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# International Consortium of Investigative Journalists Releases Highly Critical–and Flawed–Investigation of Global Medical Device Industry

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On **November 25, 2018**, the International Consortium of Investigative Journalists ("ICIJ"), a group consisting of 252 journalists from 59 media organizations in 36 countries, released:

- "Implant Files," the results of its investigation purporting to demonstrate globally 1.7 million injuries and nearly 83,000 deaths allegedly linked to what it called "poorly tested implants," and
- The "International Medical Devices Database" ("IMDD"), a searchable portal allegedly collecting product safety data and notices from 11 countries and purportedly creating a way for a user to research the safety of their device even if described differently in other countries.[1]

The ICIJ rollout included a dedicated Twitter hashtag (#ImplantFiles) and summary page with videos,[2] a website, and multiple articles in leading national and international newspapers such as *The Wall Street Journal* and *The Guardian*. Manufacturers must be aware of the ICIJ's substantial efforts and highly critical reporting, which provides a litany of anecdotes, lumps together various international regulatory schemes, and, at least on its face, fails to engage in any independent medical analysis of the many "claims" it accepts at face value.

**Manufacturers must be aware that the ICIJ relies heavily on 5.4 million FDA "adverse event" reports ("AERs") and fails to identify the number of patients helped by the same devices it criticizes.**[3] As dozens of courts have properly held in excluding "expert" opinions based on them, AERs are inherently unreliable to demonstrate causation, much less that any given injury resulted from "poor testing." *See, e.g, In re Mirena Ius Levonorgestrel-Related Products Liability Litigation* (No. II), 2018 WL 5276431, at *10, *43 (S.D.N.Y. Oct. 24, 2018); *Hale v. Bayer Corp.,* 2017 WL 1425944 (S.D. Ill. April 21, 2017). *See also Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 44 (2011) ("[t]he fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event.").

FDA's own Adverse Event Reporting System ("FAERS") website currently states this plainly: "Existence of a report does not establish causation," "Rates of occurrence cannot

1 https://medicaldevices.icij.org/
2 https://twitter.com/i/moments/1066745865954570240
3 https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/

be established with reports," and "the FAERS data by themselves are not an indicator of the safety profile of the drug."[4]

FDA lists further limitations of adverse event reporting to include:

- "[T]here is no certainty that the reported event (adverse event or medication error) was due to the product."
- "FDA does not require that a causal relationship between a product and event be proven."
- "[R]eports do not always contain enough detail to properly evaluate an event."
- "There are also duplicate reports where the same report was submitted by a consumer and by the sponsor."

The ICIJ investigation did not result in any peer-reviewed piece of medical literature and its reporting does not purport to be one. ICIJ's reporting fails to acknowledge the many foundational limitations of AERs or why its reliance AERs (from the U.S. and elsewhere) calls into question its conclusions – an issue especially important given that its audience is the general population of media consumers who may not appreciate the difference between causation and association. The ICIJ also fails to identify the number or percentage of patients helped versus those who allegedly suffered a causally related adverse event with regard to any product – certainly a key data point if one is taking an honest look at a product's post-market safety profile.

Regardless of these known problems with ICIJ's reporting, **manufacturers should expect** that plaintiffs' lawyers will attempt to use the ICIJ's reporting and database with expert witnesses and in front of juries. **Manufacturers should be**:

- Fact-checking any product-specific claims, data, or reporting anecdotes, and ensuring that experts are made aware of any issues;
- Devising a litigation strategy related to ICIJ's reporting and database information;
- Ensuring that the public is made aware of relevant flaws in ICIJ's reporting and/or conclusions; and
- Ensuring that the ICIJ's reporting is dealt with appropriately during jury selection and in any instructions the judge may give to jurors.

The ICIJ investigation presents the potential for serious and unfair prejudice in a litigation setting. **Manufacturers must be prepared** to deal with all of the legal and factual issues arising from the ICIJ's reporting.

## Questions or Information

If you have any questions about this alert, please contact Adam M. Masin at amasin@goodwin.com.

4 https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm (Last visited: 11/26/18)

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