OFFICE OF THE CENTER DIRECTOR

Documenting Differing Professional Opinions and Dispute Resolution – Pilot Program

CONTENTS

PURPOSE

This MAPP provides a new pilot procedure for Center for Drug Evaluation and Research (CDER) staff to express their differing professional opinions (DPOs) concerning regulatory actions or policy decisions with significant public health impacts in instances when the normal procedures for resolving internal disputes are not sufficient. The DPO procedure provides:

- Short time frames for hearing DPOs so they can be resolved expeditiously
- Review of the DPO by qualified staff not directly involved in the decisions
- Evaluation of the pilot after 1 year to determine whether it adds value to the regulatory decision-making process

BACKGROUND

- When any regulatory action or policy decision is considered, CDER must reach an institutional position. The process is complex and may involve primary reviewers, team leaders, supervisors, and managers within one or more organizational components.

  The existing process provides many opportunities to discuss and resolve scientific differences in the course of decision-making, and these discussions enhance the quality of the decisions. Opportunities include meetings among review team members, meetings with supervisors and management within the Center and Agency, meetings with sponsors, CDER regulatory briefings, and Advisory Committee meetings.

  CDER's decision-making process ensures that regulatory actions and policy decisions consider an array of perspectives and concerns. In the free and open discussion of Center issues within a scientific and regulatory environment, differing professional views are expected. Individual employees are strongly encouraged to discuss their differing views and resolve any differences

through discussion with their coworkers and their supervisors. In most cases, consensus on a course of action can be achieved.

Sometimes, however, consensus cannot be reached. In such cases, staff document their individual views, and the documentation travels with the decision package as it moves through the supervisory chain. FDA regulations provide that individual views and significant controversies or differences of opinion, and their resolution, should be documented in the official administrative file on an action (21 CFR 10.70(b)(i). Section 10.75 (21 CFR 10.75) provides for supervisory review of individual employees' decisions. CDER MAPP 4151.1 defines the roles and responsibilities of reviewers, supervisors, and management in documenting views and findings and resolving disputes.

Despite this dispute resolution process, an employee may sometimes feel that his or her opinion was not adequately considered in a setting in which an Agency action, or inaction, will have a significant impact on public health. This MAPP describes a formal process by which individuals in this situation can ensure that their views are heard.

REFERENCES

- FDA Administrative Practices Regulations, 21 CFR 10.70 and 10.75
- CDER MAPP 4151.1, Resolution of Disputes: Roles of Reviewers, Supervisors, and Management Documenting Views and Findings and Resolving Differences, Effective 8/19/96
- CDER MAPP 4150.1, Role and Procedures of the CDER Ombudsman, Effective 10/10/02

POLICY

- It is the policy of CDER to maintain a working environment that encourages employees to make known their best professional judgments even though they may differ from a prevailing staff view, disagree with a management decision or policy position, or take issue with proposed or established practices.

- ***CDER is absolutely committed to the protection of employees from retaliation in any form for expressing differing viewpoints.***

- If there are disagreements between a reviewer and a supervisor about a regulatory action or policy decision, the responsible supervisor must take the differing opinions into consideration and make a decision. In all cases, the views of all persons involved in the process must be respected. The official administrative record should reflect any differences of opinion.

- When an employee believes a decision is to be made, or the Agency is failing to act in a situation that will have a significant negative impact on the public health, it is CDER's policy to ensure that the employee has the opportunity to express a DPO and to have his or her views heard and carefully considered by CDER management.

- The CDER Ombudsman will be the focal point for receiving and facilitating resolution of DPOs. The CDER Ombudsman already provides a venue for staff to raise differing views outside the

management chain. The Ombudsman will now be directly involved in facilitating the resolution of DPOs.

- These DPO procedures are not intended for the resolution of routine disputes that can be addressed through the normal procedures for documenting and responding to different scientific and regulatory viewpoints. Rather, the DPO procedures should be reserved for the most serious differences of opinion when an action or inaction by CDER could have a significant negative impact on public health.

PROCEDURES

- Any CDER employee may initiate the formal DPO review process by preparing a written statement that includes:

  - A summary of the position with which the person disagrees, whether it is a prevailing staff view, an existing management decision or stated policy position, or a proposed regulatory action or policy decision, or failure to act
  - A description of the submitter's views and how they differ from the above
  - A description of the nature of the disagreement (e.g., interpretation of data, methodology, judgment)
  - An assessment of the possible significant negative consequences to the public health should the submitter's position not be adopted by CDER
  - A list of at least three potential candidates (FDA employees) for the *ad hoc panel* that will be convened (see below)

Note: The statement may be brief, but if it does not include these five elements, it will not be processed as a DPO.

- The statement should be clearly marked "Differing Professional Opinion" and sent either through the employee's supervisor to the CDER Ombudsman or directly to the Ombudsman.
- Within 5 business days of receipt of the DPO, the CDER Ombudsman, in consultation with the Center Director, will consider the merits of the DPO and determine whether the consequences of the decision/action/inaction in question are potentially sufficiently serious to warrant filing the DPO. In most cases, the Ombudsman will ensure that all other avenues for resolution (e.g., dispute resolution process, Advisory Committee discussion, CDER regulatory briefing) have been exhausted before a DPO is filed. However, in some cases, an individual may believe that his or her professional opinion will not be considered by his or her supervisors or that there is not time to exhaust other options for dispute resolution without seriously endangering the public health. In this case, the submitter should include in the DPO package a written request to bypass these other mechanisms and move directly to a DPO.
- If the CDER Ombudsman, in consultation with the Center Director, determines that the potential consequences of the contested decision/action are not potentially significant enough (do not have the potential to have a significant impact on public health), the Ombudsman will notify the person submitting the DPO in writing that the DPO will not be filed, and will retain the DPO in the files

for the record. If the DPO is not filed, the employee should be encouraged to document the views in the normal administrative manner (see 21 CFR 10.70).

- If the CDER Ombudsman, in consultation with the Center Director, determines that the DPO should be filed, the Center Director will appoint an ad hoc DPO review panel to review the DPO. To the extent possible, DPO panels should not include individuals who have directly participated in the decision-making process up to the time of the DPO. However, they should include individuals with the *relevant technical expertise and experience* to understand the complex issues at hand.

- The DPO review panel should include a chairperson (usually an Office Director) appointed by the Center Director. The chair will appoint two or three additional members:

  - One member who has relevant technical expertise
  - One member chosen from the list proposed by the employee submitting the DPO
  - When appropriate and feasible, one member with relevant technical expertise external to the Agency chosen by the ad hoc panel chairperson. Because of the short time frames involved, this member must be a special government employee (SGE).

- The Ombudsman will forward the DPO package statement to the ad hoc panel as soon as the panel has been appointed.

- The DPO review panel will:

  - Determine whether sufficient documentation was provided by the DPO submitter to complete a detailed review and, if not, request additional information
  - Notify the Ombudsman when sufficient documentation has been provided to begin review
  - Request technical assistance and additional documentation (e.g., reviews, meeting minutes) from appropriate sources within or outside the Center, as necessary
  - Review the DPO and all other relevant materials, and make a written recommendation to the Center Director regarding the appropriate course of action to be taken. If the panel is unable to reach consensus, the report should reflect the differing opinions of the panel.

- Once the panel has received the necessary information to begin its review, the panel should take no more than 30 calendar days to make a written recommendation to the Center Director.

- The Center Director should review the panel's recommendation and provide the employee who submitted the DPO and other Center staff included in review chains associated with the DPO with a written decision and rationale for that decision within 5 business days after receipt of the panel's recommendations.

- All records pertaining to DPOs will be maintained in the pertinent regulatory submission file(s), if applicable. If the DPO is not related to a specific regulatory submission, records will be maintained by the CDER Ombudsman.

RESPONSIBILITIES

Reviewers/Participants in Decision Making

- File a DPO only when you feel an Agency action or inaction is likely to have a significant negative effect on the public health and you have either exhausted existing mechanisms for resolving disputes, or you feel the existing mechanisms are not likely to lead to a timely and satisfactory resolution of your concern
- Submit the DPO to your supervisor or directly to the CDER Ombudsman
- Prepare any material that will assist in dispute resolution or panel consideration of the DPO
- Submit a list of at least three candidates with appropriate technical expertise to serve on the ad hoc review panel
- Be aware of any review clock or other limitations or timelines as they may pertain to any regulatory decisions, and allow adequate time for Division and Office meetings

Supervisors, Division Directors, and Office Directors

- Notify the CDER Ombudsman immediately when a DPO is submitted
- Support the DPO process, protecting employees from even the appearance of retaliation for having a differing viewpoint and using the DPO process

Ad Hoc DPO Review Panel

- Review all information submitted in the DPO
- Determine whether additional information is needed and communicate that to the CDER Ombudsman
- Make a written recommendation to the Center Director within 30 calendar days of receipt of all necessary information

Center Director

- Consult with the CDER Ombudsman to determine whether the potential consequences of a regulatory/scientific decision are serious enough to warrant initiating the DPO process
- Appoint the chair of the DPO ad hoc panel
- Issue a written decision and rationale for that decision on the DPO within 5 business days of receipt of recommendation from the ad hoc panel

CDER Ombudsman

- In consultation with the Center Director, determine whether the DPO contests an action or inaction likely to have significant negative public health impact
- Review the DPO package submitted and work with submitter to ensure that the package is complete
- Notify the CDER Director and all individuals within the submitter's supervisory chain that a DPO has been received
- Serve as the project manager for the DPO process
- If this process concerns a regulatory submission, work closely with the Division/Office Project Manager to enter all relevant material into the division file system (DFS), the administrative file, and the action package
- Ensure distribution of the written decision

EFFECTIVE DATE

This MAPP is effective on the date of publication and will be implemented as a pilot for 1 year from the date of publication. At that time, the process will be evaluated and modified as needed.