

KEY FINDINGS

- Price controls have caused a decline of research and development efforts on drugs in Europe
- The costs of innovation, mostly originated in the US, are mainly borne by the American consumers
- The European free-riding might soon be unsustainable, particularly in case the US follows the European lead in price controls
- The Italian weakness is partly due to the bottleneck in the distribution system
- Cost containment policies impact mainly the industry's profits and discourage its operations
- In the long-term, a thorough overhaul of Italian healthcare policies is needed
- In the short-term, the elimination of VAT on drugs, the opening of the distribution market and an end to political price-fixing might help

Alberto Mingardi is Director of Istituto Bruno Leoni.

Carlo Stagnaro is Director for Market Ecology of the same Institute.

Distribution and drug prices

An ever shorter cover between Europe and the US

by Alberto Mingardi & Carlo Stagnaro

The debate on drug reimportation from Canada trained the spot, in the United States and therefore in the rest of the world, on a significant, albeit often unspoken issue. Facing the fact that the US is the largest market in the world for consumption of pharmaceutical drugs, the American patient pays a significantly higher price for his drugs than his European counterpart. The European per capita pharmaceuticals costs is 60 per cent below the American one:¹ inevitably, this difference discourages the development of innovative drugs, as confirmed by the flight to America of European drug firms that still have R&D efforts.²

In 1990 European corporations were outspending their American counterparts by between 5 and 8 billions dollars. In 2000, the gap was 17 to 24 billion dollars in favor of American drug companies.³

The importance of research in this industry makes this a touchy issue. The R&D outlays of pharmaceutical companies as a percentage of sales grew from 11.4 per cent in 1970 to 17.7 per cent in 2001.⁴ The cost of the development of an innovative drug is estimated at about 880 million dollars.⁵ The fact that producing the "first pill" entails such astronomic costs, although they are going to steeply lessen with each new produced one, is among the most peculiar facts of an industry about which the public has very great expectations and which it is not willing to forgive for its perceived shortcomings.⁶

In the course of the debate on the importation of drugs from Canada, the

Nobel prize laureate Milton Friedman asked some pertinent questions:

"the question is where is that \$800 million going to come from? The answer that we have given, whether the right answer or the wrong answer, the answer we have given is that it's going to come by giving the producer of the drug a patent, a monopoly privilege to sell that drug, to exclude others from the sale of that drug."⁷

A study conducted by the International Trade Administration of the U.S. Department of Commerce on the enforced drug prices structure in several OECD countries reckoned that price controls help to reduce the global revenues of the pharmaceutical industry by an amount estimated at between 17.6 and 26.7 billions dollars each year.⁸ It is clear that the fate of the freedom of the market in which US drug companies operate is closely linked to the future of price controls and politically dictated price levels in the rest of

the world. Moreover, European companies suffer not only for being unable to make the necessary investments. Because of the unfavorable economic environment, they struggle to innovate the very facilities that should lead their research and development efforts. In an age characterized by sudden technological change, the presence of such hurdles helps to explain, at least in part, the gap between the European and the American industry.⁹

The consequences of the drugs pricing and distribution system are also felt on the other side of the Atlantic. The American adherence to the free-market (notwithstanding a strong regulatory regime by the FDA)¹⁰ granted Big Pharma the continued opportunity of benefiting from the resources needed to invest in research. The fact that the US prescription drugs market is worth 126 billion dollars each year, while the German market—the largest European one—is under 20 bn dollars, and the second largest market in the world, namely Japan, does not arrive to 53 bn dollars,¹¹ makes every decision taken by the US government very sensitive, both for drug companies and, consequently, for the patients that benefit from their research and development efforts.

Concurrently, the free-riding by European countries does appear a markedly unsustainable course: ironically, the price controls in force in almost every development economies endangers the American exception. Pressures on the United States to take the course of socialized medicine come from many quarters and some steps in that directions have already been taken.¹² The prospect of a “globalization” of socialized medicine emphasizes all the flaws of a situation in which Europe is content with living off the American golden eggs goose. When the fact is taken into account that in 1998 as much as 33 of the best-selling (and, therefore, most appreciated) drugs were of American origin, it is clear that the very future of an innovative healthcare industry depends on that goose.

Beyond any moral issues, the danger exists that, if the United States will achieve further European-style

legislative “progress,” that overstretched goose might lay her last egg.

1. Monopsony and price controls

The problems in the distribution of drugs cannot but be ascribed to the peculiar form of its market, namely that of a monopsony. A monopsony is the situation in which there is only one buyer for a commodity or service, which can therefore exert its “market power.”¹³

In the pharmaceutical industry, the socialization of medicine that prevailed in the course of the Twentieth century all over the Western world, concentrating in the hands of government the supply of healthcare services for most of the population, reflects on this particular market pattern.¹⁴

The presence of only one buyer is anyway less important than the nature of the buyer itself. Although the conventional theory of monopoly power and perfect competition has been severely

criticized and is legitimately considered with some skepticism,¹⁵ in this case to speak of “market power” is appropriate. The government is in fact a very noteworthy actor, namely the one social actor that can avail itself of coercive power.

Thus, government is not only the bottleneck through which the demand of drugs must flow, but it can also regulate the offer by political means: on one hand, the approval requirements of new drugs, justified for safety reasons, cause the arrival on the market of innovative products to be slower and, much more important, they establish a basically “regulated” market, in which the introduction of new products is impossible without the approval of the regulator.¹⁶

On the other hand, the fact that government agencies are the overwhelmingly largest buyer of drugs (the Italian National Survey of Drugs Use reports¹⁷ that in average, four seventh of the drugs are reimbursed by the state health system, while just three-sevenths are privately bought) brings the government to inevitably exert some control on prices. Not only the condition

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of sole buyer of drugs confers to the government a disproportionate bargaining power, but the coercive character of government empowers it to dictate the very boundaries of the market itself.

From the perspective of the industry, there is no way out price controls: either accept them, or withdraw from a particular national market, are the only existing options.

The retaliation opportunities offered to a private buyer are very limited: even if a consumer deems the price of a particular drug to be too high, he can only abstain from buying it. The most he can do is to protest in any public venue available, in the attempt to gather support against what he judges to be an injustice. If a large enough number of other consumers will follow his example and avoid buying the expensive product, he can hope that this may encourage the producer to lower the price. In general, however, the price is fixed by the dynamics of the market, namely the regular interaction of demand and supply.

This pattern does not obtain in a situation in which one actor can make use of coercive powers and in which the one check to this powers is provided by an institutional pluralism on the international scene. Luckily, there is no “drug policy in one country” and it is likely that national regulators will adjust their decisions to those taken by other national agencies abroad or, in other terms, that they are interested in the continued existence of a varied and vivacious offer.

Under this respect, it is widely deemed that on the international scene a case of free-riding is obtaining at the expense of the United States.¹⁸ The former FDA Commissioner Mark McClellan observed in September 2003 that:

“In many ways, the economic consequences of overly strict price controls on drugs are no different than violating the patent directly through compulsory licensing to make copies of the drug. Either way, there isn’t likely to be a fair payment based on the value

of the new patented product. This year, Americans, who account for a fraction of prescription drug use worldwide, will pay for about half of all pharmaceutical spending worldwide. By contrast, citizens in the world’s third largest economy, Germany, paid less than five percent. The same kind of drug payment disparity is true for many other developed nations who have about as much ability to pay as Americans do.”¹⁹

This vicious circle follows a well-known pattern: price controls make European countries a less attractive regulatory environment for drug companies; drug companies focus on the relatively freer market, namely the American one, charging on its freedom the price of innovation; European countries free-ride the American market, causing their price controls to tighten or to persist, and so on.

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In 1990 sales in the US accounted for 31 per cent of the global market, while Canada and the five largest European countries accounted together for another 30 per cent. In 2001, in contrast, the aggregated sales in Canada

and the five largest European countries accounted for a mere 20 per cent of the global market, while the US accounted for an astonishing 46 per cent. The gap was even wider for biotechnologies (in 2002 the biotechnology industry revenues were 16.5 bn dollars in the United States, as opposed to a meager 5 bn dollars in the five largest European countries as a whole).²⁰

Research, however, is driven not much by revenues, as by profits. Under this respect, the gap between the US and Europe is likewise unmistakable: total European profits for the pharmaceutical industry passed from 33 per cent to 18 per cent of global profits between 1992 and 2002, while profits in America grew from 47 to 62 per cent in the same time frame.²¹

The most common advice to investors is don’t put all your eggs in the same basket; the eggs of the patients all over the world are instead surprisingly concentrated in the American basket. The result is that European governments enjoy a benefit that the receivers of Soviet Russia could not avail themselves of, namely to live off price controls without paying their cost. This is to say that the European markets are apparently

free from the well-known economic consequences of market controls: scarcity, producers leaving that particular market, dearth of innovation. The reason is that somebody is footing the bill of European statism: the American consumer.

However, we are on the brink of a momentous change: if the reimportation of drugs in the American market was to materialize, to the benefit of parallel traders and at the expense of manufacturers; if the recent examples of judicial show-trials, as in the case of Vioxx, were to be repeated, if the boost in the demand for government-paid drugs caused by the prescription drugs benefit recently introduced in the Medicare program were to tempt the federal government to introduce price controls; if all these conditions were to obtain, would European patients face the prospect of not being able of benefiting from innovative drugs anymore?

2. Distribution and drug prices in Italy: is there room for a reform?

In the long term, there is only one way out of the dismal scenario just illustrated: namely, to overcome the governmental monopsony or, in other terms, breaking the vicious circle of socialized medicine.²²

It is clear that this solution is politically rather unlikely, at least in the short term. Exit strategies from the crisis of the welfare state are currently being outlined,²³ but they still belong to a host of options that is struggling to gather a firmer consensus, at least in the major European social-democracies. The European "social model," while clearly in crisis, is strenuously backed by its constituencies.

The issues heretofore illustrated, however, are no less relevant for this: on the contrary, the attention of observers and politicians is consistently focused on the Gordian knot of drug costs. This attention is basically due to two reasons:

On the one hand, demand is growing, largely caused by the progressive ageing of the population, which entails the demand of more attention to healthcare

issues and to the diseases of old age. As an example, the total Italian healthcare spending grew by 67.99 per cent between 1995 and 2003, passing from 48.136 bn to 80.864 bn euros and confirming the trend, in common with all other OECD countries, of growing more than the cost of living.²⁴

On the other hand, by virtue of the crisis of the welfare state, European countries must struggle just to keep healthcare spending under control. However, keeping healthcare spending in check entails chiefly intervening on current spending, which reflects on health workers and hospitals: both alternatives are hugely unpopular. The first one threatens the support of healthcare workers for politicians. The other one entails unpleasant consequences for the territorial support base of these very

same politicians, especially when the demand for exhaustive healthcare services in close proximity to their users is taken into account.

Cutting drug spending involves an intervention on price caps and asking the

pharmaceutical industry to contribute to foot the bill. In its turn, this entails acting not on an "internalized" price of the national health service, but instead on an "externalized" price, namely limiting the harm just to the industry, whose workforce is not geographically concentrated and is more or less negligible from a voting perspective (in Italy, the numbers are some 84,000 employees).²⁵ Moreover, as we have seen, the current international regulatory scene allows governments to make the most of the current state of affairs, in the expectation that the American market will in any case support the research efforts of the pharmaceutical industry.

Some figures are in order: in 2004, facing a total public health spending of some 86-87 bn euros, the costs due to drugs contribute for less than 12 bn euros.

If in the last 20 years the percentage of over-65 is passed in Italy from 13.1 to 18.4 per cent, the share of spending for drugs as a percentage of GDP was not growing in the same proportion, passing from 0.65 per cent in 1980 to 0.85 per cent today. This figure must be

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* less 6.8% for Discount on industry's revenue

** NHS discount \geq 3.75%

Figure 1. Price makeup of reimbursable drugs

taken with particular care: the slight grow in public drug spending, in fact, relates to a population tier that consumes four times more drugs than the general population.

Moreover, the pharmaceutical spending is limited by a ceiling of 13 per cent of the total health spending (which in its turn amounts to 6.5 per cent of GDP). It is to be remarked that the percentage of 13 per cent includes VAT: net of VAT, the spending is 11.8 per cent. The ceiling on drug spending is methodologically incongruous. First of all, it smacks of hypocrisy (other spending items are not capped at all). Moreover, it is tantamount to a legal limit imposed a priori to all cases in which a drug-based treatment might turn out to be the best solution, deliberately disregarding all technological progress in the medical field.

Such a ceiling does not seem to have a rational justification from a spending perspective, either: it might be in case a drug-based treatment be alternative to

a hospital stay. This may well be the case, but this would entail a case-by-case decision process hardly suitable to a centralized decisional framework such the current one. Such a rationale, at any rate, ought to prevent an absolutist implementation. In conclusion, the ceiling does not equates to a saving in relation to the total healthcare spending, as instead in relation to drug spending.

On the assumption of the need to limit spending, the problem must be faced of pursue this goal in the less discouraging manner for those companies that invest in research and development. Pending a radical overhaul of the welfare state, with resources and freedom of action restored into private hands, thus solving the thorny issue of the drugs monopsony, is it possible to find small niches for a less intrusive and punitive regulation?

The spending ceiling approach is no longer feasible. Drug prices in Italy are already among the lowest in

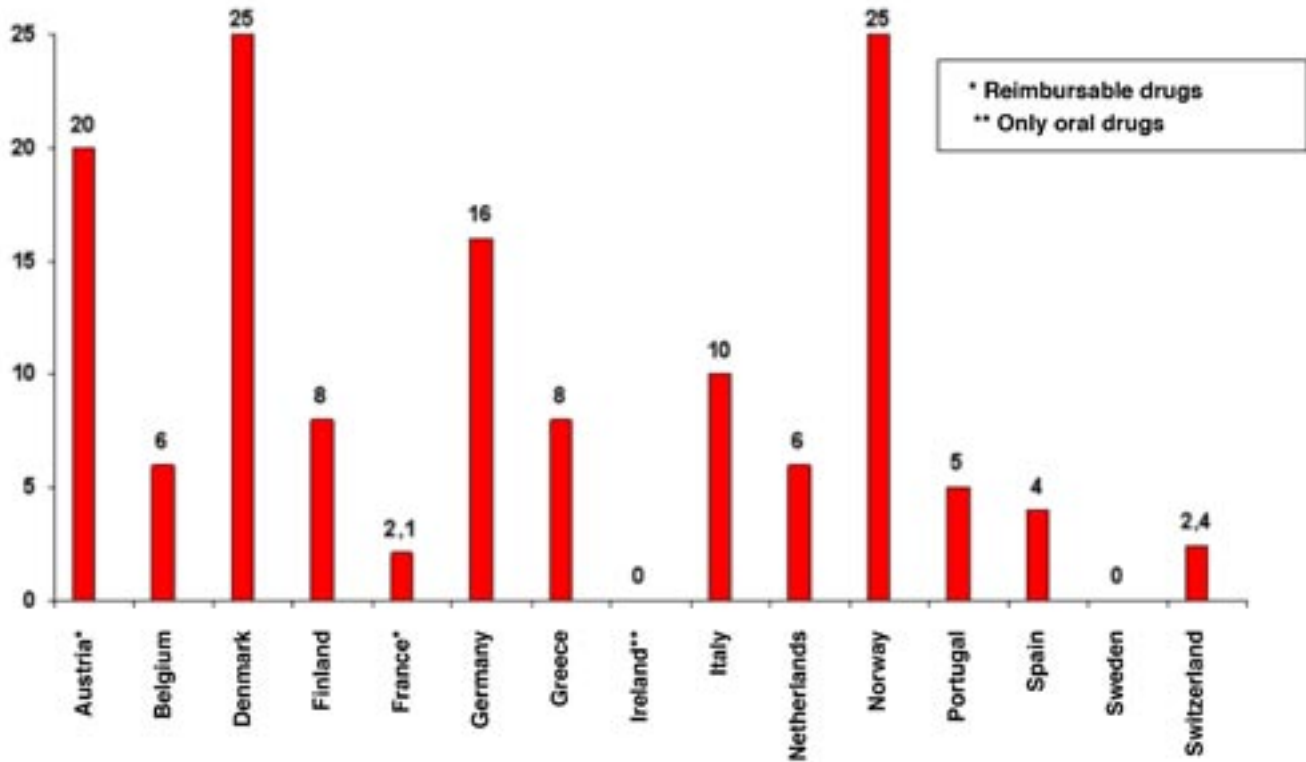


Figure 2. VAT rates on 'ethical' drugs in Europe

Europe (24 per cent below the average) and decreased by 1 per cent in 2004 and by a further 5 per cent in 2005.²⁶

A number of improvements can instead be envisaged, that take into account not much as the total price, as its makeup instead. Specifically, even considering other countries that impose a spending ceiling, the Italian circumstances are worrying from at least two perspectives: the burden of VAT on the price of drugs, and the distribution costs.

It is quite clear that neither factor does impact the manufacturer. We believe that, if this industry is to be regulated (accepting the fact the opposite view is fated to remain a minority view for the foreseeable future), two goals ought to be privileged:

- To reduce the cost for the consumer
- To limit the impact of regulation on innovative companies

This second point would entail a significant change for Italy, where the drug retailers lobby was able to

ward off each and every timid attempt to erode its privileges (for the foreign reader, it may be useful to remind that Italian drugstores can only be managed by specialized professionals, that the number of outlets is strictly limited, and that drugs—both prescription and over-the-counter kind—can only be sold in drugstores).²⁷ Most importantly, achieving that goal might be a reasonable option in a changed institutional setting, one in which reconciling the tasks of securing savings to consumers, safeguarding innovative firms, and guaranteeing current privileges appears increasingly impossible.

The recently enacted "price guarantee" executive order made a partial opening²⁸ in that direction. Article 4 of this order provides for "private- and government-owned drugstore to be allowed to sell over-the-counter and self-medication medical preparations with a discount of up to 20 per cent of the maximum price recommended by the manufacturer." For the first time, the executive order shifted the burden for limiting drug spending on the shoulder of drugstore managers and owners.

For no apparent reason this move only applies to a part of the non-repayable drugs in commerce, leaving out the prescription drugs (the so-called Tier C, which accounts for 60 per cent of the overall consumption). Nonetheless the outcome, at least in the expectations of its supporters, will be to stir the waters, encouraging more competition between outlets and causing prices to lower for the end users.²⁹

The chances of such a scenario to materialize seem to be few, in view of the stout corporative resistance of the drug retail industry, a market characterized by the absence of freedom of entry and, therefore, by the absence of the basic factor that usually translates competition into lower prices.³⁰ At any rate, it is nonetheless a significant step forward. That it may be enough, is an altogether different matter.

As regards non-repayable drugs, 6.65 per cent of the price (net of VAT) goes to the distribution agent, while 26.7 per cent is reserved to the retailer (as provided by the Italian Law n.662, December 23rd, 1996). As it can be seen, more than a third of the price (net of VAT) is reserved to actors whose contribution only consists in distributing a product that others have developed and manufactured, without adding anything of their own.

3. Three proposals

When this makeup of the price of drugs is taken into account, it is apparent that a change of the price composition itself might promise at the same time to lower the prices for the consumers and the national health service, and at the very least to guarantee the current margins of drug companies.

Two steps in this direction may be envisaged:

First, a steep reduction of the VAT on medical preparations, which in Italy amounts to 10 per cent of the price.

It is one of the higher levels in Europe: Sweden and Great Britain impose no VAT on prescription drugs (while the VAT on over-the-counter drugs the rate is decidedly higher, at 25 and 17.7 per cent, respectively); Switzerland charges a rate of 2.4 per cent; France applies a VAT between 2.1 and 5.5 per cent; Spain charges a VAT of 4 per cent, Portugal of 5 per cent, Belgium and the Netherlands 6 per cent, Greece and Finland 8 per cent.³¹

The elimination of VAT on drugs might entail a number of positive results:

a) A larger coverage of the drug spending of the national health service, since the 13 per cent ceiling is calculated on gross prices

b) An improved image for its political supporters. In this case, in fact, the sales tax is charged on a peculiar kind of consumption, and creates the unpleasant impression (as it happens, it is more that a mere impression) that the government makes a profit on sickness. The VAT on drugs, in fact, does not repay the government for its (inexistent) investment for the production of a given

drug, but is nothing less than a "cut" exacted from the sick and ill.

Second, a widening (and, in the future, an opening) of the distribution system. However little worth may have a suggestion with not much chance of ever being translated into reality, the study group Aging Society observed that a number of possible alternative channels (first of all, department stores) are willing to "make do" with a profit of just between 4 and 10 per cent of the drug price net of VAT.³² If such willingness could be tested, of course, this would cause savings of at least 16.7 per cent on the price net of VAT.

The value of this proposal, however, lies in the fact that it would widen the range of competition, helping to get over the problem of the planned distribution of outlets. The Italian law 362 enacted in 1991 provides for the availability of a drugstore for every 4,000 people in each municipality above 12,500 inhabitants,

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and for one for every 5,000 people in municipalities with a smaller population. Federfarma, the Italian pharmacies association, states that Italian drugstores cover on average 3,336 inhabitants.³³ The fact that the glass is not as full as it might otherwise be proves that the current situation is unsuitable to the population's needs. Quite the opposite: regulation, both in the political and the territorial sphere, prevent the opening of a substantially larger number of outlets in larger towns and, at any rate, dictates the recourse to the peculiar Italian form of "drugstore," not necessarily the most efficient channel of distribution for drugs and medical preparations.

Codacons, a consumers' association, has recently advanced the proposal (in line with a repeated suggestion of the Italian antitrust authority) of allowing drugs to be sold in department stores.³⁴ The proposal is actually quite modest, as it provides for:

- The sale in department stores of over-the-counter medications only
- The presence in each department store of a dedicated counter manned by a trained pharmacist

From the perspective of safety (a very proper concern, although it is often advanced to defend corporate vested interests), nothing would change in relation to the current system. The person helping the customer to choose the most suitable medication, to package it and to deliver it into the hands of the patient would still be a doctor specialized in pharmacology, that is somebody who possesses the skills needed to operate in such a field. The notion that a trained doctor may "loose" his skills if forced to operate outside a traditional drugstore is nothing but risible.

The most remarkable change, instead, would be the multiplication of outlets: in time, this would make harder to fix the price of drugs by administrative fiat and might favor, at least for that particular market segment, a real degree of competition.

Moreover, as correctly noted by Antonio Nicita, "not only the liberalization of 'non-ethical' drugs might afford the consumer lower prices, but it might fur-

ther drive the pharmaceutical profession to provide an offer of a combination of products and services more suitable to the needs of customers."³⁵ In fact, as can easily be observed on the shelves of most drugstores today, the impression is that if drugs are still out of department stores, department stores are already within drugstores.

On the one hand, if the need of skilled human resources is felt to sell such atypical products as drugs and medical preparations, the employment of this very same skilled staff to sell diapers, baby formula and lip balm is obviously a waste. On the other hand, if the wish of the owner or manager of a drugstore to widen the range of products he can sell is perfectly legitimate, the presence on the shelves of the drug-

store itself of different products than strictly drugs and medical preparations weakens the case for the exclusive right of drugstores to sell drugs: the more "generalist" a drugstore become, the less deserving of a specific protection it appears.

A third interesting proposal is the shift to a different system of price planning which, although still filling the requirements of the national health service, might at least allow the most innovative forms an easier way to recoup the cost of their investments in research.

The proposed model is the same used in Britain,³⁶ which, at least in principle, affords the drugstore managers no profit margin. However, since there is no government-dictated price percentage in the distribution channels, it is in practice an open market system in which a broad range of manufacturers, wholesalers, and pharmaceutical groups negotiate discounts on the prices recommended by the British National Health Service. The NHS-provided price-list is the basis of the Pharmaceutical Price Regulation Scheme (PPRS), a voluntary agreement which only applies to branded and prescription drugs.

The difference between a ceiling such as the one in force in Italy and the PPRS is that this latter does not dictate a ceiling to prices, but instead to profits: as an example, the companies that in 2004 were sell-

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ing to the NHS branded medical preparations for an amount above 1 million pounds were required to apply a discount of 7 per cent.³⁷

In actual fact, we find the notion of penalizing the profitability of a firm problematic from an ideological perspective, as this system betrays the belief that the quest for profits by a pharmaceutical company is not legitimate or, in other terms, the persistence of a prejudice against the notion that the fight against illness and disease can be driven by the common incentive structure of a free market. At any rate, a system such as the British one appears more flexible and, although the need of containing spending, not less acute in Britain than in Italy, drove the government to favor the use of generic drugs, the observers feel that the system features enough flexibility to reward in the mid-term the most innovative firms. More specifically, the price for new drugs can be fixed at will by manufacturers: this allows a sort of price discrimination, in which the early users that first benefit of the results of research are de facto asked to contribute more. The situation is thus rather close to that that would obtain in a free market for pharmaceutical products.

Conclusions

In the long term, the only solution to the problems caused by the drugs monopsony is a slow but steady return of private providers of healthcare services and products. The unsustainability of the welfare state calls for different answers, however unsettled and embryonic they may be.

So long as government will be the prevailing buyer of drugs, it seems unlikely that price controls can ever be eliminated. The one short term viable solution seems to be a lightening of the burden of price controls on innovative forms, by intervening on direct taxation, distribution, and price bargaining schemes.

Istituto Bruno Leoni recommends the elimination of VAT on drugs and the broadening of distribution channels as a first step for guaranteeing lower prices to consumers and less insecurity for manufacturers.

Endnotes

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2. See, as an example, Charles River Associates, "Innovation in the Pharmaceutical Sector. A Study Undertaken for the European Commission", Novembre 2004, http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2004/nov/EU%20Pharma%20Innovation_25-11-04.pdf. The most significant examples are the British firm Glaxo Smith-Kline, which moved its headquarters in the US in 2000, and the Swiss company Novartis, which moved its research center in Cambridge, Massachusetts.
3. European Federation of Pharmaceutical Industries and Societies, "The Pharmaceutical Industry in Figures: Key Data, 2003 Update," p. 4.
4. PhRMA, *Pharmaceutical Industry Profile*, 2002 p. 76.
5. Boston Consulting Group, *The Contribution of Pharmaceutical Companies: What's at Stake for America*, Settembre 1993, p. 93.
6. A representative case is the controversy followed to the withdrawal from the market of the painkiller Vioxx manufactured by Merck.
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8. International Trade Administration, *Pharmaceutical Price Controls in OECD Countries. Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, US Dept of Congress, Dicembre 2004, <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>, pp.19-20.
9. See Alfonso Gambardella, Luigi Orsenigo and Fabio Pammolli, "Global Competitiveness in Pharmaceuticals: A European Perspective," Report prepared for the Enterprise Directorate-General of the European Commission, November 2000, http://europa.eu.int/comm/enterprise/library/enterprise-papers/pdf/enterprise_paper_01_2001.pdf.
10. Cfr., for example, Roger D. Feldman, *American Health Care: Government, Market Processes and the Public Interest*, New Brunswick, N.J.: Transaction/ Independent Institute, 2000.
11. Quoted in John E. Calfee, *Testimony at Senate Committee on Finance*, April 27th 2004, http://www.aei.org/publications/filter.all,pubID.20476/pub_detail.asp.
12. Cfr., for example, Stephen Moore, "Drug Bill is Socialized Medicine", *Human Events*, 12 settembre 2003, <http://www.humaneventsonline.com/article.php?id=1789>, e Michael F. Cannon, "Medicaid's Unseen Costs", *Cato Policy Analysis* n. 548, August 18th 2005.
13. The essence of monopsony lies in the fact that the buyer can restrict demand—thus causing prices to lower—until its marginal utility expense curve crosses over the marginal value curve. By definition, marginal expense exceeds average expense (identical with offer) and therefore the value of the purchased goods exceeds their price (in a perfectly competitive market). This notion is consistent with the attempt to contain drug spending as a cost containment measure commonly adopted in countries featuring administered or controlled prices regimes and entails a lesser profitability of such markets (as shown by the comparison between Europe and the United States).
14. In OECD countries, 60% of total drug spending is government-borne. Cfr. <http://www.oecd.org/dataoecd/39/40/35019864.pdf>
15. See, as an example, Murray N. Rothbard, *Man Economy and State*, Auburn, Al: Mises Institute, 1993, pp.629-754; Pascal Salin, *La concurrence*, Paris: PUF, 1995; Alberto Mingardi (ed.), *Antitrust. Mito e realtà dei monopoli*, Soveria Mannelli: Rubbettino/ IBL, 2004; Fred Smith, "Perché non abolire l'antitrust?" in Alberto Mingardi & Paolo Zanetto, *Colpirne uno per educarne cento. Il caso Microsoft e il futuro della concorrenza in Europa*, Soveria Mannelli: Rubbettino/ IBL, 2005.
16. For more information about the standards of the Italian regulators, see: http://www.agenziafarmaco.it/archivio_sicurezza.html.
17. Cfr. *L'uso dei farmaci in Italia*, 2005, http://www.agenziafarmaco.it/documenti/volume_definitivo_osmed_2004.pdf.
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22. Cfr. Pierre Lemieux, *La medicina socializzata*, IBL Occasional Paper, 2004.

23. Cfr., for example, Wilfried Prewo, *Oltre lo Stato sociale*, Soveria Mannelli: Rubbettino / IBL, 2005.
24. OECD News Release, June 8th 2004, <http://www.oecd.org/dataoecd/39/40/35019864.pdf>.
25. Agenzia Italiana del Farmaco, *La sperimentazione clinica dei medicinali in Italia*, Roma, 2004, p.13.
26. *Farmindustria Annual Report*, 2005.
27. A particularly significant example of the prevailing mindset in Italy is the confirmation by the Council of State of the TAR (Administrative Court) decision which nullified the "privatization" (in actual fact, a long-term lease) of a number of municipal drugstores in Milan, granted in 2001 by the city council to Ademnta, a German company. Cfr. Giannino Della Fratina, "Farmacie, il comune dovrà restituire 130 milioni", *Il Giornale*, August 27th 2005, <http://www.ilgiornale.it/a.pic1?ID=24448>.
28. It is to be remarked, however, that this order provides for a biennial, as opposed to a yearly fixing of Tier C drugs, with the result of a further element of rigidity in this market, the one in which a relative freedom in price-setting gave a breathing space to manufacturers, otherwise bound to politically fixed prices for their products in other segments.
29. Under this respect, Stefano Capri remarked that "the spending for drugs on which a discount is applicable amounted in 2004 to 2.040 millions euro, while the spending for drugs excluded from the above-said executive order was 3.035 millions euro". "Concorrenza e farmaci: si può dare di più", *la voce.info*, August 3rd 2005, http://www.lavoce.info/news/view.php?PHPSESSID=a35c63f3d5d074e9587db023573767b7&SEARCH=farmacie&ACTION=search&AUTHOR=&RECORD_PAGE=5&button.x=0&button.y=0&id=2&cms_pk=1690&from=index.
30. The fact that competition causes prices to lower is due not much to the presence of a plurality of actors in a given market, as instead to the fact that, whatever the number of competitors, in principle there is always the chance that a further competitor can enter the market which, adopting an innovative strategy (better services, lower prices), can erode the position of established actors.
31. EFPIA, *The Pharmaceutical Industry in Figures. Key Data 2005*, p.13, http://www.efpia.org/6_publ/infigures2005.pdf.
32. Cfr. "Sintesi della proposta per il contenimento della spesa farmaceutica", *Ageing Society - Osservatorio della Terza età*, September 2004, p.8, <http://www.ageingsociety.com/studio250904/sintesi2509.pdf>.
33. Federfarma, *Rapporto farmacie/farmacisti in Italia*, Maggio 2005, https://www.federfarma.it/cms_published_2/farmacisti_IT.html.
34. This proposal was publicized with a rally in Rome last July. Cfr. <http://www.codacons.it/comunicati.asp?id=5804>.
35. Antonio Nicita, "La concorrenza fa bene alla salute", *la voce.info*, August 3rd 2005, http://www.lavoce.info/news/view.php?PHPSESSID=a35c63f3d5d074e9587db023573767b7&SEARCH=farmacie&ACTION=search&AUTHOR=&RECORD_PAGE=5&button.x=0&button.y=0&id=2&cms_pk=1689&from=index.
36. For a comparative overview, see Mary E. Wiktorowicz, "Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain and France", *Journal of Health Politics, Policy and Law* - Volume 28, Number 4, August 2003.
37. Department of Health, *Pharmaceutical Price Regulation Scheme. 8th Report to the Parliament*, March 2005, p.22, <http://www.dh.gov.uk/assetRoot/04/10/69/24/04106924.pdf>.



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