Specific recommendations to improve the FDA's medical device oversight processes

FDA's Medical Device User Fee Act (MDUFA) Reauthorization Stakeholder Meeting

June 9, 2021 (via webinar)

Michael T. Abrams, MPH, PhD
Public Citizen's Health Research Group

(I have no financial conflicts of interests)

Recommendations from Oct. 27th meeting…

1. Request more discretionary funding for FDA.
2. Mandate more adherence to randomized control trials with definitive endpoints.
3. Require FDA to advance metrics for assessment of the benefit-to-risk ratio for clearance, approval, or rejection actions.
   - public health impact should be reported to Congress and the public, near & long-term (10 yrs).
4. Require FDA to publish their technical reviews of all PMA supplements for which the changes could alter safety or effectiveness.
5. Require industry to publicly report number of devices which are sold and implanted.
6. Reject provisions which allow lax standards for review including:
   - PMA approvals based on literature reviews of studies of other approved devices,
   - use of supplemental approval pathways for new device models,
   - over-reliance on post-approval and MDR studies.
7. Encourage Congress to pass legislation to override *Riegel v. Medtronic*, a Supreme Court decision which limits patients' rights to sue the makers of faulty PMA devices.

Recommendation A

- The letter of commitment and future performance reports to Congress should include, by year for the reporting year and retrospectively…
  - Counts of devices made/sold/deployed
  - Counts of device withdrawals, by type (e.g., voluntary or mandated)
  - Counts of serious adverse medical device events by pathway type (e.g., 510(k), PMA, breakthrough)

…along with analyses considering the causes/correlates of these negative outcomes, especially as it pertains to FDA gate-keeping authority.

- ❖ Consumers are concerned that dangerous devices get approved prematurely because of low standards for clearance and approval and financial pressure from manufacturers.

Recommendation B

- Performance reports to Congress that include tallies showing how many devices are approved using the highest standards of evidence (i.e., well-designed randomized controlled trials with meaningful clinical outcomes) versus clearance or approval with limited or no evidence from clinical testing.

  - Goal: reduce inappropriate use of “short-cuts”

Case Study: Spinal Cord Stimulators (SCS)

- Public Citizen Report: June 10, 2020 (Carome MA)

- 1981-2019: FDA approved six original pre-market applications (PMAs) (Class III) approved for totally implanted SCS
  - at least one based on a seriously flawed clinical study,
  - at least three based on only published scientific literature for other spinal cord stimulator systems, and the published literature was significantly flawed.
- 1980-2019: 945 of 1,008 PMA supplements were FDA approved, many of them new models.

Consequences include serious injuries and death:

	Class II (external power supply)	Class III (implanted power supply)
Medical Device Adverse Event Reports (MDRs)	40,457	179,917
Injuries	38,545	118,272
Deaths	174	757
Most common MDRs	Infection, lead migration, heating, falls, lead fracture, electrical shocks, headaches	
Recalls	5	44
Class 1 recalls*	0	0
Total number of devices implanted (denominator)	?Proprietary?	

Recommendation C

- The FDA's medical device user fee reauthorization process should eliminate exclusive, secretive industry meetings and instead host stakeholder meetings that include consumers and manufactures at the same negotiating table

  - Revise language in 21 USC 379j-1, and elsewhere in FDCA as necessary

Thank you. For more information:

Michael T. Abrams, M.P.H., Ph.D.
Health Research Group
Public Citizen
Washington, D.C.
mabrams@citizen.org
www.citizen.org