FDA Regulation of Combination Products - Issue Brief
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INTRODUCTION

The Combination Products Coalition, a diverse group of drug, biological product, and medical device manufacturers with substantial experience in the combination products area, is concerned that lack of transparency in the way FDA regulates combination products could hinder patient access to innovative products that have the potential to make treatments safer, more effective, and more convenient. Combination products, comprised of a drug and a device, a biological product and a device, a drug and a biological product, or a drug, device, and a biological product, often incorporate cutting-edge, novel technologies that hold great promise for advancing patient care. Patients have already seen the benefit of combination products in therapeutic areas such as oncology, cardiology, neurological and metabolic disorders, and several other areas. Further, the explosion of new technologies such as mobile health, molecular diagnostics, and cellular and tissue engineering are expected to make available even more innovative products for patients.

ISSUE

The combination products industry has grown and is expected to continue growing at a rapid pace. This growth presents challenges to FDA's Office of Combination Products (OCP), which is tasked with timely responses to regulatory submissions as well as advancing combination product regulation. The OCP has excelled at informal, product-specific advice. However, to enable patient access to safe, effective, and innovative products, ***transparency*** and ***clarity*** on regulatory issues impacting combination products must be improved.

Transparency means that the FDA provides clear information regarding their current interpretation of regulation in an open and timely fashion. For combination products, industry particularly needs published (redacted) Requests for Designation (RFDs), Form FDA-483s, Warning Letters, and Untitled Letters relating to compliance with regulations applicable to combination products.

Clarity means that the information provided by FDA is consistent and can be meaningfully applied. The need here is particularly acute with respect to Good Manufacturing Practices (GMPs) and post-market safety reporting requirements for combination products, submission requirements (initial and post-market), classification and jurisdiction determinations, and clinical trials on combination products.

ACTION

We call on Congress to ensure transparency in jurisdiction, enforcement, and other regulatory issues impacting combination products and to ensure timely and transparent development of guidance and rules for combination products, without compromising access to Agency personnel. As a first step, Congress should strongly urge the Agency to include combination products within the Agency's Transparency Initiative. Information published under the Initiative would include the most common inspection observations and practices as they pertain to combination products.