SMG 2010.18

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA OPIOID POLICY STEERING COMMITTEE

Effective Date: 11/20/2017

1. PURPOSE.

As FDA assesses the benefits and risks of a drug product, it must make certain that its decision making is based on all of the available information. Opioids present unique challenges: they have significant benefits when used as prescribed, yet cause enormous harm when misused and abused. For opioid drugs, product review—in both preapproval and post approval settings— requires FDA to assess the risks of misuse and abuse.

FDA establishes the FDA Opioids Policy Steering Committee, a policy Committee on FDA-wide opioid matters (herein referred to as Committee). The purpose of the Committee is to evaluate novel approaches to the opioid crisis and to identify ways that the Food and Drug Administration (FDA) can be impactful. This charter describes the duties and responsibilities of the Committee, its organization and operating procedures, and responsibilities of its members.

2. POLICY.

The Committee serves as a cross-cutting, senior Agency team and forum for innovative problem solving to address the opioid crisis of addiction. The Committee is tasked with generating novel approaches within FDA to identify regulatory, policy, and scientific issues requiring evaluation and modernization. The Committee addresses issues relating to continuous improvement of the FDA’s impact on the opioid abuse crisis, including but not limited to, programmatic system improvement, internal and external communication strategies, outreach, education and training.

The Committee ensures alignment of FDA's centers and facilitates internal consensus and development of unified FDA positions on cross-cutting issues.

The Committee's role is to serve as a steering committee to assist in implementation and policy review, rather than clearance or communication regarding opioids. The intent is to not cross over into a Center's role or to infringe upon a Center's routine work product.

Although the Committee does not meet with external stakeholders, it may communicate with external stakeholders, as needed, to gather information to understand related issues or to move forward policies.

3. RESPONSIBILITIES.

A. Responsibilities of the Committee:

1. Evaluate concepts and ideas for combatting the opioid abuse crisis.

2. Establishes working groups or opens dockets for public comment on matters related to the Committee.

3. Reports directly to FDA's Principal Deputy Commissioner, including preparing and submitting annual reports on activities completed and a project plan for future activities for the following calendar year.

4. Promotes and coordinates internal and/or external communication of policy decisions when appropriate.

B. Responsibilities of Committee Members:

1. Represent their organizational unit views on issues under consideration by the Committee.

2. Serve as point of contact for communications with their organizational unit, including their senior managers about Committee deliberations.

3. Attend meetings in person or by teleconference. If a member cannot attend a meeting, an alternate may be designated by the Committee member. The alternate must be able to represent the organization in place of the member. If deemed appropriate by the Chairperson, email communication may be used to obtain Committee input.

C. Responsibilities of the Committee Chairperson:

1. Directs the activities of the Committee.

2. Facilitates discussion on issues within the Committee.

3. Reviews proposed issues and determines when issues are appropriate for Committee review and discussion. If the proposal is not selected for Committee review by the date specified, the Chairperson (through the Executive Secretary) provides an explanation for this decision. Reconsideration by the Committee of such decisions can be requested.

4. Leads oversight of agency-wide opioid strategy, policy, priorities, and projects conducted in collaboration with other federal agencies and in alignment with the HHS Opioid Strategic Plan.

5. Leads the monitoring, performance, and implementation of agency-wide activities by coordinating and integrating competing requirements and priorities of internal agency stakeholders.

D. Responsibilities of the Committee Vice - Chairperson:

1. Assists the Chairperson in performing his/her duties and responsibilities.

2. Acts as the Chairperson if he/she is unable to attend or carry out his/her duties.

3. Performs activities at the direction of the Chairperson which may include research, problem solving, and other activities.

4. Oversees the coordination and integration of cross-agency collaboration on opioid working group activities and objectives; evaluates and assesses these efforts to leverage diverse and collaborative networks, promote information sharing, eliminates redundancy and ensures alignment to FDA’s strategy.

E. Responsibilities of the Executive Secretary:

1. Maintains the Committee roster and roster of any working groups formed (including information such as the creation date, Committee-assigned responsibilities, and sunset of working groups).

2. Manages the identification of gaps and impediments that are negatively impacting successful OPSC strategy implementation efforts and develop solid and well-researched recommendations for policies and procedures designed to reduce these gaps.

3. Prepares documents and papers as requested by the Chairperson.

4. Distributes documents relevant to the activities of the Committee.

5. Schedules pre-meetings as necessary and assists in preparing materials for scheduled meetings.

6. Arranges and organizes meeting logistics.

7. Notes action items generated during Committee meetings and follows up on action items.

8. Maintains a repository, organized by year and including reports, summaries of meeting discussions, a log and status of issues discussed and actions assigned, and copies of the Committee decisions and actions that can be accessible to all staff across Centers.

F. Committee organization:

1. The Committee sits in the Office of Medical Products and Tobacco (OMPT) in the Office of the Commissioner.

2. The Committee Chairperson is FDA's Principal Deputy Commissioner.

3. The Committee Vice Chairperson is appointed by the Chairperson.

4. The Executive Secretary is appointed by the Chairperson.

5. The Committee is composed of:

a. Senior Agency leaders, as designated by the Commissioner, in coordination with the Chairperson.

b. Other participants, observers, and consultants from within the agency may participate in the activities of the Committee at the discretion of the Chairperson.

4. PROCEDURES

A. The Committee will meet generally on a monthly basis.

B. Special meetings may be scheduled at the discretion of the Chairperson.

C. Agenda items can be suggested by the members who serve as representatives on the Committee as well as by the Executive Secretary and the Chairperson.

D. Experts from Agency staff will be sought and invited to participate in the discussion at the Chairperson's discretion.

E. Experts from Agency staff will be sought and invited on to participate in sub-project working groups at the Committee's discretion as needed.

F. Meeting minutes with action items and an updated decision log will be maintained for each meeting.

5. COMMITTEE RECORDS.

A. The Chairperson and the Executive Secretary ensure that the activities of the Committee, including annual/quarterly reports, recommendations, decisions, issues, action items, and other pertinent materials attributable to the Committee, are documented and communicated to senior management and relevant staff, as appropriate.

B. The Committee will review this charter at least annually based on experience gained by the Committee; revisions can be made as needed.

6. TERMINATION

The Committee will sunset on May 23, 2018, one year after the date of inception, with the option to extend the sunset date at the discretion of the Chairperson.

7. EFFECTIVE DATE.

The effective date of this charter is November 20, 2017.

8. Document History - SMG 2010.18, "FDA Opioid Policy Steering Committee"

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	10/27/2017	N/a	Office of Medical Products and Tobacco	Scott Gottlieb, M.D., Commissioner of Food and Drugs

Back to General Administration, Volume III (2000-3999)