurology at the University of Colorado School of Medicine, co-director of the Rocky Mountain MS Center at Anschutz Medical Campus, and Fellow of the AAN, is concerned about incentives paid to physicians for enrolling people in clinical trials—as well as those targeted to patients who participate in trials. Like many others, Dr. Corboy believes it is unethical for a physician to accept a per-patient enrollment fee.

Some researchers contend that clinical trials provide a mechanism for uninsured patients to get medical care. Dr. Corboy agrees that trials sometimes offer patients their only real chance at effective therapies. But he believes this only adds another potential conflict of interest to a situation that is already ethically ambiguous since patients may be tempted to accept on the basis of financial need. If those uninsured or underinsured patients experience an acute attack and require treatment or hospitalization while on the trial, they may be unable to pay for it, Dr. Corboy says. The researchers are then in a position of having an established relationship with the patient and wanting to provide care, but there’s no mechanism to pay for it. “How can we ignore treatment?” he asks.

“There may also be non-financial conflicts of interest, including enhancement of career or perception in the community, associated with physician participation in clinical trials,” Dr. Corboy explains.

However, Dr. Corboy recognizes the value of relationships be-

tween doctors and industry. “There are many legitimate relationships with industry, and I believe that these are necessary,” Dr. Corboy says. Physicians, if acting properly, are one of the important non-pharma intermediaries—along with the FDA, other regulatory agencies, and institutional review boards (bodies charged with reviewing and approving research on human subjects)—that stand between the companies and the public, according to Dr. Corboy. If physicians don’t participate in the design and publication of clinical trials, the public may not find them credible, he adds.

“The key is for the public to encourage scrutiny, and for physicians to not sell their souls,” Dr. Corboy stresses. He suggests that patients ask the researcher the following questions when offered a clinical trial:

- ▶ Do you or your family own any patents or significant stock holdings for the drug or device being studied?
- ▶ Do you receive any payments beyond those for the actual performance of the study—for example, extra incentives such as enrollment fees?
- ▶ What are all my options for treatment, especially those not related to this or any other study?
- ▶ What happens if I am injured in the clinical trial, or if my neurologic condition worsens? Who is responsible for payment for my injuries or worsening in those contexts? Will you provide treatment if there are complications or worsening of my underlying condition?

REFERRALS

If your neurologist refers you to only one facility for a test such as an MRI scan, it should raise concern. Current laws called Stark regulations, which govern Medicare and Medicaid patients, place strict prohibitions on self-referrals, which are referrals to an imaging center in which the physician has a financial interest. An exception to the rule enacted in 2007 directs physicians who have ownership in imaging centers that provide MRI, CT, or PET scans to provide written notice of a list of alternative facilities in the area which provide the same service.

Critics of self-referral arrangements contend that they create an inherent conflict of interest given the doctor’s position to benefit financially from the arrangement. “Consumers should also be aware that there is tremendous variation in pricing of these services,” Dr. Santa points out. “Scans may be substantially more expensive at hospital or physician-owned facilities than at those that operate independently,” he says, advising fellow physicians that “We all need to be more vigilant about the places to which we’re referred and assertive in asking about cost.”

Kickback Charges and Settlements

Although the Sunshine Laws have spawned an outpouring of opinions, one thing is clear: It is not uncommon for neurologists to have relationships with industry. Just this May, Abbott Laboratories reached an agreement to pay \$1.6 billion to settle federal and state claims resulting from an investigation into its epilepsy medication, Depakote (valproic acid is the generic name). The settlement covered allegations that Abbott paid kickbacks to doctors to induce them to promote or prescribe the drug off-label for dementia and schizophrenia (1.usa.gov/KfuENP).

Similarly, last May, Merck Serono SA agreed to pay \$44.3 million to settle allegations that it illegally promoted the MS drug Rebif (interferon beta-1a) between 2002 and 2009 using inducements that included sending doctors to various training meetings and conferences at upscale resorts, promotional speaking engagements, advisory and consultant meetings, and independent medical and educational grants, according to the Department of Justice (bit.ly/IW567V, 1.usa.gov/LCTIoX, 1.usa.gov/mgDJJb).

And in 2004, in a highly publicized whistle-blower case, Warner-Lambert agreed to plead guilty and pay more than \$430 million (1.usa.gov/NtwuuH) to resolve criminal charges and civil liabilities in connection with its Parke-Davis division’s illegal and fraudulent promotion of unapproved uses for Neurontin (gabapentin).

Patients being referred for tests should ask:

- ▶ Do you have an ownership interest in this facility?
- ▶ Are there other facilities of comparable quality nearby?
- ▶ Can you tell me how much the test costs and how that compares to other facilities? The physician may not know this, but the office manager and billing office should. In either case, the patient may need to do a bit of comparison shopping.

SHINE A LIGHT

“For those involved with industry who believe in the value of what they do, so-called Sunshine laws—such as the Physician Payment Sunshine Provision of the Affordable Care Act—will mean that they need to more aggressively disclose their interests and activities up front and provide the patient with the opportunity to ask questions and satisfy themselves about the propriety of the relationship. For others, that will mean divesting themselves of relationships that are difficult to justify,” Daniel G. Larriviere, M.D., chair of the AAN’s joint Ethics, Law and Humanities Committee, told *Neurology Today*, the AAN’s magazine for neurologists, earlier this year. (The Sunshine Act is a provision of the 2010 Patient Protection and Affordable Care Act that requires pharmaceutical, medical device, biological, and medical supply manufacturers to track and report payments made to physicians and teaching hospitals.)

“As these databases become more widely known and utilized,” Dr. Larriviere concluded, “patients will determine whether the relationship is appropriate or not, and physicians will have to change their practices accordingly or risk losing business.” NN