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Convergence of regulatory affairs and reimbursement/market access

The purpose of this study is to describe the evolution of convergence drivers between global regulatory science and reimbursement paradigms, outline the similarities and differences between 'safety and efficacy' and 'reasonable and necessary and to explain how cost effectiveness variables can be considered during evaluation of drug approval applications. In the European Union, specifically the UK and Germany, regulatory approval and reimbursement determination for biomedical products goes hand in hand. But few biomedical product companies in the US have taken advantage of the pilot programs that enable, for example, the parallel pursuit of both FDA approval and CMS national coverage determinations. These are intended to alleviate some of the process heavy FDA and CMS requirements that the industry often views as hampering innovation. At the same time, pursuing both approvals to market and universal coverage with Medicare in parallel can seem daunting to biomedical product developers. It calls for smarter study design that matches the expectations of the FDA, CMS and private payers. That means not only focusing on clinical endpoints that prove the products to be safe and effective, but also demonstrating that the product is reasonable and necessary, and superior to others in its category. This presentation will outline both the benefits to the parallel review pilot program on the device side and the key factors device developers need to consider when pursuing a joint approval, including: Advocate for more transparency in the process – medical device companies often shy away from opening the door to a conversation with the FDA, but in this case, dialog and gathering as much information as possible is key; establish guiding principles – timelines and expectations for both the FDA and CMS need to be clearly defined before trials begin; know when to call it quits–device developers can withdraw from the process at any time and need to see and interpret signs for decoupling the pursuit of both milestones. Through better design of the clinical development process, biomedical product manufacturers can address both regulatory science as well as payer standards during the commercialization process.

Biography

Stephen F Amato has over 25 years of experience in the pharmaceutical, biotechnology and medical device industries. He is the Program Director of the Biomedical Regulatory Affairs Program in the Professional Advancement Network (PAN) at Northeastern University. Steve has also been the Managing Director of tJun 17 Life Sciences, LLC, an organization that facilitates the global commercialization of early stage medical technologies. Prior to founding and directing operations at tJun17 Life Sciences, Steve was the Executive Director of Marketing at Anika Therapeutics where he served as the Head of Anika's Marketing Department. In this role he managed all aspects of the company's product portfolio including market segmentation, targeting, and positioning, pricing and promotional strategies. From 2000 to 2007 he was the Group Director of Knee Repair at Smith & Nephew Endoscopy where he managed a $140 M orthopedic product portfolio. Earlier in his career, Steve worked for Visible Genetics, where he was responsible for developing and launching genomic molecular diagnostics products used for subtyping Human Papilloma Virus (HPV) and other infectious disease agents. He has also worked with Critical Therapeutics on the development and commercialization of treatments for gram-negative sepsis. Steve holds an AB in Biochemical Sciences from Harvard University, a in Molecular and Cellular Biology from Boston College's Graduate School of Arts & Sciences, and an MBA from the Carroll School of Graduate Management at Boston College. He has also received the US Regulatory Affairs Certification (RAC) designation and is a Consultant for the Regulatory Affairs Professional Society (RAPS).

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