MDUFA and Post-market Surveillance Topics

DEVICE EVENTS™
MASTERING MEDICAL DEVICE DATA

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MDUFA is primarily used to fund pre-market approval and clearance activities by CDRH.

There has long been pressure on the FDA to get innovative devices to market more quickly.

New does not always mean innovative.

510K devices can have a predicate that is no longer even on the market

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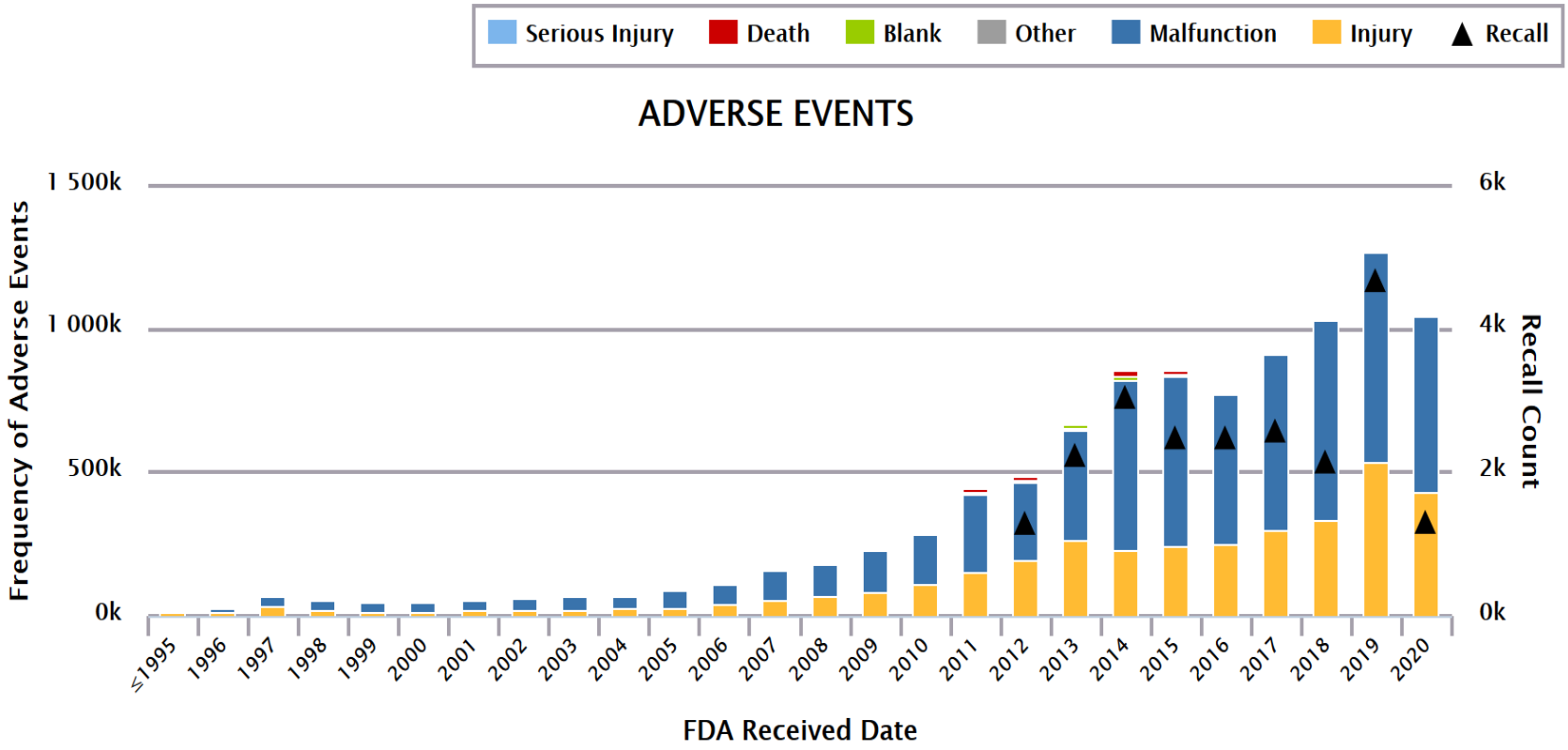
Adverse events have increased steadily as the number of devices on the market increased



2020 is on-pace to exceed 2019

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Adverse event reports are still the primary mechanism to identify signals (patterns of problems) with medical devices.

***MDUFA funding does not pay for post-market surveillance reviewers. They are paid through the congressionally approved FDA budget.**

Post-market surveillance funding needs to keep pace with pre-market MDUFA funding in order to even just "keep up" with current device issues.

***MDUFA funding has supported a few, very small pilot projects.**

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As a Public Health Analyst at FDA from 2012-2014, I observed there were approximately 65,000 adverse event reports per month to review.

When the FDA furloughed government employees in 2013, the post-market surveillance division was reduced to one analyst who was part of the Public Health Service.

One employee was left to review 65,000 reports.

The Pre-market division, funded by MDUFA, continued working through the furlough.

Why this matters.

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As of 2014, each post-market surveillance analyst was reviewing between 10 and 20,000 reports per year.

2 analysts had to leave before 1 replacement analyst could be hired.

When 80 new scientists were approved for hire at CDRH, they were all designated as pre-market and paid for with MDUFA funding.

Congressional funding to the FDA is not keeping pace with MDUFA hires.

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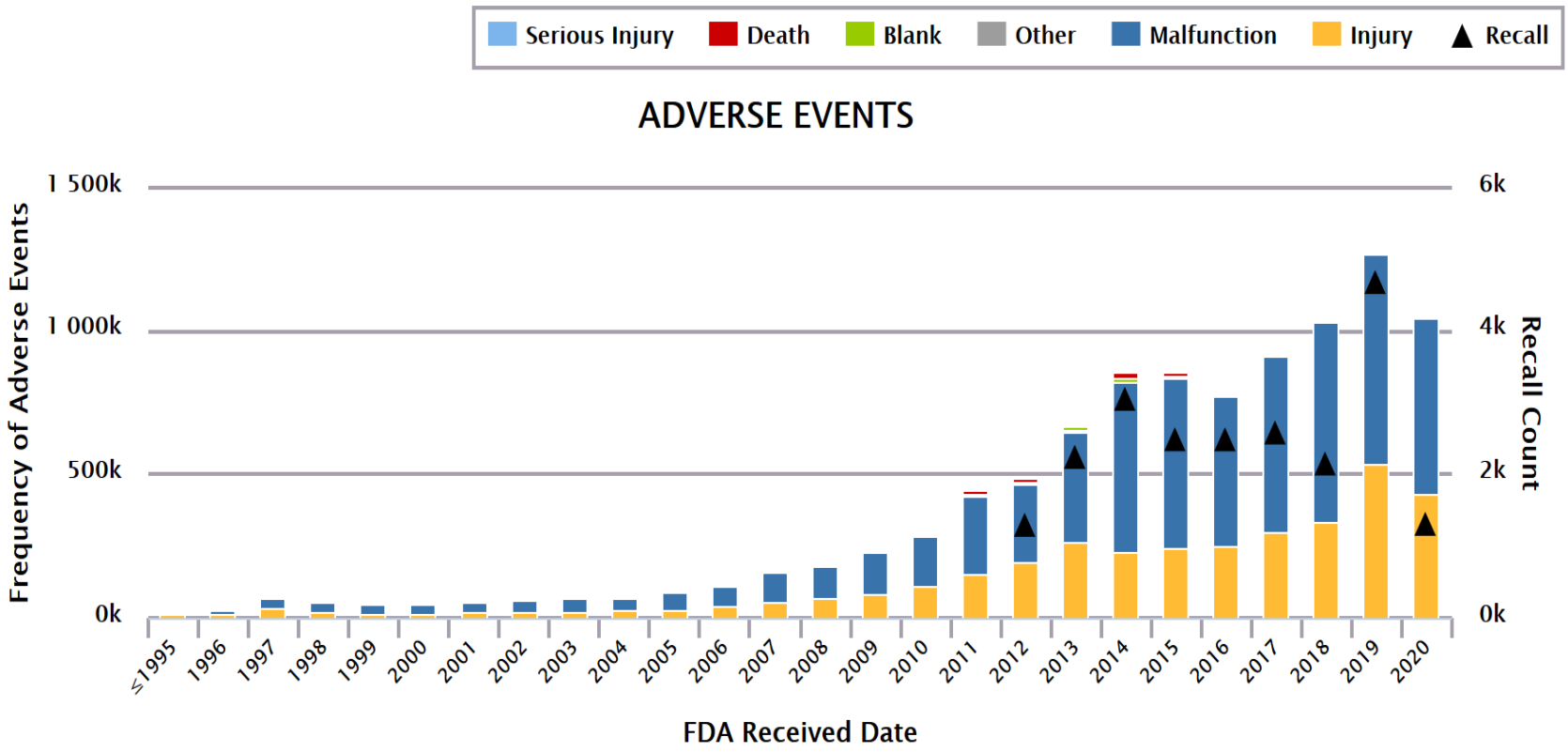
If Pre-market approvals continue at this pace, post-market surveillance of these devices needs to keep pace.



The FDA is responsible for the safety and effectiveness of devices it clears/approves.

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How can the FDA keep up with this pace?

There are now over 1 million reports per year being submitted to the FDA

***FDA and CMS efforts to require UDI on claims and in Electronic Health Records has likely stalled due to COVID-19 and technological and regulatory complications.**

***UDI labeling of Class I devices has been postponed 2 years.**

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Adverse Events Then

- ☑ 2000 (52,571)
- ☑ 2001 (58,393)
- ☑ 2002 (69,381)
- ☑ 2003 (76,913)
- ☑ 2004 (81,786)
- ☑ 2005 (98,961)
- ☑ 2006 (119,651)
- ☑ 2007 (171,339)
- ☑ 2008 (194,442)
- ☑ 2009 (241,885)
- ☑ 2010 (302,973)

Adverse Events Now

- ☑ 2011 (444,949)
- ☑ 2012 (486,658)
- ☑ 2013 (681,069)
- ☑ 2014 (862,568)
- ☑ 2015 (862,313)
- ☑ 2016 (786,248)
- ☑ 2017 (923,389)
- ☑ 2018 (1,044,849)
- ☑ 2019 (1,282,247)
- ☑ 2020 (1,052,578)

2/3 of Enforcement Actions Begin as an Adverse Event Report

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What Needs to Happen Now?

1. **CDRH needs to increase the number of post-market surveillance analysts to keep pace with the number of devices on the market.**

Note: Good technology helps, but does not replace the need for analysts.

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What Needs to Happen Now?

2. If CDRH wants to prioritize Innovation over Safety and Effectiveness while approving or clearing new devices, then they need to be just as willing to strengthen enforcement actions when a signal is found, indicating that a device might be more risky than initially thought.

3. CDRH needs to utilize mandatory recalls more readily than they currently do (most are voluntary).

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What Needs to Happen Now?

3. CDRH needs funding to improve signal identification technology, & not rely on NEST, which has numerous third party dependencies (device registries & EHRs).

4. CDRH needs to utilize moratoriums, when possible, if post-market studies are more than 1 year late.

The theory of MDUFA makes sense…

The scope of MDUFA still needs improvement.

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