

New Drug Development in 2016 Progress, Challenges, and Prices

Faculty Presenter

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Scholars' Summaries

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Dr. Thomas Roberts' lecture focused on new drug development in 2016. He gave a very interesting overview on the new drugs that are being tested and precise information on the marketing business. I was deeply fascinated by his talk because it showed an incredible knowledge of the topic. Coming from another country, I especially appreciated his honest point of view on the excessive cost of many drugs and how the costs have increased in just a few years. It is shocking how much the patients have to pay for some drugs here in the United States compared to many other places worldwide, and the costs that the companies have to deal with during the process of approval of new drugs cannot be an excuse. This was the first time I had heard anyone talking about drug costs and how they can affect the many families that have to deal not only with a terrible disease but also with the risk of bankruptcy in order to continue treatment with drugs unaffordable for many. American policy should address this topic and demonstrate understanding that health care is a right, not a privilege only accorded to some.

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This lecture by Dr. Roberts highlighted the current state of drug development and future directions and challenges. In recent times, new drugs are being developed and approved at a faster pace than ever before in the history of this country. In recent years, FDA approval times have been around or below 15 months, and the total amount of time a drug is in development has shrunk from almost 15 years down to nearly 10 years. Additionally, pharmaceutical companies have become more cost effective, decreasing overall R&D spending per new molecular entity (NME) approval over the past decade. This is due in part to pharmaceutical companies developing an increased appreciation of the value in studying a drug in a selected population. While the market share may be greater in an unselected patient population, the probability of approval and value of a drug to a targeted population often are financially favorable. For the oncologist, this is exciting because it means trials are being conducted that are more in line with the goals of precision medicine – bringing the right drug to the right patient. However, drug development remains very risky. At present over 4300 companies are in drug discovery and development, while only 261 companies have developed a new molecular entity (NME) since 1950. Importantly, dozens of NME drugs enter clinical trials and fail to successfully bring one new drug to registration. Further, the oncology space is crowded with over 1500 antineoplastic drugs at some point in the developmental pipeline as of January 2014. A major issue that is gaining public attention is the rising cost of drugs. This has led to efforts to conduct value-based evaluation of drug prices, such as health outcomes per cost over time. Peter Bach has evaluated oncology drugs and found that monthly costs have grown exponentially over time. Worse, price does not seem to have any relationship to drug efficacy. The current rate of rising costs is unsustainable in the long term, but there are several models for bringing value-based pricing to oncology drugs, including allowing Medicare to directly negotiate prices, creating value-based pricing, allowing government agencies to use comparative effectiveness research, allowing Medicaid to require best price, encouraging net price transparency, or allowing re-importation of drugs. One innovative model was an agreement between Novartis and Cigna/Aetna on performance-based pricing for a novel heart failure medication, Entresto. The deal sets a reimbursement rate that falls or rises based on the drug's performance. In summary, while the efficiency of drug development continues to improve, rising drug costs will likely limit the system as it currently exists. New risk-sharing models between pharmaceutical companies and payors may help to preserve innovation while slowing the currently unsustainable rise in costs.