ISSUE BRIEF
NOVEMBER 2019

What Can the United States Learn from Pharmaceutical Spending Controls in France?

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ABSTRACT

ISSUE: U.S. health care payers and policymakers are looking for strategies to combat high drug prices and spending. In the United States, spending on prescription drugs grew an average of 3.6 percent annually from 2008 to 2017, a rate far more rapid than in other developed nations like France, where retail drug spending declined during this same period.

GOALS: Describe and assess France's system of pharmaceutical price and spending controls to identify potential lessons for the U.S.

METHODS: Analysis of legal texts and government reports and interviews with policymakers and members of the French pharmaceutical trade association.

KEY FINDINGS AND CONCLUSION: To control spending, France sets maximum prices for new products that reflect the added value of the new drug compared with a comparator product. The country also prohibits price increases after a new drug's launch and, after five years, lowers prices and obtains additional discounts based on market competition. France also requires manufacturers to pay rebates if spending exceeds a national pharmaceutical spending cap set by Parliament. By employing approaches used in France, private and public payers in the U.S. could reduce drug spending without restricting access to new drugs.

TOPLINES

- In France, retail drug spending declined 1.98 percent from 2008 to 2018, while in the United States it grew an average of 3.6 percent annually from 2008 to 2017.

- The French health system controls drug prices by determining maximum prices based on added therapeutic value and external reference pricing; employing negotiation to set prices and limit price increases; and capping total spending to a global budget.

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HOW FRANCE CONTROLS PHARMACEUTICAL PRICES AND SPENDING

U.S. brand drug prices, among the world's highest, have become a budgetary and policy problem.[1] Retail pharmaceutical spending has grown an average of 3.6 percent annually from 2008 to 2017 and is expected to grow faster in the coming decade. In contrast, in France, retail drug spending declined 1.98 percent from 2008 to 2018 — all without blocking access to innovative medicines.[2,3] As U.S. payers and policymakers explore cost-control options, France's spending controls are worth consideration.

France's pharmaceutical cost-control strategy has two parts. First, the government contracts with manufacturers to purchase new medications at a price that reflects their added therapeutic value. Second, it uses a budget cap to keep national health insurance (NHI) drug spending in line.[4]

Appraising the Value of Drugs

France's Transparency Commission (*Commission de la transparence,* or CT) rates new drugs on a five-point scale indicating their added therapeutic value (*l'amélioration du service médical rendu,* or ASMR) in relation to a comparator drug[5] — typically, the lowest-priced comparator. The commission considers differences in mortality, morbidity, and undesirable effects or risks.[6] The ratings set parameters within which the Health Care Products Pricing Committee (*Comité économique des produits de santé,* or CEPS) must negotiate maximum prices.[7] From 2009 through 2016, the CT evaluated about 85 new medications per year. Exhibit 1 displays average yearly ratings.

Price Negotiation Linked to Assessment of Drug's Added Value

In France, drugs with ASMR ratings of I through III and certain ASMR IV drugs are assigned higher prices than the lowest-price comparator.[8] The CEPS negotiates prices so that they are neither higher nor lower than the highest or lowest prices in the United Kingdom, Germany, Italy, and Spain.[9] For ASMR IV drugs, treatment costs generally cannot exceed the French price of their comparator. ASMR V drugs offer no improvement and are priced lower than their comparator on the French market, typically 5 to 10 percent lower.[10]

For each new medication, the CEPS negotiates a five-year contract with the manufacturer that specifies the price and anticipated sales volume. This discourages the marketing of drugs for indications that are approved by the European Medicines Agency (EMA) but not reimbursed by health insurance, as well as the marketing of drugs for off-label uses. The agreement on price and anticipated sales volume constitutes a cap on revenue. When sales exceed the contract cap, manufacturers pay rebates of between 50 percent and 80 percent.

The CEPS has the option of employing a performance contract under which the manufacturer refunds a portion of the price if the drug does not produce specified clinical results.[11]

Exhibit 1. Transparency Commission Added Therapeutic Value (ASMR) Rating of New Drugs, 2009–2016

ASMR rank	ASMR I: Major improvement	ASMR II: Important improvement	ASMR III: Moderate improvement	ASMR IV: Minor improvement	ASMR V: No improvement
Annual average number of drugs	1.4	3.3	8	22	51
Pricing	By reference to prices in U.K., Germany, Italy, and Spain: Neither higher than the highest price nor lower than the lowest price.	By reference to prices in U.K., Germany, Italy, and Spain: Neither higher than the highest price nor lower than the lowest price.	By reference to prices in U.K., Germany, Italy, and Spain: Neither greater than the highest price nor lower than the lowest price.	Treatment costs cannot exceed the French price of the comparator.	5% to 10% lower than the French price of the comparator.

Note: AMSR = l'amélioration du service médical rendu.

Data: Loïc Guillevin, Jean Ponsonnaille, and Anne d'Andon, *Commission de la Transparence de la Haute Autorité de Santé Bilan 2014–2017* (text sollicité par la Commission II de l'Académie national de médecine), p. 12, table 2. Copy on file with author. Eight-year averages calculated by the author.

COVERAGE FOR PRESCRIPTION DRUGS IN FRANCE

France's national health insurance (NHI) does not cover a new medication unless authorized by the Ministry of Health. It typically follows the recommendations of the Transparency Commission (CT), which assesses each drug's therapeutic value.[12]

The CT assigns each drug a rating of 1 to 5 corresponding to its medical benefit, referred to as the "medical service rendered" (*service médical rendu,* or SMR), which determines the percentage of price that NHI reimburses. The CT considers the gravity of the problem, the medication's effects, and its public health impact. NHI reimburses 100 percent of medicines for afflictions that lead to death if untreated and for grave, long-term illnesses, such as diabetes. It reimburses other medications as follows:

- 65 percent for drugs awarded a **major** or **important** SMR
- 30 percent for drugs with a **moderate** SMR
- 15 percent for **low** SMR drugs
- 0 percent for drugs receiving an **insufficient** SMR.

However, NHI fully reimburses all expenses for people suffering from chronic diseases, so the average reimbursement rate is higher.[13] Supplemental private insurers often pay part of uncovered expenses.

Negotiated Discounts and Market Competition

Once a list price has been set based on the value of the drug, CEPS negotiates a confidential discount (typically 10% to 30%), which is paid as a rebate to the Central Agency for Social Security Organizations.[14] This is similar to negotiations between manufacturers and insurers in other European Union (E.U.) nations (see box on page 4). Hospitals in France can sometimes obtain additional discounts through a competitive bidding process and price negotiations when competing drugs exist.

Pricing on Older Drugs

France reduces prices on older drugs to pay for newer drugs. After the initial five-year contract, the CEPS negotiates lower prices in line with a drug's brand and generic comparators. Once a year, it also reduces prices on high-cost medicines within each therapeutic class or group to bring them in line with other drugs in the same group.[15]

During the past decade, the CEPS financed the purchase of new drugs mainly by reducing the prices of older medicines. The budget also strengthens the CEPS' negotiating position when pricing new drugs.

Cap on Growth of Pharmaceutical Company Sales

Beginning in 1997, annual legislation in France has set a target for NHI spending growth rates known as ONDAM. Since 2004, the annual pharmaceutical target growth rate has been 1.08 percent, one-third of the 3.01 percent growth rate for total medical spending.[16] For the past two decades, legislation has capped the growth of pharmaceutical companies' total sales. The 2019 target rate for company sales growth on reimbursed drugs was initially 0.5 percent but was later increased to 1 percent; the growth rate for 2020 is set at 0.5 percent.[17]

When manufacturer sales exceed the cap, the law requires manufacturers to pay a clawback, a set rebate based on company sales revenue. Each firm pays 50 percent to 70 percent of its sales revenue after the budget cap is surpassed depending on the amount of overspending, with each firm's clawbacks capped at 10 percent of revenue.[18] Companies can cut their clawback payments by about 20 percent if they join a voluntary framework agreement, which sets rules for price negotiations.[19]

E.U. INFLUENCES ON PHARMACEUTICAL MARKETS

The European Union (E.U.) helps shape French policy.[20] Although firms can import medicines among member states without duties, the E.U. does not control prices or coverage as these remain national competencies.[21] Each nation undertakes health technology assessment (HTA) to evaluate drugs, make coverage decisions, and set prices. However, the European Commission, the executive branch of the E.U., is entertaining a proposal to coordinate HTA across nations.[22] Nations vary in their willingness and ability to pay; some have fixed pharmaceutical budgets.[23] Consequently, manufacturers market through national subsidiaries and set distinct prices in each country.[24]

To address national price variations, European states incorporated external reference pricing into their price controls in the 1990s. Currently, 25 of 28 E.U. countries employ reference pricing to cap drug list prices.[25] Each nation uses the price in designated nations as a benchmark. They accept that manufacturers grant discounts to other countries for purchasing higher volumes and certain other factors but aim to keep prices in line with those of selected reference-price countries. Consequently, prices in one nation influence prices across the E.U.[26] The WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (founded in 2010) publishes list drug prices for European states.[27]

Manufacturers have responded to these policy developments by keeping real prices secret. Around 2011, they raised or maintained list prices while selectively providing confidential discounts. Sometimes manufacturers offered larger discounts in return for obtaining higher list prices. Today, virtually all E.U. nations have public list prices yet receive confidential discounts of 10 percent to 30 percent off the allowable price.[28] Although these discounts are not made public, national health insurance (NHI) officials sometimes believe they can estimate real prices.

IMPACT ON INNOVATION

Critics often contend that capping prices will eliminate or slow access to new medicines. It hasn't in France, where manufacturers sell the full spectrum of innovative drugs available in the E.U. In fact, France explicitly rewards innovation by requiring the CEPS to pay more for new products that offer an important therapeutic improvement and to set prices that are consistent with reference prices in other E.U. countries. This system provides incentive to bring drugs to market that offer significant therapeutic improvement, rather than "me too" drugs.

However, industry critics note that the process of evaluating the added benefit of new drugs and reaching a price agreement is slower in France than in some other European countries. A European Commission directive set a goal for completing such work in 180 days. In 2017 it took France 168 days to complete this process, with another 45 days until the price was published in the official journal.[29]

In part to compensate for such delays, France's compassionate-use program permits patients to access products before the CEPS and manufacturer have reached an agreement on price, and sometimes even prior to the firm receiving marketing approval by the EMA. Firms set prices of such drugs and then reimburse NHI the difference between their initial price and the negotiated price.[30]

In the few rare cases when the Transparency Commission found a new drug to have no therapeutic advantage over existing products and the CEPS and manufacturer were unable to reach an agreement on price, the company chose not to market the drug in France. Industry observers report that the CEPS is reluctant to set a price that results in a drug not being sold in France, unless there are alternative products that can meet patients' needs or the medication in question has minor therapeutic value.

KEY FEATURES OF THE FRENCH SYSTEM AND IMPLICATIONS FOR THE UNITED STATES

Health technology assessment (HTA) provides a principled means to set list prices.

France evaluates new medicines, and NHI pays more if new drugs are superior to similar products and less if they offer no improvement. The CEPS establishes new drug prices in relation to existing drug prices and sets the maximum NHI pays.

In contrast, U.S. insurers don't cap prices based on an independent assessment of their clinical value, so manufacturers of patented drugs can demand uncompetitive prices. The Institute for Clinical and Economic Review conducts cost-effectiveness analysis and comparative clinical effectiveness analysis of new drugs to assist in value-based pricing for payers, such as the U.S. Department of Veterans Affairs, that are interested in obtaining such information.[31]

While current U.S. legislation that mandates discounts from benchmark market prices lowers prices for Medicaid, it lacks a principled basis. Existing legislation also does not control prices for Medicare or private insurers. Moreover, manufacturers can dilute the effect of discounts by raising list prices. U.S. insurers could save money and provide incentives to create innovative medicines if they assessed the value of new drugs and allowed prices higher than a comparator drug only when the new drug has added therapeutic value.

Employing a formulary that can exclude medicines provides leverage to lower prices.

France excludes drugs from coverage unless manufacturers sell at prices that the CEPS accepts. As a result, manufacturers sell at lower prices in France than in the U.S., where payers are limited in their ability to exclude drugs from their formulary. Medicare could cut drug spending if it negotiated payment and if manufacturers had an incentive to lower prices. Today, however, manufacturers can demand high prices because legislation requires Medicare to cover most medicines without regard to price.[32] Medicaid must cover many medicines without regard to list price as long as it receives a fixed discount. Several states also require Medicaid to cover all FDA-approved drugs used to treat cancer. And three-quarters of Americans live in states where state laws require insurers to cover anticancer medications for off-label uses.[33]

Key Components of French Pharmaceutical Pricing

1 Health Technology Assessment

- Independent government commission assesses comparative therapeutic value of new drug

2 Maximum Allowable Price

- Agency determines maximum price consistent with HTA
- New products enter five-year contract with no price increase and capped sales volume
- Manufacturers pay rebates if total sales volume exceeds contract

3 Negotiated Prices

- Agency negotiates confidential discounts of 10% to 30% off maximum allowed price
- Hospitals negotiate additional discounts from manufacturers when competing products exist

4 Price Decreases over Time

- Agency usually decreases prices after five years
- High-priced drugs in each class lowered over time toward lowest-price drugs in class

5 Annual Spending Cap

- Parliament sets budget for total drug spending growth
- All manufacturers pay back share of revenue if total spending exceeds the target

Private insurers can exert some leverage when there is competition within a therapeutic class by excluding certain drugs or requiring patients to pay higher copayments unless they choose a preferred drug. They also restrict access by requiring prior authorization to use certain drugs or step therapy, where patients must first fail on a preferred drug before trying higher-cost alternatives. The ability to exclude drugs based on price would provide greater leverage in negotiating discounts.

Negotiating total sales (quantity and prices) helps control spending.

Spending is a function of unit price and volume, and manufacturers often lower prices in exchange for increased sales. Consequently, insurers can more effectively control spending when they link prices with sales volume. In France, the CEPS negotiates contracts that cap total sales determined by the number of patients that can use the medication for approved indications. Contracts reduce prices as sales volumes increase, and manufacturers pay rebates if they exceed authorized sales.

In the U.S., Medicare, Medicaid, and private insurers could control spending and obtain price discounts if they use contracts that link price to the volume sold. Louisiana is experimenting with one approach called a "subscription model," which guarantees a fixed payment in exchange for unlimited access to an expensive specialty drug for hepatitis C, reducing the per-unit cost.[34]

Global budgets control spending and provide leverage to negotiate prices.

Despite price controls, France's drug spending rose steeply from 1980 to 2000. Spending growth slowed and remained stable after Parliament set annual pharmaceutical budgets and recouped a large share of overspending through clawbacks. Budget controls also helped the CEPS negotiate lower prices.

In the U.S., Medicare, Medicaid, and large health plans should explore developing pharmaceutical spending budgets that would give them greater leverage to negotiate prices. Congress and states should consider legislation that allows government programs to require manufacturers to pay clawbacks if drug spending exceeds their targets.

Contracts prevent manufacturers from raising prices after launch.

France's NHI purchases medications using five-year contracts that prohibit price increases. In contrast, in the U.S., pharmaceutical firms can raise prices at will and often do.

American health plans and pharmacy benefit managers (PBMs) should consider purchasing drugs using multiyear contracts that specify a fixed price for the duration. In addition, payers can include a cap that prevents price increases over inflation as measured by the consumer price index, which is similar to legislation recently introduced in Congress.[35]

Older drug prices can be lowered so they are similar to comparable therapies.

France compares prices of generics and brand drugs used for similar purposes and lowers the prices on high-priced drugs to promote price consistency. American insurers should consider adopting policies that revise older drug prices in a similar manner.

External reference pricing reduces price discrimination but is difficult to implement.

France uses European reference pricing to set prices for new innovative drugs. Because other E.U. countries purchase medications at less than list prices and often receive rebates, the CEPS employs intelligence to estimate the difference between list prices and actual cost paid and obtains similar discounts.

The Trump administration has proposed using international reference pricing to lower prices for physician-administered drugs covered under Medicare Part B.[36] However, policymakers cannot determine the amount that other nations pay for drugs by looking at list prices, because France and other E.U. nations always pay less than list prices and sometimes also receive rebates and clawback payments. If Medicare intends to set prices based on the prices paid by other countries, it should use the net price (or an estimate of the net price) after discounts, rebates, and clawbacks. Otherwise, the U.S. will still pay significantly more than other nations.

CONCLUSION

Using regulation versus relying on markets to advance goals is at the center of a long-standing debate in U.S. health policy. Many analysts contend that regulation is inefficient and precludes competition. France shows that regulation does not prevent price competition and can even make use of market prices.

Although no country's system can be fully replicated in the U.S., there are lessons from studying how countries like France achieve lower drug prices. The French system determines maximum drug prices based on added therapeutic value and external reference pricing. It employs negotiation to set prices and limits price increases. It caps total spending to a global budget. Each approach might be implemented in the United States or inspire similar reforms.

NOTES

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Editorial support was provided by Christopher Hollander.

ACKNOWLEDGMENTS

This study was supported in part by the IMéRA Institute for Advanced Study and the Integrated Cancer Research Site. Many thanks to Dominique Maraninchi for support of the project and to Claude Le Pen and Valérie Paris for comments on a draft and guidance in the research. Thanks to the Health Care Products Pricing Committee for assistance with my research.

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The Commonwealth Fund

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