Recall Communication Recommendations

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MASTERING MEDICAL DEVICE DATA

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Recalls are almost always voluntary and on the manufacturer's timeline, effectively de-valuing the FDA's reputation for protecting patients.

When a device is recalled, the device it was based on (the predicate) does not also fall under scrutiny for safety problems.

The FDA needs to mandate recalls and do it in a more timely fashion. Safety signals typically take 2 months to 2 years to be acted upon.

Recalls often occur in concert with the clearance of a newer model.

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The public's trust is violated when the FDA doesn't enforce the rules and fine companies who abuse the public's trust.

The public, in this instance, includes physicians and care providers who put their trust in the FDA.

Recalls are not timely and many times the FDA allows a commercial withdrawal in place of a recall.

A commercial withdrawal and recall are incredibly different.

Why this matters.

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Recall	Commercial Withdrawal
Hospitals are notified	Hospitals only learn of withdrawal when/if seeking to re-order. Hospitals use up the rest of the stock.
Physicians are notified	Physicians often think a newer version means the device is improved. Physicians who have already paid for the devices continue to implant them.
Some patients are notified—most are not	No patient notification and limited funding available if explant is needed.
Some patient recourse available for Class II devices	Patients left in the dark and often with no legal recourse.

Physicians often still believe a device is safe if it's not recalled.

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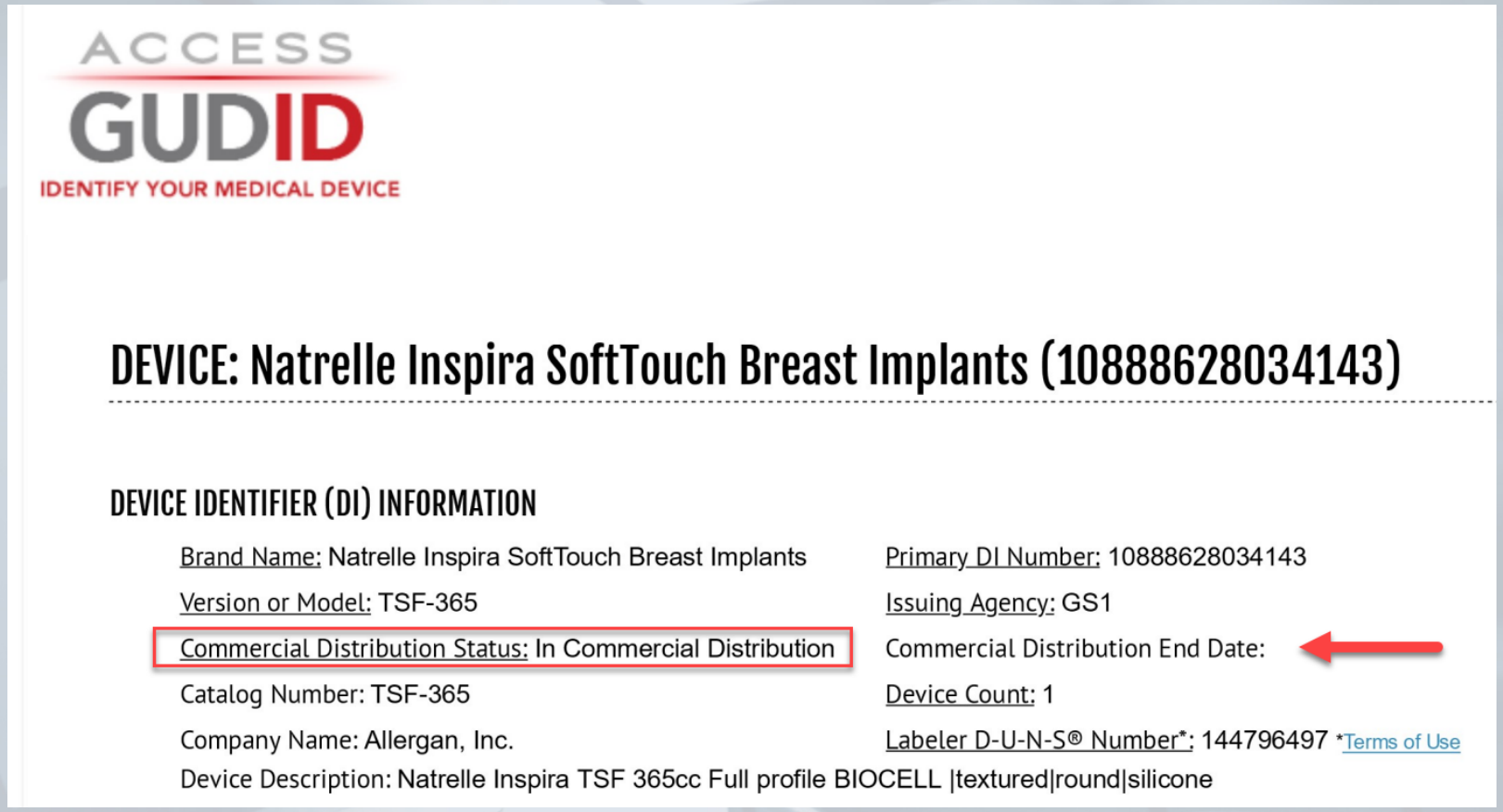
The Access GUDID Database (public-facing) needs to be updated BY THE FDA for recalls and market withdrawals.



Allergan recalled this device in 2019 and the database still states it's in commercial distribution.

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What Needs to Happen Now?

1. **CDRH needs to increase post-market surveillance staffing 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.

Recall notices need to be understandable to patients and actionable. If I have this device, what do I do now?

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