Policy Proposal for the Establishment of the FDA Office of Patient Affairs:

The Issue:

- Low Visibility of Involvement Opportunities
- Pervasive Adverse Conflict-of-Interest Determinations
- Confusion on the FDA’s Role in Single-Patient Expanded Access Requests
- Little to No Coordination between Medical Product Centers on Patient Engagement Initiatives

The Solution:

Elevate the Current Patient Liaison Program to the level directly under the Commissioner as the newly-named Office of Patient Affairs

The Office of Patient Affairs Will:

- More effectively recruit patient representatives to serve as special government employees (SGEs)
- Conduct conflict-of-interest screenings for patients to become special government employees
- Train patient representatives on the FDA and its regulatory framework
- Maintain a database of qualified patient representatives
- Chair the newly-established Patient Engagement Council that helps coordinate patient engagement opportunities across the agency
- Serve as the FDA’s external representative for patient affairs
- Educate and Assist Patients and physicians seeking single-patient expanded access requests
- Report to the Commissioner on patient engagement throughout the centers
- Report to Congress biennially on patient involvement in FDA practices

The Cost:

Aside from the potential hiring of additional FTEs to carry out the FDA’s statutory responsibilities to patients (which are growing regardless of this proposal), there is no cost to the proposal.

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