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NARRATIVE MATTERS



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An MS Patient Loses Trust When She Finds Out Her Doctor Is Paid By Drug Companies

As of 2013, a national physician payment database created under the Affordable Care Act will make such information available to all.

BY MARAN WOLSTON

Last year, four years after showing initial symptoms of multiple sclerosis (MS), I walked out the door of one neurologist's office and, after several months of searching, switched to a different doctor. It was the final act in a series of events that had gradually eroded my trust in the first neurologist's judgment, which I believe was colored by his financial relationships with drug companies who manu-

facture and market medicines for MS patients.

I had started to see this neurologist not long after I experienced my first MS symptom: the sudden onset of visual distortion in my right eye. I suspected I needed glasses, but when it was determined that I had 20/20 vision, I was referred to a neuro-ophthalmologist and, finally, to the neurologist in question. With the help of three magnetic resonance imaging (MRI) scans over

the next year, he found an increasing number of lesions on my brain and eventually diagnosed multiple sclerosis. The disease's name actually refers to these multiple scars or scleroses that form in the brain and spinal cord over time.

Drug Trials And Tribulations

On the actual day that he told me I had MS, my neurologist said I didn't need to begin treatment immediately. But at my next appointment, he told me that I qualified for a clinical drug trial he was conducting and asked if I was interested in participating. I said I'd like to know more about it, and he put me in contact with the study nurse, who showed the trial's consent form to me. The profile of the possible side effects it detailed was frightening, and I opted not to participate.

Given my background in medical ethics, I was familiar with the potential conflicts of interest that exist for physicians participating in clinical pharmaceutical trials. Assuming that my neurologist was being compensated for running the trial, in addition to his earnings from seeing patients in his neurology practice, I'd asked him if that was the case, and he confirmed that it was.

It was the kind of situation I would have advised students in my ethics courses to think deeply about. But in this real-world situation with my own health in question, my naturally skeptical faculties were silenced by an internal conflict. I'd recently been diagnosed with a serious chronic disease, and I wanted to be privy to any new studies or information that came my doctor's way.

At that moment, any worries about my physician's potential conflict of interest were trumped by a sense that I was lucky to have a neurologist on the front lines of MS research. But, in retrospect, this was the first step in what I later saw as a betrayal of trust.

About six months later, during a routine appointment, my neurologist told me that given the development of new lesions shown on my most recent MRI, it

was time to start a disease-modifying treatment. He said that if I decided not to do so, my level of disability in ten years probably would be much greater than if I began therapy at that moment. Among the few available treatment options we discussed was Copaxone (glatiramer acetate), the MS medication that's supposed to have the fewest systemic side effects. This is one of a number of so-called specialty drugs for MS that patients self-inject either daily or every other day into the fatty layer just below the skin, in the arms, thighs, hips, or lower stomach. I agreed to start using it.

But life on Copaxone wasn't easy. Typically the medication doesn't cause fatigue, nausea, depression, or any of the other unpleasant side effects associated with other MS drugs, which is one of the main reasons that my doctor had recommended it over other options. It can, however, as I quickly found, cause brutally painful *local* side effects. Patients are advised to cycle through the various possible injection sites so as to avoid inserting the needle into the same area repeatedly. But no matter where I injected the drug each day, the injection site swelled up into a huge welt and felt like a gigantic bee sting.

About a week after starting Copaxone, I got a call from a nurse at Shared Solutions wanting to know how my injections were going. My neurologist had asked if he could give my patient information to Shared Solutions, and I'd agreed, assuming it had something to do with my health insurance. Soon I began to receive letters and packages from Shared Solutions, including directions for self-injecting, refrigerator magnets, a box for carrying Copaxone syringes on a plane, and invitations to MS education dinners. The nurse who called that day was extremely personable and helpful, and I spent nearly an hour talking with her on the phone.

But the local side effects from the medication continued to worsen. I don't ordinarily use a cane to walk, but every time I injected Copaxone somewhere in my legs, I needed a cane just to move around my house. Why, I began to ask myself, was I taking a drug that was making me feel worse than I'd felt before? As the days went on, it occurred to me there was no way to really know if the medi-



cation was helping me. My next MRI might reveal fewer lesions, but since this could happen even without taking a medication, whom exactly was I helping by taking it?

Within a few weeks of interacting with Shared Solutions, I realized that the organization had nothing to do with my health insurance. Some Internet research and a closer reading of the documentation they'd sent revealed that Shared Solutions was a subsidiary of the pharmaceutical company that makes Copaxone.

It is common for patients like me, who are on costly specialty drugs, to be assisted by companies like Shared Solutions. Some of these are subsidiaries of drug companies; others are divisions of health insurers or pharmacy benefit management firms. One of their roles is to help patients stay on medication, even when they're inclined to stop taking it because of side effects.

There is evidence that staying on medication—even on drugs costing \$25,000–\$45,000 a year, like those for MS—produces better outcomes for patients and yields cost savings overall, relative, say, to the higher costs of being hospitalized for a severe flare-up of disease or even entering a nursing home.

I was thankful for the assistance of the Shared Solutions nurses, but also uneasy.

It worried me that none of them ever suggested that I discontinue treatment—or switch to another treatment—even after I reported that my injection site reactions were affecting my quality of life. Despite the fact that my neurologist insisted that I begin disease-modifying therapy, I was never con-

tacted by him, his nurse, or anyone else in the neurology clinic with questions about how my Copaxone injections were going. The entire time I took it, the only people who checked in on me, trouble-shot my initially imperfect injection techniques, and answered my questions were the nurses from Shared Solutions.

Maybe I'm old-fashioned, but as a patient I felt that the party who *should* have been helping was my neurology clinic, not a division of a pharmaceutical company.

After about five months of taking Copaxone, and increasing numbers of welts on my body and increased difficulty walking after injections, I unilaterally decided to stop taking it. At my next neurology appointment, one month after I stopped taking Copaxone, I told my doctor I'd stopped because of its unpleasant and difficult side effects. He agreed that it made sense to quit the drug.

Distorted Objectivity?

My next neurologist appointment, less than a year later, was my last visit to his office. At this appointment my neurologist informed me that I'd begun to develop lesions inside my brain stem. He explained that this was a very bad place to have lesions, occupied as it is with regulating some of the body's basic functions, such as breathing. He strongly recommended that I go back on MS treatment, suggesting this time a drug called Tysabri (natalizumab), which had worked wonders for some of his patients but also carried some amount of risk. Worried about the new lesions, but knowing little about the drug he was advising, I told him I'd think about it. I needed to be convinced through my own investigations that this drug would be worth taking.

As I researched Tysabri (having a background in chemistry was a help), I found that it originally had been approved by the Food and Drug Administration (FDA) in 2004. But the FDA had quickly put the drug on clinical hold after three patients taking it developed a condition called PML—or progressive multifocal leukoencephalopathy—a debilitating brain disease that is often fatal. Many humans are carriers of a latent virus called the JC virus (or

polyomavirus JC), which can activate if a person's immune system is weakened for an extended period of time. Tysabri—an immunosuppressant—is understood to weaken the immune system to the extent that the JC virus is activated in some patients who carry it, leading to PML.

In 2006 the FDA allowed Tysabri to be reintroduced for use by some MS and Crohn's disease patients, under the condition that each patient taking it be enrolled in a strict monitoring program. Even so, MS patients taking Tysabri are still dying from PML. According to the most recent safety update from the FDA (issued in April 2011), for every 1,000 patients receiving between twenty-five and thirty-six infusions, 1.5 will develop PML. Since the drug was reintroduced in 2006, 102 people worldwide taking Tysabri developed PML. As I understood it, Tysabri should be used only with patients who are experiencing rapid disease progression and haven't experienced a clinical benefit from other disease-modifying drugs.

To me, it was a red flag. Although the previous drug regimen hadn't worked for me, I didn't appear to fit the protocol for the new one. And then there was the earlier suggestion about participating in a clinical trial at a time when treatment wasn't necessarily warranted and the subsequent hand-off to Shared Solutions while I was taking Copaxone. Now, learning the dangers of Tysabri—including what I felt was a nontrivial number of deaths linked to it—I had serious questions about where my neurologist's loyalties lay. Did his allegiance lie with the drug companies or with me?

Was my skepticism justified, or was I being too sensitive? I needed more information—something concrete.

In Minnesota, where I live, a "sunshine" law mandates that payments any doctor receives from a drug company be reported to the Minnesota Board of Pharmacy, which enters the amounts and types into a database that's accessible to the public. Minnesota was one of the first states to pass such a law, but as a part of the Affordable Care Act of 2010, the Department of Health and Human Services is about to institute a national physician payment database that also will be publicly accessible. Records of payments made in 2012 will be avail-

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able on a public website during or before September 2013.

We were lucky to already have a database like this in Minnesota when I needed it, but I'm also lucky to have a friend—a medical ethics professor—who told me the database existed. When I looked up my neurologist's name there, what I found was damning. He'd received more than \$300,000 from drug companies between 2006 and 2008 (2009 data weren't yet available).

Major contributors to this sum were Biogen—the manufacturer of Tysabri and the sponsor of the clinical trial my neurologist suggested to me early on—and Teva Pharmaceuticals—the manufacturer of Copaxone. In addition to many payments from these companies for acting as a speaker, my neurologist also had been compensated for "promotional/marketing consulting services."

I knew that I had felt pressured to take medications by my neurologist. When I found that he had been paid large sums of money—six times my yearly salary—to work for the manufacturers of those same drugs, my loss of faith was complete. I never returned to his neurology clinic again.

In fact, I have no idea whether my neurologist's advice and judgment were affected by his relationships with the drug industry. But because I was his patient, the effect of those relationships was not a theoretical question—an issue to be bantered about over coffee or in the seminar room. It would have been foolish of me not to consider the possibility that the relationships were affecting my care. Having MS is difficult enough. The last thing I needed was to worry about whether my neurologist was acting in the best interest of the drug companies or in the best interest of me, his patient.

Doctors often say that their drug industry relationships don't affect their judgment or prescribing behavior. But in point of fact, the results of a survey—

cited by Dana Katz and others in a 2003 issue of the *American Journal of Bioethics*—reveal that the more gifts a physician receives, the more likely he is to think the gifts don't influence his behavior.

Other studies included in the comprehensive article by Katz and colleagues suggest that despite a physician's *thinking* that receiving compensation or gifts from a drug company doesn't influence his professional objectivity, influence can occur on an unconscious level. And with unconscious factors at work, it's understandably difficult for patients to trust physicians who have drug company relationships. Even if physicians claim, in all good faith, that the relationships and payments don't affect their judgment, they might not be aware of if or how the gifts actually do.

Clinical trials serve an important social goal of exploring new treatment options that could improve the lives of patients. These trials can't take place without subjects, so I understand why there is a need to recruit patients. At the same time, incomes doctors derive from drug companies in the form of "marketing consulting services" and "speaker fees" create an unconscious social expectation of reciprocity, which, just like any gift, has the potential to corrupt and distort any person's advice.

In this case, the potentially corrupted and distorted advice comes from a doctor who is assumed by the patient to be a trusted caregiver. In an ideal world, clinical drug trials would be funded and administered by neutral, independent parties, eliminating ethical conflicts for physicians.

Needed: Disclosure And Transparency

As a patient, I find it inexcusable that doctors aren't routinely required to disclose their conflicts of interest to their patients. This should be done in the same way—and for precisely the same reasons—that doctors are required to disclose conflicts when they write academic articles. The response of patients to such disclosures won't be uniform. They might trust their physicians less; their trust might be unaffected; or, seemingly paradoxically, they might trust them more, perhaps because they

appreciate their physicians' honesty.

I also believe that it should be made transparent to every patient—by his or her doctor—why any third party such as Shared Solutions is involved in his or her treatment. And that should be especially true when the third party has a financial interest in the arrangement.

Transparency, however, isn't a silver bullet. A number of studies have found that people who receive gifts—physicians included—provide advice that is more biased after disclosure than was the advice given previously. Regardless, transparency about conflicts of interest is a step in the right direction. After they receive the information, it's up to patients to decide what it means to them.

When it comes to understanding and managing their medical care, patients are at what might be termed an epistemic disadvantage. Most of us aren't as knowledgeable about our conditions as our physicians are, and only a few of us have access to and the background needed to read and understand peer-reviewed academic articles that pertain to our situations. Even fewer patients have the ability to fully and independently investigate the conflicts of interest of their physicians or any others involved in their care. This will change

I asked if many patients inquire about possible conflicts of interest. He shook his head “no.” I was the only one.

when the national, publicly accessible database of payments to physicians is created—that is, assuming patients are aware that the new database exists.

As a patient experiencing a neurological disease that has no known cause and no known cure, I expected my neurologist to be direct and honest with me. I expected honesty in interpreting my MRIs; in giving me a prognosis; in explaining his rationale behind treatment recommendations and in providing verifiable, scientific information about them; in educating me about MS; and in telling me about any conflicts of interest with drug companies. Actually, I expected that my neurologist would have no financial conflicts of interest whatsoever.

After months of searching for a new neurologist, one who didn't accept drug industry money and whose services would be covered by my insurance plan,

I finally found one I like. I trust him, and he's remained my doctor. I trust his interpretation of my recent MRIs, and I took his advice when he said I should go back on an approved MS treatment. I've been able to fully commit to getting the care I need precisely because I have no reason to question my doctor's loyalties. During my first appointment with him, I told him that having my doctor not receive industry payments is one of my criteria for choosing a neurologist. I asked him directly if he had any industry relationships; he told me he didn't. At the end of our conversation, I asked if many patients inquire about possible conflicts of interest. He shook his head “no.” I was the only one. ■

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