

## ***Editorial***

### **The FDA's Critical Path Initiative: A Brief Introduction**

The US Food and Drug Administration (FDA) "is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation."<sup>1</sup> In addition, as of June 2009, the FDA is responsible for regulating tobacco products.<sup>2</sup> Fulfilling these responsibilities is a formidable task, much of which is taken for granted by the general public.

For many readers of this journal, the FDA's most salient role is regulation of the approval and marketing of drugs.<sup>3</sup> In that context, the FDA and the pharmaceutical industry are often portrayed or perceived as adversaries; however, their goals are much more aligned than that characterization would suggest. In fact, a less well recognized role of the FDA is its responsibility "for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable."<sup>1</sup>

In 2004, the FDA released a report titled "Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products."<sup>4</sup> This report served as a wake-up call, presenting sobering statistics regarding the huge gap between the substantial investment in basic biomedical research and the disappointing number of submissions of new drugs and biological products to the FDA and regulatory agencies worldwide. The pipeline of safe and effective medical products was actually contracting rather than expanding. Hence, there was growing concern that anticipated advances in treatment based on promising scientific breakthroughs (eg, genomics, proteomics) would never materialize.<sup>4</sup> Something needed to be done.

The Critical Path Initiative is the "FDA's national strategy for transforming the way FDA-regulated products are developed, evaluated, manufactured, and used."<sup>5</sup> As stated in the 2004 report, "To get medical advances to patients, product developers must successfully progress along a multidimensional critical path that leads from discovery or design concept to commercial marketing."<sup>4</sup> To facilitate the steps along this path, better scientific tools and processes are being developed to improve the efficiency of preclinical and clinical trial research, including new approaches to safety testing, trial design, end-point development, and analyses. The intent is for these tools (eg, biomarkers, patient-reported outcome measures) and processes to be developed collaboratively in a precompetitive environment so that they can be made available to all researchers and developers of medical products (eg, pharmaceutical firms) who can use them.<sup>6</sup>

After more than 20 years in academia, I am now Director of the Patient-Reported Outcomes Consortium within the Critical Path Institute (C-Path). C-Path is a private, nonprofit organization created by the University of Arizona and the FDA in 2005 that is dedicated to supporting the FDA's Critical Path Initiative.<sup>7</sup> C-Path is one of a few organizations that have formed public-private partnerships with the FDA to address priority areas within the Critical Path Opportunities List.<sup>8</sup> Another is Duke University, whose Clinical Trials Transformation Initiative is aimed at improving the quality and efficiency of clinical trials.<sup>9</sup>

The goal of the Critical Path Initiative is to ensure that the science associated with the medical product development pathway keeps pace with the tremendous advances in basic biomedical sciences. Everyone gains when those advances can be translated more rapidly into safe and effective innovative therapies. The Critical Path Initiative is a joint effort involving scientists from industry, academia, and the FDA, and I am honored to be a part of it.

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