Advancing Health Equity in Medical Devices

DEVICE EVENTS™

MASTERING MEDICAL DEVICE DATA

Madris Kinard, MBA

Founder and CEO, Device Events

FDA's Unique Device Identification (UDI) External Program Manager (former)

FDA's Adverse Events Subject Matter Expert for Devices MAUDE (former)

Author, JAMA Internal Medicine invited commentary: Identification and Market Removal of Risky Medical Devices

Co-author, American Medical Association Journal of Ethics: Is the FDA Failing Women?

Member, MDIC Science of Patient Input, Post Market Working Group and Safety Communications Subgroup

Member, Patient Safety Action Network (PSAN) and Breast Implant Safety Alliance (BISA)

No disclosures: I have not been paid to attend or present today.

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Equity and inclusion for all people and populations is at the forefront of discussions for CDRH clinical trials, moving forward, to be sure that devices being cleared or approved by the FDA take sex, age, gender, ethnicity and geographic location into account.

It is also critical, moving forward, that we use the data we already have to learn from the past and present.

Transparency of clinical trials outcomes and adverse event data is paramount to our success.

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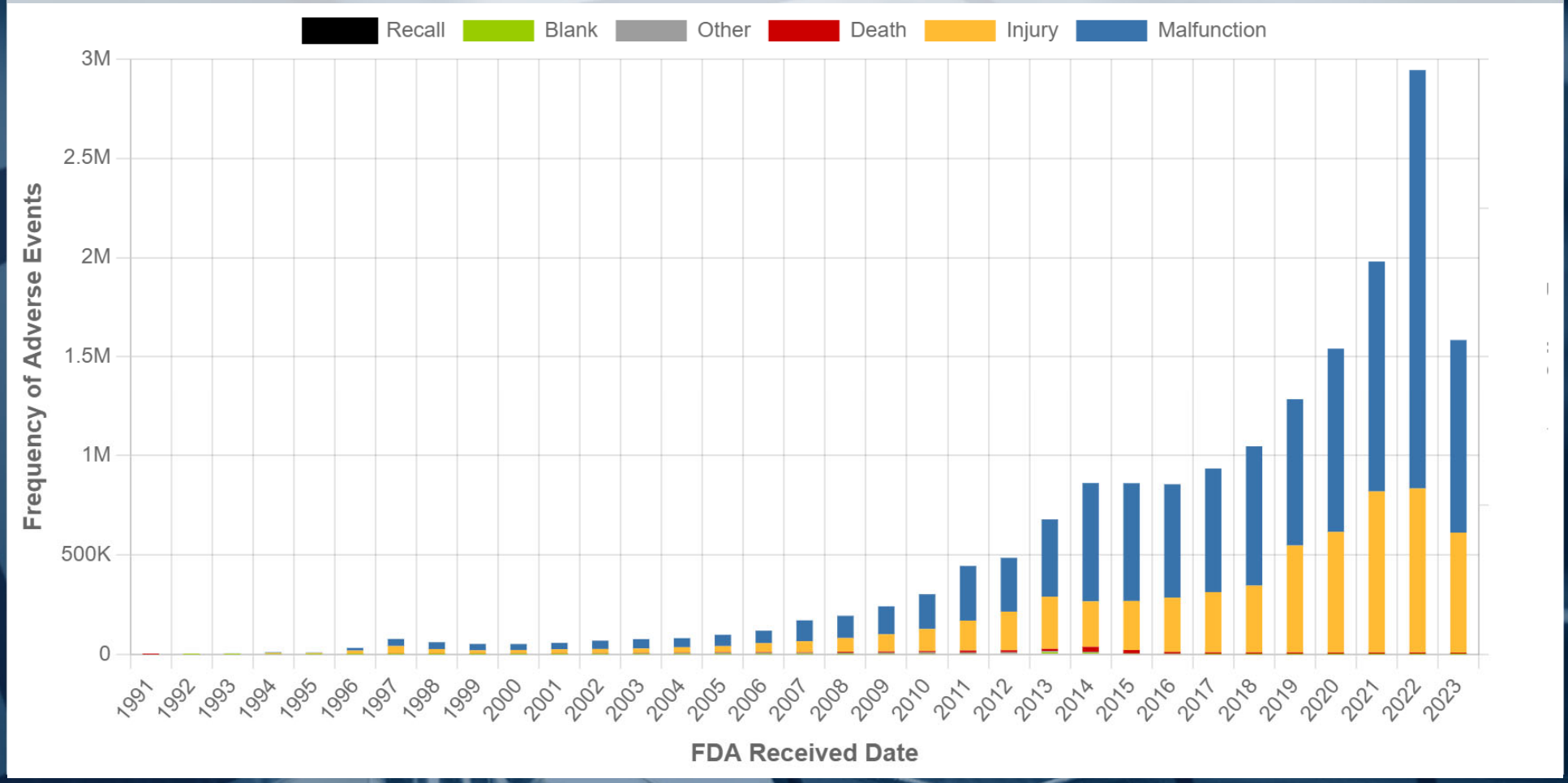
Many of the devices already on the market were not approved or tested with diverse populations in mind.



The FDA now receives close to 3 million Adverse Event reports per year

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The form used to submit adverse events to the FDA includes fields for sex, age and demographic data—we simply have not been able to see those fields due to redactions. CDRH's concern has been that the data in an adverse event would uniquely identify a patient. Now that we have 17 million MAUDE reports (and 6 million summary reports), that is less likely to occur.

If CDRH were to un-redact these fields, scientists, care providers and patients would have over 25 years of data that could be used for retrospective studies to better understand the efficacy of a device used in pediatric patients, the elderly and diverse populations.

Device companies could also use this data to design more innovative devices.

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If the FDA were to un-redact this data, we would have access to the age, sex and demographic data reported by:

Reporter Occupation

Check All | Uncheck All

- Other (6,050,045)
- Physician (2,468,276)
- *blank* (2,363,940)
- Dentist (1,727,643)
- Other Health Care Professional (1,313,858)
- Patient (921,197)
- Nurse (371,093)
- Not Applicable (361,471)
- Health Professional (355,972)
- Biomedical Engineer (329,664)
- Medical Equipment Company Technician/representative (227,042)
- Unknown (185,057)
- Attorney (159,495)
- Risk Manager (107,575)
- Pharmacist (49,169)
- Lay User/patient (46,603)
- Service And Testing Personnel (38,370)
- Patient Family Member Or Friend (36,799)
- No Information (27,959)
- Medical Technologist (17,145)
- Other Caregivers (16,618)
- Service Personnel (7,397)
- Respiratory Therapist (6,639)
- Physician Assistant (6,284)
- Emergency Medical Technician (3,266)
- Radiologic Technologist (3,008)
- Paramedic (2,904)
- Medical Assistant (1,296)
- Dental Assistant (1,228)
- Hospital Service Technician (1,062)
- Physicist (967)
- Nursing Assistant (597)
- Physical Therapist (525)
- Dental Hygienist (299)
- Phlebotomist (260)
- Home Health Aide (228)

Note: "Other" and "*blank*" Reporter Occupation was primarily for diabetic testing devices and Alaris pumps.

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The practice of medicine has changed drastically in the last 10 years (and not all due to covid).

What can we do to bring safe, effective and innovative digital health technology to patients?

- We have EHRs that allow patients to view visit summaries and test results – what data do we have on usage?
- Watches and devices to monitor heart health and diabetes – how can patients be sure their device has not been recalled or even check to see if it is FDA approved or cleared?
- Could AARP or Consumer Reports assist the FDA with a campaign to educate the public about Unique Device Identifiers (UDI)?
- How are we engaging home health care workers?
- How can we re-boot the MedWatcher smart phone app to send adverse event reports to the FDA (with UDI barcodes)?

How can we continue this discussion beyond today and affect change?

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Madris@DeviceEvents.com
240-424-8562

Founder and CEO, Device Events

Member, Breast Implant Safety Alliance

Member, Patient Safety Action Network

Member, MDIC Science of Patient Input Workgroup

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