

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of Clinical Policy and Programs

Effective Date: December 14, 2018

1. Office of Clinical Policy and Programs (DCJ).

- A. Provides executive leadership, management and policy direction to all Food and Drug Administration (FDA) medical-product-related programs.
- B. Directs the activities of FDA's special medical programs, including the Combination Products, Orphan Products Development, Clinical Policy, and Pediatric Therapeutics.
- C. Directs efforts to integrate the programs, as necessary, of Drugs, Biologics, and Devices and Radiological Health and thereby ensure the optimal use of all available FDA resources and tools to improve the safety and proper labeling of medical products.
- D. Directs the development of integrated strategies, plans, policies and budgets to build FDA's medical product- related scientific and regulatory capacities and programs, including recruitment and training of key personnel and development of information systems.
- E. Represents FDA on medical product- related matters in dealing with the Office of the Secretary of Health and Human Services, the White House, other elements of the executive branch, and with the Congress.
- F. In conjunction with FDA's leadership and International programs represents FDA on medical product- related matters in dealing with foreign governments and international organizations.
- G. Directs FDA efforts to build consistency and uniformity in the evaluation for safety and efficacy of new medical products.

2. Healthcare Patient Affairs Staff (DCJ1)

- A. Supports, develops, and executes triage and navigation services for inbound patient/health care provider (HCP) inquiries, as well as, manage an outbound patient and HCP communication platform.

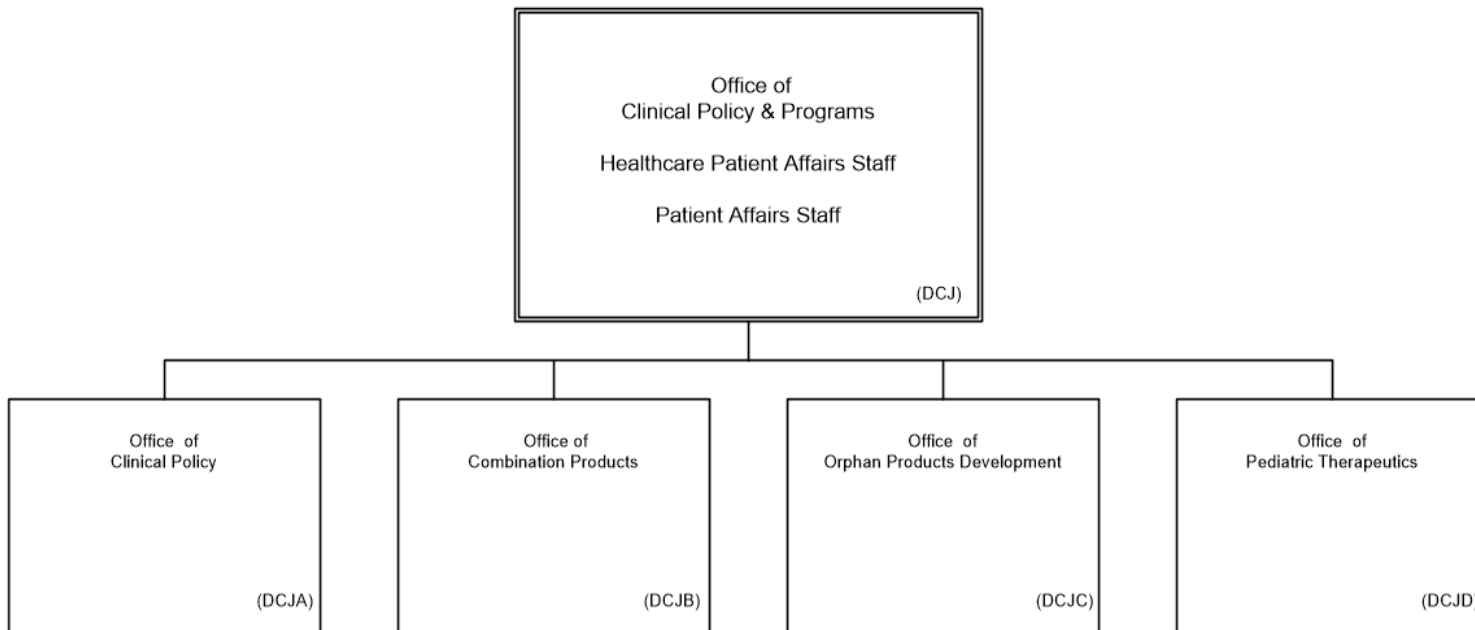
3. Patient Affairs Staff (DCJ2)

- A. Coordinates FDA-wide efforts (e.g., OC Listening Sessions, EMA-FDA Cluster) and /or cross-cutting efforts upon Center requests as they relate to patient affairs. Serves as the single, central entry point to FDA for the patient community.

4. Authority and Effective Date.

The functional statements for the Office of Clinical Policy and Programs were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Clinical Policy and Programs organization structure depicting all the organizational structures reporting to the Director.

These organizations report to the Office of the Clinical Policy & Programs (DCJ):

- Healthcare Patient Affairs Staff
- Patient Affairs Staff
- Office of Clinical Policy (DCJA)
- Office of Combination Products (DCJB)
- Office of Orphan Products Development (DCJC)
- Office of Pediatric Therapeutics (DCJD)