



**Association for Ethics in Spine Surgery**

**Written Testimony of Dr. Charles D. Rosen  
President of the Association for Ethics in Spine Surgery**

I am Dr. Charles Rosen. I am a Clinical Professor of Orthopaedic Surgery at the University of California, Irvine, School of Medicine, specializing in spinal surgery which I perform, teach, and research.

My testimony is in my capacity as president of the Association for Ethics in Spine Surgery which I founded in 2006 in response to the ever increasing negative influence of industry on the treatment of back pain and spinal disorders in this country, and in particular on spinal surgery and research. Influence is exerted by device manufacturers who are enabled by a small but growing minority of spine surgeons on their payroll. To join my association, spine surgeons must declare in an affidavit that they do not accept compensation in any form from device manufacturers. We currently have close to 250 members enrolled or in the process of enrolling.

I will give you an inside view of the influence peddling of device makers and its effects, what happens if one voice concerns over this issue, and lastly, my recommendations to address the problem.

Spinal surgery for back pain costs billions of health care dollars every year and is increasing. In a single routine 2 hour spinal operation a surgeon can easily implant \$25,000 worth of hardware in the form of multiple \$1200 screws, \$5000 cages, \$12000 disc replacements, \$5000 bone graft substitutes, spacers, or \$20,000 spinal cord stimulators. Multiply this times a hundred surgeries per year for just one spine surgeon and then times the thousands of spine surgeons in the country, and one can see the enormous financial incentive for a device company to influence a surgeon to implant their products.

To exert this influence, companies often pay large sums of money, sometimes in the millions, to high profile spine surgeons who can write favorable papers about their products under the guise of unbiased research. In the last few years DOJ actions have led to 5 major companies being ordered to reveal the surprising size and extent of these amounts on their websites. As revealed in the New York Times a few weeks ago, the Department of Justice is investigating whether such surgeons on the payroll revealed to the FDA these conflicts of interests when they submitted evidence for approval of a certain brand of lumbar disc replacement.. Many such surgeons are also in governance positions of the professional societies and on the editorial boards of journals. This allows them to influence the choice of presentations in society meetings, choice of educational workshops, as well as papers chosen for publication. Sometimes company stock is used by smaller companies to incent surgeons to promote their product, giving them a bias for surgical results to appear favorable. Also, companies frequently pay surgeons just to continue being exclusive users of their products, or to switch over to them from a competitor's since one single surgeon can generate millions in sales each year. Because such behavior is illegal, it may be disguised as a fee for a sham consulting arrangement, for a royalty of little significance, or a hollow title such as key decision maker.

Now, the effects of this strategy are very successful. For example, most of the 4000 members of a large educational society called the North American Spine Society (NASS) do not take money from any company, and only want to do what's best for their patients. They rely on the information they receive from their professional society - in this case NASS - to be unbiased and to help them decide what implants to use, if any at all. Yet, few know of the enormous sums of money that many board members and well known authors are paid by industry. So called ethical disclosure rules are obscure in revealing the real extent of these financial rewards. For example, NASS has levels of disclosures indicated by categories without details. The highest category means that a surgeon receives greater than \$10,000 per year or owns greater than 10% of a company. This does not reveal if it is \$11,000 or one Million dollars. I submit to you that if this were fully exposed, then most surgeons, as well as patients, would reconsider their choice of procedures, and whether many should even be done at all.

I believe another problem is device distributorships, which are growing rapidly. Here, surgeon shareholders will form companies to manufacture or purchase their own devices at a fraction of the retail price of the major companies. All agree to implant only these devices. Then they share in the subsequent profits. This is an incentive for over utilization of implants and procedures, as well as limiting patient choice to one manufacturer of products that may not be the one best for the patients. These patients in my experience know nothing of the substance of these relationships, if even of their existence. .

Industry and its consultants cultivate a public mind set for selling that which is propagated by direct patient advertising, media announcements touting medical breakthroughs, and vast use of the internet to plant information on searches and in chat rooms that are covertly sponsored by industry. In this mind set, every new expensive high tech, device and procedure is an

advancement in surgery, even if results are only good for a year or two before the need for revision operations set in. It's a world where testimonials by doctors and patients over- rule independent studies and are enough to demand that payment be made for even the least validated procedure. Voicing concerns is labeled as impeding medical advancement or as a sign of ulterior motives. This leads to efforts at silencing the critic by underhanded attacks.

And attacked I was.

In 2004, the first lumbar disc replacement approved for implantation in this country was approved by the FDA in what I criticized as a poor study. I'll briefly mention my reasons because they're so easily grasped if the veneer of long words and the dubious stamp of FDA approval is stripped away. And remember, studies can be designed anyway one desires. This particular study was a small one with only a few hundred patients ; 2/3's of patients were still on narcotics 2 years after the disc replacement and this belies claims of success ; the first 25% of all the patients – those usually with all the complications - were eliminated by design from the final results; the control operation it was compared to was one with a 60% failure rate – a low bar to clear; and even the function of the device - namely continued motion– was not correlated with pain relief . One study in Europe even showed that over 90% of successful disc replacement patients had pain relief because paradoxically the device had spontaneously frozen up, acting as a conventional fusion.

In trying to understand how this was all allowed, I wondered whether the full financial involvement of the authors of the study was revealed to the FDA, which is the precise focus of the current Department of Justice investigation into the more recently approved lumbar disc replacement. Based on those recent questions, I wonder if the situation isn't similar with the first lumbar disc replacement that was approved.

After I voiced my concerns, an email went to almost every orthopaedic surgeon in the country saying I was doing this because I was in cahoots with Jim Cramer of Mad Money TV fame to short the stock of one of the largest multi-national companies in the world which happened to make the first disc replacement that was FDA approved. The email was from a highly visible industry consultant who publishes a weekly orthopaedics newsletter and one who organizes many disc replacement symposiums. After I contacted him to say this was absurdly untrue, I was threatened with a law suit for libel if I defended my self publicly. Even last week, I was attacked and libeled again by him in the same fashion because of the recent New York Times article. However, interestingly, he appears forced to reveal that his newsletter is partly funded by the Viscogleisi brothers who are part of the recent Department of Justice probe into the FDA's approval of the latest disc replacement. In any case, this modus operandi appeared to be the new theme for much of what lay in store for me. Namely, money trumps truth and science.

As I started seeing dozens of patients with failed disc replacements in some of the most horrible, unremitting pain I have seen in all my years of practice , in patients whose lives are effectively ruined, I was deeply moved. The Association for Ethics in Spine Surgery was born

to make surgeons and the public aware of the often negative influence of industry and the doctors on their payroll.

The attacks on me continued. Down to the last person, they all were by surgeons or others on industry's payroll. After 8 years of being continually promoted in good standing at the University of California, Irvine I suddenly received a bad evaluation and was told I might be fired soon. I later was told the person at UCI initiating this was a paid consultant of a major disc replacement manufacturer and was even on a 1998 FDA committee to evaluate disc replacements.

Additional attacks continued. Our current department Chairman notes the numerous occasions he was accosted by various people within the orthopaedic and neurosurgical world with the same message --- fire Rosen from the department. The chairman recognized that they were trying to discredit me, with no actual proof or comment of wrong doing. No hard reason is ever given except that essentially I am somehow "disrupting" the spine world. Such people include surgical department chairmen from UC campuses, including my own, as well as various academics in spine surgery from out of state. The request to have me fired has come from the head of a prominent orthopaedic foundation under a not – for – profit charter for education and research who is , as all they all are, a highly paid industry consultant. ( Incidentally, for me, this also begs the question of whether industry funded foundations, funded either directly or indirectly, yet still influence ultimate product use by surgeons, should have tax exempt status.). One well known academic spine surgeon even approached a colleague of mine at UCI and spread the rumor that I am critical of disc replacements only because of a desire to get paid for testifying in malpractice suits against surgeons, which is untrue. I have not now, nor in the last 16 years of practice, testified against any surgeon in any malpractice case. Nor do I intend to. It seems the main thing all these personal attacks have in common is that they are by the minority of spine surgeons on industry's payroll. .

The attacks worsen. At one point, the national weekly orthopaedic newsletter I mentioned , sent a reporter to try and associate me with the a local scandal of sorts that had nothing to do with me at all.

The attacks through the internet increase by companies utilizing their industry sponsored "chat" rooms and websites to discredit me. They are effective because the public does not know of the paid promoters and posters involved in what poses as patient education. Despite the financial purpose, many tout 501c 3 status as evidence of their purely charitable nature. One such site discusses disc replacement arthroplasty. On this site I am said to be critical of replacements because I am paid millions by a competing manufacturer. This is untrue.

Some of the fallout from these attacks is in other areas, including locally where I work. At UCI, neuroscience research is internationally renowned, and a ground breaking research program for spinal cord injury victims was begun. However outside our department are those that wish me fired, and commensurate with this, will not allow my directing such a program

despite the fact that my fellowship training was specifically in spinal cord injury. Such actions do an injustice to the American public and citizens of California who look to the University of California to advance science, not to use it as a personal weapon. It is even more unfair to those who suffer life in a wheelchair, longing for research to free them of their bonds.

My research and opinions are difficult to get published in the spine literature. I sometimes wonder if it's the subject matter itself.

Before finishing, I will give you my recommendations.

Firstly, I believe the exact dollar amount of any type of industry compensation from all companies to surgeons, particularly those who are writing papers and running professional societies, should be available for all to see. Their claim of right to privacy is hollow when it occurs in the context of making very public their opinions on devices to buy. And this disclosure should not be limited to only big cap companies as this will just move the game to the dozens of smaller ones. Frankly, I don't see how putting a yearly payroll on line is a troublesome reporting burden either.

Secondly, physicians running not-for-profit medical organizations for research or education should not be on industry's payroll. I suggest that the hidden agenda is in fact ultimately for profit in many cases, and thus the tax exempt status is improper.

Thirdly, device distributorships owned by spine surgeons where they profit from implanting their own devices, is in effect, selling product to unknowing patients. In my opinion, this leads to excessive device implantation and surgery that may not otherwise occur without the profit from this.

Fourthly, industry money going to individual physicians at universities must be more tightly regulated. The public, as do I, look towards academia for the unbiased truth, and this should be the standard.

Finally, no one on the FDA panels should be a paid consultant. Industry has too much influence designing studies to get the desired results. What seems to be a familiar pool of favored consultants should be eliminated. Although a recent outside consultant for the FDA claims that there are not enough doctors without conflicts to be on the panels I say that this is patently untrue. At least 2/3 of spine surgeons in this country takes no money from industry, and haven't been really approached to volunteer for FDA work. Last year I responded in a certified letter to a request for volunteers for spinal issues. I never received even the slightest acknowledgement, though I certainly believe I 'm qualified.

Thank you.