Accreditation Council for Continuing Medical Education
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November 20, 2014

Margaret A. Hamburg, MD, Commissioner
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2013–N–0502

Dear Commissioner Hamburg:

We write with comments specifically about PROJECT 2: HEALTH CARE PROVIDER EDUCATION UNDER REMS: REMS and Continuing Education (CE) for Health Care Providers, within the Report: "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) September 2014."

In the above documents, the FDA makes it clear that the Agency may want the education associated with its future REMS to:

- Be designed to address the risk of individual drugs, and to
- Contribute measurably to reducing risk

The FDA is considering mandating that the education associated with REMS be **accredited** continuing education because this would increase participation, provide access to new communication channels for REMS education, and recruit the educational standards and regulation of the CE accreditation systems of the ACCME, ANCC, and the ACPE in service of the goals of REMS.

The ACCME agrees with the FDA on these points, and looks forward, as we have in the past, to supporting the FDA's REMS initiative.

In the Report: "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies," the FDA observes that the past "effort to develop and implement a class-wide REMS-based CE training module proved to be a lengthy and intensive process" and that "To include CE training for individual drugs, FDA needs to determine if a more efficient approach would be feasible." The FDA outlines a process in which "the FDA will analyze, prioritize and adapt approaches to achieving priority objectives, and eliminate from further consideration approaches whose barriers cannot be mitigated or overcome. FDA will consult with stakeholders to determine their opinions and preferences about Agency decisions regarding priorities and objectives. The Agency will then synthesize findings and publish a report." The ACCME has represented our understanding of Project 2 of the Report: "Standardizing and Evaluating Risk Evaluation and Mitigation Strategies" in attachment 1.

We observe that the project plan has many similarities to the process used to develop the ER/LA Opioid REMS, including the associated CE construct. We believe that we could apply some lessons learned from our recent experience with the "effort to develop and implement a class-wide REMS-based CE training module" to augment the project process – without impinging on the FDA's independence, authority, or procedural requirements.

We share the following from, "Why Good Projects Fail Anyway" by Nadim F. Matta & Ronald N. Ashkenas, *Harvard Business Review*, September 2003,

"Big projects fail at an astonishing rate."

"Unless the end product is very well understood, as it is in highly technical engineering projects such as building an airplane, it's almost inevitable that some things will be left off the plan. And even if all the right activities have been anticipated, they may turn out to be difficult or even impossible, to knit together once they're completed."

"Managers use project plans, timelines, and budgets to reduce what we call "execution risk"—the risk that designated activities won't be carried out properly—but they inevitably neglect these two other critical risks—the "white space risk" that some required activities won't be identified in advance, leaving gaps in the project plan, and the "integration risk" that the disparate activities won't come together at the end. So project teams can execute their tasks flawlessly, on time and under budget, and yet the overall project may still fail to deliver the intended results."

"The key is to inject into the overall plan a series of mini-projects—what we call *rapid-results initiatives*—each staffed with a team responsible for a version of the hoped-for overall result in miniature and each designed to deliver its result quickly."

From **Why Good Projects Fail Anyway,** by Nadim F. Matta and Ronald N. Ashkenas, *Harvard Business Review*, September 2003

Some of the issues causing challenges with the ER/LA Opioid REMS, as a case-study, can be attributed to these "white space risk" and "integration risk" concepts. For example:

- **Numbers of learners –** The model prescribed by the FDA through which REMS for ER/LA Opioids was integrated into accredited CME turned out to limit the education's reach from the start. The plan did not begin with a strategic analysis of how best to get to the most learners most efficiently. Also, the fact that conditions were set where non RPC- supported CE was essentially excluded from being counted added further limitations. In addition, commercial supporters' budgeting constraints added further limitations.
- The **amount of education on risk** , which is clearly a priority for the FDA, was significantly reduced by the FDA simultaneously saying that, **1)** the education should be a 2-3 hour module and at the same time saying that, **2)** the education must cover all of the "Blueprint." In the "white space" of this concept are the unknown prescriber-centered factors contributing to public risk. We need data to evaluate whether the blueprint content is the most effective for ensuring that prescribers reduce risk.
- The **collection and reporting of data** descriptive of the scope, content, and impact of accredited REMS CE enterprise is important. However, a myriad of issues occurring in the "white space" between the RPC, the FDA, and the ACCME have emerged as barriers to seamless integration, as we try to transform REMS CE into accredited CE. The process we have now 1) does not address the system issues that are contributing to complexity, 2) is reducing the perception of feasibility and 3) is untested as to its transferability to multiple single-product REMS.
- **The Blueprint itself –** was created to overcome an unanticipated "integration risk" that emerged in the "white space" of this project when several preconceived and fixed notions converged. Specifically, 1) the FDA had preconceived ideas about the correct content for accredited CE, 2) the FDA and industry assumed that because it was a REMS that industry would create the content, 3) the CE enterprise assumed that accredited CE providers would build content based on need, 4) the CE regulators would not allow industry to control content and 4) the FDA's position that the FDA had to approve all content before it was delivered to prescribers.

Together, we need to look for a solution to this dilemma that resides within the "white space" between each of our domains.

There are other issues, already identified, where barriers to the hoped-for outcome may lie in the "integration" and "white space." These may not be identifiable by the FDA working in isolation in Phase 2 of its proposed Project. For example:

- From risk to gap to need -- What is the feasible or viable way to translate the health outcomes we are trying to reverse into professional practice gaps from which professionals' educational needs can be identified? Perhaps a **rapid-results initiatives** designed to translate the product risk data and information supplied by the FDA into professional practice gaps and from that deduce the educational needs that underlie that gap.
- From need to activity – What is the best way to facilitate the seamless integration of educational needs into accredited REMS CE that can then be smoothly integrated into the education system of the learners? Perhaps another **rapid-results initiative?**
- Accredited REMS CE development as part of the approval process for new drugs – The execution of the appropriate REMS CE for a single, new product presents "white space" and " integration risk," as there is so much unknown patient risk and CE activities do not usually focus on one product. Our sense is that there is a great need, and great opportunity, for a rapid results initiative created by the CE provider community through which the CE provider community can develop models for integrating appropriate REMS CE for a single, new product into their programs.
- Plan-Do-Study-Act Cycle from the FDA to CE and back to the FDA again – In a manner of speaking, the FDA has invented an innovative Plan-Do-Study-Act Cycle for REMS CE that by default is burdened by the unique internal and external constraints present within each of the FDA, drug sponsor, and CE domains. Perhaps we could implement open and transparent **rapid-results initiatives** designed to simulate this PDSA process, building on the results of other rapid-results initiatives that will identify the impact the constraints are having on the innovation. Perhaps the project could suggest alternate pathways for mitigating the obstruction that respect the constraints.

We want the FDA project to succeed.

We recognize that the FDA is responsible to the people, through Congress, for ensuring drug products are safe and risk is minimized. We understand that the FDA has limitations and specifications on how it must proceed. However, we ask that the FDA consider integrating into this project the time and opportunity for input from several open and transparent "rapid result initiatives" into its process for determining the feasibility of accredited REMS CE.

This does not have to be a closed process. Many groups may be interested in convening stakeholders to produce feasible and viable models and solutions for the various open questions. The ACCME would be more than willing to convene groups over issues, especially important ones that other groups see as a priority for them.

Perhaps the FDA would request additional rapid results initiates along the way, during Phase 2, when it became evident that a new process was being created with other parts of the system expected to play a role.

And, in closing we reflect on another quote from Matta and Ashkenas:

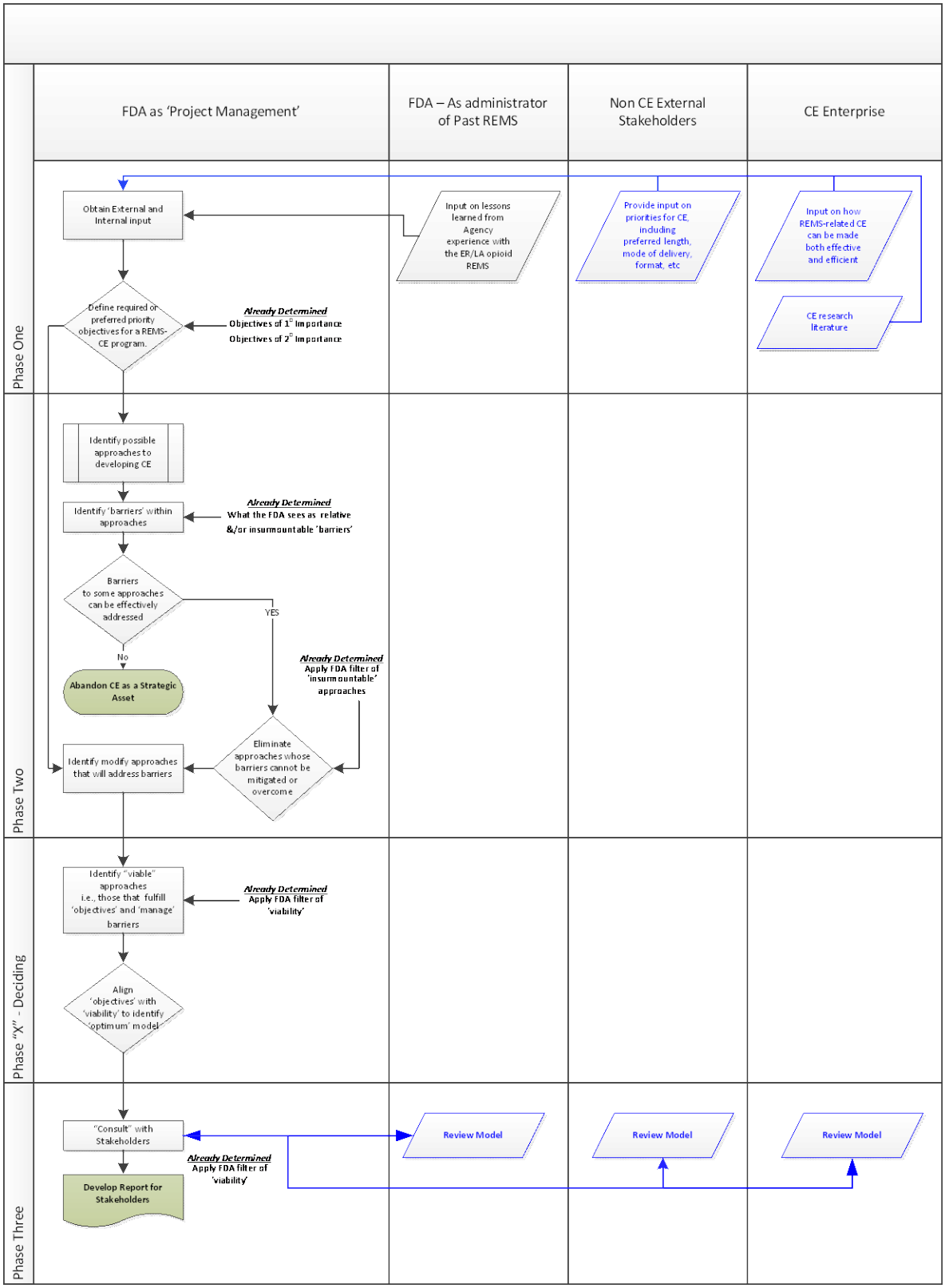
> "Attempting to achieve complex goals in fast-moving and unpredictable environments is humbling. Few leaders and few organizations have figured out how to do it consistently.
>
> We believe that a starting point for greater success is shedding the blueprint model that has implicitly driven executive behavior in the management of major efforts.
>
> Managers expect they will be able to identify, plan for, and influence all the variables and players in advance, but they can't. Nobody is that smart or has that clear a crystal ball.
>
> They can, however, create an ongoing process of learning and discovery, challenging the people close to the action to produce results—and unleashing the organization's collective knowledge and creativity in pursuit of discovery and achievement."

From **Why Good Projects Fail Anyway,** by Nadim F. Matta and Ronald N. Ashkenas, *Harvard Business Review*, September 2003

We applaud the FDA for its willingness to utilize the accredited CE system as a strategic asset. We are respectful of the due-diligence process the FDA has outlined and look forward to participating.

Sincerely,

Murray Kopelow, MD, MS(Comm), FRCPC
President and Chief Executive Officer


FDA as 'Project Management'
FDA – As administrator of Past REMS
Non CE External Stakeholders
CE Enterprise
Phase One
Phase Two
Phase "X" - Deciding
Phase Three
Obtain External and Internal input
Input on lessons learned from Agency experience with the ER/LA opioid REMS
Provide input on priorities for CE, including preferred length, mode of delivery, format, etc
Input on how REMS-related CE can be made both effective and efficient
CE research literature
Define required or preferred priority objectives for a REMS-CE program.
Already Determined
Objectives of 1° Importance
Objectives of 2° Importance
Identify possible approaches to developing CE
Identify 'barriers' within approaches
Already Determined
What the FDA sees as relative &/or insurmountable 'barriers'
Barriers to some approaches can be effectively addressed
YES
No
Abandon CE as a Strategic Asset
Already Determined
Apply FDA filter of 'insurmountable' approaches
Eliminate approaches whose barriers cannot be mitigated or overcome
Identify modify approaches that will address barriers
Identify "viable" approaches i.e., those that fulfill 'objectives' and 'manage' barriers
Already Determined
Apply FDA filter of 'viability'
Align 'objectives' with 'viability' to identify 'optimum' model
"Consult" with Stakeholders
Already Determined
Apply FDA filter of 'viability'
Develop Report for Stakeholders
Review Model
Review Model
Review Model