



The Italian Pharmaceutical Sector: Innovation and Affordability

James C. Robinson

Leonard D. Schaeffer Professor of Health Economics
University of California, Berkeley

Who am I?



James Robinson

Professor, University of California Berkeley

Visiting Professor, Bocconi University

Contact information

james.robinson@berkeley.edu



James Robinson is Leonard D. Schaeffer Professor of Health Economics and Director of the Berkeley Center for Health Technology (BCHT) at the University of California, Berkeley. Professor Robinson's research focuses on the biotechnology, medical device, insurance, and health care delivery sectors. He has published three books and over 150 papers in peer-reviewed journals. Professor Robinson's econometric research centers on economic incentives on consumer choices, employer spending, and health outcomes. His policy research focuses industrial policy and models for financing innovation, authorizing market adoption, and determining prices for drugs, devices, and diagnostics. H

Overview

- Italy: A tale of two perspectives
 - Commonwealth Fund: Importance of universal coverage and cost control
 - FREOPP: importance of consumer choice and innovation
- Regional variability in a national system: example from biosimilars
- Balancing affordability and innovation in health care
- Industrial policy: lots of talk, we're waiting for action

Suggested Readings on Italy

Commonwealth Fund

<https://www.commonwealthfund.org/international-health-policy-center/countries/italy>

Foundation for Research on Equal Opportunity

<https://freopp.org/italy-health-system-profile-29-in-the-world-index-of-healthcare-innovation-134a8fc399f3>

Comparing Health Systems Internationally

- All comparisons of national health systems are flawed in that they rely on assumptions, arbitrary weighting to create indexes, incomplete and sometimes inaccurate data, and the conscious/unconscious biases of the creators
- The Commonwealth Fund (CMWF) places emphasis on uniformity and equity in delivery, comprehensive coverage with minimal cost sharing, cost reduction
- The Foundation for Research on Equal Opportunity (FREOPP) places emphasis on individual choice, financial sustainability (spending / GDP), and innovation

Commonwealth Fund Perspective: Universal Coverage, Moderate Spending

- CMWF is broadly positive towards Italy as having a health system based on the British NHS model: universal coverage, spending as a low share of GDP: 8.8%
- How does Italy control health spending?
 - Primary care physicians own their own practices but are paid capitation for their services, eliminating the FFS incentive to increase utilization
 - Specialist physicians are paid FFS but many are employed by hospitals and are paid a salary
 - Hospitals are paid on a DRG basis for each admission, subject to annual budgets that eliminate any incentive to increase volume
 - Drug prices are negotiated nationally, and regions have incentive to minimize use of expensive options since these must be paid from fixed regional sub-budgets

FREOPP Perspective: Weak Innovation and Limited Consumer Choice

Fiscal sustainability 19/31.
Low spending but low GDP.

Quality 25/31: Decaying infrastructure, regional inequalities, no focus on patient experience

Choice 30/31: FREOPP focuses on choice of insurance

Technology 20/31: Would be lower if FREOPP focused on biomedical innovation and adoption (rather than EMR)

Overall Rank	Country	Overall Tier	Overall Score	Quality	Choice	Science & Technology	Fiscal Sustainability
1	Switzerland	Excellent	59.56	73.35	46.53	47.28	71.06
2	Germany	Excellent	59.28	60.99	47.95	46.90	81.28
3	Netherlands	Excellent	59.14	65.70	50.42	49.97	70.46
4	United States	Excellent	54.96	59.71	57.65	75.14	27.33
5	Ireland	Excellent	54.48	67.07	41.77	40.71	68.39
6	Israel	Good	51.14	63.89	43.20	38.79	58.69
7	Singapore	Good	50.37	55.77	46.84	47.98	50.89
8	Czech Republic	Good	49.80	52.22	40.80	27.39	78.78
9	Belgium	Good	49.65	56.55	39.23	44.89	57.95
10	Taiwan	Good	49.19	57.15	46.42	25.28	67.90
11	Australia	Good	48.38	69.51	45.38	26.67	51.97
12	Norway	Good	48.26	64.16	32.06	43.74	53.11
13	United Kingdom	Good	47.78	58.76	42.01	49.39	40.97
14	Denmark	Good	47.59	57.53	34.15	52.63	46.03
15	Sweden	Good	47.40	61.73	38.18	49.72	39.98
16	Hong Kong	Good	47.35	48.36	37.13	28.29	75.61
17	Canada	Good	47.05	61.55	38.72	34.43	53.48
18	Austria	Good	46.59	58.57	43.36	40.90	43.52
19	South Korea	Good	46.47	61.39	44.92	18.83	60.75
20	New Zealand	Good	45.97	64.66	35.69	30.32	53.22
21	Portugal	Moderate	44.82	69.22	40.18	27.01	42.87
22	United Arab Emirates	Moderate	44.68	50.62	32.71	22.77	72.61
23	Finland	Moderate	43.65	52.60	27.20	46.78	48.04
24	Spain	Moderate	43.31	49.06	38.58	35.10	50.50
25	Hungary	Moderate	41.47	43.61	32.97	31.15	58.16
26	Slovakia	Moderate	41.36	43.70	34.47	27.46	59.80
27	Greece	Moderate	40.12	44.13	42.88	32.60	40.86
28	France	Moderate	40.08	55.98	35.13	39.17	30.03
29	Italy	Poor	37.29	50.57	30.42	30.39	37.81
30	Japan	Poor	34.11	66.66	35.72	18.88	62.55

For Purposes of Comparison: The US healthcare system in the FREOPP Index

The US lags in efficiency (financial sustainability) but leads in science and technology innovation

Drugs, biologics, devices, diagnostics, digital therapeutics, algorithmic decision support tools, genomics

But we rank low in choice and very low in fiscal sustainability

Overall Rank	Country	Overall Tier	Overall Score	Quality	Choice	Science & Technology	Fiscal Sustainability
1	Switzerland	Excellent	59.56	73.35	46.53	47.28	71.06
2	Germany	Excellent	59.28	60.99	47.95	46.90	81.28
3	Netherlands	Excellent	59.14	65.70	50.42	49.97	70.46
4	United States	Excellent	54.96	59.71	57.65	75.14	27.33
5	Ireland	Excellent	54.48	67.07	41.77	40.71	68.39
6	Israel	Good	51.14	63.89	43.20	38.79	58.69
7	Singapore	Good	50.37	55.77	46.84	47.98	50.89
8	Czech Republic	Good	49.80	52.22	40.80	27.39	78.78
9	Belgium	Good	49.65	56.55	39.23	44.89	57.95
10	Taiwan	Good	49.19	57.15	46.42	25.28	67.90
11	Australia	Good	48.38	69.51	45.38	26.67	51.97
12	Norway	Good	48.26	64.16	32.06	43.74	53.11
13	United Kingdom	Good	47.78	58.76	42.01	49.39	40.97

Italy: A National System with Regional Differences

- Italy has a national, single payer, health care financing system but relies heavily on provinces to administer the budget and operate health services
- The national government is responsible for overall funding, distributing budgets to each region based on age-adjusted population. It also conducts drug evaluation (CEA) and price negotiations with manufacturers
- Provincial governments are responsible for allocating budgets across health care facilities, professionals, supplies, and other services
- Provinces in the south are prone to overspend the health budgets allocated to them. In these situations, the national government reasserts central control
- The mix of national and regional authority reflects the larger political history of the nation, including relatively late unification (1860s) and distinct cultures between the north (civic republicanism), the south (clientelism), and the center (papal states)

An Example of Regional Variation: Adoption of Biosimilars

- Policymakers conceptualize biosimilars as a tool to reduce health care spending, and, as such, they should be adopted faster in low-income regions (such as the south of Italy). However, it turns out that adoption also is dependent on trust on the part of patients and doctors in the national government and professional societies
- Provinces in the south generally have weaker civic traditions, governance, economies. Trust is lower in the south, including both social trust (people trusting others in their community) and political trust (people trusting their government). Incomes are also lower in the south
- Adoption reflects deeper patterns of social trust (north versus south), political trust (as measured in opinion polls), and income per capita
- For purposes of comparison, we also look at regional patterns of adoption in Germany

Regional Variation in Adoption of Biosimilars: Italy and Germany

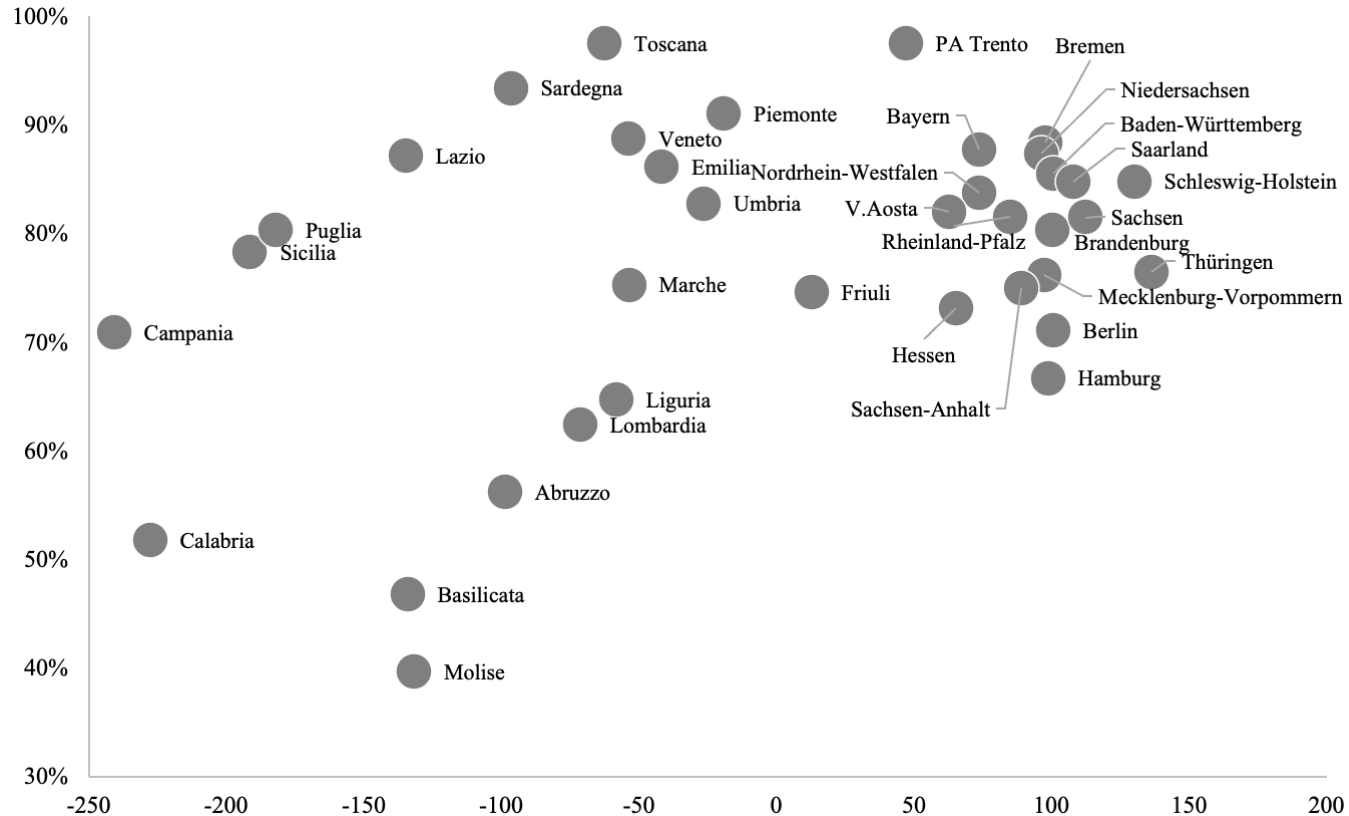
Italy: South versus North



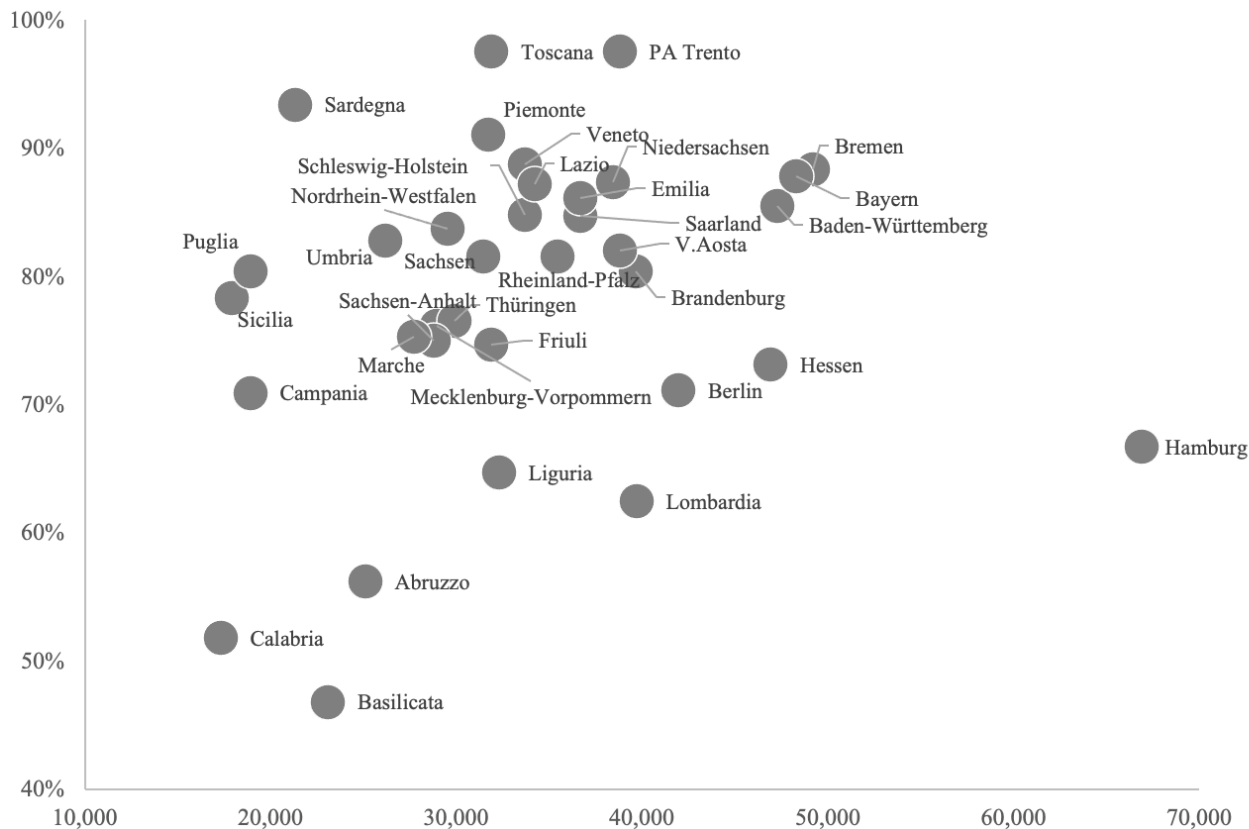
Germany: East versus West



Association between Public Trust in Government and Adoption of Biosimilars in Italy and Germany



Association between GDP/capita and Adoption of Biosimilars in Italy and Germany



Balancing Affordability and Innovation in the Life Sciences

- Health care is a service sector that presents strong affordability challenges to payers and consumers
- Spending in health care grows faster than the general economy and, in the US, is growing faster than in other nations
- Why?
 - Waste, fraud, and gouging are always with us, but they are not increasing year over year at a rate faster than the economy
 - While we do face Covid, diabetes, deaths of despair, and other epidemiological challenges, generally we are getting healthier and living longer.
- Answer: We spend more on innovative new drugs, devices, etc. that did not exist in earlier years.

The Traditional Focus of Health Policy, in Italy as in the US, has been on Access and Affordability

- The ever-rising cost of health care has created an imperative for ever more comprehensive public and private insurance
- More insurance permits more utilization and higher prices, fueling the innovation process, leading to more spending ...
- Both the US and Italy have viewed drugs and devices primarily as a budgetary challenge to be managed
 - The US seeks to meet the challenge through 'value-based payment' for providers, cost sharing for consumers, etc. These don't work very well.
 - Italy (and most EU nations) relies principally on centralized budgetary control, which is allocated to regions. This does not work very well.

New Fears

- In recent years a new focus has emerged, one that views the life sciences sector, and its expenditures, as a strength
 - The Covid pandemic highlighted the imperative for innovation
 - The rise of China raises fears for loss of technological and military advantage
 - De-industrialization drives the rise in populism and nativism
- These concerns are especially salient in Europe and, within Europe, in Italy. Italy was hit earliest and hardest by Covid. It has faced several decades of economic malaise, due to weak innovation and technology adoption. It has recently elected a far-right government with strong populist leanings

A New Focus: Industrial Policy

- In the US, Italy, and throughout the developed world, there is now a debate: how to balance innovation and affordability
- In the US, we see a bipartisan advocacy of industrial policy (though the devil is always in the details), with CHIPS, ARPA-H, etc.
- In Italy, we see an active debate (though little action to date) on restructuring AIFA and creating incentives/regulations supporting domestic R&D, manufacturing, supply chain
- How will all this align with the traditional focus on controlling spending, such as price regulation of drugs in Italy?

Italy: Enhancing Incentives for Investment?

Giancarlo Giorgetti, the Minister of Economic Development, said: "We are facing a competition between countries to attract strategic investments from the pharmaceutical industry. The government and the Ministry of Economic Development have adopted **adopted a new strategic approach to the development of the pharmaceutical industry** based on the awareness that this industry plays a fundamental role in the Italian economy not only as globally expanding industrial sector, but more generally as an element of national security in terms of citizens' health."

Giorgetti believes "that a global reflection should be opened between institutions and companies in Italy to define a **review of the system of regulation and financing of the public demand for pharmaceutical products and of the rules for their marketing and pricing**, in order to make the attraction of investments compatible with the sustainability of the national health system."

Italy: Pharmaceutical Pricing & Regulation?

Pharmaceutical pricing and expenditures

The 2022-2024 budget will strengthen the national health system and improve access to treatment and prevention. A 30% boost to the funds for innovative medicines over the next three years and a higher expenditure ceiling for hospital drugs will help to support the use of innovative medicines. The new Consolidated Law on Rare Diseases will improve and accelerate access to orphan drugs across Italy.

Possible reorganization of AIFA

The imminent reorganization of AIFA, guaranteed faster access to orphan drugs and measures to support precision oncology: these are among the key health-related measures approved in the National Recovery and Resilience Plan (NRRP) Law...The industry will be anxious to learn precisely how AIFA will be reorganized: it will certainly hope that the changes will reduce long access delays.

Walking the Walk

Italy is talking the talk on innovation and industrial policy. Will it walk the walk?

And what about the United States?

Italian government plans access reforms to attract pharma



- Post-COVID recognition that industry plays an important role in national economy and health security
- System of drug funding and pricing requires review
- Current model of closed silos, spending caps and paybacks is out of date
- Need to reduce bureaucracy and speed up access