

MEMORANDUM of UNDERSTANDING between  
FOOD and DRUG ADMINISTRATION and  
NATIONAL TREASURY EMPLOYEES UNION CHAPTERS 254 and 282  
regarding the IMPACT and IMPLEMENTATION of RESOLUTION of DIFFERING  
PROFESSIONAL OPINIONS and EQUAL VOICE MAPPS

This constitutes the agreement of the parties (the National Treasury Employees Union (NTEU) and the Food and Drug Administration (FDA or Agency) concerning the implementation of the differing professional opinions (DPO) and equal voice (EV) policies and procedures (MAPPS).

The EV MAPP will provide the framework and principles for the implementation of Equal Voice (EV) in the Center for Drug Evaluation and Research (CDER). The DPO MAPP will provide the Center for Drug Evaluation and Research (CDER) staff a procedure to express differing professional opinions concerning regulatory actions or policy decisions with significant public health impact in instances when the normal procedures for resolving internal disputes are not sufficient.

In order to implement the above described MAPPS, the Parties hereby agree to the following provisions:

1. The Agency will add the FDA-NTEU Collective Bargaining Agreement (CBA) to the references section of both MAPPS.
2. "Alignment" will be defined as follows: "A state of general support for a position to be taken or a decision to be made. Alignment does not necessarily mean full agreement by all disciplines or organizational components involved in a decision. Rather, alignment indicates that all involved individuals agree to support the action to be taken. This alignment should be based on the knowledge that all perspectives (including alternative opinions) and a range of potential options were considered and informed and justified the final action. Therefore, the action to be taken can be considered reasonable, even if the action differs from an individual's recommendation(s). It is essential that the views of all persons involved in the review process be respected and that individual reviews should not be pressured to change their viewpoints if alignment cannot be achieved."
3. The definition of Administrative File will include a clarification that an employee who worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file.
4. The Agency will use "business days" to measure timeframes throughout the MAPPS, except where the MaPPs refer to the Agency Staff Manual Guide on dispute resolution, which uses calendar days.
5. The Agency will change the first bullet on page 4 of the DPO MAPP to read: "The package should be sent to the CDER Ombudsman."

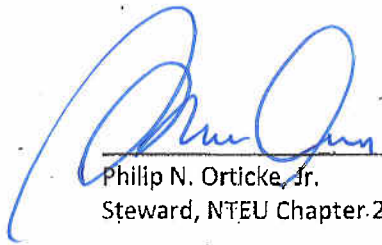
6. The Agency will expand the definition of “a significantly negative public health impact” in the DPO MAPP by adding the following parenthetical: “e.g., a major increase in the frequency, severity or both of a possible adverse effect or health outcome impacting a large subset of the population.”
7. The Agency will include the following language in the PROCEDURES section of the DPO MAPP: When practicable, individuals who participated in the decision-making process may recuse themselves from the DPO panel.
8. The Agency will add the following language to the 4<sup>th</sup> bullet in the POLICY section of the EV MAPP: “Concerns raised late in the EV process and/or close to the deadline by any party are difficult to incorporate in timely decision-making. Therefore, all participants in the decision-making process are responsible for raising concerns as early as possible in the process to allow adequate time for resolution of differences of opinion. However, it is understood that some concerns may not emerge until later in the review process, or that emerging concerns may subsequently impact a participant’s or participants’ opinions about the decision-making process or the decision to be made.”
9. The Agency agrees to modify the second paragraph of the Background section of the EV map as follows, “In most cases, alignment on a decision is achieved through discussion as the reviews proceed. It is essential that the views of all persons involved in the review process be respected and that **individual reviewers should not be pressured to change their viewpoints if alignment cannot be achieved.** The administrative file reflects differences of opinion ~~if~~ they exist.”
10. The two MAPPs and the FDA Staff Manual Guide 9010.1, Scientific Dispute Resolution at FDA will be discussed in the New Reviewer’s Training, not CDER orientation, which is a more general orientation and includes non-review staff.
11. Periodic training will be given to CDER bargaining unit employees about the concepts recorded in the two MAPPs and the FDA Staff Manual Guide 9010.1, Scientific Dispute Resolution at FDA.
12. This MOU will become effective upon Agency Head review under 5 USC § 7114 (c) (2) or on the thirty-first (31<sup>st</sup>) day after its execution date, whichever occurs first.

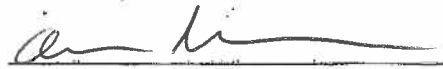
For NTEU/Chapters 254 & 282

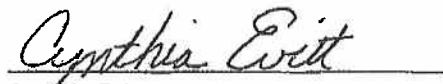
*August 26, 2010*  
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Executive VP, NTEU Chapter 282


For FDA/CDER

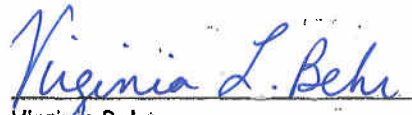
Deborah Henderson  
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Director, Office of Executive Programs  
CDER

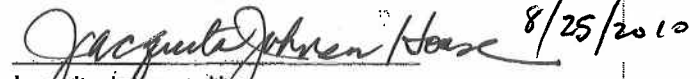
  
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