FDA PUBLIC MEETING MEDICAL DEVICE USER FEE AMENDMENTS 2023-2027

OCTOBER 27, 2020

USA PATIENT NETWORK

MDUFA V
AND
THE CONSUMER

PENNY BURAU & LINDA J L RADACH

HOW'S IT WORKING?

MISSION & METRICS

Industry/FDA

MISSION: Resources & Process

METRICS:

- Speed to Market
- Quality Review Processes
- Response Times

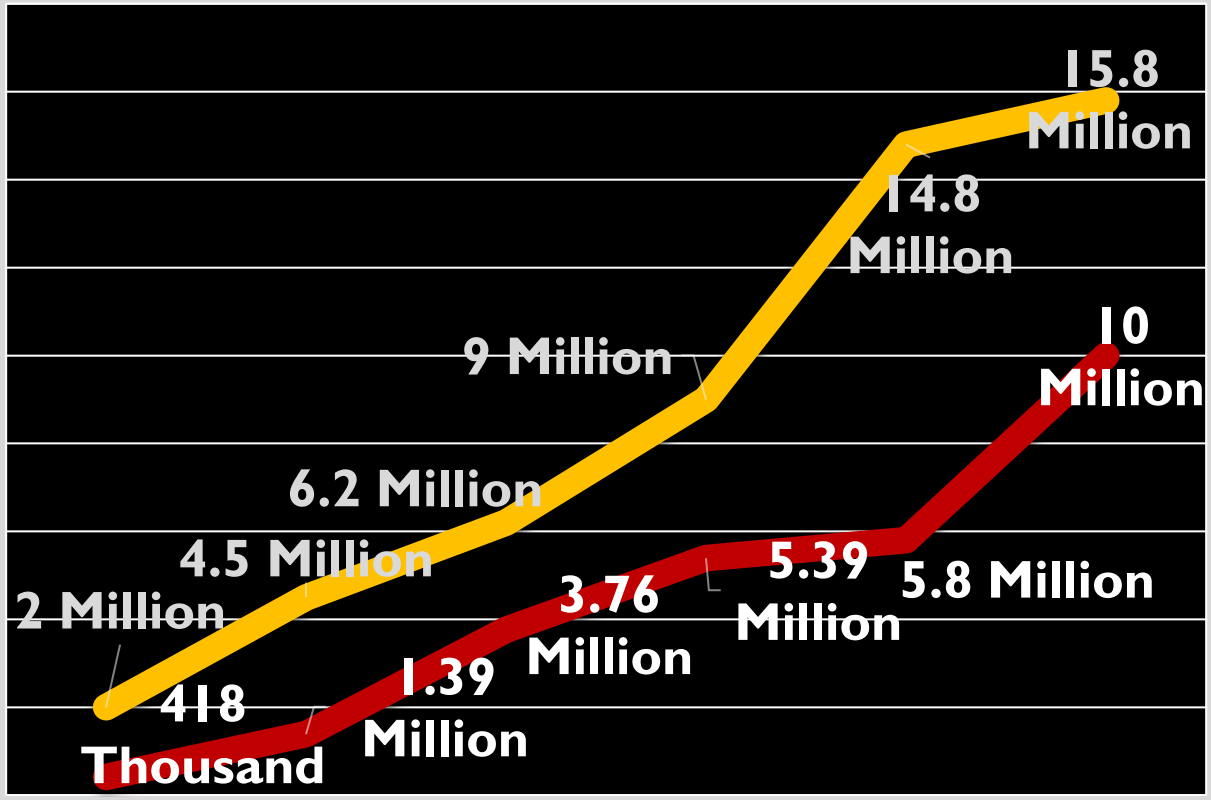
Patients

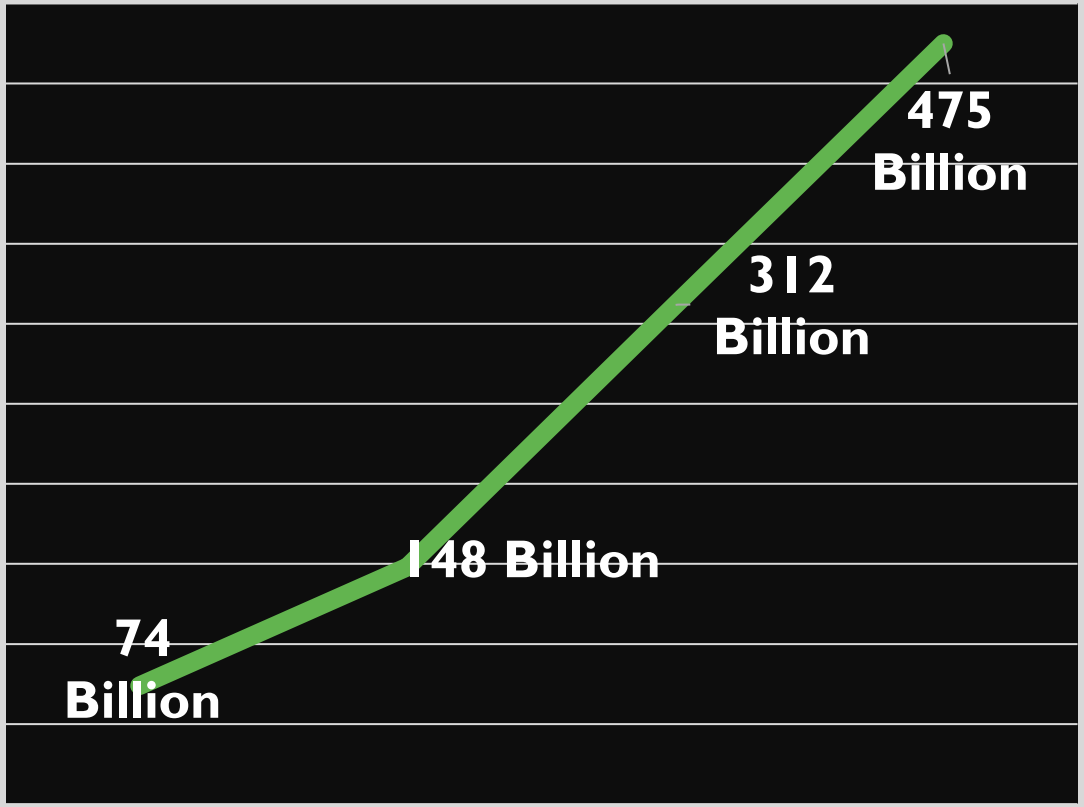
MISSION: Improved Outcomes

METRICS:

- Safety & Effectiveness
- Patient Outcomes
- Quality & Reliability

HUMAN COST IN MILLIONS





INDUSTRY GROWTH IN BILLIONS

https://www.expertinstitute.com/resources/insights/medical-device-injuries-fda-data-reveals-increasing-risk and Madris Tomes - Device Events

HOW'S IT WORKING?

FDA and INDUSTRY GRADE

A(CCESS)

PATIENT GRADE

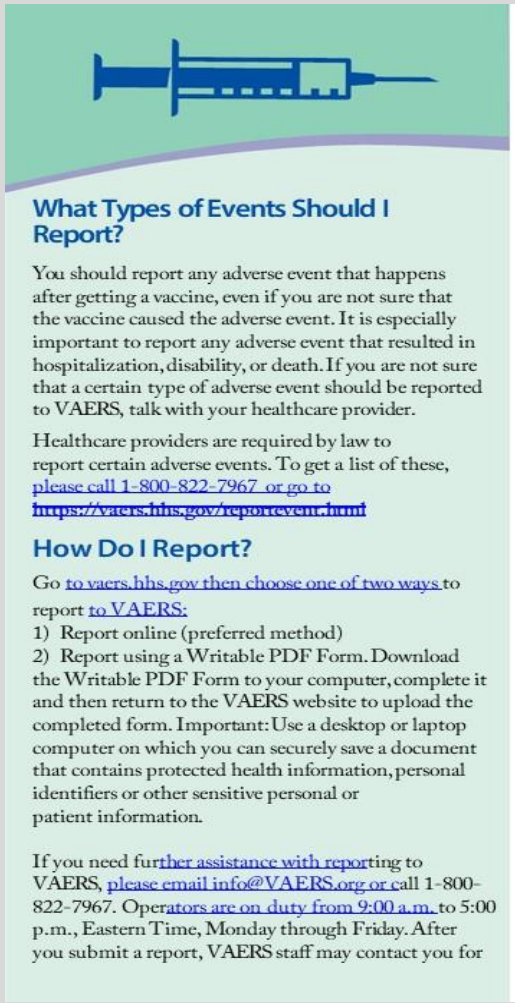
F(AILING)

HOW TO IMPROVE?

PRIORITIZE SAFETY & EFFECTIVENESS

510(k) Predicates
NESTcc Clinical Data
Balanced Resources for Pre and Postmarket
Adverse Event Reporting Education

HOW TO IMPROVE?



What Types of Events Should I Report?

You should report any adverse event that happens after getting a vaccine, even if you are not sure that the vaccine caused the adverse event. It is especially important to report any adverse event that resulted in hospitalization, disability, or death. If you are not sure that a certain type of adverse event should be reported to VAERS, talk with your healthcare provider.

Healthcare providers are required by law to report certain adverse events. To get a list of these, please call 1-800-822-7967 or go to https://vaers.hhs.gov/reportevent.html

How Do I Report?

Go to vaers.hhs.gov then choose one of two ways to report to VAERS:

1) Report online (preferred method)
2) Report using a Writable PDF Form. Download the Writable PDF Form to your computer, complete it and then return to the VAERS website to upload the completed form. Important: Use a desktop or laptop computer on which you can securely save a document that contains protected health information, personal identifiers or other sensitive personal or patient information.

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967. Operators are on duty from 9:00 a.m. to 5:00 p.m., Eastern Time, Monday through Friday. After you submit a report, VAERS staff may contact you for additional information.

CDC and FDA use VAERS data to monitor vaccine safety. VAERS data are also available to the public after all identifying formation, such as names and addresses are removed to protect the privacy of the patient.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a separate federal program that provides compensation to individuals whose injuries may have been caused by certain vaccines. Please be aware that reporting an event to VAERS does not constitute filing a claim with the VICP. Information on the VICP can be obtained by calling 1-800-338-2382 or visiting their website at http://www.hrsa.gov/vaccinecompensation/.

For More Information

• Centers for Disease Control and Prevention
For general information on vaccines and immunization schedules you can call 1-800-CDC-INFO (1-800-232-4636) or visit www.cdc.gov/vaccines.

• Food and Drug Administration
For safety and effectiveness information on FDA-licensed vaccines you can call 1-800-835-4709 and visit www.fda.gov/cber/vaers/vaers.htm.

VAERS

vaers.hhs.gov

Tel: 1-800-822-7967
Fax: 1-877-721-0366
info@vaers.org

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Food and Drug Administration

CS279807A

Do Your Part for Vaccine Safety—

Report to

VAERS

Vaccine Adverse Event Reporting System
A National Program for Monitoring Vaccine Safety

CDC FDA

THE ECOSYSTEM AND MDUFA

PRIORITIZE PATIENT OUTCOMES

Business Focus on Quality
Increased Presence of Patient Voice

THE ECOSYSTEM AND MDUFA

BUSINESS CASE FOR QUALITY

- Provides transparent, objective information
- Protects Patient Outcomes
- Reduces costs of recall events by half

  ON AVERAGE - $2.5-$5 billion per year & 10-13% Stock Price Jump
- Increases revenues $3.5 Billion

https://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_business_case_for_medical_device_quality.ashx

THE ECOSYSTEM AND MDUFA

BUILDING AN ENVIRONMENT OF QUALITY

- **Adopt quality practices used by other industries such as** life testing and failure analysis
- **Cross research biocompatibility of materials**
- **Use quality materials** to lengthen product lifecycle and reduce revisions.
- **Develop integrated, cross team** development processes

https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/public%20sector/regulatory%20excellence/the_business_case_for_medical_device_quality.ashx

THE ECOSYSTEM AND MDUFA

INCREASED RESPONSIVENESS TO PATIENT VOICE

Pervasive Patient Representation

Balanced Patient Voice (Rare Disease, Harmed, Public)

THE ECOSYSTEM AND MDUFA

ALIGNED MISSION AND METRICS

Prioritizes safety and effectiveness
Postmarket equally balanced with premarket
Pursues quality and reliability
Serves the mission of protecting public health