Massachusetts Institute of Technology

Program on the Pharmaceutical Industry

Our Mission and Objectives

At the MIT Program on the Pharmaceutical Industry (POPI), our research and educational programs explore the challenges and opportunities before the pharmaceutical industry from discovery and development of new drugs to issues of manufacturing and marketing.

A wide variety of factors are driving a major shift in what the "world" of pharmaceutical policy looks like. The past decade has been one of ongoing public debate about regulation, pricing, and healthcare financing. Meanwhile, the industry itself has undergone significant changes as a result of consolidation. All of this has unfolded in the context of unprecedented advances in medical science and technology – an area in which POPI has a particular interest. We seek to help guide the thinking about the new environment, one of growing uncertainty, widening challenges, and ever-increasing opportunities for the industry to make an even more substantial contribution to the health of society as a whole.

POPI's unique strength is the multidisciplinary nature of our research, which builds on the strong foundation provided by its residence at the Massachusetts Institute of Technology. Over the years, we have built excellent relationships with faculty across the Institute's schools, and this has allowed us to make our greatest contribution of expertise and resources. Today, we count among our researchers some 28 MIT faculty members and three research fellows. Our research and educational programs incorporate and integrate the life sciences and clinical medicine, management science, engineering, economics, and technology. Thanks to this unique strength, POPI is able to address the most pressing issues from a perspective that affords rich insights and deep understanding.

POPI is strengthened even more by our relationships with other academics around the world, who today number nearly two dozen. We also work with important thought leaders in industry and government. Students, too, are an important part of our strength. We have graduated 27 doctoral students and introduced dozens of MBA students to pharmaceutical industry topics. In all, we've reached more than 1,000 students. POPI has developed three new subjects at MIT, two new curricula, and our research has been used in another six. The students we educate at MIT graduate and move on to positions throughout the pharmaceutical industry, in other academic settings, and in government agencies, including the U.S. Food & Drug Administration.

The dispersion of our students bolsters our ability to draw on a variety of resources and perspectives to fuel the innovative thinking that is central to our research. We are also able to take advantage of MIT's outstanding corporate relations program, which involves major pharmaceutical firms and smaller biotech firms.

POPI ensures a wide audience for our research through a number of avenues. We visit nearly a dozen companies each year, and work closely with dozens of companies that supply data for our research. Our researchers make several presentations to industry associations and trade groups each year, including PhRMA, the National Pharmaceutical Council, and others. We have published widely in peer-reviewed journals, and two of our co-directors write a regular column on scientific and technological challenges facing the industry for a leading trade publication. We also meet regularly with government agencies and offer testimony to legislative committees.

All of these activities support POPI's objectives, which are – in short – to develop a deep understanding of the process of change in the pharmaceutical industry, and of the evolving role of the pharmaceutical industry in the delivery of healthcare.

POPI's Recent Accomplishments

Over our long history, POPI's contributions have been significant. Our research has helped create a more profound understanding of the dynamics of the pharmaceutical industry, the interplay of healthcare policy and drug development, and the criticality of ensuring that innovation thrives to ensure that society continues to reap the benefits of drug therapies. In the recent period, our research has helped advance knowledge in – among others – the areas of drug development for unmet medical needs, the economic evaluation of pharmaceuticals, improved drug manufacturing, the regulatory process, and the impact of technology as a driver of change in the pharmaceutical industry.

Targeting Unmet Medical Needs. Ensuring that new drugs reach the patients who need them is key to having the best possible healthcare system. The tremendous costs involved in developing new drugs for unmet medical needs, and the costs of the drugs themselves to payers, require that access and distribution be effective to the greatest possible degree. How can retrospective administrative databases of medical services utilization and costs help to identify scenarios of "undertreatment" of disorders that are in need of new and innovative therapies? To help identify the value of developing drugs for unmet medical needs, POPI research leaders Anthony Sinskey and Stan Finkelstein, in collaboration with David Wierz of Wyeth Pharmaceuticals and William Marder of the MedStat Group, have undertaken the task to measure the extent of unmet medical need. Using a large claims database for MS patients, they have preliminary results that suggest that the new and costly interferon therapies may be reaching only a portion of those who might potentially benefit.

The Impact of Health Plan Benefit Design and Consensus Guidelines on Care. Two POPI studies in the context of pharmaceutical therapies for asthma have reported results. One study, led by POPI researchers Ernst Berndt and Stan Finkelstein, and William Crown of the MedStat Group, analyzed medical claims data on nearly 20,000 patients with asthma, and found evidence suggesting that "tiered" systems of drug co-payment that are now common in managed health care plans do not appear to adversely influence treatment selection, as recommended in naturally-accepted consensus guidelines. The other study, led by Stan Finkelstein, and collaborators Randall Stafford (Stanford University) and Iain Cockburn (Boston University), analyzed a national physicians' survey database, and found that medical visits for asthma have declined, while consensus guideline consistent clinical care has gained increasing acceptance.

Improving Drug Manufacturing. POPI's Consortium for Advances in the Manufacturing of Pharmaceuticals (CAMP) Program works to identify, research, and develop new manufacturing technology. CAMP's objective is to improve healthcare delivery by lowering product costs, increasing quality, and decreasing new product time-to-patient. Major headway has been made to develop and disseminate its light induced fluorescence (LIF) technology. Under CAMP directors Charles Cooney and G. K. Raju, LIF has been licensed to Honeywell, and the first units have been placed in CAMP-member pharmaceutical companies for applications in manufacturing. These instruments are being used in powder mixing product development, and in the monitoring of tablets emerging from a high-speed tablet press, enabling the sampling of tablets "non-invasively."

Ensuring Innovation Under Regulatory Regimes. Examining the factors that influence the rates of worldwide diffusion and market entry of drugs, POPI doctoral student Margaret Kyle found that drugs are more likely to be introduced in the "home" market of the sponsoring firm and when they have application in multiple therapeutic classes; and less likely to be launched in countries that regulate pharmaceuticals, especially when there is already a competitor in the market. She used econometric methods to analyze a panel dataset derived from every drug developed since 1980 that was introduced to the market in one or more of the 21 OECD countries. The results help inform decisionmakers in industry and government and are important input to corporate strategies and public policies with respect to pharmaceutical innovation.

Technology as a Driver of Change in the Pharmaceutical Industry. Only 18 new molecular entities (NMEs) were introduced to market by research-based pharmaceutical firms in 2002. Why did the industry achieve only what is a recent low, given the adoption and acceptance of new technologies, especially combinatorial and parallel approaches that have revolutionized drug discovery and have led to a record number of new targets and lead compounds? History suggests that the convergence of technologies is necessary to realize the full benefits of innovation. POPI research is examining how these advances in science and technology, relevant to drug discovery and development, are changing the way component "go/no go" decisions are made throughout the typical gestation period for a new drug. Focusing initially on the oncology therapeutic area, and using a dataset of cancer drug candidates assembled from published conference abstracts, we are finding evidence that new metrics of efficacy and toxicity, occasioned by advancing technology, are becoming widely used and are leading to more efficacious, targeted therapies.

POPI's Current Initiatives

POPI research has as its general theme the implications of advancing science and technology in drug development and changing medical practices. To advance our work in this area, we are holding three focused workshops to outline key questions to be addressed by our research teams. From those workshops, new teams of collaborating researchers will be constituted. They will bring together faculty and doctoral students from the multiple disciplines at MIT that have traditionally been a part of our research, along with representatives from industry and government. These projects are our current funding priorities.

Advances in Science and Technology and Their Impact on Changing Medical Practices in Pain Management. POPI is mapping scientific advances that are leading to pharmaceutical and medical device innovation likely to present new options for medical practitioners in the treatment of pain, as an example of what may take place in many therapeutic areas. The underlying notion of this research is that the "new biology" – network biology and "omics" – will lead to a portfolio of new therapies that will become available to treat disorders characterized by pain. Our research addresses questions about the incentives that need to be in place to make possible continued commercialization of such products, and also to ensure access on the part of persons who need those products.

Advances in Science and Technology and Their Impact on Changing Medical Practices in Diabetes Management. Two interrelated current epidemics in the United States – diabetes and obesity – create a challenge for effective intervention and an imperative for social action. The phenotype of diabetes is well understood, however, the difficulty of identifying specific genetic defects that play a primary role in pathogenesis has hampered drug development. POPI is identifying research questions that will explore how advances in clinical practice resulting from recent progress in science and technology will affect diagnosis and management of patients with diabetes.

Specifically, we want to look at efforts to target specific biochemical pathways and to refine the molecules that target these pathways. In addition, we will explore how technology delivered through point-of-service diagnostics can help create the rationale for pharmacological intervention to prevent diabetes complications early in the course of the disease.

Process Development and Regulatory Review in the Future of the Pharmaceutical Industry. Regulatory agencies and the pharmaceutical industry share a common goal of delivering safe and efficacious therapies. Tremendous opportunities exist for improving the strategies and tactics to bring therapeutic products to patients, but they are unfolding in an environment of changing technology, product innovation, and consumer expectations. What are the barriers to innovation in process development and review? How can uncertainty in process development and review be managed? What does the ideal manufacturing process look like? What is the objective of chemistry manufacturing and controls (CMC) review from the perspectives of the FDA and the industry? These are among the questions to address.

Therapeutic Decisionmaking in the Context of Behavioral Economics. The 2002 Nobel Prize in economics was awarded to Daniel Kahneman for having integrated insights from psychological research into economic science, especially concerning human judgment and decisionmaking under uncertainty. This research will apply some of those insights to the process of medical treatment selection. We will explore the problems inherent in the fact that patients are unable to predict accurately at one time how they will feel and think at another time, and how this affects behavior. Since patients are often called upon to make decisions about courses of treatment such as chemotherapy that will have a strong impact on them in the future, these insights can be of tremendous value to the healthcare system. Meanwhile, an increasing number of technologies are becoming available to record and monitor physiological data. Simultaneously, people with chronic disease often make health-related decisions underestimating the long-term impact of choices and the relevance of past experience. Monitoring health can be used to expand the individual's frame of reference while making local decisions.

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