

# Debating the Risks and Benefits of a Mandatory Product Registry

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# What Problems Would a Mandatory Product Listing Regime Fix?

- Marketers of drug-spiked products don't comply with FDA requirements
- FDA and DOJ don't seek injunctions, seize products, or prosecute for product listing violations
- With some effort, firms can comply and place the onus back on FDA/DOJ to make the harder case
- If these marketers do submit labels, they won't declare, e.g., sildenafil or tadalafil

# What Problems Would a Mandatory Product Listing Regime Fix (cont.)?

- Firms already have to register facilities biannually
- Labels already have to bear contact information for the “responsible person”
- Firms already have to maintain one-up-one-down shipment records
- FDA can already view labels in the NIH database, in the Supplement OWL, on various seller websites, and elsewhere in the marketplace

# What Problems Would a Mandatory Product Listing Regime Fix (cont.)?

- The “Certificate of Free Sale” program already exists
- Compliance with a mandatory product listing requirement would not substitute for an FDA certificate
- Would foreign governments or purchasers nevertheless read too much into a listed product’s status?

# What Burdens Would a Mandatory Product Listing Regime Create?

- For a given firm, potentially 100s or 1,000s of product listings to input at once
- Routine updating for new products, discontinued products, and label changes
- Requirement to label products with an FDA-assigned identification number?
- Potential complexities of coordination across own-label distributors, contract packers, and contract manufacturers

# What About Potential Unintended Consequences?

- User fees?
- Driver's license versus birth certificate?
- Commercial impacts for FDA delays in updating the public-facing database?
- Plaintiff's bar buffet?
- Availability of information on contract-manufacturing relationships?

# Conclusions

- FDA already has adequate authorities to regulate the dietary supplement industry
- A product listing regime won't fix identified problems
- Don't discount the burdens, particularly on small businesses
- Don't discount the potential unintended consequences

**Thank you!**

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