Bloomberg Law

Pharmaceutical Law & Industry Report®

Drug Development

Cheaper Trials Would Lower Drug Prices, FDA Chief Advises

Decreasing the time and cost it takes to develop a drug would lower drug prices, FDA chief Scott Gottlieb said Sept. 11.

If drugmakers used combined-phase—also called seamless—trials, rather than the traditional three phases of study, they would save time, cut costs, and reduce the number of patients who have to enroll, Food and Drug Administration Commissioner Gottlieb said. Seamless trials are increasingly being used for oncology drugs, and the FDA's Oncology Center of Excellence is taking steps to better evaluate and cultivate this approach, he told attendees at a conference hosted by the Regulatory Affairs Professionals Society.

Reducing the time and cost of drug development will lead to lower drug prices. Developing a new drug takes 10 to 15 years and costs an average of $2.6 billion, Andrew Powaleny, director of public affairs at the Pharmaceutical and Research Manufacturers of America (PhRMA), told Bloomberg BNA in an email. But a consumer group has concerns that studying a drug in fewer patients could lead to more safety issues once the drug is on the market.

Potential Safety Issues While seamless trials offer opportunities to get drug products to patients quicker, the traditional three-phase trials offer built-in time to understand the long-term toxicities of a drug, Jeff Allen, president and chief executive officer of the Friends of Cancer Research, told Bloomberg BNA Sept. 12.

''But I think that's one reason this type of approach is often reserved for therapies that have a truly transformative potential and have demonstrated really unprecedented activity in which it's becoming clear that the size of the treatment effect and the associated benefits may outweigh the risks,'' Allen said.

Michael Carome, director of Public Citizen's health research group, told Bloomberg BNA Sept. 11 he's concerned that smaller clinical studies will lead to less information about the safety of drugs.

Carome said that safety data on drugs is already limited because the number of patients enrolled in a clinical trial is relatively small and the duration of the trial is short compared to the number of patients who are going to take the drug and the time they will take it in the real world.

''So already we have circumstances in which we don't know a lot about the safety of drugs, except for the most common, serious adverse events,'' Carome said. ''This push to make studies smaller is just going to exacerbate the problem.''

But Douglas Peddicord, executive director of the Association of Clinical Research Organizations (ACRO), told Bloomberg BNA in an email, ''reducing the number of patients that must be enrolled in support of development program studies is a positive for researchers and patients alike, as long as the FDA's high standards for evaluation of safety and efficacy are maintained.''

Drug Industry Support The pharmaceutical industry generally supports the idea of seamless clinical trials.

Mace Rothenberg, chief development officer of oncology for Pfizer Inc.'s global product development group, told Bloomberg BNA Sept. 12, ''We're delighted that Commissioner Gottlieb identified this as an area of exploration.''

Seamless trials have a valuable goal of improving efficiency and shortening times for new market entry, Rothenberg said.

On the other hand, Rothenberg added, people shouldn't think they can go from phase I, to phase II, to phase III in one simple trial. The most common situation might be a company going seamlessly between two of those phases, rather than all three.

It's important to recognize that the cost of drug development isn't the only factor driving drug prices, he continued. He said the drug's impact also is considered when setting its price, such as whether the drug delays disease progression, prolongs life, or cures a disease.

Companies also consider the impact of the drug on the overall health-care system when setting the price, Rothenberg said. So even though some drugs have a hefty price tag, they could be replacing a less effective treatment and the new drug could shorten hospitalizations, he said. Examples of this would be drugs that treat Hepatitis C or diabetes.

PhRMA's Powaleny also said, ''America's biopharmaceutical research companies are committed to working with the FDA to explore innovative approaches to drug development and clinical trials aimed at enhancing the efficiency of the development and review processes and accelerating patient access to safe and effective medicines.'' Members of PhRMA include AstraZeneca Pharmaceuticals LP, Bayer Corp., Merck & Co., and Novartis Pharmaceuticals Corp.

By Bronwyn Mixter

To contact the reporter on this story: Bronwyn Mixter in Washington at bmixter@bna.com

To contact the editor responsible for this story: Brian Broderick at bbroderick@bna.com

 ISSN 1542-9547