

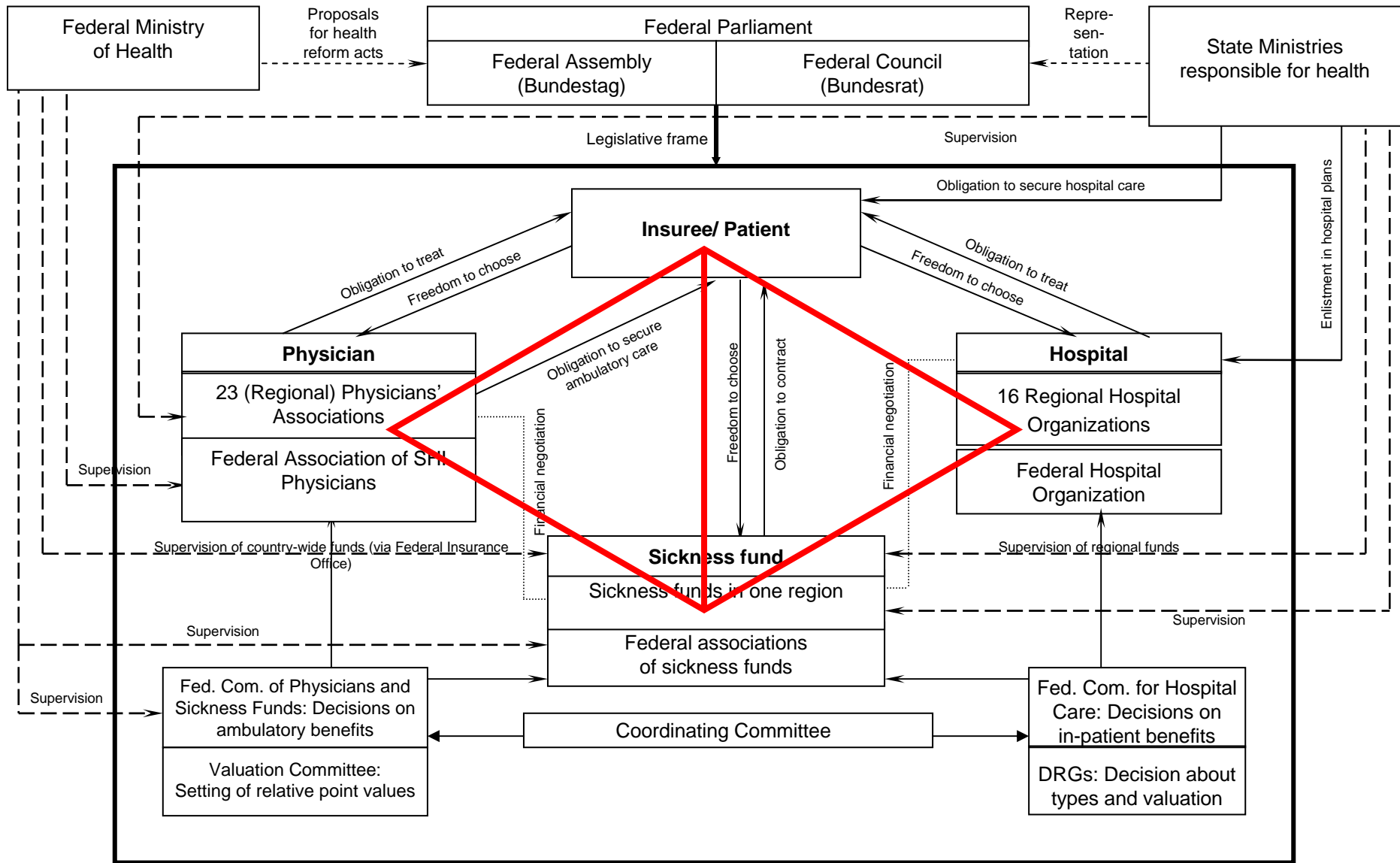
Pharmaceutical regulation in Germany: an overview

**Reinhard Busse, Prof. Dr. med. MPH
(together with K.-D. Henke & J. Schreyögg)**

**Professor of Health Care Management,
Technische Universität Berlin
Associate Research Director,
European Observatory on Health Care Systems**

Structure

- Decision-making in German health care
- Expenditure for pharmaceuticals
- Market interventions (and their effects)



Statutory health insurance 2000

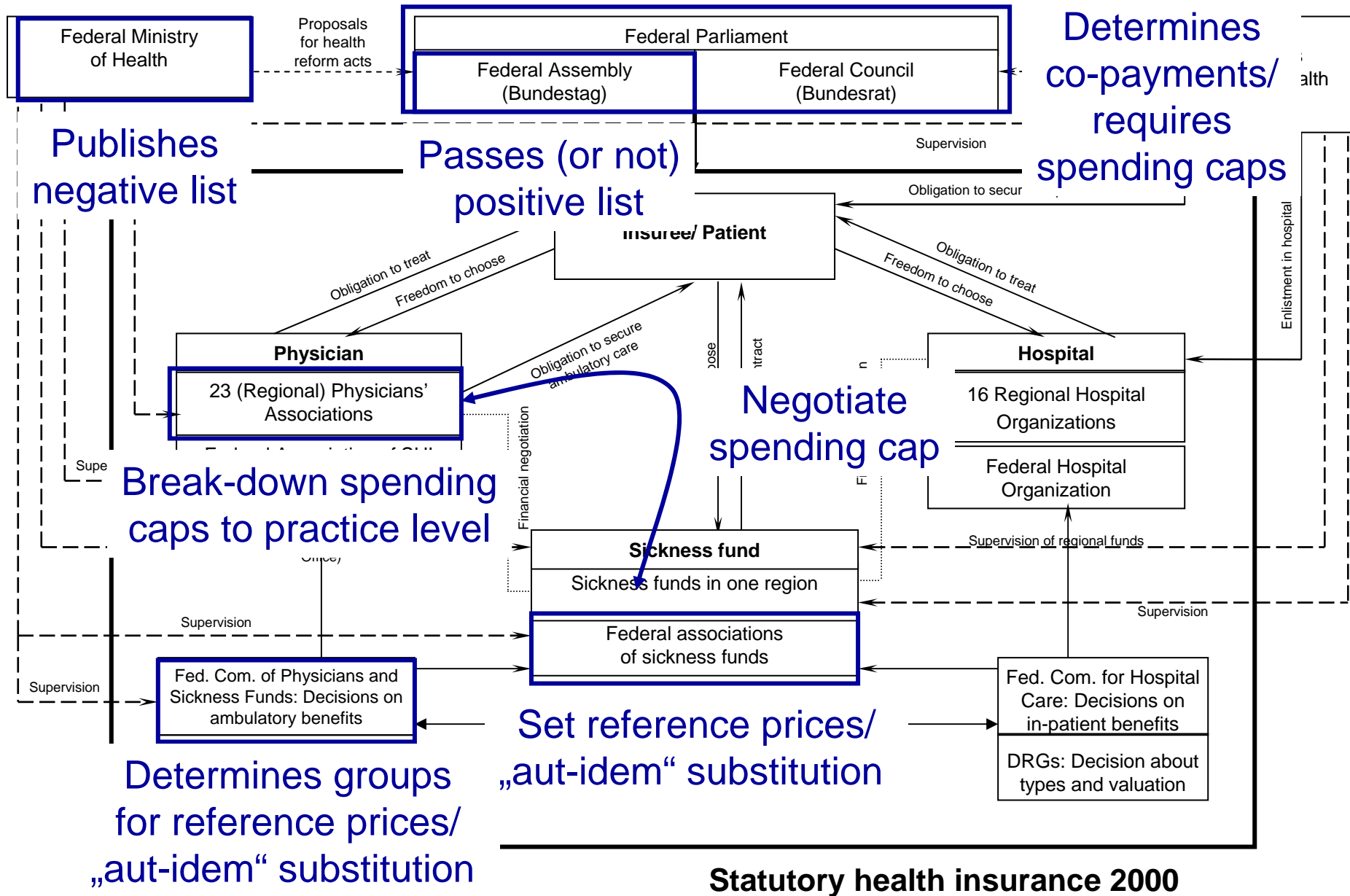
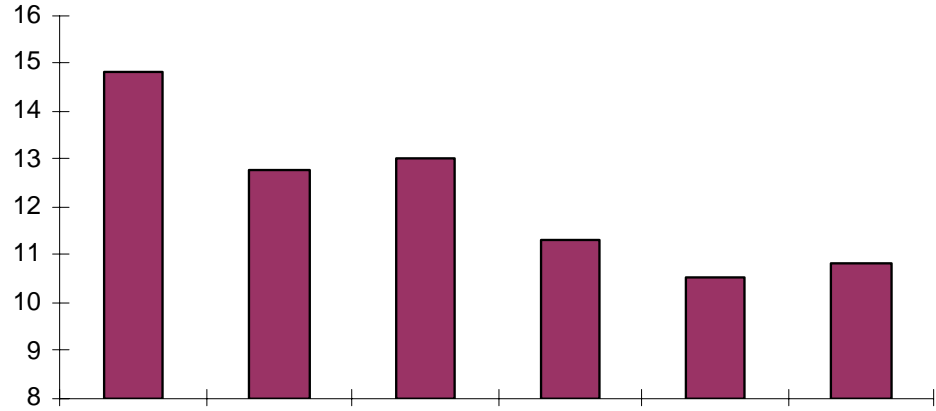
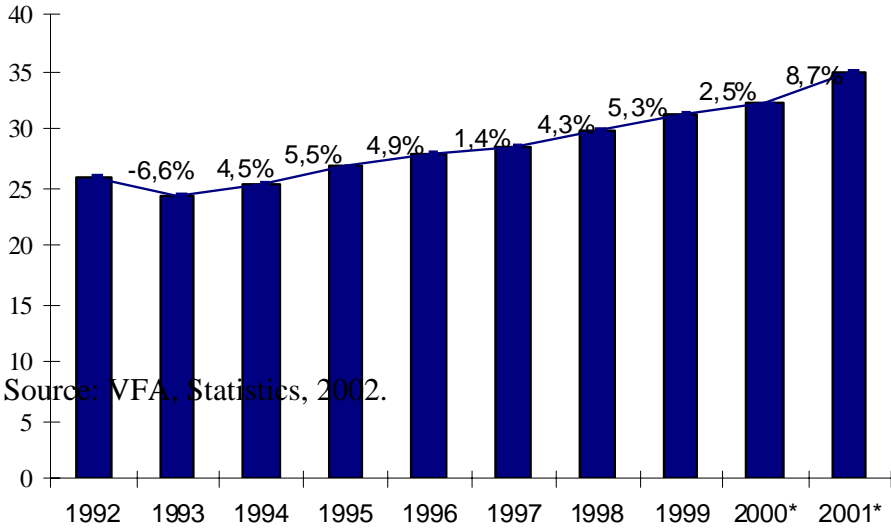


Figure 1: Number of prescriptions per insurant and year



Source: VFA, Statistics 2002, 2002 (package size has not changed significantly over the years)

Figure 2: Growth of the total pharmaceutical market in Germany (in billion €)

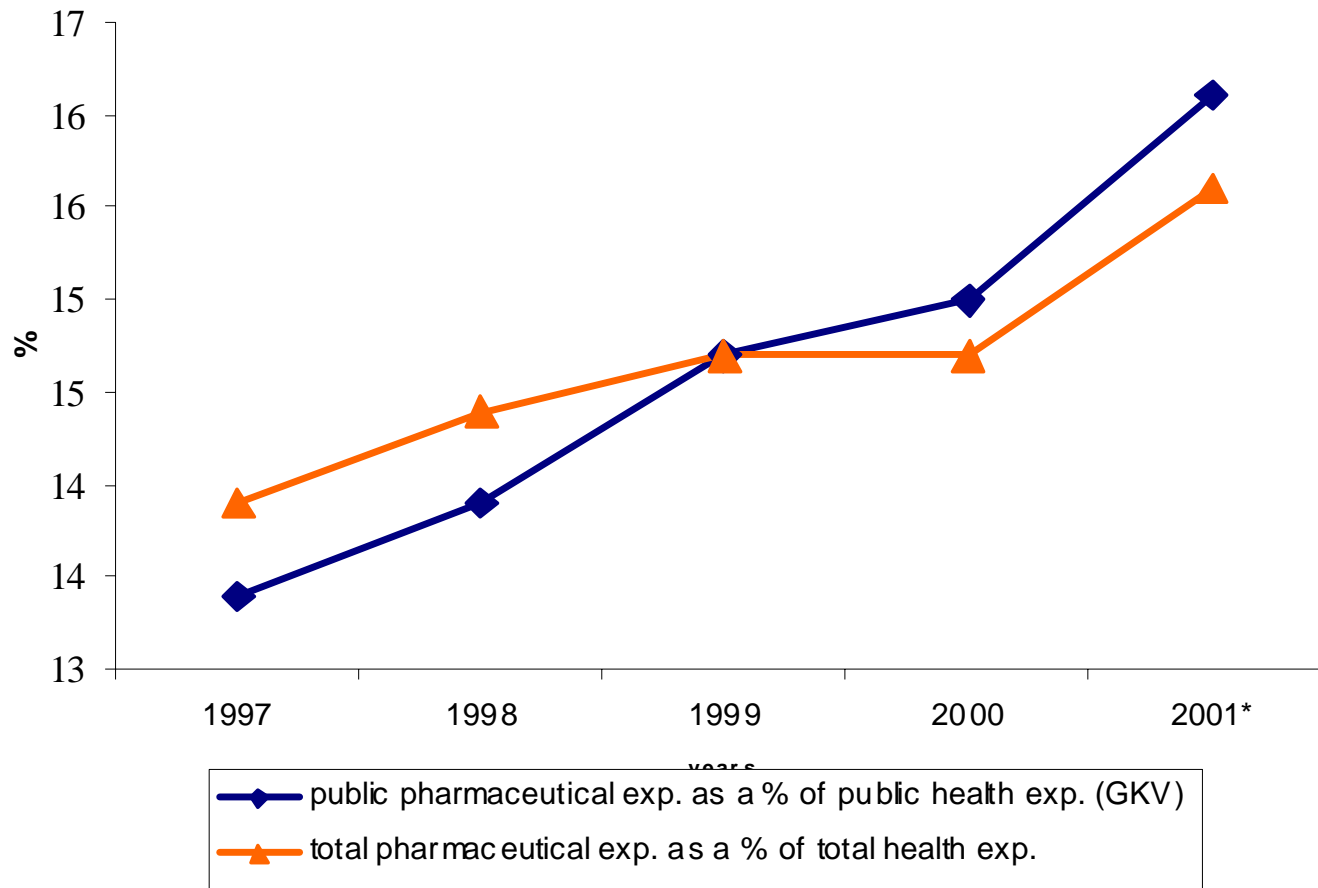


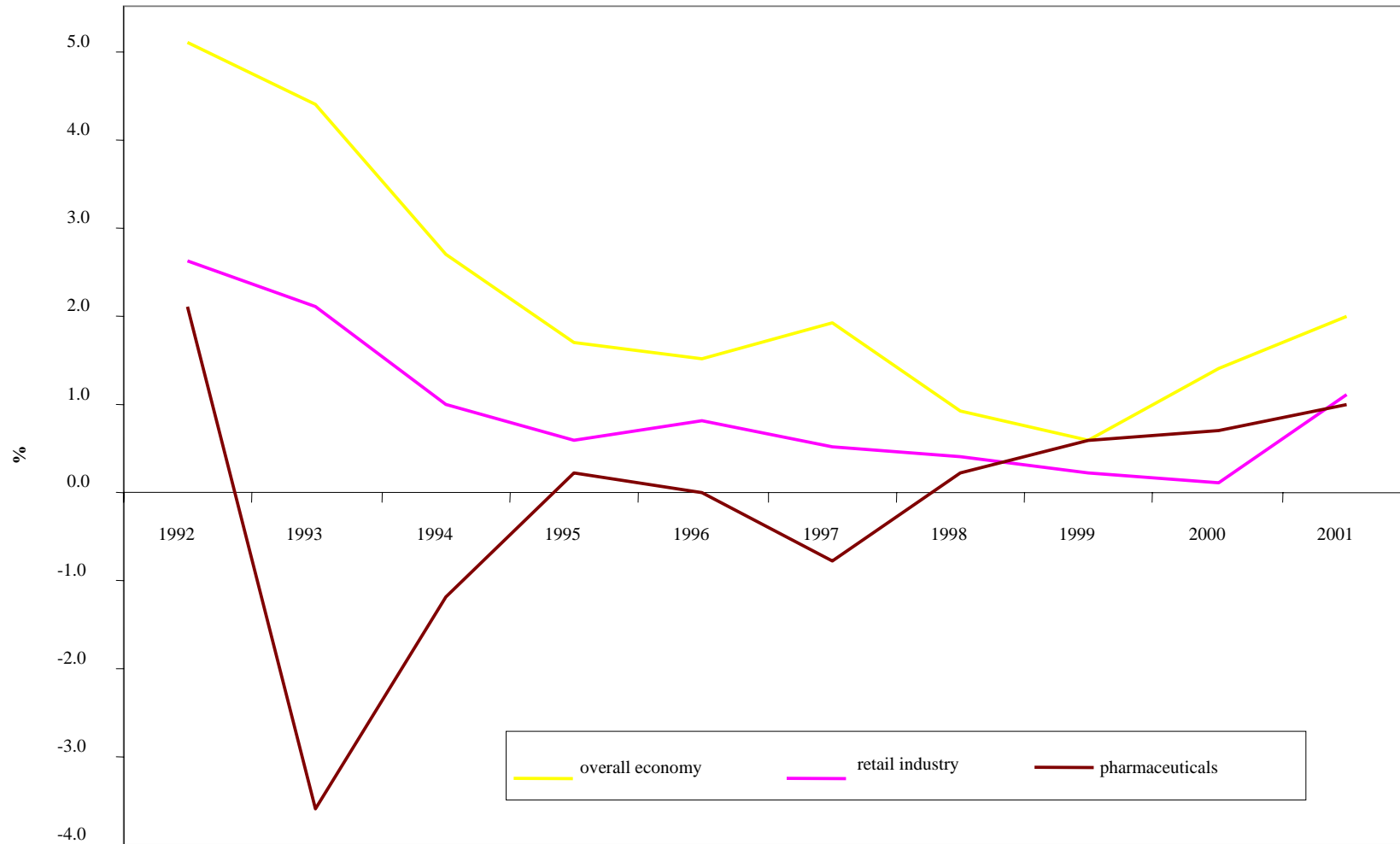
Source: VFA, Statistics, 2002.

The German pharmaceutical market is big – and growing!

... faster than overall health expenditure (which in turn is growing faster than the economy as a whole)

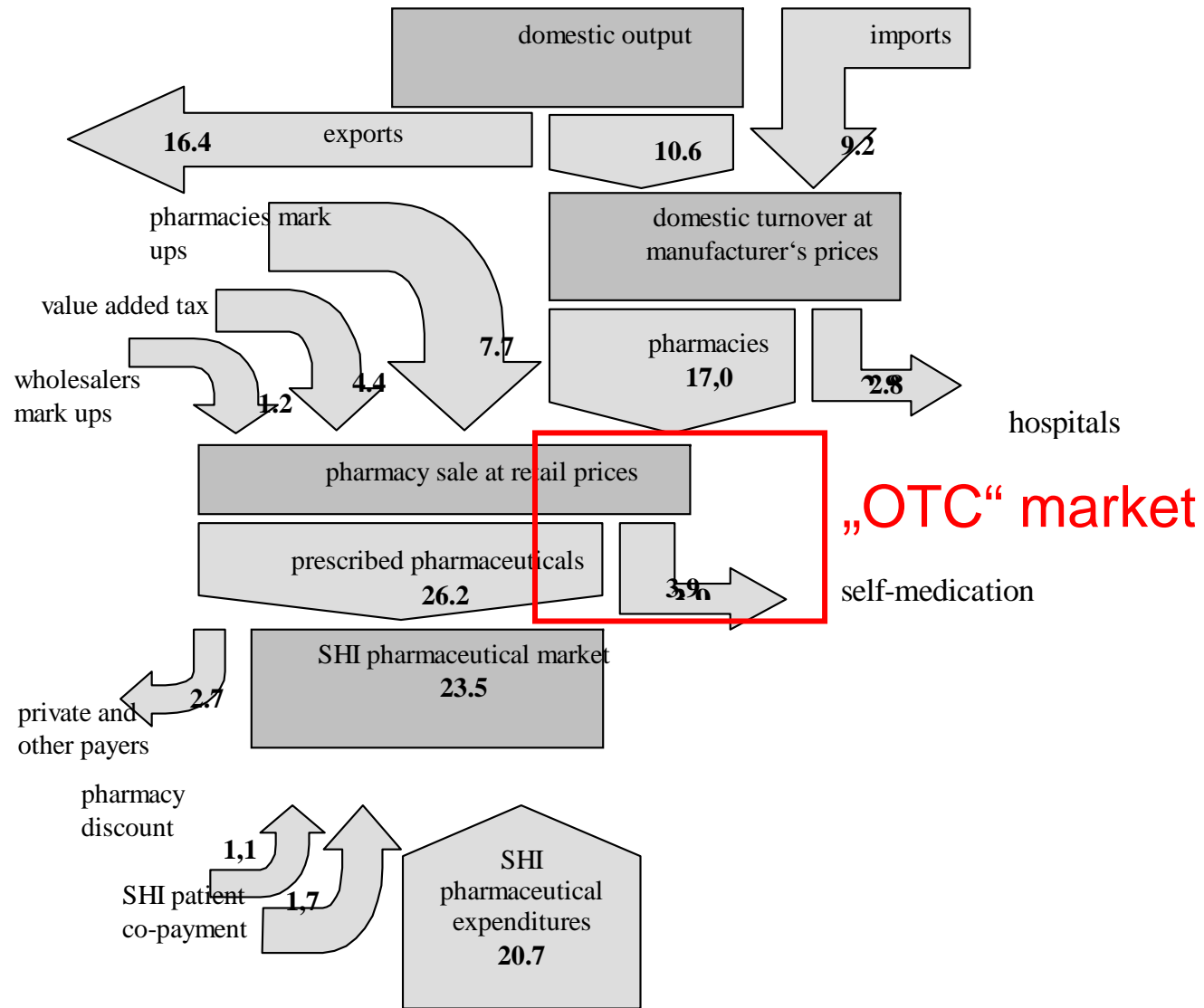
Figure 3: Pharmaceutical expenditure as % of health expenditure





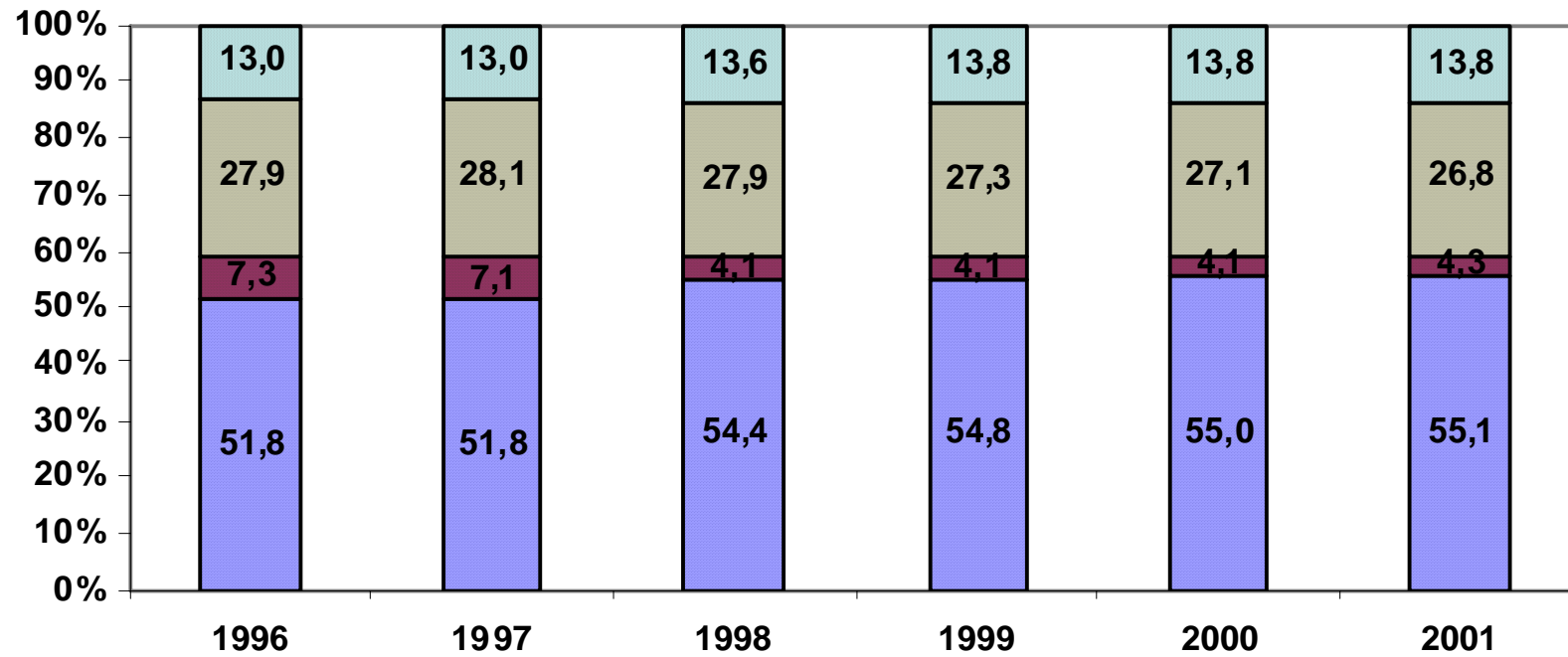
It's not the prices per se!

Figure 6: Production, distribution and funding of pharmaceuticals in Germany in 2001



Source: VFA Statistics 2002.

Figure 7: Composition of retail prices

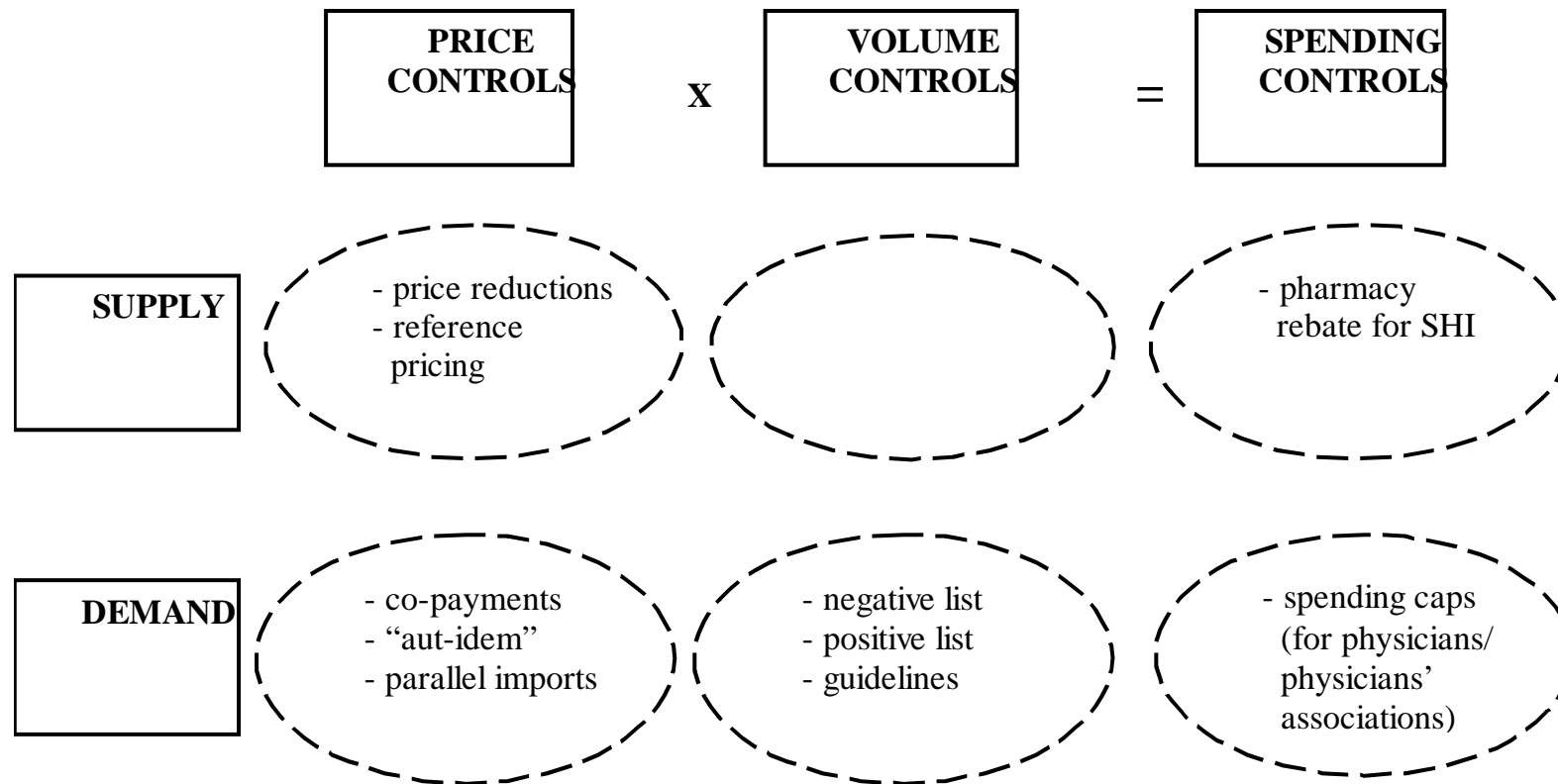


Source: VFA 2002.



Market interventions

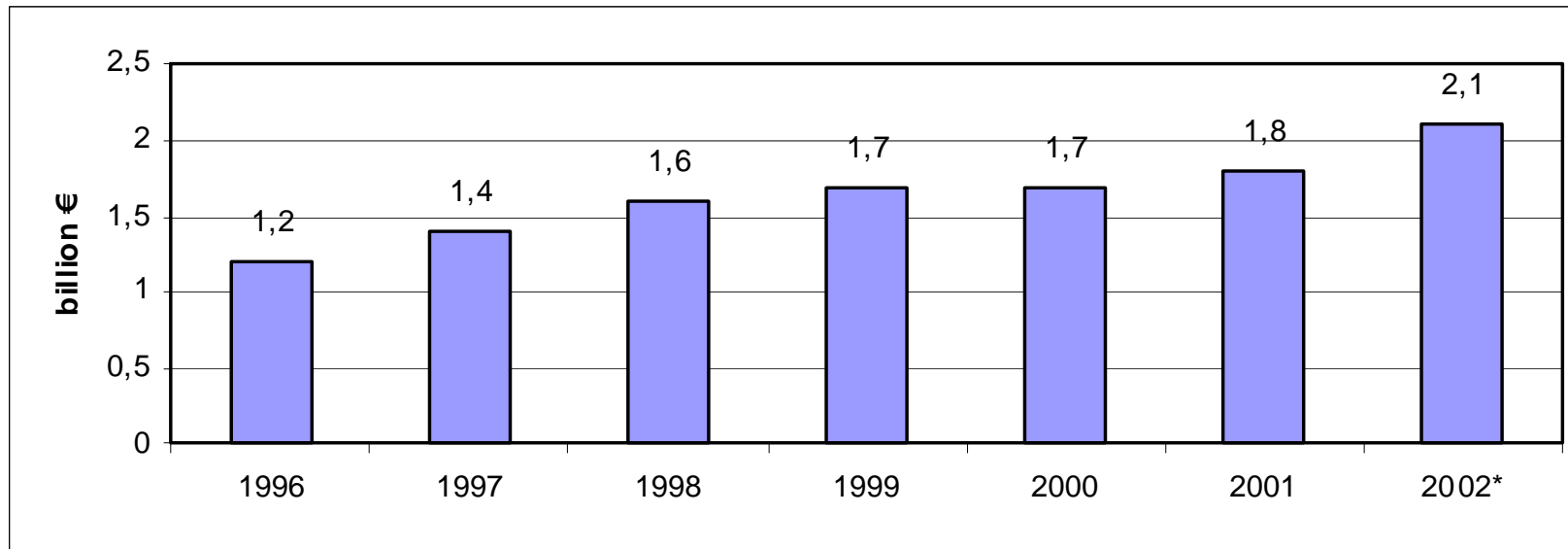
Figure 8: Types of market interventions in the German pharmaceutical market



Supply-side

- Price reductions (various times; usually for non reference-priced drugs)
- Reference-pricing
- Pharmacy rebate for SHI

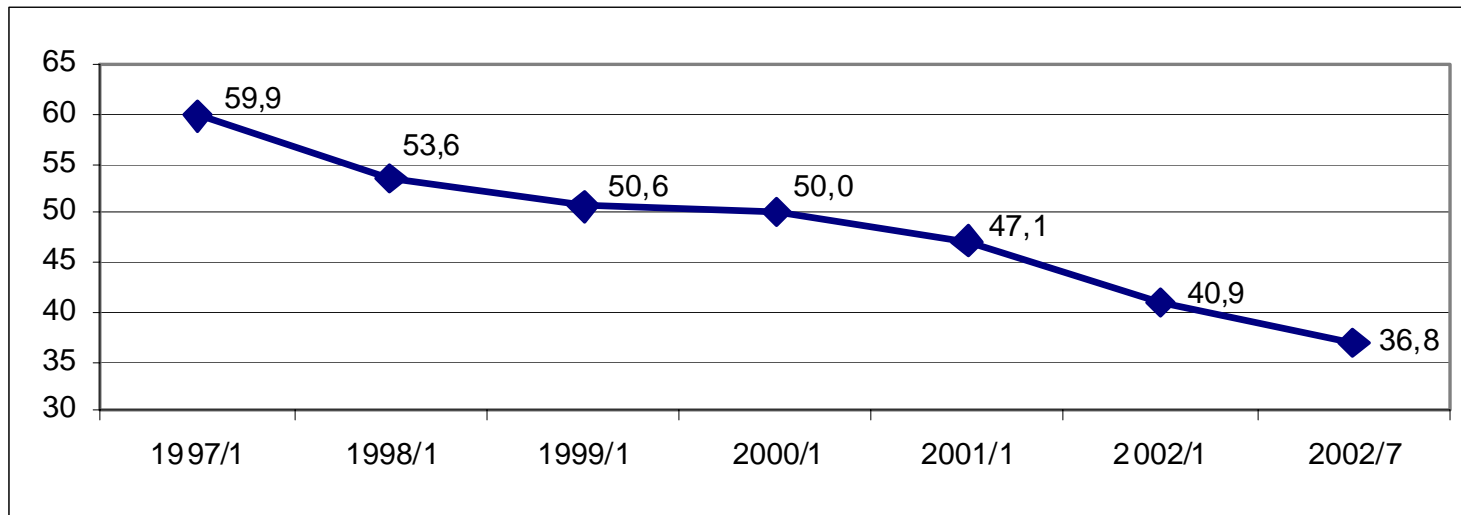
Figure 10: Reduced expenditures for sickness funds due to reference pricing



Source: BKK for various years; VFA 2002.

Somewhat contradictory ...

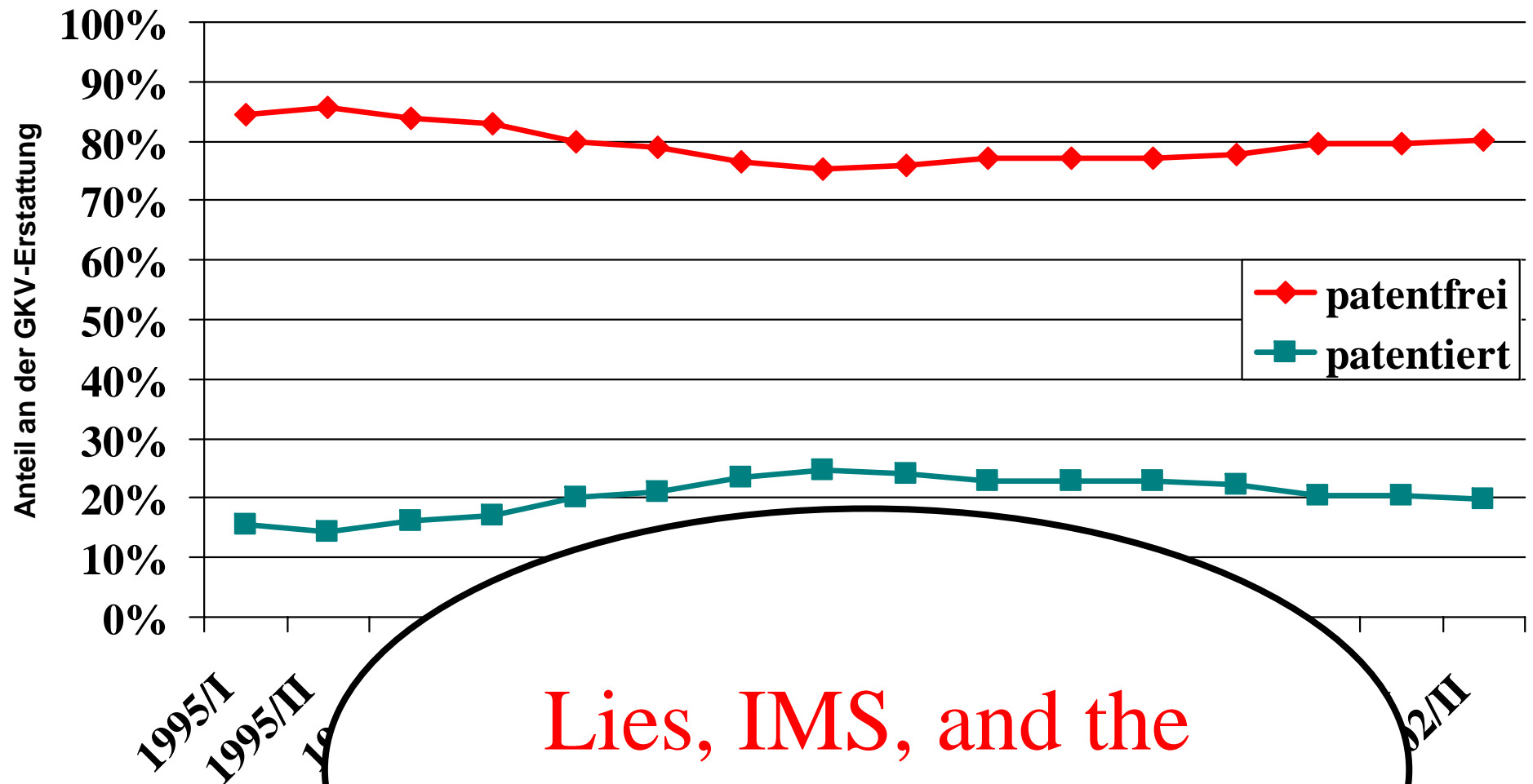
Figure 11: Market share of reference-priced drugs as percentage of the total pharmaceutical expenditure



Source: BKK for various years, Boehringer Ingelheim 2002.

These data seem strange as patented drugs only account for around 20% of total pharmaceutical expenditure.

SHI pharmaceutical market: patented vs. patent free products



Lies, IMS, and the pharmaceutical industry?

Basis bis
Basis ab

2.Hj.

Quelle: IMS

Demand-side

- Co-payments
- Negative list (since 1983)
- Positive list (1st attempt failed 1995; 2nd currently about to fail)
- Spending caps (since 1993; until 2001)
- „Aut-idem“ substitution
- Parallel imports
- Guidelines

Co-payments: up and down (in EUR per pack)

	1994- 1996	1.1.- 30.6.97	1.7.97- 1998	199- 2001	2002- 2003	2004?
S	1.53	2.04	4.60	4.09	4.00	4.00
M	2.56	3.07	5.62	4.60	4.50	6.00
L	3.58	4.09	6.65	5.11	5.00	8.00

Budgets and spending caps since 1989

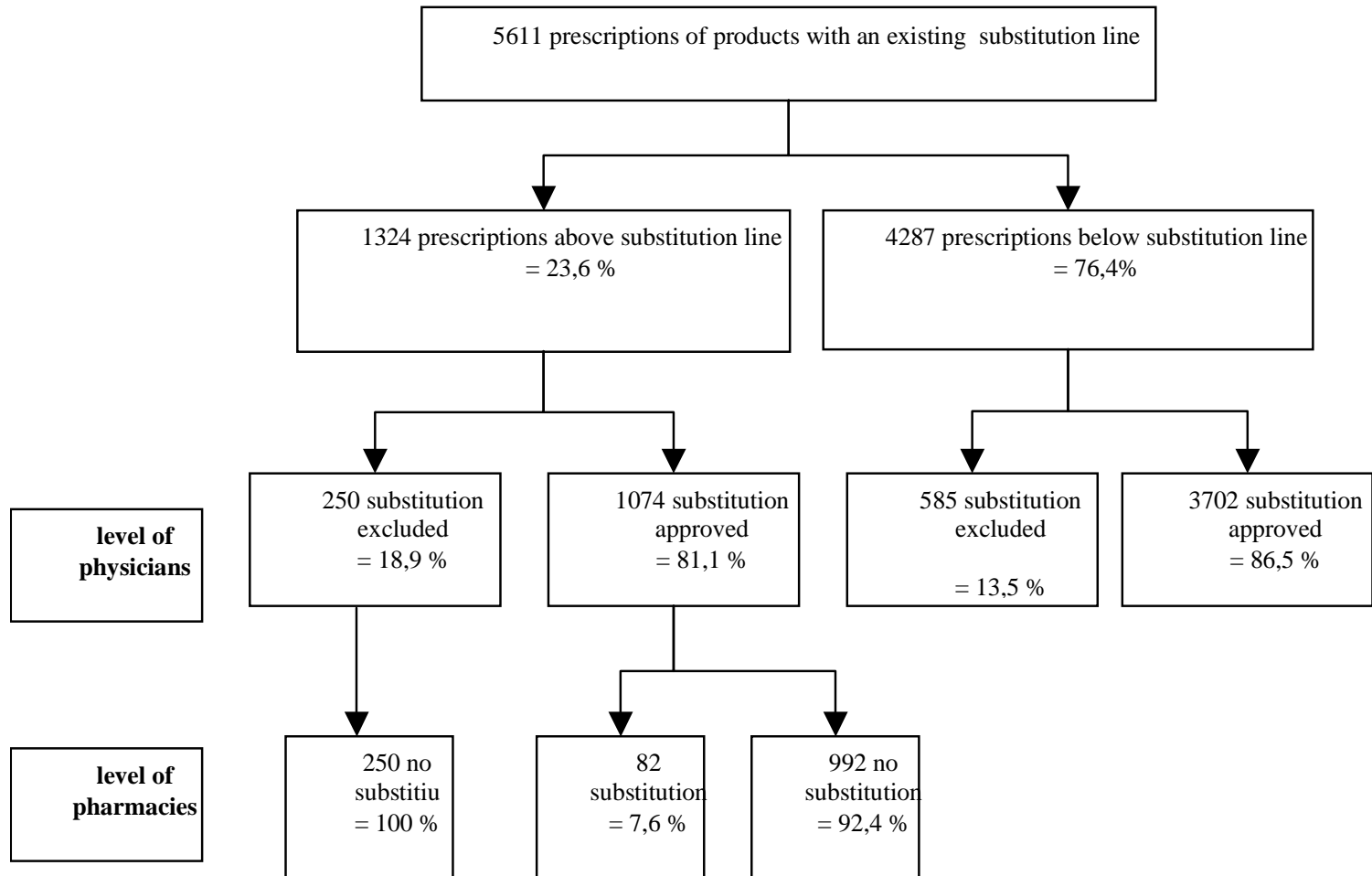
	Ambulatory care	Hospitals	Pharmaceuticals
1989 to 1992	negotiated regional fixed budgets	negotiated target budgets at hospital level	no budget or spending cap
1993	legally set regional fixed budgets	legally set fixed budgets at hospital level	legally set national spending cap
1994			negotiated regional spending caps
1995			
1996	negotiated regional fixed budgets	negotiated target budgets at hospital level	negotiated target volumes for individual practices
1997	(target volumes for individual practice)		
1998	Failed attempt to introduce global budget	negotiated target budgets at hospital level with legally set limit	legally set regional spending caps
1999			negotiated regional spending caps
2000			
2001	negotiated target volumes for individual practices		

<ul style="list-style-type: none"> • Act to Newly Regulate Choice of Sickness Fund • Act to Introduce the Residency Principle for Physicians' and Dentists' Reimbursement • Act to Reform the SHI Risk Adjustment Mechanism 	<p>2001</p> <p>Health care Reform a la Ulla Schmidt</p>
<ul style="list-style-type: none"> • Act to Adjust Reference Price-Setting Regulations • Pharmaceutical Spending Cap Lifting Act 	
<ul style="list-style-type: none"> • Act to Limit SHI Pharmaceutical Spending • Act to Introduce a Case Fees-System in Hospitals 	<p>2002</p>

Measures 2002

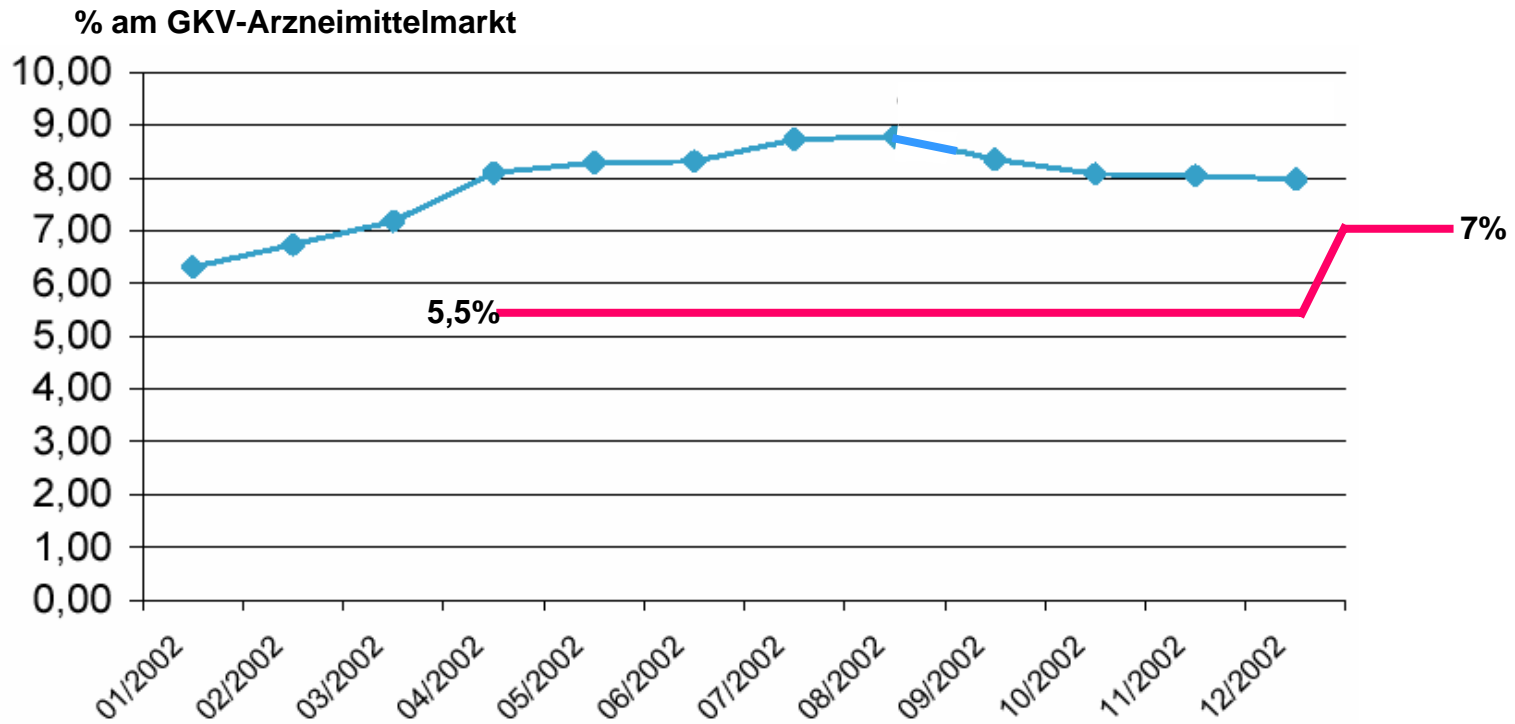
- Guidelines & voluntary limitations
- Increased pharmacy rebate
- „Aut-idem“ substitution
- Parallel import requirements tightened

Figure 9: Random test on substituted prescriptions in southern Germany



Source: Pharmafact 10/2002.

Market share parallel imports (compared to legal minimum)



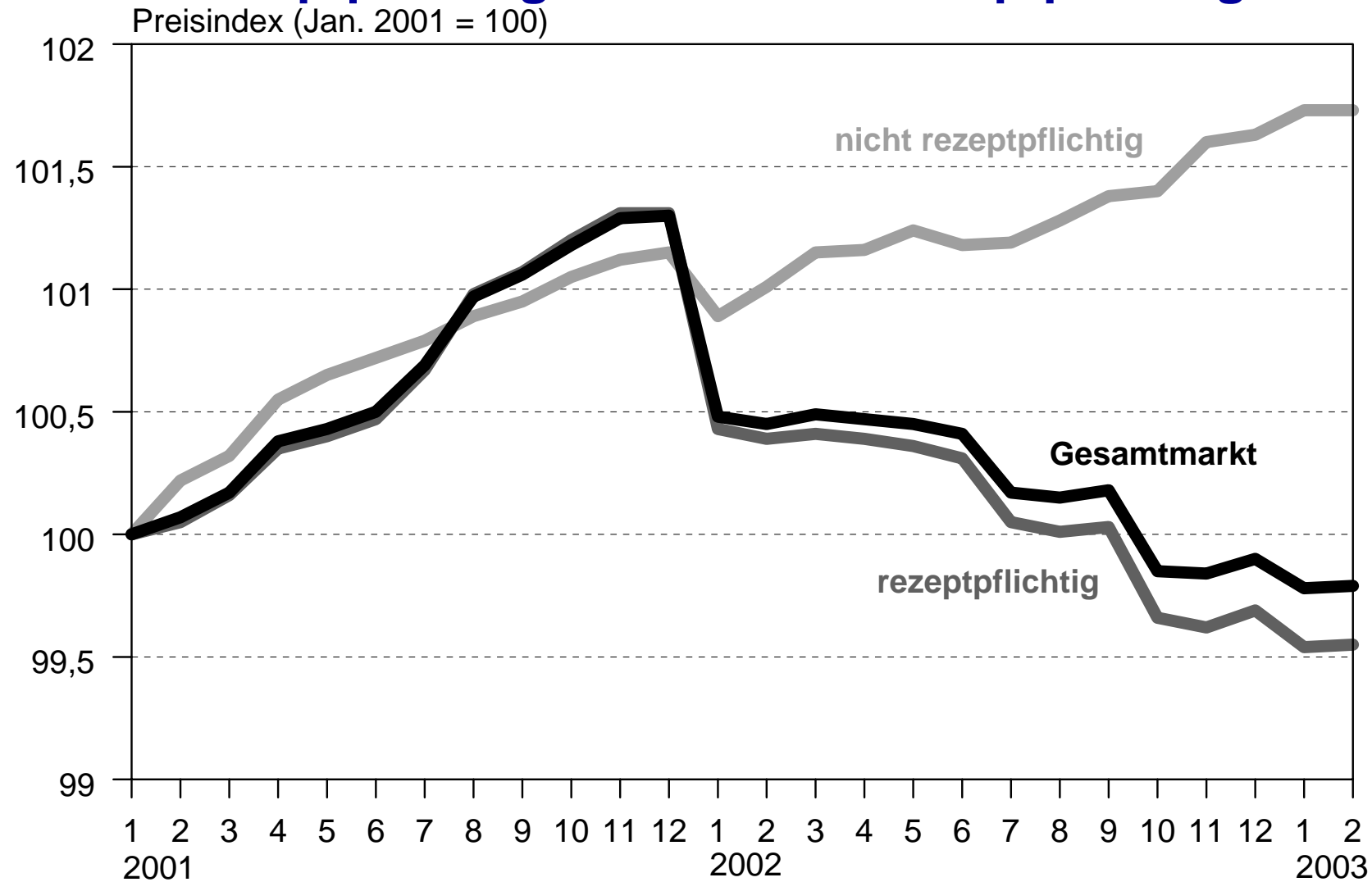
Quelle: IMS

— Pflichtquote gem. Vertrag zwischen DAV und GKV

Currently proposed in Health Care Modernisation Act

- „German Centre for Quality in Medicine“ charged with fourth hurdle
- Immediate reference-price if no added benefit
- Higher co-payments, lowered for patients in disease management programmes etc.
- OTC no longer prescribable (except children and certain indications)

Preisentwicklung von erstatteten Arzneimitteln rezeptpflichtig versus nicht rezeptpflichtig



Quelle: WIdO, GKV-Arzneimittelindex: Preisinfo 02/2003. Basis: zu Lasten der GKV abgerechnete Arzneimittel