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'Implant Files': New Device-Failure Database Benefits Companies And Savvy Consumers, But May Befuddle Others, Experts Say

by Shawn M. Schmitt

The International Medical Devices Database from the International Consortium of Investigative Journalists – an output of ICIJ's recent string of "Implant Files" stories that were critical of industry – offers information on more than 700,000 device recalls, field safety notices and safety alerts documented in 11 countries. While device-makers and shrewd consumers will discover a bevy of useful data in the public repository, it could prove confusing for laypeople. A recalls expert and an ex-FDA official weigh in.

Device-makers and industry-savvy consumers will discover a bevy of useful information in a new international database of product recalls and safety notices, but the public repository could prove confusing for laypeople, experts say.

The *International Medical Devices Database* (IMDD) from the International Consortium of Investigative Journalists is an output of ICIJ's recent string of "*Implant Files*" stories that were critical of industry.

In its Implant Files series, ICIJ makes the case that patient safety is being compromised in countries throughout the world, with insufficient tracking of adverse events and recalls, and companies putting profits before safety. More than 250 journalists worked on the yearlong investigation. (Also see "*The Implant Files: EU Blamed For Regulatory Inadequacies The World Over While 'Wrath'-Behrendt Fumes*" - Medtech Insight, 26 Nov, 2018.)

The IMDD includes information on device recalls, field safety notices and safety alerts documented in 11 countries: the US, Canada, Mexico, Switzerland, Spain, Australia, Finland,

Lebanon, the Netherlands, India and Peru. ICIJ will add data from more countries as it becomes available.

There are more than 700,000 events stored in the database, says ICIJ, which collected the data from public sources and FOIA requests. FOIA is the United States' Freedom of Information Act.

> *"To be able to look at data on competitors is a huge plus, because right now, extracting that type of information … is extremely challenging," consultant Ricki Chase says.*

ICIJ said it made the repository "in the public interest to provide vital safety alerts and potential recourse to patients who, in most parts of the world, have been shut out from such information until now" – but that doesn't mean device manufacturers can't use data in the IMDD to their advantage. Ricki Chase, a compliance practice director for Lachman Consultant Services and a former US FDA investigations branch director, told *Medtech Insight* that the database could give firms a leg up in both the pre- and post-market arenas.

"I think, from a manufacturer's point of view, it is a good data repository for them for a few reasons," said Chase, who joined Lachman in 2016 after spending 16 years at FDA, where she was also an investigator, medical device specialist and supervisory investigator.

"For one, firms can make sure that information they have on which they're basing things like 510(k)s, for instance, is valid. Because when you're going to do a 510(k), you want to understand what your predicate device is going to be, and you want to understand what problems there might be with that predicate device," she said.

"And from a post-market point of view, it would be expected that manufacturers would be keeping their finger on the pulse of their competitors that have those predicate devices, or same or similar devices coming onto the market," Chase added.

"So, collectively, if you make infusion pumps, then you really need to have your finger on the pulse of what's going on in the infusion pump market and what some of those issues are."

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"From a marketing standpoint, the database gives you some intel into what's happening with competitors. That's very valuable," consultant Chris Harvey says.

Chris Harvey, director of recall solutions with consulting firm Stericycle, agreed with Chase's assessment.

"If a manufacturer is developing a new product or has a similar product in the market already, they'll want to know what some of the issues are that are occurring with those devices, and the recalls that have occurred," he said in an interview.

The database "does give firms a mechanism to be able to proactively look at, say, what are the other catheter recalls, and what the reasons were for those recalls," Harvey said. "It doesn't necessarily give you the full root cause analysis, but it does give you a bit of background on the issues that are occurring."

A Broader View Of Data

While companies can use publicly available recall and adverse-event data from FDA to help them make decisions about the products they make, information in the IMDD gives manufacturers a more global view of what's going on with a particular device.

"For quality and regulatory folks, a lot of times they're just looking at recalls published in the FDA Enforcement Report, looking for trends, looking for what's happening with products that are similar to what they make," Harvey said.

"But what this new database does is provide added historical visibility, not only for the US, but for some of the other regions around the globe on what's happening. And they can use that to make their product safer," he said.

IMDD: First Impressions

Ricki Chase: "Manufacturers will be able to work within the system and understand what they're looking at. They understand the interrelationships between, say, somebody who, quote, 'owns' a product, and somebody who might be having somebody else manufacturer it for them – that type of thing, and all the different nuances that go along with product ownership. So, I think they'll be able to ferret that out. And the database appears to be very comprehensive. Obviously, I have no way to validate the data, but it appears to be very comprehensive, which is good.

Consultant Chase – who gave tips on mining FDA compliance and enforcement data in a recent *Compliance 360°* podcast from *Medtech Insight* – says "the problem with FDA's data is that it's limited to the FDA. So, the most obvious plus to manufacturers is that [the IMDD] draws in post-market information from other countries of interest." (Also see "*Podcast: Compliance 360° Part 14 – Leverage FDA Data To Stay In The Agency's Good Graces*" - Medtech Insight, 27 Nov, 2018.)

She pointed out that some device firms "try to draw a line in the sand" by telling FDA that OUS post-market data on same or similar products is irrelevant and doesn't warrant collection.

"But it's not irrelevant," Chase said. "FDA has said that manufacturers have a responsibility to understand what's going on in the market with same or similar devices, and that market isn't defined only as the United States." The new international database helps firms fulfill that agency expectation.

And device-makers can gain insight into competitors by using IMDD data – an advantage for companies that might not otherwise be able to find that type of information on their own.

"I found the database to be slightly annoying, though, in that it wouldn't let me sort my findings by date. I specifically looked for a recall I knew was old but ongoing, and it wouldn't let me sort those records by date. And a lot of times it takes three or four clicks to get to the data you're looking for. And you really have to pay attention to the dates. Is this something that happened in 1991 and the product is still not on the market? Or is it something else?"

Chris Harvey: "I found it very easy to access the data through a zip file. The data is very comprehensive. It's broken down into a few different spreadsheets. There's a need for the viewer to sort through the data quite a bit, but it does give visibility to historical recalls and the manufacturers. But the user would still have to really roll that data up.

"The data is very granular, so having some type of rollup or filter system would assist a layperson with being able to narrow down the data they're looking for. But someone who is a little more experienced with recalls, I definitely believe there's some value with this database. It's a good start. We [at Stericycle] are going to definitely review this data and see what opportunities there are for us to use it."

"To be able to look at data on competitors is a huge plus, because right now, extracting that type of information from the EMA [European Medicines Agency], or the UK's MHRA [Medicines and Healthcare products Regulatory Agency], or Health Canada – it is extremely challenging. So, having at least some of that data in one place is very nice," Chase said.

Again, consultant Harvey agreed. "From a marketing standpoint, the database gives you some intel into what's happening with competitors. That's very valuable."

He also singled out Europe as a region that is difficult to extract medical device post-market data from. Information from only three European countries – Switzerland, Spain and the Netherlands – is currently found in the IMDD, which is hardly representative of the EU as a whole.

"The thing is, within Europe there are different competent authorities and there are different nuances from country to country. So you're not getting the full picture by only getting data from a few countries within the EU," Harvey said. "That's definitely something that's a good call-out and important for a user of this database to understand: that there's still a number of recalls that are not included in [the IMDD]. It's just a snapshot of some regions."

Harvey, whose firm publishes a quarterly *recalls index* for a variety of commodities, hopes the new database will spur other countries and regions to add to it.

"We often find it difficult at Stericycle to get data from certain countries on what's being recalled, especially in the pharmaceutical and device industries," he said.

Database Puts Pressure On Industry

On the flip side, the new International Medical Devices Database puts added pressure on industry to ensure that manufactured products are of high quality.

That's because "consumers are becoming more and more savvy. They're understanding that there are ways for them to get information that they probably didn't know they had access to before," Chase said.

"Consumers are not stupid. If they're so interested in device failures that they're going to look at this data, then they're going to look at this data in a way that they can hopefully draw some conclusions," she said. "If they care enough to [use the IMDD], then they're doing it for a reason. Because your average person isn't thinking, 'Oh, I'm just really curious about post-market data on medical devices.'"

Because the database offers a greater visibility of device troubles, highly interested consumers familiar with industry will likely hold manufacturers' feet to the fire even more when they make products that malfunction.

"And if you couple that with FDA's initiatives to get patients more involved in medical devices and medical device development, and to use real-world data in making decisions about benefit-risk analysis of medical devices, this database gives more information that can be brought in and considered," Chase said.

Added Harvey: "The database gives visibility to what issues are occurring and why. For example,

in our latest recall index we noted that *software was the top recall cause* for the 10th quarter in a row. Someone looking at this database can probably start to identify that problems with software is a common issue occurring with device manufacturers.

"So, I can see where there could be a little more pressure on device manufacturers to understand what's causing those problems," he continued. "Are they rushing to market? Are they not investigating as much as they need to? This kind of data could bring some of that up to industry."

Useful For Many, Confusing For Some

The new database also gives patients the flexibility to research the safety history of any device that a physician might use on them.

"Let's say you're going to have your knee or hip replaced," Chase said. "I always tell people, don't agree to do that until you ask the physician – and be very specific – which device they intend to use, clear down to the manufacturer, make and model. And then go do your homework."

The IMDD "allows patients to have more of a voice and to do that type of homework, so they can come back to the doctor and say, 'You know, so-and-so company has had a lot of recalls and I'm a little concerned about that,'" she said.

> ***"The IMDD database does allow the consumer to have … a voice about potential concerns, and I think there's value in that," Chase says.***

"Unfortunately, many doctors – *many* doctors – are completely oblivious. And if you say, 'This company has had a lot of recalls,' the doctor will probably say, 'Oh, it's fine,' because some representative got that doctor to sell that company's artificial knee," Chase said. "But the IMDD database does allow the consumer to have that discussion and have a voice about potential concerns, and I think there's value in that."

But while she believes the IMDD can "benefit a savvy consumer," Chase said she's worried about the ability of laypeople to digest the data, which can be confusing for those outside industry.

In fact, ICIJ admits on an *FAQ page*: "This is not easy data to understand."

"You're going to see problems pop up when less-savvy consumers fish around for XYZ device,

and they look at the database information, and they don't know what it means," Chase said.

"There are a lot of nuances with this data, and if consumers don't really know what they're looking at, they can become easily confused," Chase said. "Either they'll draw completely wrong conclusions that make the picture look worse than it is, or they won't draw the proper conclusions, which would really tell them how bad things are.

"It's really good in a lot of ways, but I think the database has some room for improvement in the way people could look for and understand the data from more of a novice point of view."

For example, Chase suggested the addition of a so-called "alias" function to use when searching for a particular firm.

"I've seen some databases that use that alias function," she said. "What happens is, if somebody types in, say, 'Fresenius,' then a menu pops down and says, 'All of these companies are related to Fresenius.' That way the researcher can understand that these other companies are related to Fresenius in a corporate-wide relationship. That would tell a lot about the company as a whole, and not just about a particular product."

Chase said database users could get a better picture if the IMDD would link companies that are under a corporate umbrella and interrelate their data.

"Look, the database is good, but it's like any other new tool: as it grows, they'll get feedback, and it will get better and better," she said.

From the editors of The Gray Sheet