11TH ANNUAL MEETING OF THE SAS

2011

THE INTERNATIONAL SOCIETY FOR THE ADVANCEMENT OF SPINE SURGERY
Hello. Thank you the for invitation.

I’m a spine patient … and a very angry one.

I’m here today as an advocate for millions of US patients like me who are needlessly suffering, … deteriorating, … and sometimes dying … while they wait for FDA approval on the medical devices they desperately need … devices that are often ALREADY in successful use in other nations.
I became LIVID when I figured out that my government and my insurer were the only barriers between me and the best solution for my spine problem. Worse … I’m just one of thousands in this country.

Because of my experience, I’ve vowed to instigate changes in FDA practices, and in insurance regulations, to guarantee all US citizens equal access to – and reimbursement for – the most current, successful medical technology which the doctor and patient agree is appropriate.

Let me tell you a bit about my story … and then I’ll share the changes I’m working toward to resolve these problems. Maybe you can help me and your patients – because it shouldn’t be this way!
Was concurrently dealing with ... 

- (2005-07) 5th metatarsal fracture, non-union
- (2006) Cervical spondylotic myelopathy with stenosis
  - C4-5 and C5-6; C6-7 “iffy”
- (2008) Chronic migraine
- (2009) Hypothyroidism

I became LIVID when I figured out that my government and my insurer were the only barriers between me and the best solution for my spine problem. Worse ... I’m just one of thousands in this country.

Because of my experience, I’ve vowed to instigate changes in FDA practices, and in insurance regulations, to guarantee all US citizens equal access to – and reimbursement for – the most current, successful medical technology which the doctor and patient agree is appropriate.

Let me tell you a bit about my story ... and then I’ll share the changes I’m working toward to resolve these problems. Maybe you can help me and your patients – because it shouldn’t be this way!
Treatment choices …

• Do nothing; wait for quadriplegia
• Have fusions and chronic pain
• Wait for artificial cervical disc FDA approval

In my case, my choices were to:
1. Do nothing and wait for quadriplegia
2. Have fusions – which I later learned meant I’d likely still have chronic pain, and could expect to have serial fusions in the future
3. Wait a couple of months for an artificial cervical disc in the FDA approval pipeline

   I did my research and chose ADR because I wanted to retain neck motion, … to avoid future serial fusions, … to avoid any cage or strap hardware which usually cause chronic pain, … to avoid a cervical collar which would aggravate my TOS symptoms, … and to have a 2-4 week recovery instead of 4-6 months.

   Dr. Chou was willing to support my waiting until the FDA approved the ProDisc-C – with lots of restrictions on me, of course. How long could it take? There were over 17 ADR options in regular use almost everywhere in Europe – including this one!
It shouldn’t be this way!

Instead of a couple of months, the FDA took another 12 months to approve it. What was bizarre was that they restricted the ProDisc-C to just one level and from kyphotic patients – which I’d become. WHY? In other countries, this device has had years of success in thousands of patients in multi-levels, and is NOT restricted from kyphotic patients. … WHY does the FDA impose such restrictions when the manufacturers have data to refute them?

Still, I spent months fighting my insurance company and state department of insurance for reimbursement. Even though it’s FDA approved, most insurers – including mine – will call newly-approved devices “investigational.” HEY! The investigating is done and it’s approved; it no longer “investigational”!

When appeal … after appeal … after appeal … after appeal failed, I gave up – which is what Blue Shield was counting on. I switched my disc choice to the M6-C and desperately searched for US trials – but they were closed and the few that were open were limited to one level … and I needed 2, possibly 3 levels.

By then I'd degenerated to the point that Dr. Chou and I feared I was in serious danger: all of my limbs were numb, … my continence was a huge issue, … my balance and grip unreliable, … I was almost a prisoner in my home for fear of paralyzing accidents, … and I depended on others for everything but my most basic needs … I refused Dr. Chou's requests to reconsider fusion but I knew I couldn’t continue to safely live this way.
I couldn’t believe that the M6-C discs were made 40 miles from my house and I couldn’t get them here. My only option to get the best devices for me was to find a trusted foreign surgeon with expertise implanting the devices I’d chosen.

It took research and months of fund raising. We drained what savings we had, … accepted $5,000 in gifts from friends and family, … stripped my life insurance policy of cash value, … incurred credit card debt, … and my then-76-year old husband returned to work.

But I did have my two-level ADR surgery in October 2009 with Nick Boeree at The Spine Clinic in England. My pain relief was immediate and my discs are functioning flawlessly. Dr. Chou is thrilled with the results, too, and does my follow-up.

I’d like to note that my surgery cost less than half of what a like-surgery typically costs in the US … and I was in a private hospital. I venture to say that much of the huge cost difference can be tracked back to FDA process delay expenses.
OK, so I managed to get the best solution for me. But it shouldn’t have taken all of my limited energy and money to get it if our FDA approval process and our health insurer requirements worked right.

And what about the other Marti Conger’s in this country? There are 200,000 or more fusions done on US patients every year ... people who are waiting for access to medical devices that already have CE-marking and years of track record. I know, because I receive calls and emails every week from spine patients – from auto mechanics to heart surgeons – who want to know how I managed to get mine done and how they might get the treatment they need – somehow, somewhere.

And what about all of the other devices common in Europe but bogged in the FDA process – CoreValve heart valves, PFO devices for migraine patients, and the list goes on. Products ... usually invented here ... aren’t available to US patients for years after patients around the world have already had them.

It shouldn’t be that way!
Patients’ call for immediately action

- FDA focus on patients; go for “reasonable assurance”
- FDA improve approval process, including PMAs
- FDA accept trusted nations’ regulatory findings, immediately approve successful products for marketing, and then monitor them.
- Congress require health insurers to cover FDA-approved devices which the doctor and patient agree is the most appropriate.

I do appreciate the challenges the agency faces – from all directions. I appreciate their need to protect patients. However, our FDA MUST reset their priorities back to patients’ needs and away from political “risk aversion.”

Patients are looking for “reasonable assurance” NOT “absolute assurance” – “absolute” is impossible. Verify that the product is safe and will function as designed, then let the patient and doctor make the decision.

The FDA must accept the regulatory findings of other trusted countries and unions (i.e., from Europe, Australia, Japan, and others), and immediately approve – or, at a minimum, “fast-track” – products with strong track records. Then monitor them like they do FDA-approved products.

Requiring known products to restart the approval process is a waste of time and resources – and often patients’ lives. Data from products approved outside of the US are a tool and support for the FDA’s need for data to avoid risk.

The last step is legislation … legislation requiring all health insurers – public, private, federal – to pay for FDA-approved procedures and devices which the doctor and patient agree are appropriate.

The sooner we do these things, the sooner US patients will have access to the devices they need at a reasonable price – instead of waiting 2 to 10 years for devices invented here and abroad.
How you can help …

• Stay current on “new” or “foreign” technology
• Tell patients about ALL options – including foreign
• Help us spread the word
• Help us put pressure on federal and state governments

I realize that skepticism about new technologies is real. You’ve heard lots of FDA fodder such as:
• “We aren’t going to use our people for guinea pigs.” What? We don’t.
• “Non-US results aren’t appropriate for the US market.” WHY? Europe and North America are both ethnic melting pots.
• “Only the US can test products sufficiently to be sure they’re right.” BUNK This arrogance of “not invented here = not good enough” is causing US patients to wait 2 to 10 years longer for products
• Oh, and my favorite: “The CE-marking process is “easier” [and therefore, not reliable].” WRONG. It only LOOKS easier because the CE process is reliable, consistent, transparent, and reasonable – opposite of the FDA process – and usually takes less time and money … resulting lower product costs.

Please help me spread the word and put pressure on federal and state governments.
There’s so much more I want to share, but my time is up. Thank you for your focus.

The Q/A time is next.

I’ll also be briefly available after the session.

Marti Conger, M.Ed
Patient Advocate

- Cell: 707.315.3914
- Marti@CongerResources.com
- FaceBook: Patients for Medical Device Innovations