Is a Major Reorganization of FDA Underway?

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The Food and Drug Administration operates in an environment where laws, scientific knowledge, product complexity, and public expectations continually evolve. Regulations constantly change to keep pace with emerging public health issues, industry advancements, globalization, and consumer needs. In September 2013, FDA Commissioner Margaret Hamburg, announced the formation of a working group within the agency, known as the Program Alignment Group (PAG), to be comprised of executive-level members of every center in FDA, including the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA).

The Program Alignment Group Recommendations

The PAG was charged with evaluating how to bring greater clarity and transparency about relative roles and responsibilities within FDA, as well as improved operational and program alignment to avoid duplication of function and effort. The Commissioner noted that this work was "imperative" for FDA to succeed in the future and opined that the agency needed to transition to an agency with "coherent policy and strategic development, well-designed and coordinated implementation and a de-layered management structure."

Although the work of the PAG has operated with little publicity, on February 3, 2014, Commissioner Hamburg disclosed the recommendations of the PAG for a newly aligned agency in a memo to executive-level staff.[1] The purpose of the new alignment is to "chart a course for modifying Agency functions and processes to improve communications and collaboration and to clarify roles, responsibilities and decision rights across all agencies." The intent is to organize FDA's regulatory and compliance activities around well-defined commodity-based and vertically-integrated regulatory programs.

The memo identifies six "core" areas around which FDA will organize its regulatory and compliance activities:

1. Pharmaceutical quality (including drugs regulated by CDER and veterinary drugs)
2. Food and feeds
3. Medical devices and radiological health
4. Products regulated by CBER
5. Tobacco
6. Bioresearch Monitoring (BIMO)

These specific areas of regulatory focus will have direct governance and budgets to ensure resources are allocated to strategies, priorities, goals, and training to advance performance and oversight in these distinct areas. FDA will also apply this commodity-based approach to its import operations. Likewise, FDA laboratories will also become more specialized and will report to a senior executive level scientist heading the Office of Regulatory Science within ORA. As part of this overall alignment, the Commissioner noted that although ORA will be more fully aligned with the

1 The memorandum may be accessed here: http://www.agg.com:80/files/uploads/Documents/Program Alignment Recommendations - Decision.pdf

centers, it will not lose its operational or fiscal resources.
The PAG recommendations also endorsed the implementation of specialized resources when needed. For example, it was pointed out by the PAG that some medical devices have become so complex that sub-specialists in a specific technical or medical field may be necessary to carry out effective oversight. Likewise, advanced training and new methods of management within ORA may be required.

FDA also indicated it plans to develop a new work planning system tailored to risk factors, public health outcomes, past inspectional history, and operational experience. The objective is to incorporate a multi-year outlook on agency priorities and activities to achieve effective management of resources to meet future program needs.

In addition, FDA plans to revise the way it implements compliance policies and enforcement actions to limit ineffective layers of case review to improve coordination and prioritization.

Next Steps

The Commissioner acknowledges in her memo that many details will need to be worked out to implement this new course. In particular the extent and pace of specialization in the six core commodity areas must be decided with more specificity. In this regard, all Center Directors, the Deputy Commissioners for Foods and Veterinary Medicine, Global Regulatory Operations, and the Associate Commissioner for Regulatory Affairs must establish an Action Plan for each program that will define with more precision the operational changes and decisions outlined in the memo, as well as the processes for their implementation. The goal is to have all Action Plans complete no later than October 1, 2014.

AGG Observations and Comments

- As the PAG is an internal working group, still in its infancy, our comments are speculative but best-guess projections, based on our experience and familiarity with FDA. FDA has undergone “reorganization” of one sort or the other many times in the past, and it is premature, in our opinion, to label this a complete and permanent overhaul of FDA.
- As long as Commissioner Hamburg remains in her leadership post at FDA, implementation of these changes will likely progress. But, because of the agency’s visibility, the potential sensitivity of its decisions, and its ever-changing responsibilities, which are traceable to changes in the law from Congress, it bears repeating that no Commissioner is ever able to set a fixed, future agenda for the agency.
- These announced changes will likely not have an immediate direct effect on the regulated industry, as the present focus will be on internal changes within FDA. Over time, the described changes to FDA’s organization and focus may significantly affect the way FDA inspections and compliance decisions are handled, but, until then, companies subject to FDA’s jurisdiction will probably experience little or only incremental change.
- Commissioner Hamburg is action-oriented and tends to get things done. However, we also know that FDA does not make or accept change suddenly, unless it is under pressure from Congress or the Secretary of the Department of Health and Human Services, or the agency is responding to a public health crisis. Most FDA Commissioners talk about efficiency, alignment, and collaboration, which are admirable goals, but are difficult to execute when trying to modify the culture of an entrenched government bureaucracy. That is, one should expect some internal resistance to dramatic organizational change. Indeed, the Commissioner in her memo acknowledges that the “move toward a specialized program-based model will take time and a level of organizational change across both the Centers/Directorates and ORA.” As a result, she admits that implementing this vision “will require further discussion and delineation in the near term regarding roles and responsibilities, metrics and accountability, and decision rights.”
- In addition, Commissioner Hamburg is a political appointee, and her tenure could end at the direction of the President, and certainly her position may change with the 2016 election. While she might continue if a Democrat president is elected, this is less likely if a Republican is elected. If a change in leadership at FDA occurs, a new commissioner might not advance the PAG initiative or could decide to go in a different direction.
- The announced overhaul will likely focus more on FDA’s post-marketing surveillance schemes and its inspection resources, which now are spread across the different centers. The planned changes are less likely to translate into significant change with regard to the marketing approval process for new products. The focus of the

PAG initiative is more on inspections, compliance, and enforcement, and less on product reviews within the centers. Where we might see some change is the use of an FDA inspector, who is more familiar with drug Good Manufacturing Practices, to conduct pre-approval or GMP inspections of pharmaceutical facilities, rather than the current prospect that such inspections will be performed by a random inspector in a District Office of FDA. This change should not affect the work of the review division directly, as this involves actions within ORA and the FDA District Offices. However, an indirect effect might be that a more thorough investigation could potentially delay product approvals if the inspection goes poorly or, conversely, might improve the review process by having a more knowledgeable and focused investigator centered on the most appropriate issues to ensure regulatory compliance.

- More likely, the effect of the PAG initiative on the operations of the review divisions likely will be mixed. To use FDA's phrase, it is trying to be more "commodity-based." As such, more experienced reviewers with particular substantive experience with a drug, therapeutic area, or technology might delay the application review with tougher questions, requests for additional data, and concerns about what has not worked in the past. Conversely, a more seasoned and proficient reviewer might improve the review process by concentrating on the most relevant questions and issues, cutting to the chase, being more clear in communications, and, perhaps, evidencing a willingness to "think outside the box."
- The "good news" is the PAG's decisions reflect FDA's recognition that, long-term, it needs to operate in ways that are more faithful to today's regulatory science and correlate to the increasingly cross-functional complexity of the majority of products FDA is tasked with evaluating.

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