MD+DI Editor Says Consumer Reports Article on Dangerous Devices is Dangerous Reporting

The Associated Press

These days it might feel as if defending the medical device industry and the 510(k) system is a losing battle. Consumer Reports released its scathing analysis of the medical device regulatory state last week. And it is sure to get consumers' attention.

(Photo: http://photos.prnewswire.com/prnh/20120404/LA82440) But while the device industry is in the spotlight, now is a good time to remind people that the device industry has long understood that the regulatory framework-particularly 510(k) or substantial equivalence-is broken. In fact, the medical device industry has been leading the charge to fix the process.

It is unfortunate that in its quest to make the medical device system understandable to a layperson, Consumer Reports misrepresented some key details in the regulatory process, thereby causing additional confusion and creating a dangerous precedent in media coverage of the medical device industry.

Lies and Statistics The Consumers Union is not correct in its representation of the industry, claiming, "most medical implants have never been tested for safety." This is blatantly untrue. The truth is that devices are tested extensively for safety and effectiveness.

"The [Consumers Union] is completely discounting any testing other than clinical trials," says Floyd Larson, president of PaxMed. "You wouldn't believe the amount of testing that is done on devices," he says. Larson explains that much of the effort that goes into developing testing for medical devices is done on a pro-bono basis.

"Clinicians, regulators, and industry members make a significant effort to develop tests that are as close to clinical trials as possible." The report also mischaracterizes the process of the 510(k), saying that "For most implants and other high-risk devices brought to market, manufacturers do nothing more than file some paperwork and pay the Food and Drug Administration a user fee of roughly $4,000 to start selling a product that can rack up many millions of dollars in revenue." In this statement, the Consumers Union is guilty of oversimplification and overgeneralization. "I'd estimate that 99% of all high-risk devices have randomized clinical trials, and are done with good science under the auspices of FDA," says John DeLucia, vice president, regulatory affairs and quality assurance for iCAD.

A 2010 report led by Stanford University researcher Josh Makower, and sponsored by the Medical Device Manufacturers Association (MDMA) estimated that putting a medical device through the 510(k) process could cost a manufacturer up to $24 million. That figure factors in bench and functional testing, human factors,

environmental engineering, biocompatibility testing, sterilization validations, documentation systems, equipment and product validations, as well as many other basic safety and efficacy tests-all of which are required by FDA to prove good manufacturing practices (GMPs).

It is telling that the people interviewed by the Consumers Union have been notably critical of the medical device industry, and that the report did not include any experts from FDA or from the industry.

Larry Pilot, an attorney and former FDA official with more than 30 years in the industry, explains that such reporting is dangerous.

"When Consumer Reports publishes this type article presenting a very negative image of the device industry, large numbers of readers will be influenced and then will influence others. Those who have been identified as 'experts' in the article have been persistent critics of the industry and not credible to those who do have a balanced understanding of fact and law." I posit that the Consumer Reports article has let its subscribers and the media covering the story down by not providing objectivity to its analysis. But instead of worrying about how Consumer Reports has misrepresented the medical device industry (doing so is surely a losing proposition, anyway). I thought it might be more useful to tackle the report's recommendations for change, and present some better alternatives.

CR Recommendation 1: Require that implants and other "life-sustaining" devices be tested at least as rigorously as drugs.

To demand pharma-like testing shows a distinct misunderstanding of the nature of devices. John Brennan of Eucomed explains the difficulty of testing devices like drugs. "When it comes to requiring the same type of clinical data for devices as for drugs, it is worth highlighting that for pharmaceuticals randomized control trials are relatively straight-forward to perform, and efficacy and relative safety can be statistically demonstrated in support of obtaining a marketing authorization provided that the clinical trials are sufficiently powered (depends on the number of patients)," he says.

For medical devices, Brennan explains, randomized clinical trials are difficult to perform: "you can't implant a placebo hip," he says.

Further, "clinical trials cannot be blind or randomized due to strong ethical and practical issues," he says. A device's effect depends on too many other factors: clinician training and experience, patient selection, and care delivery settings, which can vary by region, hospital, and country. "We therefore believe that 'real world' data from observational studies performed under routine conditions are equally important (structured postmarket surveillance)." CR Recommendation 2: End the practice of "grandfathering" high-risk new implants and life-sustaining devices.

This is another misnomer. By "grandfathering," Consumer Reports is referring to substantial equivalence. But substantial equivalence is not exactly the same as

grandfathering. The term "grandfathering" only applies if no improvements or changes are made. But such a state is in direct opposition to the intention and practice of the law. "The prospective intent of the Medical Device Amendments of 1976 anticipated that devices would be modified and improved. FDA/CDRH are responsible for determining when the nature of the modifications or intended use and compliance with the regulatory controls is not sufficient to provide reasonable assurance of safety and effectives," says Larry Pilot.

Therefore industry and FDA have already responded to Consumer Reports demand that FDA "end the practice of grandfathering." Any devices "grandfathered" more than 30 years ago have certainly been subject to significant improvements if the underlying technology had any healthcare benefit-and they have undergone rigorous testing to prove safety and efficacy.

CR Recommendation 3: Create a "unique identifier system," or IDs for implants, so that patients can be quickly notified about recalls and safety problems.

As Karen Conway, at GHX can tell you, such a system is already in the works and will be in practice likely within the next 2 years. FDA has indicated that it will issue its proposed rule for a unique device identification (UDI) system for medical devices. "It's with the Office of Budget and Management right now," says Conway. She also points to Senate bill, S.2193. Senator Chuck Grassley (R-IW) introduced the bill this month to require that the Office of Management and Budget finalize a UDI rule by the end of 2012. "The sooner this system is in place, the better for patients who have received medical devices," Grassley said in a Q&A on his home page.

Conway explains that once the OMB finalizes the plan, it will be about 18 months before the rule can take effect. She also explains that the plan would roll out so that the most risk-averse devices would see adoption first. "Class III, which is mostly implants, would be first, followed by Class II and Class I products." CR Recommendation 4: Create national registries so that problems can be spotted quickly and patients notified.

In the Consumer Reports article, Diana Zuckerman compares medical devices to a coffeemaker or toaster oven, saying these appliances have serial numbers "so if a problem is found, the company can contact you to warn you. Your artificial hip or heart valve doesn't." Wrong. All implants have serial numbers. "We know exactly what patient had what implant. Traceability is the first order of business," says DeLucia.

Conway also points out that a national registry might be unnecessary if the UDI system is harmonized. A UDI system that is owned and maintained by FDA is key, she says. But far better than a national registry is a device identification system that is global. FDA has worked to harmonize UDI in Europe, North America, Asia using the Global Harmonization Task Force (GHTF) and the Asian Harmonization Working Party (AHWP). "Such a system would make it easier for global manufacturers to comply," she says. Further, "if you can assign global UDIs that would work for registries around the world, however they define themselves (Swedish, Swiss, Kaiser Permanente, or Joint Replacement, for example),

theoretically you could just take that information from different registries and compare them," Conway says.

That is, the need for a national registry would be a moot point.

CR Recommendation 5: Increase the user fees paid by manufacturers for regulatory review so that the FDA has enough money to do its job.

More user fees won't necessarily fix the regulatory system. Like most problems, you can't just throw money at it and expect the problem to go away. For Consumer Reports to say user fees would fix a problem again indicates an extreme misunderstanding of the processes involved.

"User fees are not going to improve a process," says John DeLucia.

From his perspective, "the only benefit of increasing money is that it might help products get to market faster, but [user fees] wouldn't necessarily make [devices] any safer." Floyd Larson explains trends his company has observed: "We have had recent experiences that show us that, as FDA has more money and hires new reviewers, often the quality of the reviews goes down dramatically," says Larson. New reviewers with lots of scientific knowledge ask many questions that are 'nice-to-know' scientifically, but might not be relevant to the clearance decision." Larson says he isn't trying to tell reviewers that don't know they're business. But, "it takes time to understand what medical device safety and effectiveness is about-user fees can't fix that." Roll Back the Rhetoric Are there improvements to be made to medical device regulatory systems? Absolutely, which is why FDA, industry, and a host of experts have been working to do so for the better part of a decade. Nora Iluri, founder of Clarimed says, "When quality is an issue, you shouldn't focus on increasing the hurdles for innovation. You should encourage innovation by making it easier to understand what the quality issues are and promote the development of new solutions to solve them. This can be achieved through improved transparency and processes to better understand what is working and what is not-both pre- and postmarket." As DeLucia says, criticizing FDA and the medical device industry is an old story. "This is an easy target and the report looks at three examples that are fairly well understood by FDA," he says.

The bottom line is that we don't need more rhetorical excesses on public health policy. We do need clear, balanced arguments, solutions to problems, and language that isn't intended to cause panic.

About Heather Thompson Heather Thompson is Editor-in-Chief for MD+DI, and has more than 10 years in the publishing industry, covering FDA-regulated technologies.

She joined MD+DI in 2004. Thompson holds a BA in English from University of California, Irvine. Her areas of research include emerging medical technologies, regulatory analysis, and policy.

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