

Written statement of:

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US House of Representatives**

Hearing titled:

**“Regulatory Reform Series #5 - FDA Medical
Device Regulation: Impact on American Patients,
Innovation, and Jobs.”**

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FDA Medical Device Regulation: Impact on American Patients, Innovation, and Jobs

It shouldn't be this way!

Thank you, Mr. Chairman and members of the Committee – my fellow citizens – for your invitation to testify about how the FDA approval process impacts patients and, therefore, medical device innovation and jobs.

My name is Marti Conger. I'm a spine patient, and a very angry one. Because of my experience, I've vowed to instigate changes in FDA practices to guarantee all US citizens equal access to the most current, successful medical technology which the doctor and patient agree is appropriate.

I became livid when I figured out that my government was the main barrier between me and the best solution for my spine problem. Worse, I'm just one of too many in this country with the same barrier.

I believe it's my civic duty to make things better for my fellow citizens who are also awaiting successful devices that are essential to their health and/or life sustainability. Specifically, I'm asking Congress to

require the FDA to accept the regulatory findings of products with strong track records from other trusted countries and unions (i.e., from Europe, Australia, Japan, and others), and put them into the marketplace or, at a minimum, "fast track" them. Then monitor the devices as they currently do in the marketplace.

I came to testify as an advocate for the millions of US patients like me who are needlessly suffering, deteriorating, *and sometimes dying* while they wait for the FDA to approve the medical devices they desperately need; particularly Class III devices that are often already in successful use in other nations.

Let me tell you a bit about my story. Then I'll share the changes I'm working toward to resolving the problems US patients face relative to medical device access. I ask you to help me, because it shouldn't be this way!

A bit of my story

My thoracic outlet syndrome ("TOS") specialist identified a cervical spine issue in 2006, and quickly sent me to the UCSF Spine Clinic, to a neurosurgeon who'd been a participating physician in artificial cervical disc clinical trials.

I've been dealing with multiple, life-altering health issues and, since I can't take opiates or narcotics (or their substitutes), I was already physically and mentally drained from chronic pain and raging paresthesia.

My neurosurgeon's diagnosis had me reeling, but he immediately started educating me. After we reviewed my films in detail, we discussed my options and their benefits and consequences. In my case, my choices were to:

1. Do nothing and wait for quadriplegia in the next couple of years
2. Have fusions – which I later learned meant I'd likely still have chronic pain, and possibly have serial fusions in the future
3. Wait a couple of months for an artificial cervical disc in end of the FDA approval pipeline – one successfully used in multiple cervical spine levels in Europe since 2003

I did my research and chose artificial disc replacement (“ADR”) over fusion because I wanted to:

- retain neck motion,
- avoid future serial fusions,
- avoid any cage or strap hardware which usually cause chronic pain, and
- have a two–four week recovery instead of the typical four–six months for fusions.

My neurosurgeon was willing to support my waiting until the FDA approved the artificial disc – with lots of restrictions on me, of course. Naively I thought, “How long could it take? There are already so many good ADR device options in regular use in Europe – including this one!”

Instead of a couple of months, the FDA took another 12 months to finish approving it. More bizarre was that they restricted the device to just one level and from kyphotic patients – which I'd become. Why? In other countries, this device has had years of success in multiple levels in thousands of patients, and is not restricted from kyphotic patients. Why does the FDA impose such restrictions when the manufacturers have data to refute them?

While I waited for device approval, my spine degenerated to the point that my neurosurgeon 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 nearly a prisoner in my home for fear of paralyzing accidents. I depended on others for everything but my most basic needs. I admit I refused my doctor's requests to reconsider fusion but I also knew I couldn't continue to safely live without treatment.

After much research, I changed my artificial disc choice to a newer technology that emulates the human disc and which had been available and successful outside the US since 2005. Since the device had been in the FDA process since 2006, I desperately searched for Spinal Kinetics' M6-C trials in the US, but the few that were open were limited to one level. I needed two, possibly three levels, which is approved and successful outside the US.

Nor could I believe that the newer cervical disc technology, which my doctor and I felt was best for my problems, were made forty (40) miles from my house and I couldn't get them here!!! Yet, they were widely available in Asia, Europe, and elsewhere. The only option to get the best devices for me was to go abroad.

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-75-year old husband had to return to work full time (and still does due to my health).

At last, I had my two-level ADR surgery in October 2009 with Nick Boeree at The Spine Clinic in southern England. My pain relief was immediate and my discs are functioning flawlessly. I had surgery on Wednesday, toured Winchester Cathedral on Sunday, and flew home a couple of days later. My US neurosurgeon is thrilled with the results, too, and does my follow-up.

I'd like to note that my surgery, done in a private hospital, cost less than half of what a like-surgery would typically cost in the US. Based on studies presented in previous hearings by Congressional Committees on this subject, I venture to say that much of the huge cost difference can be tracked directly to approval process delay expenses incurred by the manufacturer.

While I was blessed to get the best solution for me, I still say there is absolutely no reasonable justification for having to wait years and raise tens of thousands of dollars to get access to a successful, US-developed technology if our FDA approval process and our health insurer regulations worked for patients.

It shouldn't be that way!

And what about the other Marti Conger's in this country? For example, there are more than 200,000 spine fusions done on US patients every year when there are far better solutions available everywhere except the US. People 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 other spine patients – from auto mechanics to

engineers to heart surgeons – who want to know how they might get the treatment they need ... somewhere, somehow. It shouldn't be that way!

And what about all the other devices successful and widely used abroad but bogged in the FDA process – CoreValve heart valves, PFO devices for certain migraine patients, and the list goes on. Products, often 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!

The US was once the ultimate place to get superior medical treatment. Now, instead of being the first to benefit from our own medical technology advances, we're often the last and we're not benefiting from the delays.

In sum:

- Patients with means are flocking to Europe for devices – frequently invented in the US – that are approved abroad or approved with unnecessary restrictions.
- Patients who can't scrape enough together to travel to get to more effective devices denied them by the FDA either: 1) succumb to archaic methods in-country, 2) do nothing, 3) degenerate beyond treatability, or 4) die waiting to get the right treatment.
- US inventors are more and more often choosing to forego the US market because of the onerous and often adversarial FDA approval process that costs millions more than the equally safe EU process.
- Fewer and fewer non-US inventors are willing to run the FDA gauntlet to gain product approval, further diminishing US access to new medical technologies. Those that do are simultaneously moving forward in Asia and Europe with their 4th and 5th generation of the same device which will likely never see the light of day in the US.

It shouldn't be that way!

Unfortunately, I'm one of many with the personal experience to prove it. The devices I traveled to England to receive have been available in Europe since 2005 with a strong track record, and are still years away from the marketplace in the US. It makes no sense that the FDA doesn't recognize data from other, trusted nations with robust regulatory systems.

Remember, there are people waiting for these devices! People who are dying, or failing beyond recovery, or not being able to live a normal life, draining all of their finances to get care until they receive the proper treatment.

With each inappropriate process decision or delay, there are real people who need solutions now; people like me, Rob, Christine, Patrick, Wayne, Linda, Victoria, Alexander ... It just shouldn't be that way!

FDA and skepticism

First we must recognize that the FDA's CDRH has been making a herculean effort to keep pace with an industry that's innovating exponentially – both technologically and scientifically. This requires huge changes in infrastructure, type of intellectual property, culture, and the will to make those changes at the speed required. While change isn't easy for any organization, change is necessary for the FDA and CDRH to give US patients more timely access to safe and effective new therapies. These changes are vital for the sake of US patients' health.

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

I also acknowledge that the skepticism about new technologies is real. We've all heard enough FDA “fear fodder.” For example:

- “We aren't going to use our people for guinea pigs.”

Be serious. No one – here or abroad – is serving as guinea pigs!

- “Non-US results aren't appropriate for the US market.”

Why? Both Europe and North America are ethnic melting pots.

- “Only the US can test products sufficiently to be sure they're right.”

The arrogance of “not invented here = not good enough” is causing US patients to wait much longer for successful products.

- “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 and usually takes less time and money, which results in equally effective products and lower product costs.

What must change now

It's time for the agency and insurers to remove themselves from patient/doctor decisions. The ultimate decision about healthcare should be between a patient and their physician. We, the public, need the FDA to determine reasonable assurance of safety and efficacy. As a patient I don't expect, nor is it desirable for, the FDA to seek "absolute" assurance; it isn't feasible because every body is unique. The valuable time used to find the ever illusive "absolute" assurance often means that patients are denied product access or, when the product is finally approved, the cost is so high and/or insurers refuse to cover them that they're not accessible. Please, verify that the product will function as designed (which includes safety); then let the patient and doctor make the decision.

The FDA needs to accept the regulatory findings of products with strong track records from other trusted countries and unions (i.e., from Europe, Australia, Japan, and others), and put them into the marketplace or, at a minimum, "fast track" them. Then monitor them as they currently do in the marketplace.

If just "fast tracking," accept all of a manufacturer's scientific evidence collected from device pre-approval testing, trials, and actual market experience without bias or discrimination regardless which trusted nation in which the evidence was collected. For products with existing foreign approvals that required human trials, additional US human trials should be a last resort after all other evidence has been reviewed.

Nor should the agency place medically unfounded restrictions on devices – particularly when the manufacturer has evidence to refute the proposed restriction(s). For example, don't limit an artificial cervical disc to one level when the product is shown successful in multiple levels in the same patient.

The impact of "not-invented-here"

Eliminating the "not-invented-here" bias at the FDA applies most to scientific evidence; doing so is critical to making significant progress in getting successful products to the US market faster. What is important is the quality of the data – not where the data was collected.

Requiring known devices to restart the approval process is a waste of time and resources – and often costs patients' lives while they wait. The data from successful products approved outside of the US is a tool and support for the FDA's need for data to avoid risk.

By the time a US or EU manufacturer decides to bring their CE-marked product to the FDA, they already have more pre- and post-approval evidence about their product for the FDA to make a decision than they'd ever get from more trials in the US.

A “poster child” for the data acceptance and use restriction issues is the artificial cervical disc. Currently there are approximately fifteen (15) CE-marked artificial discs in successful use in Europe – including discs from ten (10) US manufacturers. (I don't have data for Asia or on the Americas, other than the US.)

Of those eight (8) US-invented discs, only three (3) are available in the US. Further, in the US, each of those three (3) has the restriction that only one disc may be implanted in any one patient – a decision successfully left to the product designer and patient expert, manufacturer and doctor, in the EU. This is critical as most spine patients need more than one disc.

Disc	CE date	# Levels	FDA	# Levels
Bryan	2000	C3 – C7; per dr. & manf.	2009	1 per FDA
ProDisc-C	2003	C3 – C7; per dr. & manf.	2007	1 per FDA
Prestige ST	2005	C3 – C7; per dr. & manf.	2007	1 per FDA
Cervicore	2008	C3 – C7; per dr. & manf.	In trials in 2008 @ 1 level	TBD
Kineflex	Pre-2005	C3 – C7; per dr. & manf.	In trials since 2005 @ 1 level	TBD
M6-C	2005	C3 – C7; per dr. & manf.	In trials since 2006 @ 1 level	TBD
Mobi-C	2006	C3 – C7; per dr. & manf.	In trials since 2006 @ 1 level	TBD
PCM	2003	C3 – C7; per dr. & manf.	Trials done 02/2010 @ 1 level	TBD
Prestige LP	2004	C3 – C7; per dr. & manf.	Unknown status	TBD
Secure-C	2003	C3 – C7; per dr. & manf.	In trials since 2006 @ 1 level	TBD

(Note: Data is based on research by the author.)

Despite having had to conduct the same types of trials and evidence gathering to earn the European CE-marking, each disc manufacturer has had to start from scratch when they decided to enter the US market. (See the chart above.) Are European bodies so different than US bodies that patient trials (the crux of approval processes) must be repeated?

Again, manufactures with a CE-mark are actually more prepared for FDA approval than those without. They bring with them both pre-approval evidence and post-approval data. For example, artificial cervical disc replacement surgery is conducted in the EU as commonly as fusion is conducted in the US; due to its long-term consequences, fusion is considered the procedure of last resort outside the US.

Going through more trials and more pivotal studies just because the data wasn't gathered in the US or isn't in the perfect format delays patient access for years and adds millions of dollars in manufacturer costs that will be

passed on to the patient, thus further affecting accessibility.

Regardless the current economic or political environment, the approval process needs to be more transparent and reliable to reduce cost and time to market, and to remove delays that are costing patients a fortune in quality of life, medications, medical expenses, and economic productivity. The US model isn't functioning as efficiently and effectively as other approval process models abroad. There must be change that serves patients.

A call to action

There are hundreds of thousands of US citizens waiting for access to thousands of medical devices that already have proven their mettle in trusted nations. Most of our fellow citizens don't have the resources or physical capability to get to devices that should be in common use in the US as they are already in other countries. I am asking you to help me to:

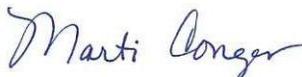
require the FDA to accept the regulatory findings of products with strong track records from other trusted countries and unions (i.e., from Europe, Australia, Japan, and others), and put them into the marketplace or, at a minimum, "fast track" them. Then monitor them as they currently do in the marketplace.

The FDA CDRH approval processes are driving US inventors out and foreign inventors away from the US market. US patients go without or go overseas for medical technologies invented here.

The sooner we enact change, the sooner US patients will have access to the devices they need at a reasonable price – instead of waiting two (2) to ten (10) years for devices invented here and abroad.

Your fellow citizens desperately need your help. Many patients don't have time to wait.

Respectfully submitted,



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