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Presentation at the Medical Device User Fee Amendments (MDUFA) Reauthorization Stakeholders Meeting

U.S. Food and Drug Administration, Via Webinar

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I am Michael Abrams a health researcher at Public Citizen. I have no financial conflicts of interest.

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This slide recasts the recommendations I made at the October "kickoff" meeting of these reauthorization stakeholder proceedings. As my red emoji indicates, to date it my recommendations have mostly been ignored. I base this on the discussions we have had, and on my review of the industry negotiation summaries thus far available on the Food and Drug Administration (FDA) website.

Here, I put forth my list again, and request that FDA staff review it carefully and craft specific reauthorization language to address each point.

With the few minutes I have today, I will offer specific suggestions to advance several of these points. Before I do, I will jump to recommendation 7, which is based on the simple inference that:

> Consumers want the ability to hold manufacturers accountable when their medical devices fail because of dishonesty or negligence. Accordingly, the FDA should encourage Congress to override the *Riegle v. Medtronic* decision with legislation that prevents manufactures from hiding behind the imperfect FDA premarket approval process.

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Now onto three other specific recommendations. First,

- The letter of commitment and future performance reports to Congress should include, current year and retrospective…

- 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 regarding the causes/correlates of these negative outcomes, especially as it pertains to FDA gate-keeping authority.

The rationale for such reporting is straightforward: Consumers are concerned that dangerous devices get approved prematurely because of low standards for clearance and approval and financial pressure from manufacturers.

The FDA thus should ask Congress to grant it the resources and mandate to track its successes and its failures. Information that is not only evidence of performance, but information to advance public health.

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Next, and related to the previous recommendation, we call upon the FDA to seek codification in the Food, Drug, and Cosmetic Act of:

- 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.

The goal of this recommendation again relates to concern about "fast-tracking" approvals or clearances, pressured often by industry's financial interests.

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Why do we feel such data is necessary? Because we know in the past that the FDA has approved devices that subsequently proved harmful to consumers. Here is a reminder of one example that I presented back in October. Spinal cord stimulators for pain have led to injury and death, and many of them have been approved without well-designed clinical trials testing the actual device for which approval was sought. The consequences of using such devices can be debilitating, even deadly. This type of information, we believe, should be regularly included in medical device oversight reports to Congress. No system of this complexity is expected to be perfect, and thus regular surveillance is especially important.

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One final recommendation pertains to the MDUFA reauthorization process. Industry negotiations are unnecessarily decoupled form the stakeholder process, even though both sets of meetings aim toward the collective goal of maximizing public health vis-a-via device regulation. Moreover, consumer interests are central to the discussions. As it stands presently, industry is given disproportionate negotiating leverage.

So, we recommend that in the future:

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

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Thank you. Contact information.