PathWise

FDA Priorities for 2016

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Note: This White Paper focuses on FDA's strategic priorities for 2016. It is primarily divided into two areas; Biopharma (via CDER/CBER) and Medical Devices (via CDRH).

INTRODUCTION

At the end of each calendar year, FDA issues strategic priorities (areas of focus) that the Agency intends to emphasize the following year. This year is no exception. These priorities are typically communicated via formal presentations and informal conversations with department heads. The following is a combination of these sources, presented in order of priority (based on risk to the public). Although these priorities are divided into the two sectors mentioned above, it would be wise to read through both to get a better feel for the breadth and scope of all of FDA's initiatives.

BIOPHARMA (CDER/CBER)

PRIORITY 1) Fill 680 job vacancies. FDA's chronic understaffing has become acute. FDA feels that its mission to uphold the public safety is at risk. The primary areas of increasing headcount will be towards field inspectors.

> **WHAT IT MEANS TO INDUSTRY:** Expect more inspections, but from less experienced inspectors.

PRIORITY 2) The re-negotiation of the prescription drug, generic drug and Biosimilar user fee programs, which expire in 2017.

> **WHAT IT MEANS TO INDUSTRY**: There is no chance that these programs will expire (they make too much money for the Agency.) There is a high chance that the user fees will go up.

PRIORITY 3) Reevaluate the regulations on drug advertising and promotion in light of current jurisprudence around the First Amendment. Headlines were made regarding off-label

promotions via the First Amendment argument. FDA will not back off its stance that these promotions are a bad thing.

> **WHAT IT MEANS TO INDUSTRY**: too soon to tell, but don't start promoting product off-label just yet; FDA will find receptive legislators to help better define these regulations.

PRIORITY 4) Issue draft guidance on generic versions of abuse-deterrent opioid formulations.

> **WHAT IT MEANS TO INDUSTRY**: FDA is highly concerned over opioid abuse. FDA will encourage and fast-track development efforts on effective abuse-deterrent opioids.

PRIORITY 5) Integrate the Sentinel Network into routine drug safety activities.

> **WHAT IT MEANS TO INDUSTRY**: FDA wants to use technology driven initiates to improve post market drug safety surveillance efforts. FDA sees this as a great opportunity to harvest additional information that may not be apparent in normal surveillance activities.

PRIORITY 6) Further implement statutory provisions on track and trace legislation. Another priority is to continue implementation of Drug Quality and Security Act of 2013.

> **WHAT IT MEANS TO INDUSTRY**: Dispensers must be able to provide lot-level product tracing information—namely, transaction information, history, and statements—for 6 years.

PRIORITY 7) Continue drug label improvement initiative as "a lot of labels are out of date,"

> **WHAT IT MEANS TO INDUSTRY:** Continued scrutiny of labels controls.

PRIORITY 8) Develop a more robust process and policy documents on how to evaluate a biomarker as a surrogate endpoint for accelerated approvals.

WHAT IT MEANS TO INDUSTRY: FDA is encouraging a science-based decision process, and will allow biomarker surrogates, potentially streamlining clinical trials.

PRIORITY 9) Improve combination product inter-center review process. With increasing numbers of combination products and their complexity, FDA wants better coordination, especially amongst CDER/CBER and CDRH.

WHAT IT MEANS TO INDUSTRY: For those that do it right, a more streamlined approval process. For those that skirt the regulations; more pain.

PRIORITY 10) Continue to push standards development and standardized electronic submissions. Emphasis on eCTD formatting.

WHAT IT MEANS TO INDUSTRY: electronic is in; paper is out.

MEDICAL DEVICE (CDRH)

PRIORITY 1) Leveraging "Big Data" for regulatory decision making. Continued emphasis on science and data driven approaches.

WHAT IT MEANS TO INDUSTRY: You must establish safety and efficacy via a statistically relevant data set. With 'Big Data' tools readily available, industry cannot excuse themselves for a lack of access to data.

PRIORITY 2) Using evidence from clinical experience. High risk Class II devices with special controls will be scrutinized.

WHAT IT MEANS TO INDUSTRY: Be prepared for clinical trials to establish safety and efficacy for devices that require clinical evidence. Be aware that FDA is paying more attention to the need for clinical evidence.

PRIORITY 3) Improving the quality and effectiveness of reprocessing reusable medical devices. FDA has found issue recently with reprocessing and sterilization of reusable devices.

> **WHAT IT MEANS TO INDUSTRY**: increased scrutiny on reprocess techniques/ processes and sterility assurance.

PRIORITY 4) Developing computational modeling technologies to support regulatory decision making. See #1 above for similar emphasis.

> **WHAT IT MEANS TO INDUSTRY**: (same as #1) You must establish safety and efficacy via a statistically relevant data set. With 'Big Data' tools readily available, industry cannot excuse themselves for a lack of access to data.

PRIORITY 5) Enhancing the performance of digital health and medical device cybersecurity. Somewhat vague, but this refers to the continued implementation of the UDI guidance.

> **WHAT IT MEANS TO INDUSTRY**: you had better have and be implementing a UDI strategy. If you do not, it will become critical to do so this year.

PRIORITY 6) Incorporating human factors engineering principles into device design.

> **WHAT IT MEANS TO INDUSTRY**: It is somewhat incredulous that the HF principles have not already been universally adopted in Class II and Class III submissions, but if they have not yet been developed, urgently consider implementing right away.

PRIORITY 7) Modernizing biocompatibility and biological risk evaluation of device materials.

> **WHAT IT MEANS TO INDUSTRY**: Develop critical thinking (with risk) based decision making to rationalize the type and extent of biocompatibility testing needed with device submissions.

PRIORITY 8) Advancing methods to predict clinical performance of medical devices and their materials.

WHAT IT MEANS TO INDUSTRY: Utilize scientific computing methods to better predict safety and efficacy outcomes before testing in humans.

PRIORITY 9) Advancing the use of patient reported outcome measures in regulatory decision making.

WHAT IT MEANS TO INDUSTRY: FDA will deeply scrutinize non-objective measuring tools. Use validated patient reporting measurement tools.

PRIORITY 10) Collecting and using patient experiences and preferences in regulatory decision making. See above.

WHAT IT MEANS TO INDUSTRY: same as #9, above.

SUMMARY

As is the case every year, FDA has delivered specific goals and objectives for areas of emphasis for FY2016. Based on previous experience, these goals and objectives will indeed be priorities for FDA. It would be good internal company practice to ensure these priorities are reviewed and assessed for relevance within each companies' regulatory framework.

About the Author:

Peter Knauer serves as a Senior Compliance Advisor to Biotechnology and Medical Device companies. Peter has twenty-five years of experience in Regulatory/Quality Compliance, Product Development and Operations. Peter has lead nine successful NDA/BLA approvals, and multiple 510(k) medical device clearances. Previously, Peter served as COO, Vice President and Head of QA/RA/CMC for companies such as Symic Biomedical, BioUtah and British Technology Group (BTG) in the United Kingdom. He has also held leadership positions for Protherics UK Limited and MacroMed in Salt Lake City, UT. Peter started his career at Genentech, Inc. where he held numerous positions in pharmaceutical engineering and drug delivery management. Peter holds a Master's Degree in Mechanical Engineering from San Francisco State University and a Bachelor's Degree in Materials Science Engineering from the University of Utah.