Chapter 4

Health Services in an Open Transatlantic Market: A European Perspective

Fabio Pammolli, Massimo Riccaboni, Chiara Bonassi

Introduction

Markets for health care services are much more complex than markets in other highly regulated industries, such as public utilities, due to asymmetric information. Unlike most publicly regulated goods and services, consumers often do not know, and can not ascertain themselves, the quality of health care service, and may not even be able to observe whether a suggested treatment quality was actually provided or not. "Credence goods" are goods and services whose quality is better understood by an expert than the consumer himself (Darby and Karni, 1973; Dulleck and Kerschbamer, 2006). Depending on market and institutional settings, information problems in the provision of health care services could lead either to undertreatment or to overtreatment and overcharging.

Traditionally, the provision of services has been mainly a domestic activity, while the pharmaceutical industry has been highly internationalized. However, technological change, trade liberalization and patient mobility are progressively opening up service markets to foreign competition. Thus, offshoring and trade of professional health services has been recognized to be a prominent example of a new type of trade (Bhagwati *et al.*, 2004; Mankiw *et al.* 2004; Markusen, 2005; Amiti and Wei, 2005). Medical services such as teleradiology (Levy and Yu, 2006) and arthroscopy (Baldwin 2006) are often cited as paradigm examples of how globalization might threaten highly educated workers both in Europe and the U.S.

Meanwhile, increasing consolidation of insurers, providers, and the health industry, including pharmaceutical companies, device manufac-

turers, and other suppliers of health services, is transforming national health care markets. The reduction of information asymmetries and patients' switching costs is affecting productivity and is modifying the sources of market power in health care.

Above all, health care is an innovation based, R&D intensive sector. Technical change is embedded in both goods, such as drugs and medical devices, and health care services, with important consequences in terms of static and dynamic efficiency conditions (see Ahn, 2002). Thus, markets for health care services have to provide incentives for both cost-reducing and quality-enhancing technological change. In other terms, the allocation of resources devoted to R&D and the direction of technical change are influenced by the way in which health care is financed.

The demand for health care is a function of the state of technology, and hence of previous R&D undertakings (Weisbrod, 1991). Historically, public coverage and insurance have sustained the development of quality-improving technologies. In his work in 1992, Newhouse states that almost three-fourths of the increase of health care spending in the last century is attributable to technological change. Jones (2002) finds that technological progress may have accounted for as much as half of total spending growth over recent decades throughout the OECD.

Finally, the health care sector is heavily regulated. In the past, regulation was designed to guarantee safety, efficacy, and quality and, moreover, to deal with potential market failures and need for complex chains of principal agent relations — patient-physician, physician-payer, payer-society — to deal with market and administrative inefficiencies associated with credence goods.

Regulation is not only meant to guarantee and improve access to better health services, but also to control health care expenditure, both on the supply side (tariffs, price controls), and on the demand side (co-payment schemes, formularies, contract design).

Historically, health policy has been under the responsibility of national state authorities. In almost all EU Member States health care is tax funded: healthy young workers pay for the care of sick, usually older citizens. Moreover, European countries have opted for different financial frameworks and regulation schemes to control health care costs, for both pharmaceutical products and hospitals.

Such a fragmentation of the European institutional and regulatory framework is preventing both the European Union and Member States from taking an active and positive role in balancing and aligning different interests through managed competition (see Abbott, 1995).

The current equilibrium is neither efficient nor sustainable. The total level of health spending and its allocation among different services and products tend to perpetuate national historic patterns of care and consumption, instead of responding to the interest of European patients in opening up health care markets to trade and dynamic competition. At the same time, universal tax funded systems and strict public regulation of health care markets in many Member States prevent the rise of a pluralistic system in which public coverage coexists with a complementary private insurance sector. In the past, young generations relied on future generations to pay for their care. At present, demographic changes—a falling birth rate and growing life expectancy—are likely to cause severe funding problems within the existing framework, which will worsen over the years.

Both in Europe and in the U.S. the key challenge for governments is how to design pluralistic systems of health care delivery and financing, in which multiple plans and market forces can act to promote competition.

Public and private programs can converge to make patterns of care responsive to individual preferences balancing different incentives, without imposing excessive financial burdens on individuals or denying necessary care because of inability to pay (see Feldstein, 1995).

In this context, public authorities should design fine-tuned regulatory policies in health care markets, stimulating innovation and dynamic competition and, at the same time, dealing with market imperfections and asymmetric information.

Against this background, this chapter focuses on some of the existing barriers to market integration and trade liberalization in health care. Institutional fragmentation in the regulation of health care markets tends to be remarkably high, since both health provision and financing are considered as key components of fiscal and redistributive policies by individual States.

There is growing demand for reducing administrative barriers to market integration in Europe. In 2005 the European Parliament, in its

"Report on Patient Mobility and Healthcare Developments in the EU," called for the Commission to act on a wide range of issues related to patient mobility and cooperation among national health systems, starting for harmonization of health payment schemes across member states. Coordination among European countries to deal with patient mobility starts to be perceived as a priority by an increasing number of European Countries and citizens, since intra-EU mobility has been increasing dramatically as a consequence of progresses in the EU labor market enlargement and integration. Such harmonization can be achieved only by reducing transaction costs and regulatory barriers and promoting a pluralistic system in health financing, with international private actors complementing the role of the public and contributing to both cross border mobility of patients and to a better integration of health services markets across the Atlantic.

The Institutional Context of Health Care Services in Europe

The regulatory framework governing cross border provision of health services within the European Union has become more and more complex over the last decade. Cross-border provision of services (such as remote diagnosis and prescription and laboratory services), and the use of services abroad are covered by Article 22 of Regulation 1408/71, now replaced by Articles 19-20 of Regulation 883/2004, under the primary purpose of granting social security coordination across member states. Permanent as well as temporary presence of providers in host countries is admitted under Directive 36/05, which regulates the recognition of professional qualifications. Thanks to better transportation and communications and lower cross-border restrictions, patient mobility is becoming the easiest way to benefit from cross-border provision of health care. At the same time, it calls for coordination among Member States' health care and funding systems.

In hospital markets, different schemes have been introduced both in the U.S. and in European countries to pursue allocative efficiency among providers. Diagnosis-related groups (DRGs) and prospective payment schemes have replaced cost-plus reimbursement schemes, stimulating efficiency in the use of inputs and competition among providers. Price regulation via "prospective-payment" insurance schemes can induce competition and mobility, provided that hospitals

compete for contracts with multiple institutional health purchasers. Providers are forced to compete reducing inefficiencies and "differentiating" their own services through specialization, instead of performing cost-shifting among patients (Anderson *et al.* 1993; Wallack *et al.* 1996).

Discussions on how to promote access to health care and hospital services in the Single European Market started in 1998, following a series of case law judgments by the European Court of Justice. Until then, the Community mechanism enabling patients to receive treatment abroad was designed by Regulation 1408/71. Urgent medical treatments were provided to EU citizens temporarily visiting a Member State according to the recipient statutory scheme, applying the reimbursement conditions and tariffs of the hosting country. Financial compensations between Member States were cleared either by computing current costs or on a flat rate basis.

According to the Community legislation, patients needed prior authorization from their competent institution in order to be reimbursed by their home country. In some cases national discretion has been limited as authorization has to be released whenever health treatments can be covered at home but with undue time delay.

This legal framework still remains in place, but in 1998, through the *Koll and Decker* rulings, the European Court of Justice established new principles on the reimbursement of health services provided to patients abroad. When health services are provided for remuneration, the fundamental principle of free movement of goods and services, set out in Articles 30 and 49-50 of the EC Treaty, must apply.

An important element of modernization has been introduced by Regulation 883/2004, with the European Health Insurance Card (EHIC), designed to assure direct provision of occasional and "necessary" health treatment in any EU country.

Moreover, the Court ruled that for non-hospital services patients may move in any other Member State without requiring prior authorization, and be reimbursed according to the rules of their home health system. However, in case of hospital services, state authorization is still required, subject to the condition that the home health care system cannot provide medical care within a reasonable limit of time.

In general, legal uncertainty still affects cross border health care provision in Europe. Available case studies[1] highlight that procedures under the EHIC scheme do not work efficiently; sometimes patients do not receive direct health care treatments and are forced to out of pocket payments. Furthermore, stringent national authorization policies for planned care have been undue obstacles of cross border provisions, limiting the choices of patients and the opportunities offered by the Single Market.

Information asymmetries can harm the negotiating process between health care purchasers and providers. In particular, when the quality of a service cannot be clearly identified ex-ante (i.e. before service delivery), a problem of incomplete markets arises. Incomplete contracts, in turn, increase the likelihood that further reductions in costs are made at the expense of quality (*quality-shading hypothesis*, Domberger and Jensen 1997).

As stated by the European Commission (2006) "a key concern about the application of internal market rules is clarity over which Member States' authority is responsible for supervising health services for each of the different kinds of health service.… For example, which authority is responsible for ensuring the quality and safety of health services provided to people from other Member States, whose complaints and how patients will be compensated when they suffer harm, and if there are errors, whose liability rules apply and how those errors will be followed up?"

Another important issue related to contracting in an international context is continuity of care. As a result, contracting with foreign providers should include arrangements for follow-up assessment and exchange of medical records and practices.

To deal with these issues, the European Parliament and the Council invited the Commission to develop specific proposals by the end of 2007.

[1] See M. Rosenmoller, M. McKee and R. Baeten (2006), *Patient mobility in the European Union—Learning from Experience.*

Fragmentation and Convergence in Pharmaceuticals

Control on public expenditure in pharmaceuticals has been pursued in most European countries mainly through price regulation schemes (price cap regulation, reference pricing, price volume agreements, price negotiations, cost effectiveness criteria, ex post price cuts). Traditional approaches to price regulation combined with the fragmentation of the regulatory framework have induced a bias toward static versus dynamic efficiency, thus reducing the price premium and market incentives for new innovative drugs *vis-à-vis* the U.S. market.

Since R&D activities in pharmaceuticals are more and more concentrated in the U.S. (see Pammolli and Riccaboni, 2007; European Commission, 2006), the current international division of labor does not appear to be sustainable, and a coordination effort between Europe and the U.S. has to be undertaken.

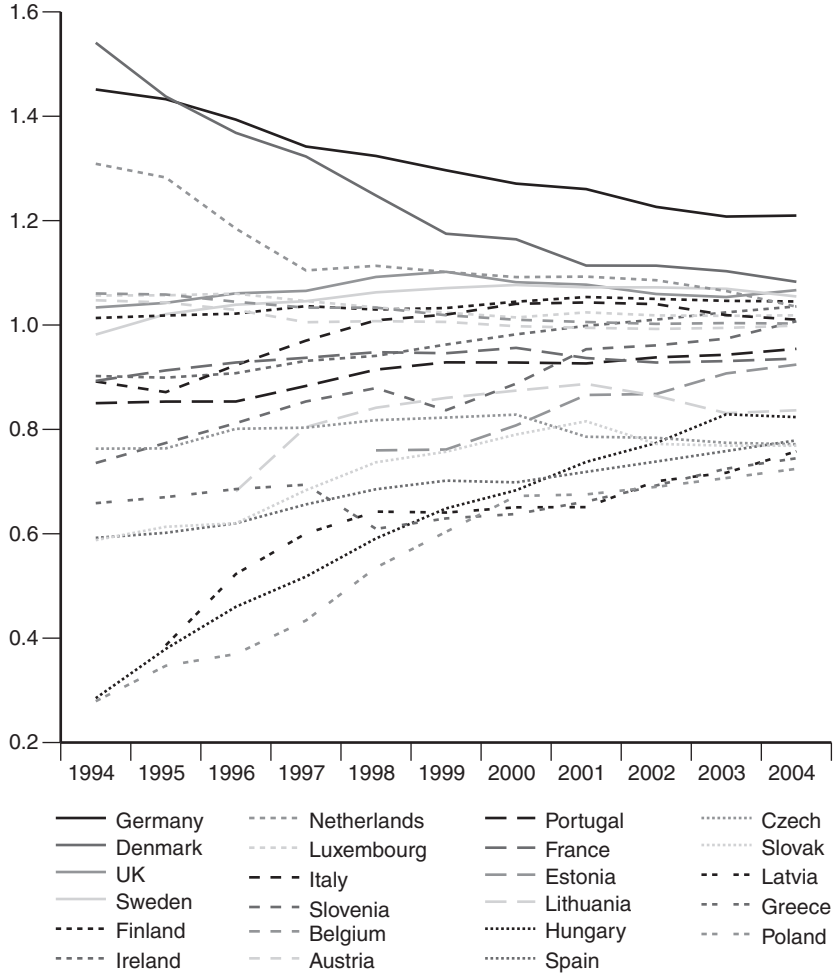
The pharmaceutical industry accounts for a large fraction of both private and public health expenditure. Kyle (2006) reports that the share of pharmaceuticals in total health care ranges from four percent in the U.S. to around 18 percent in France and Italy, while, according to OECD (2006), total health care expenditure as percentage of GDP is above 15 percent in the U.S., while for France and Germany it is higher than 10 percent.[2]

European markets are highly regulated, heterogeneous and fragmented. In France, Belgium and Spain cost-sharing is a proportion of the price of drugs. In the United Kingdom, Germany and Italy, co-payment is determined on a flat rate basis. Similarly, exemption schemes are highly differentiated: some countries such as Germany provide a maximum co-payment level; others, such as the UK, exempt the poor and elderly; and still other Member States specify particular categories of "essential drugs" for which there is no charge (Italy and France).

Other measures tend to influence physicians' prescription behavior through positive lists of reimbursable drugs or negative lists of non-reimbursable pharmaceuticals, clinical guidelines and financial incentives. Moreover, pharmacists sometimes have generic substitution rights if doctors have not formally opposed substitution of the branded products.

[2] For the U.S. and France the reference year is 2004, while for Germany it is 2003.

Figure 4.1 Price convergence in EU25, median prices, 1994-2004 (EU-15 average price = 1).



Source: our computations on IMS Health.

In this context, price convergence across national pharmaceutical markets has been driven by cross country reference pricing schemes and parallel trade rather than by regulatory integration and free market competition (Figure 4.1).

So far, efforts aimed at developing a Single Market for pharmaceuticals have failed. Excess fragmentation of pricing and reimbursement schemes, as well as cost containment policies in Europe, had a negative effect on both incentives to innovate and the introduction of new drugs.

Although there has been a gradual move towards harmonization of regulatory standards on market authorization (Mutual Recognition and Centralized Procedures), pharmaceutical companies still must negotiate with individual countries on price and reimbursement. Cross-country differences in price regulation schemes imply an excessive market fragmentation and, moreover, tend to delay the launch of innovative products.

Table 4.1 shows market concentration and relative prices of the first three products in each anatomic therapeutic class of pharmaceuticals (ATC4). Concentration is measured by the concentration ratio of the first n firms/products C_n (n=1,…,10) in the market. The one-firm/product concentration ratio C_1 corresponds to the market share of the largest firm/product, while the C_n index equal the sum of the market shares of the top n firms/products in terms of sales. Market concentration of the first product in nominal values can be broken down into two components: the concentration in real values—i.e. the number of standard units sold—multiplied by its relative price (the price of the first product divided by the mean price in the market).

Table 4.1 shows that the U.S. market is less fragmented than the EU market as a whole and all the most important national markets in Europe (Germany, France, Italy and Spain), with the exception of the UK. On average, the three leading products in each of the top one hundred therapeutic categories account for 85.6 percent of total market share in the U.S., as compared with a total market share of 77.3 percent in the EU-25.

The gap between the U.S. and the EU is wide in terms of sales, while the U.S. market is as concentrated as the European one in terms of volume. Thus the higher concentration of the U.S. market is due to the "premium price" that leading products can command. Indeed, the relative price of the market leader in the U.S. is 44 percent higher than the market average price (see Pammolli and Riccaboni, 2006).

The analysis of market shares of the leading companies confirms this view (Table 4.2).

Table 4.1 Average market concentration (sales and volumes) and relative prices of the first three products on the market, top 100 ATC4 classes, 1994-2004

	$C_1(S)$	$C_1(Q)$	P_1	$C_2(S)$	$C_2(Q)$	P_2	$C_3(S)$	$C_3(Q)$	P_3
EU-25	41.72	34.70	1.20	64.61	56.95	1.13	77.31	71.47	1.08
EU-15	41.18	34.17	1.21	63.83	56.05	1.14	76.53	70.49	1.09
U.S.	49.72	34.63	1.44	74.96	59.48	1.26	85.56	70.74	1.21
Germany	29.97	22.94	1.31	47.42	38.49	1.23	58.87	50.95	1.16
Italy	36.68	33.49	1.10	57.57	54.07	1.06	71.49	67.14	1.06
France	39.01	31.21	1.25	64.88	54.45	1.19	78.18	71.16	1.10
Spain	40.36	32.62	1.24	62.37	52.72	1.18	75.94	67.92	1.12
Czech Rep.	46.26	40.80	1.13	72.70	66.68	1.09	86.77	83.83	1.04
Portugal	46.73	39.65	1.18	70.41	61.34	1.15	84.32	79.63	1.06
Belgium	48.33	42.24	1.14	76.64	70.27	1.09	92.24	86.65	1.06
Austria	48.43	41.12	1.18	74.19	66.51	1.12	87.70	82.03	1.07
Netherlands	48.56	37.60	1.29	72.35	58.42	1.24	86.24	76.38	1.13
Luxembourg	49.54	39.93	1.24	76.49	68.20	1.12	89.91	83.20	1.08
Slovak Rep.	50.02	42.52	1.18	76.77	72.70	1.06	90.69	90.27	1.00
Poland	50.16	39.71	1.26	76.55	68.63	1.12	89.29	85.30	1.05
Ireland	51.19	43.77	1.17	77.50	72.42	1.07	91.76	87.10	1.05
Latvia	45.07	35.23	1.28	68.63	63.24	1.09	82.96	79.67	1.04
Lithuania	51.53	44.06	1.17	77.37	72.95	1.06	90.67	88.95	1.02
Finland	52.30	45.58	1.15	78.95	73.26	1.08	92.65	89.54	1.03
Greece	52.73	43.08	1.22	78.00	69.76	1.12	88.90	83.08	1.07
Denmark	53.50	45.22	1.18	80.34	75.33	1.07	93.07	91.05	1.02
Sweden	53.68	44.70	1.20	79.70	75.51	1.06	91.60	89.95	1.02
Estonia	54.71	45.13	1.21	80.74	75.51	1.07	93.32	91.67	1.02
Hungary	54.85	52.29	1.05	84.04	82.19	1.02	96.11	95.72	1.00
UK	55.69	48.34	1.15	79.61	75.16	1.06	90.20	87.75	1.03
Slovenia	61.25	54.13	1.13	88.25	84.98	1.04	97.89	97.47	1.00

Source: our computations on IMS Health.

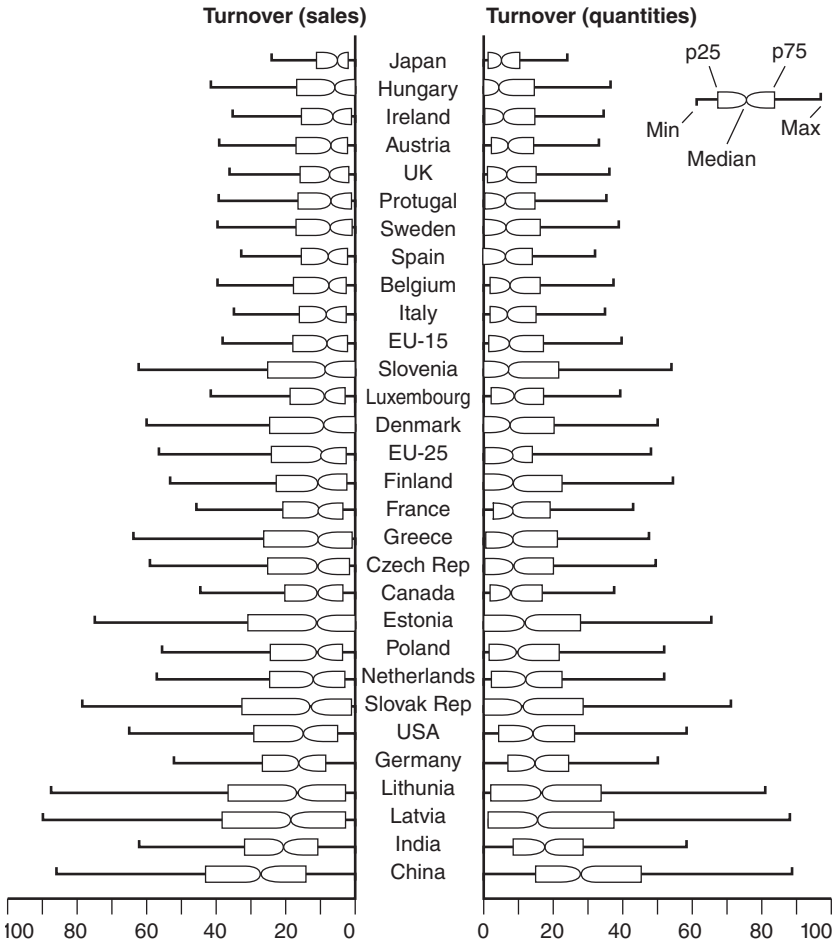
Table 4.2 Market shares of the leading company (C_1) and top three companies (C_3) and firm turnover, sales and volumes, 2004

	C_1		C_3		Turnover*	
Country	**Sales**	**Quantity**	**Sales**	**Quantity**	**Sales**	**Quantity**
EU-15	9.59	8.43	25.00	21.11	5.77	5.23
EU-25	9.40	8.29	24.78	21.24	5.76	5.04
U.S.	15.14	9.33	31.06	20.12	9.48	10.55
Italy	10.20	7.33	23.85	19.22	5.46	4.91
Belgium	12.31	8.02	29.14	21.16	5.71	5.42
Spain	9.84	6.34	21.96	16.70	6.17	5.24
France	16.95	14.77	30.92	29.94	6.22	5.69
Portugal	8.43	7.80	23.93	19.10	6.83	5.32
Germany	7.60	12.20	19.88	26.77	7.23	6.92
Finland	11.79	23.94	31.14	38.60	7.25	4.91
Ireland	14.88	15.61	33.45	30.95	7.41	6.45
Luxembourg	12.35	7.17	32.03	21.16	7.56	6.07
Austria	7.95	10.18	23.03	23.74	7.80	5.74
Greece	10.63	13.49	28.00	29.06	8.34	8.31
Sweden	14.52	21.87	32.96	43.88	8.84	7.16
UK	15.72	19.56	35.73	35.83	9.16	5.22
Hungary	9.86	19.34	28.96	38.38	9.84	7.68
Netherlands	10.72	15.55	27.37	33.42	10.05	8.70
Denmark	9.96	34.72	26.48	55.36	10.23	17.86
Slovenia	17.93	21.10	40.54	47.41	10.96	9.53
Poland	7.62	12.33	21.72	29.59	11.42	8.97
Czech Rep.	14.30	26.03	27.64	36.79	12.26	9.56
Estonia	9.33	7.04	24.36	19.36	13.94	16.72
Slovak Rep.	10.97	22.44	25.83	38.70	14.78	11.68
Lithuania	7.73	7.00	21.60	18.35	21.23	19.05
Latvia	7.58	6.20	19.39	16.83	21.98	22.89

*computed as in Hymer, Pashigian, 1962.

Source: our computations on IMS Health, Copyright 2005.

Figure 4.2 Product mobility statistics over all ATC4 therapeutic markets*



*The product mobility index is computed as in Hymer, Pashigian (1962).

Source: our computations on IMS Health.

Interestingly enough, higher concentration levels in the U.S. market do not imply less competition. Figure 4.2 shows the product mobility index for each therapeutic market (ATC4 class), defined as the sum of the annual change in the product market share (Hymer, Pashigian, 1962). Boxplots highlight the median value of the index and the 75th and 25th percentiles of the distribution. The most striking

Table 4.3 The persistence of the leading product in top 100 ATC4 markets

	Leadership change (%)										
Country	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**AP**
Portugal	6.42	6.36	7.62	9.26	7.74	4.95	5.86	9.88	8.72	9.06	13.18
Spain	6.50	9.97	7.20	10.37	7.33	9.74	7.95	6.98	8.55	8.53	12.03
Italy	7.40	9.72	8.14	9.14	7.79	7.01	9.84	7.51	9.66	7.41	11.96
Sweden	4.99	10.69	9.62	7.93	10.56	8.62	7.43	10.70	9.30	8.66	11.30
UK	10.46	8.92	8.00	8.71	10.16	8.38	9.11	9.50	8.16	7.24	11.28
Ireland	11.39	10.00	11.39	9.17	9.01	6.61	8.16	10.91	11.82	7.42	10.43
Belgium	8.36	7.24	7.56	9.58	9.78	11.36	9.86	10.31	11.52	11.08	10.35
Finland	7.76	9.67	9.85	9.79	10.88	9.50	7.19	11.24	11.31	12.06	10.08
Austria	7.32	9.38	10.09	11.31	8.92	10.54	13.84	9.53	11.78	9.82	9.75
EU-15	10.70	10.94	9.84	10.71	10.15	9.34	10.23	10.25	10.81	10.16	9.70
EU-25	10.95	11.14	10.05	10.97	10.43	9.52	10.30	10.36	10.89	10.40	9.52
France	9.30	10.57	9.82	12.01	10.42	10.28	10.00	11.00	12.76	11.28	9.31
Luxembourg	12.30	10.71	13.44	11.08	11.05	9.89	8.11	10.33	10.11	10.63	9.29
Hungary	14.46	14.98	13.67	12.67	10.67	9.86	5.26	9.73	7.07	10.93	9.15
Netherlands	9.61	10.59	11.54	10.18	14.24	10.85	11.08	10.39	9.04	12.28	9.11
Denmark	12.33	13.38	11.18	12.54	13.61	9.81	8.97	10.03	13.03	9.90	8.71
Greece	7.63	10.38	11.72	14.97	9.54	12.53	11.66	11.65	14.83	12.63	8.51
Germany	16.49	14.16	12.66	11.94	12.14	10.02	12.96	13.12	12.12	12.94	7.78
Slovenia	16.17	14.99	13.91	14.08	15.67	11.94	12.81	8.72	9.89	14.67	7.53
Poland	17.47	12.66	15.22	14.95	17.45	12.76	11.26	13.54	13.25	16.02	6.92
Estonia	0.00	0.00	0.00	66.67	11.59	11.55	16.52	19.46	16.77	13.69	6.40
Czech Rep.	18.37	18.55	15.27	15.74	18.58	15.82	13.56	11.65	16.58	13.42	6.35
U.S.	17.20	17.12	17.35	19.67	18.59	15.65	15.85	17.48	16.40	14.87	5.88
Slovak Rep.	22.22	21.35	18.86	26.32	21.28	14.74	13.76	13.31	14.66	18.70	5.40
Lithuania	0.00	73.10	28.03	25.23	22.09	19.51	28.19	16.57	17.83	19.29	4.00
Latvia	83.16	25.08	23.49	24.14	18.36	24.65	20.17	24.23	15.45	18.85	3.60

AP = Average Persistency.

Source: our computations on IMS Health.

Table 4.4 Product turnover as a share of existing products (top 100 ATC4 classes, 1995-2004)

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Avg.
Product entry rate (%)											
U.S.	12.15	16.64	18.81	15.30	15.45	9.05	14.13	n.a.	11.00	12.29	*13.87*
EU-15	9.12	9.53	9.15	11.78	11.07	10.62	9.41	9.98	10.28	10.71	*10.17*
EU-25	9.30	9.54	9.33	11.91	11.11	10.67	9.46	10.00	10.31	10.65	*10.23*
Product exit rate (%)											
U.S.	13.39	7.51	7.44	6.25	8.38	13.43	6.87	7.61	6.09	6.37	*8.33*
EU-15	n.a.	4.92	4.51	4.29	4.60	4.03	3.87	4.04	4.66	5.39	*4.48*
EU-25	n.a.	4.92	4.57	4.38	4.64	4.15	4.11	4.17	4.68	n.a.	*4.45*
Product turnover (%)											
U.S.	25.54	24.14	26.25	21.55	23.84	22.47	21.00	n.a.	17.10	18.66	*22.28*
EU-15	n.a.	14.44	13.66	16.07	15.67	14.65	13.28	14.02	14.94	16.10	*14.76*
EU-25	n.a.	14.46	13.91	16.29	15.76	14.82	13.57	14.17	15.00	n.a.	*14.75*
Product net entry (%)											
U.S.	-1.24	9.13	11.37	9.05	7.07	-4.38	7.26	n.a.	4.91	5.92	*5.45*
EU-15	n.a.	4.61	4.64	7.49	6.47	6.59	5.54	5.94	5.62	5.32	*5.80*
EU-25	n.a.	4.62	4.76	7.53	6.47	6.52	5.35	5.83	5.63	n.a.	*5.84*

Reported n.a. correspond to computed entry and exit rates outside the range of average turnover +/– two times the standard deviation interval, computed on the basis of observed product entry and exit rates.

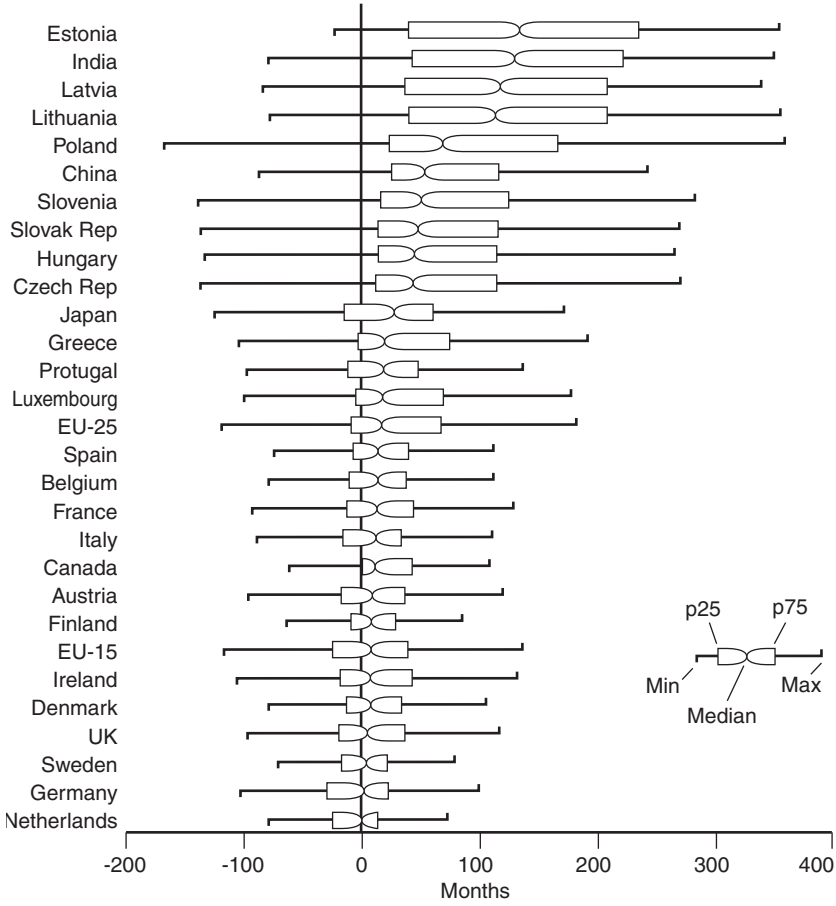
Source: our computations on IMS Health.

result is that firm turnover in the U.S. is almost double that of the EU-15 and EU-25.

The lower turnover of EU markets means higher persistency and lower market contestability. As an average, the persistency of the leading product in the U.S. is slightly less than six years, while in the EU it is almost 10 years (Table 4.3).

U.S. product turnover is more intense than in Europe (Table 4.4). Product exit rate and turnover are almost double in the U.S. than in the EU-15 (8.3 and 4.5 percent, 22.3 and 14.8 percent respectively). Product entry rates are more than 3 percentage points higher in the U.S. than in the EU-15. All in all, the process of creative destruction seems to be much less intense in the European markets than in the U.S., where new and improved products displace old ones in any given

Figure 4.3 Introduction lag (in months) from launch on the U.S. market of all molecules launched since 1975



Source: our computations on IMS Health.

therapeutic market. Low market contestability in Europe is one of the most striking consequences of market fragmentation and price regulation that undermines the productivity of European companies, since national barriers still limit, to a certain extent, the breadth of the market segment within which they can draw customers away from rivals.

Moreover, differences in price levels, as well as in reimbursement and co-payment schemes across countries, account for the delay in the

launch of new molecules in EU countries with respect to the U.S. (Danzon *et al.*, 2003; Gabrowski and Wang, 2006; Kyle, 2006).

Figure 4.3 shows that, with the exception of the Netherlands, European countries experience a time lag in the launch of new molecules. The median delay from the U.S. launch is eight months for EU-15,[3] which increases to 17 months for the EU-25.

In conclusion, EU health care markets are more fragmented and less dynamic *vis-à-vis* the U.S. due to regulatory barriers, which prevent market integration, competitive turnover, contestability, and dynamic competition. As a result, since patient, product and firm mobility are limited, price differences among countries persist to favor parallel trade and hinder product innovation.

Conclusions

Heterogeneous national regulatory frameworks, price regulation mechanisms and cost containment policies in Europe have a negative impact on market integration as well as on productivity and innovation in health care markets for goods and services.

The key challenge for EU governments is to design and coordinate pluralistic systems of health care delivery and financing, in which market forces and mechanisms of managed competition can act to generate an environment favorable to investment and innovation, while public and private programs can perform complementary functions to make patterns of care responsive to individual preferences without imposing excessive financial burdens on individuals or denying necessary care because of inability to pay.

The uneven geographical distribution of research efforts in pharmaceuticals, together with the differences in price levels for innovative drugs between Europe and the U.S., calls for revival of a transatlantic dialogue on the political economy of pharmaceuticals and medical technologies, through the lens of trade policy and protection of intellectual property rights.

[3] When considering the European aggregate, the comparison is made between the median launch across the European countries and the launch in the U.S.

Moreover, for Europe and the U.S. both productivity and the rate and direction of medical innovation will be affected by the interplay between technological advances and patterns of demand, especially in relation to the effective management of health and pharmaceutical expenditures to encourage innovation while preserving access and fiscal sustainability.

In the health care sector, Europe is suffering at the supranational level from the sort of institutional fragmentation that hindered transactions and stifled economic growth for centuries within European states themselves. In each country, the power of the state to set health and pharmaceutical policy is intertwined with political autonomy. Fearful of yielding power to the EU Commission, individual nations have private incentives to resist common reforms, regardless of the negative effects on productivity, mobility, specialization, and trade.

During the 18th and 19th centuries, problems of institutional fragmentation within European states were solved through the establishment of uniform national laws by central governments (see Dincecco, 2006). Standardization of domestic systems of weights and measures in the 19th century provides a useful illustration of centralization efforts. Beforehand, spatial fragmentation of weights and measures across towns and provinces raised the costs of commerce, hindering competition, specialization, and trade. With the implementation of nation-wide decimal systems, transactions costs between locales were significantly reduced, stimulating economic growth.

This is not to suggest that what Europe need is greater government involvement in the regulation of health care markets. The market forces that ultimately drive innovation and efficiency, rather than the visible hand of the government, should be encouraged and coordinated. In parallel, the EU Commission should have greater control over the underlying "rules of the game," establishing the legal framework that sustain market integration and patient mobility.

At this final juncture, a caveat deserves mention. A distinction between the interests of the EU as a whole and those of individual states must be made. The establishment by the EU Commission of a uniform set of rules governing health care and pharmaceutical markets in Europe would reduce transactions costs and promote efficiency through competition and market integration. In the long run, Europe

would benefit as a whole of the standardization of such rules, while rents accruing to individual countries and actors that had profited from the previous set of idiosyncratic institutional arrangement would be lost irrevocably. Hence, it is not surprising that states would resist institutional reforms with positive effects at the EU level if they were perceived to threaten traditional privileges (and associated revenue streams) at the national level.

It is precisely in this sort of situation, where the incentives of individual players diverge from the common interest, that a single centralizing authority such as the EU Commission should be granted the power to design an institutional framework that aligns the different sets of incentives of single member States.

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