

## **ANNUAL MEETING 2004**

### **GOVERNORS OF THE WORLD ECONOMIC FORUM FOR HEALTHCARE**

**DAVOS - THURSDAY 22 JANUARY**

## **ADDRESSING THE INNOVATION DIVIDE**

### **Imbalanced innovation**

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Hotel Derby, Fluela 1  
14.30 - 16.15

## The high cost of Europe’s “free ride” in pharmaceuticals

- Imbalanced innovation in the pharmaceutical industry has become a hot topic. Increasingly, Europeans are viewed as “free riders” at the expense of US consumers and insurers.
- Pharmaceutical companies must justify ever-increasing R&D investments even as the pharmaceutical profit pool has shifted heavily toward the US. From 1992 to 2002, the US gained 15 points of profit pool share—growing from 47% to 62%—while the EU lost 15 points of profit pool share—from 33% to 18%. The industry now depends on the US as its key source of R&D returns.
- But Europe’s ride is not free. Despite spending significantly less on drugs than the US, Europe suffers a net loss when all the economic and societal costs of the “free rider” model are added together.
- The model will be difficult to sustain over the next decade. The gap between its benefits and costs will become so large that the system is likely to break down.
- Therefore, fixing the “free rider” problem is in Europe’s self-interest. Leaders should act now, before the current system reaches the potential “tipping points” identified below.

Europe is getting a “free ride” on US lab coattails where pharmaceutical research and development is concerned. That’s the argument being made by US government and business leaders. They complain that pharmaceutical R&D spending has largely shifted to the US, where Americans pay the lion’s share of drug development costs. Meanwhile, they argue, consumers in Europe’s largest markets enjoy the fruits of that investment—at prices 25-35% lower than those Americans pay.

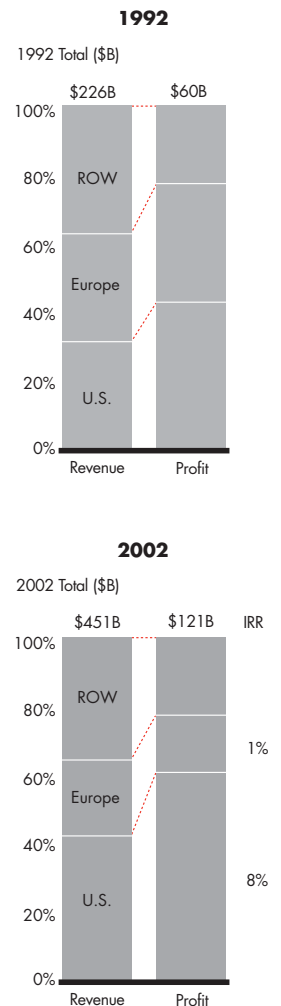
The debate on this issue has grown contentious. Americans charge that Europeans underpay for drugs by imposing onerous regulations on drugmakers that keep prices and utilization artificially low. Europeans retort that Americans overpay for expensive, marginally valuable medicines, thereby funding excessive industry marketing efforts.

Meanwhile, drugmakers must somehow justify unprecedented R&D investments totaling \$47B in Europe and the US. Yet expected rates of return on R&D investments in self-discovered drugs have fallen to 5%—compared with 9% in the late 1990s, and with the 10-12% cost of capital for pharmaceutical companies. Under the “free rider” model, the industry’s profit pool has shifted toward the US—leading many big companies to concentrate on the US, as well. (See figure 1) Indeed, the internal rate of return (IRR) for pharma companies in the US is 8%, versus 1% in Europe. As a result, the US has become the key source of returns on R&D investment for the industry.

But the conventional wisdom driving this debate—Europe profits, the US pays—is wrong. Our analysis shows that the social and economic costs to Europe, in the form of delayed access to drugs, poorer health outcomes and lower investments in research, make the model anything but free.

You don’t have to dig deep to see the stress points. Swiss-based Novartis decides to relocate its R&D to the US. Pfizer threatens not to launch certain drugs in France because of concerns regarding price levels and spillover risks. Foreign governments such as Australia feel pressure from the US in trade negotiations to increase drug prices. Empowered by the Internet, patients and physicians create new, nearly instant demand for the best medicines. And FDA commissioner Mark McClellan becomes the US government’s critic-in-chief of the “free rider” model, calling it “unfair and unjust” for Americans to bear a disproportionate share of drug costs.

Figure 1: The pharmaceutical profit pool is shifting toward the US



Source: Medical and Healthcare Marketplace Guide; IMS; Analyst reports; Expert interviews; Bain analysis

**Imbalanced innovation**

Solving the “free rider” problem is in Europe’s self-interest. Below, we lay out actions that governments and companies can take to address the imbalance. Our analysis isn’t perfectly precise. It’s not possible to nail down all the costs and benefits of the current model. Our goal is to come close, capturing a total system view based on available data and reasonable assumptions.

The innovation imbalance should not be cast as a standoff between Europe and the US. Instead, players on both sides of the Atlantic—and from government as well as industry—need to work together for lasting, systemic change.

**A “free rider” scorecard**

Europe seems to be in an enviable position. It spends 60% less per capita on pharmaceuticals than the US does—a gap that has roughly doubled since 1992. That trend has translated into major European savings: if Europe’s pharmaceutical spending per capita had matched the level of the US, Europe would have spent an additional \$160B in 2002 and \$840B cumulatively over the preceding decade. European governments are largely responsible for these cost differences. European regulations, which vary by market, have led to prices 25-35% lower than US prices for comparable drugs, while utilization rates for new drugs are 30% lower per capita than in the US.

Clearly, the “free rider” model creates direct, visible benefits for Europeans. The costs of the model to Europe, however, are equally real. They include less drug innovation; fewer high value-added jobs; loss of corporate research centers; and higher morbidity and mortality from diseases that could be treated with innovative drugs—if they were more readily available in Europe.

In drug innovation, for example, the US has outperformed Europe. In 1992, Europe-based R&D totaled \$10B, while investment in the US was \$9B. Over the next decade, however, US R&D investment increased 11% annually, to \$26B, while European R&D investment climbed 8% annually, to \$21B. The consequences for Europe: fewer high value-added jobs than in the US and thus fewer new drug patents that translated into commercial products.

The knock-on effect of this trend has been fewer first drug launches in Europe. From 1993 to 1997, Europe accounted for 81 unique new drugs, compared with 48 launched in the US. But the trend reversed over the next five years (1998-2002), when there were 44 launches in Europe versus 85 in the US.

The location of launches affects how quickly doctors and patients can access the most advanced treatments. The reason: lengthy reimbursement negotiations that follow government approval of any new drug. One study shows that the US averages a 4-month delay from initial drug launch to market. In Europe, this delay ranges from 7 to 19 months.

The considerable costs of the “free rider” model could outweigh its benefits. The key question, however, is whether the model is actually “free” in terms of its total economic and social impact.

**Adding up the cost to Germany**

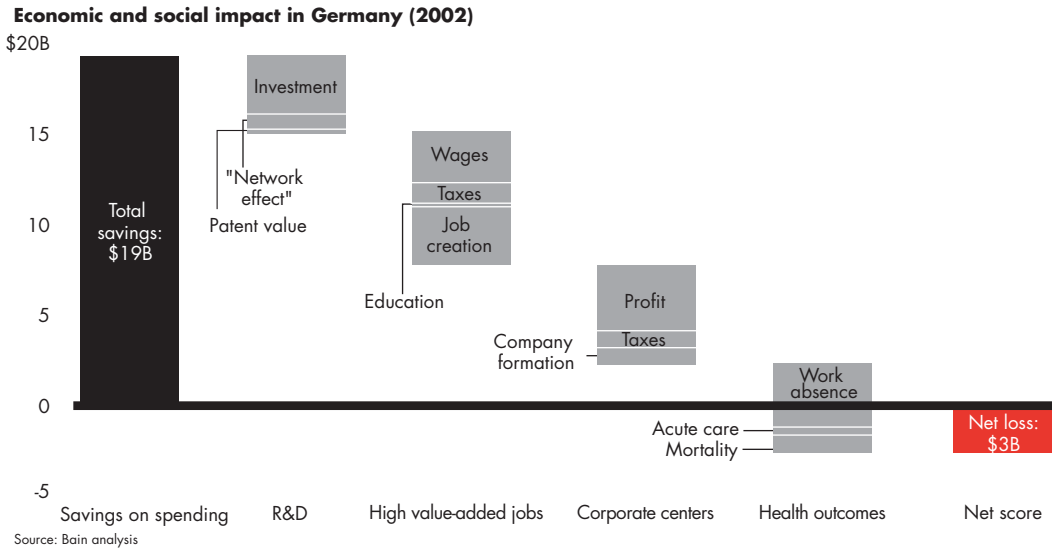
Consider Germany, which spends nearly 40% less per capita on drugs than the US does. In 2002, this saved Germans \$19B. But the country’s related losses totaled \$22B, leaving it with a net loss of \$3B. (See figure 2) The losses occurred in wide-ranging and sometimes unexpected places: in R&D spending (\$3B); in additional innovation spending that this R&D would have stimulated (\$900M);

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The key question is whether the model is actually “free” in terms of its total economic and social impact.

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Figure 2: The “free rider” model is not free for Germans



in lost patent value (\$200M); in high value-added jobs and the taxes not paid on them (\$4B); in associated jobs not created in supply and service industries (\$3.7B); in government training of high value-added workers (\$200M); in lost corporate centers, corporate taxes and local startup companies not spawned by these corporate centers (\$5B); and in poorer health outcomes driven by lowered access to the most innovative drugs (\$5B).

The calculus will differ for other European countries. But we argue that, in most if not all cases, countries are bound to score a loss.

**Tipping points**

Four industry trends are converging to push the model past the point of sustainability:

- The imbalance in pharmaceutical spending between Europe and the US is growing. If current trends continue, Americans will spend \$1,626 per capita on medicines in 2012—four times as much as Europeans.

- The industry is reallocating R&D investment from Europe to the US. In 2002, pharmaceutical R&D expenditures in Europe were roughly 20% below US expenditures of \$26B; by 2012, the European figure will fall to about half that of the US, based on current trends.
- The related shift in drug development and clinical trials leads to a preponderance of first drug launches in the US, with fewer than 10% of first launches occurring in Europe by 2012, according to trend lines.
- Delayed access to new drugs for European consumers may be linked to a widening disparity in health outcomes between the US and Europe.

These trends will likely combine over the next decade to dramatically expand the costs of the free rider model. The resulting stress, compounded by Europe’s aging population and advances in science, will likely push the system past one or more of the following tipping points, into unsustainability.

### 1. Doctor/patient backlash

European physicians and patients might revolt against growing delays and constraints in access to innovative drugs. Our 10-year projection shows that more than 90% of unique new drugs are likely to be launched first in the US. The result: more drugs would enter Europe later and face delays during reimbursement negotiations. Pharmaceutical companies may choose not to introduce certain drugs in Europe, because of lower returns and spillover risks.

### 2. The brain drain

Europe would likely experience accelerated “talent flight” as scientists and academics pursue more attractive opportunities in the US. Our 10-year projection shows that US R&D investment could become almost twice as large as that in Europe. European scientists and academics would likely pressure their governments to boost support for European-based research.

### 3. US price controls

It’s conceivable that the US government could impose price controls similar to those in European countries. Our 10-year projection shows pharmaceutical spending per capita in the US becoming twice that of Europe, and growing from 2% to 3% of US GDP. Faced with this situation, the US government might decide to fund only the US portion of pharmaceutical innovation. The industry would be forced to reduce its investment in R&D and, with it, the number of new drugs it creates.

### Taking action

In the long run, the “free rider” model appears neither free nor sustainable. Forging a solution will require critical trade-offs. While European leaders have begun a dialogue on some of these issues and have taken initial actions to reduce the system costs of the model, averting its collapse will require far-reaching change.

First, Europe could pay its “fair share” of drug costs. This would likely forestall US price regulations and ease industry pressure to slash R&D. European governments could pay higher drug prices across the board; pay prices proportional to their GDP per capita; pay full price for innovative drugs; and increase patient co-payments for pharmaceuticals.

Second, European governments could increase R&D incentives, reversing the “brain drain.” There are several means to this end: instituting tax breaks for firms’ R&D expenditures; broadening or extending patent coverage; boosting public spending on biomedical research; and funding more university-business linkages.

Third, Europe could expand access to the most innovative drugs, averting a backlash by physicians and patients. Governments could consider making faster regulatory approvals of new drugs; speeding up pricing and reimbursement negotiations; instituting open formularies and co-payments; putting fewer restrictions on direct-to-consumer communications; and disseminating drug information more widely and quickly.

The first critical step in taking action is for government and business leaders to reach agreement that the “free ride” is not free, and to recognize that all governments and all companies can benefit from bringing about change. Governments must begin by thinking more broadly. They need to recognize that focusing solely on drug prices is only one approach—and that it can distract from the opportunities for broader reforms described above. For its part, industry must tackle these issues in Europe with the same intensity and activism that it applies in the US. Working together, industry, government and all health-care stakeholders can then achieve a re-balancing, which will benefit the populations of all countries involved.

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