



# PHARMA'S FUTURE CHALLENGE

New rules, please!

By Professor Ralf Boscheck - August, 2008

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Escalating healthcare costs, fast rising drug expenditures and an apparent slowdown in the introduction of new pharmaceutical compounds and generics are rekindling antitrust concerns in Europe. Initiatives by the US Federal Trade Commission (FTC) and Department of Justice (DoJ) have signaled a return of antitrust to the sector. But public outcries over high-profile cases are no substitute for a dispassionate assessment of conflicting incentives, inconsistent regulatory standards and essential welfare tradeoffs.

Fundamental policy options need to be reconsidered to ensure a competitive supply of innovative, efficacious and safe drugs. Costs of prescription drugs, which are now three times more than a decade earlier, need to be contained. Yet, efforts to control costs by increasing substitution within or for particular drug classes may impede innovation incentives and safety considerations and invite gaming by the various stakeholders involved.

### **R&D investment and the generics challenge**

During the 1990s, annual R&D spending in the pharmaceutical industry swelled from \$8 billion to \$30 billion. By 2004, the average drug development cost per compound, pre-approval, was estimated to be around \$1.4 billion, and the average new drug required \$0.5 billion in sales to earn a return just above the industry cost of capital. As patents expire, the first generic competitor typically enters the market with a 20% to 30% discount relative to the branded product, capturing about 44% to 80% of total sales within the first full year of launch. To hasten competition and thereby price reductions, the FDC Act, which regulates the generic drug approval process, provided incentives to challenge patents. It also induced branded and generics producers to settle patent disputes in ways that may delay the entry of generics and reduce consumer welfare.

### **Off-label use: Policy standards in flux**

Next to patents, safety and efficacy standards create barriers to competition. The Centers for Medicare and Medicaid Services (CMS) – the dominant buyer in the US – has been wavering in its commitment to off-label uses and has restricted reimbursement of off-label prescriptions to those considered medically acceptable by a limited number of CMS-approved compendia. Policy standards are in flux.

## Off-label promotion, FDA regulation and efficiency concerns

Widespread off-label use is often seen to reflect the fact that actual treatment conditions do not match the accepted scientific set-up or that peer-reviewed, scientific progress outpaces the FDA certification process. This raises concern about the efficiency of centralized drug approval and the true risk of drug misuse, and also touches the very *raison d'être* of the federal regulator. The FDA requires proof of safety and efficacy, respectively, before drugs could be marketed. Prescription drugs in the US must have at least passed phase I clinical trials. But then, who or what verifies off-label claims and how may such claims be used?

## Looking beyond central regulatory control?

US legislatures and courts are growing less supportive of the agency's restrictive view on off-label prescriptions and permissible promotional allegations. Its "paternalism" is seen by some as often counterproductive, largely economically inefficient and not always based on superior performance. Is one to look beyond central regulatory approval? What are the costs and benefits of promoting innovation through time-limited intellectual property rights? Are there viable alternatives to centrally certifying product safety and promotional claims?

## Patents: Innovation versus access

Patents provide incentives for companies to undertake risky research by temporarily excluding followers from competing away supra-normal profits; they also entail the disclosure of information that may allow others to circumvent the original functional mechanism and thereby stimulate innovation and diffusion. But price distortion follows. Patents also limit efficient inventive incentives to the extent that monopoly profits do not capture the total social benefit of innovation, distort resource allocation in favor of curing rather than preventing diseases and drive so-called rent-seeking investments. Market-based answers, however, raise more questions than they are able to answer.

## Off-label drug use: Safety vs. lost benefits

Off-label use involves a trade-off between prescribing a potentially unsafe medicine and the cost of not prescribing a potentially life-saving drug. One could rely on publicly-funded clinical trials to generate valuable public information. This approach, however, is neither market-based nor does it answer the question who decides on what for whom. Moreover, its implied bureaucratic process may increase rather than reduce the actual or perceived level of drug lag and lack. Similarly, decentralized governance options – relying on industry self-regulation – and tort law may not be adequate either.

## Could decentralized controls based on central rules be the answer?

A review of the US experience points to the need to assess inconsistent regulatory standards. The current interest shared by many commentators in “thinking outside the box” – here in terms of proposing alternatives to the patent system and FDA regulation – seems unlikely to offer clear welfare improvements.

Efforts should be focused on stipulating efficient rules for dealing with patent disputes and settlements and the competitive impact of off-label substitutes. Rules are efficient if they can easily be applied across a wide range of cases and contexts without running the risk of taking too many wrong decisions.

Economists typically prefer decentralized controls based on central rules that capture clearly understood welfare trade-offs. Such rules are currently lacking in the US. As the European Commission embarks on a major antitrust inquiry into the pharmaceutical industry, one can only hope that its endeavor is accompanied by the necessary search for such principles.

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This article provides a sketch of the argument developed in Professor Boscheck’s chapter in the OWP Book 2008, *Riding the Winds of Global Change*, to be published September 2008.

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