

## **IMPROVING THE QUALITY OF LIFE FROM THE PATIENT'S PERSPECTIVE**

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Prepared for Delivery at the Medical Device Regulatory and Compliance Congress, Harvard  
3/29-31/06

Good morning ladies and gentlemen:

This is the first speech like this I have ever given, and I really appreciate the opportunity. I guess I've given a couple of hundred speeches on legal aspects of food, drug and medical device law, and I've represented clients in every FDA center and district office and in about 30 courts around the country and I taught food and drug law at Northwestern University School of Law for 30 years, but I've never had the privilege of speaking about you and me! I really appreciate your being a captive audience so that I can thank you for all of the things you've done for me.

You've kept me alive, you've protected my senses, at least some of them, you've fastened my body back together, you've taken things out of my body that shouldn't be there. And I really want to thank you for the quality of life you've given me.

Here's what I mean:

1. You kept me from going blind by
  - giving me two intraocular lenses;
  - giving me two scleral buckles clamping my retinas back in place and
  - making lasers to seal holes in my retinas.

Without you, I'd be blind. And I've represented companies that made IOLs, scleral buckles and lasers. May I see the hands of those whose companies make IOLs, scleral buckles or lasers? THANK YOU!

2. You literally saved my life. One of my heart valves was going bad, so you
  - provided a porcine heart valve for me. But it needed a little help, so you
  - provided a pacemaker for me.

Incidentally, the company that provided both of those is one of my very best and favorite clients. And you can believe they're real favorites now! May I see the hands of those whose companies make heart valves or pacemakers? THANK YOU!

3. You held my body together by
  - providing three meshes necessary to prevent strangulated hernias; and
  - providing all kinds of knives, sutures, clamps and other devices every time a doctor cut into me.

May I see the hands of those whose companies make meshes, or devices used in surgery? THANK YOU!

4. I had a very much unwanted gallstone. You produced
- a device inserted through my mouth, and consisting of a long flexible tube with a light on the end of it, a camera and a little knife to cut open the spot where they found the stone. It is called something like an endoscopic retrograde cholangio pancreatogram. That sounds impossible, but the next night I went out to a dinner, had a drink and gave a speech. That's quite a contribution to my quality of life.

May I see the hands of those whose companies make ERCPs? THANK YOU!

5. You made me prettier by
- providing a device to straighten my nose broken in a college basketball game. Think what the quality of life would have been with a broken nose shaped like a "greater than" symbol.

May I see the hands of those whose companies make orthopedic devices? THANK YOU!

So I'm a live witness confirming the deeply appreciated fact that the medical device industry improves the quality of life. I almost certainly wouldn't be alive, and would have been totally blind, but for your devices. Instead, I'm still

- a practicing food, drug and device lawyer, still talking to FDA's headquarters, centers and field offices regularly;
- serving on a couple of Harvard committees;
- serving as the Illinois Governor of the Society of Colonial Wars;
- going to church every Sunday – at least on television;
- adding to my stamp collection on an almost daily basis;
- participating in food, drug and device meetings like this and the annual conference of the Association of Food and Drug Officials. Incidentally, this will be the 17<sup>th</sup> consecutive year I've spoken at the AFDO annual conference on the history of the Association. Sounds dull, but it certainly isn't. FDA has the verbatim transcript of everything that was said at the annual meetings going back to 1902, and we re-enact those meetings. This year at the annual meeting in Albany, we're reenacting the 1906 meeting, since that was the year in which the first serious federal food and drugs act was passed. I'm really more of a casting director than speaker so if you're going to be in Albany, please let me know and you can expand on your budding career as an actor or actress!

Thanks again for making all of that possible!