By James C. Robinson and Quentin Jarrion

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Competition From Biosimilars Drives Price Reductions For Biologics In The French Single-Payer Health System

James C. Robinson (james.robinson@berkeley.edu) is the Leonard D. Schaeffer Professor of Health Economics in the Division of Health Policy and Management, School of Public Health, at the University of California Berkeley, in Berkeley, California. He is a *Health Affairs* contributing editor.

Quentin Jarrion is a research physician, Health Information Management Department, University Hospitals of Reims, in Reims, France. At the time this research was initiated, he was a visiting scholar at the University of California Berkeley.

ABSTRACT **France has a single-payer health insurance system that has the authority to impose pharmaceutical price reductions but relies on decentralized market negotiations between hospitals and manufacturers to establish prices for injected and infused biologics. Hospitals rely on biosimilars—less expensive but therapeutically equivalent variants of biologic medications—to stimulate competition. Price reductions negotiated by hospitals subsequently are adopted by the health insurance system, driving hospitals to negotiate a new round of discounts. This article measures 2004–20 trends in prices, price reductions, utilization, and market shares for three prominent biologics—Remicade, Enbrel, and Humira—and their eleven competing biosimilars. Biosimilar launches are associated with a sequence of price reductions for the reference biologic, for other biologics that treat similar conditions, and for all related biosimilars. The French experience provides lessons for the US in its efforts to use competition from biosimilars to drive price reductions and savings from biologics.**

The US is currently engaged in a debate over alternative strategies for achieving moderation in drug spending, including legislative proposals to set regulatory limits on the prices negotiated at the time of initial market launch and to ban postlaunch price increases. Some policy analysts have highlighted the single-payer health system in France as a possible model, given its authority to regulate launch prices and mandate subsequent price reductions.[1–3] A close look at the process of drug price determination in France, however, indicates that the actual process differs substantially from what might be inferred from the formal structure. Instead of determining prices in a centralized manner with an administrative formula, France relies in important ways on market competition and decentralized negotiations.

The synergies between market and regulatory mechanisms are particularly evident for innovative biologics and their less expensive but therapeutically equivalent biosimilars.[4] Biologics are large, complex molecules that must be injected or infused into the body, instead of being taken orally. They are growing in use and rising in price and now account for almost half of pharmaceutical industry sales.[5] Biosimilars charge low prices to gain market share from reference biologics, which otherwise enjoy monopoly pricing power, and are able to sustain lower prices as they have lower costs of research and development.

The mix of market and regulatory mechanisms adopted in France, and the manner in which they are coordinated, have important implications for US pharmaceutical pricing policy. The US lacks consistent incentives for physicians to prescribe low-price biosimilars and for manufacturers to compete using price reductions. Misaligned incentives impede what advocates have hoped would be a virtuous cycle of biosimilar

product launches, accelerated adoption, intensified competition, better patient access, greater savings for purchasers, and the freeing up of funds to pay for the next round of truly innovative drugs. The stunted adoption of biosimilars in the US also impedes the global development of the market because manufacturers only engage in research and development if they are convinced that there is significant revenue potential.

In this article we examine data from the French national authority in charge of setting prices for medical products and pharmaceuticals to derive lessons for the US as it pursues the use of competition to seek price reductions and savings from the use of biologics and biosimilars.

Decentralized Negotiations: The Role Of Hospitals

The French system of social security, which covers health services as well as pensions, is funded by national taxes plus contributions made by employers.[6] It is a single-payer system for medical products such as drugs, with modest contributions from patient copayments and complementary private insurance. The determination of drug prices is delegated to the Comité Economique des Produits de Santé (CEPS) (Economic Committee for Health Products) in consultation with other governmental entities such as the French National Health Authority.

The CEPS negotiates with manufacturers a national tariff for each new drug and biologic that is based on the prices of comparable products, the new product's clinical improvement over existing treatments, cost-effectiveness studies that compare the new product's clinical benefit with its price, the prices charged in other European nations, and the volume of prescriptions expected to be written (as an indicator of potential budget impact).[7–9]

These centralized administrative mechanisms are supplemented by decentralized negotiations between the manufacturer and each French hospital or hospital purchasing group. These negotiations determine the price that will be paid for the drugs to be used in hospital ambulatory clinics as well as inpatient settings and are the amounts actually paid to the manufacturers. The national tariffs negotiated with the manufacturers by the CEPS are used as the basis of the payments made by the social security system to the hospitals, not the manufacturers.

The French social security system pays diagnosis-specific case rates to cover the normal components of an inpatient admission in a manner analogous to Medicare Severity Diagnosis Related Group rates. Expensive drugs and devices are carved out of the case rates and reimbursed to hospitals using supplemental payments, analogous to the new technology add-on payments used by Medicare.[10] Drugs eligible for payments beyond the French case rates are included in the supplemental list. For these drugs, the French social security system reimburses the hospital for the amount negotiated by the hospital with the manufacturer, plus one-half of the difference between this negotiated price and the national tariff negotiated with the manufacturer by the CEPS. This gainsharing framework creates an incentive for the hospital to negotiate the lowest possible price with the manufacturer.[11]

France has a hospital-centered delivery system for ambulatory as well as inpatient care. Infused biologics such as Remicade must be administered in hospital outpatient departments; community-based specialists are not permitted to maintain infusion clinics in their private practices. Injected biologics such as Enbrel and Humira may be administered in community settings, but the initial prescription and injection must be performed in a hospital clinic by a hospital-based specialist.[12] The mandate that the first injection be performed in a hospital derives from evidence that community-based specialists rarely switch the prescriptions made by their hospital-based counterparts and that switching from biologics to biosimilars performed in hospital settings will carry over into community settings.[13]

The value of the gainsharing incentive depends on the level of the national tariff. The CEPS monitors hospital negotiations and reduces the national tariff when it observes manufacturers offering meaningful discounts to individual hospitals or to hospital purchasing groups. These reductions in the national tariff shift the economic savings generated by hospitals' negotiations from the hospitals themselves to the social security system. This reliance on hospital negotiations also provides political cover for cuts in the national tariff. Pharmaceutical firms cannot claim that the new lower price is insufficient, as it has already agreed to it with the hospitals.

The reliance on decentralized price negotiations by hospitals, as a supplement to centralized negotiations by the national insurer, requires explanation. It would seem to be counterproductive to replace the scale and sophistication of the national insurer with the smaller scale and lesser sophistication of hospitals and would also add another level of complexity to the process of price determination.[14,15] The French system relies on these decentralized negotiations because the CEPS is unable to ascertain a drug's reservation price, defined as the level below which the manufacturer will reduce its supply chain and service guarantees (for example, inventory security or

prompt delivery) or, at the extreme, withdraw its product from the French market.

The reductions in the national tariff reduce the gainsharing revenue accruing to the hospitals, as this is based on the difference between the national tariff negotiated by the CEPS and the prices negotiated by the hospital with the manufacturer. The tariff reductions therefore create incentives for hospitals to enter a new round of negotiations with manufacturers, with the goal of obtaining further price reductions that restore the gainsharing revenues. Subsequent local price reductions negotiated by hospitals lead to subsequent national tariff reductions. Hospitals are required to report to the CEPS the price discounts obtained from manufacturers. In this manner, tariffs paid by the social security system trend downward without the risk that manufacturers will exit the market.

Market Competition: The Role Of Biosimilars

The statutory authority over national prices in France is particularly evident with respect to price reductions in the years after initial market launch. The CEPS wields the statutory authority to impose tariff reductions in response to the market entry of a therapeutically similar product, a new indication being approved for the original drug, the price being reduced in another European nation, or evidence emerging that the product is less effective than previously believed. In principle, therefore, the CEPS does not need to rely on market competition but could rely on unilateral price regulation to reduce its spending on drugs.

Despite this statutory authority, the French system has relied on the market entry of biosimilars to precipitate the most important tariff reductions for biologics.[16] The launch of new biosimilars influences the tariffs of the reference biologics in different ways depending on whether the drugs are administered by a hospital-based or a community-based physician.[17–19] The difference derives from the assumption that hospitals have the ability to negotiate prices with drug manufacturers, and thereby derive information on reservation prices, but community-based physicians do not.

The CEPS audits the prices negotiated by hospitals with the manufacturers of biosimilars and periodically mandates reductions in the national tariff when it observes the hospitals obtaining meaningful savings. It requires that the national tariffs for a biologic and its biosimilars be the same, in the interest of stimulating hospital negotiations with manufacturers for both types of products. This uniformity extends to other therapeutically similar biologics, which are required to reduce their national tariffs even when a biosimilar is launched for a different reference product.[17] Reductions in the national tariff reduce the savings available to the hospitals under the former tariffs and induce the hospitals to pursue another round of price reduction with the manufacturers. Reductions in the prices negotiated with hospitals in turn lead to subsequent reductions in the national tariff.

In contrast to the experience in Europe, payers in the US have been slow to develop gainsharing incentives to drive biosimilar adoption.

Study Data And Methods

DATA SOURCES We analyzed the national tariff prices for three anti–tumor necrosis factor immunology biologics, Remicade, Enbrel, and Humira, from the beginning of 2004 through January 2020, as well as the prices for the eleven related biosimilars that entered the French market beginning in 2015. These pricing data were obtained from the Base des Médicaments et Informations Tarifaires (Drug and Tariff Information Base), which is updated every week.[20] The prices reflect the amounts paid by the national insurer to the hospitals, rather than the amount paid by the hospitals to the drug manufacturer. Each hospital pays the manufacturer the price it has negotiated, irrespective of the tariff negotiated by the CEPS with the manufacturer.

We obtained the sales volumes of each of the three biologics and eleven biosimilars when used in the hospital outpatient setting. These data include the total national volumes for Remicade and its biosimilars, as those infused products are administered only in hospital clinics in France. However, Enbrel, Humira, and their biosimilars are administered in community as well as hospital ambulatory settings. As noted above, the first prescription and injection of these drugs must be performed in the hospital setting. Subsequent injections can be performed in a hospital or in

Even a centralized single-payer system has limited power to impose price reductions on drug manufacturers.

the community, depending on whether the patient remains under the care of a hospital-based or a community-based specialist. Our data cover only the volume administered in hospital ambulatory clinics.

We calculated trends in hospital ambulatory market shares for each reference biologic, its competing biosimilars, and the combination of the three therapeutically similar biologics and their eleven biosimilars. The data allow insight into the relative success of early and late biosimilar market entrants for these treatments. We calculated changes in the national tariffs for the three biologics that occurred after the launch of each biosimilar as well as the impact on the tariff for one biologic associated with the market entry of a biosimilar for a different biologic.

Insights into the functioning of the French system for drug price determination were obtained from review of the CEPS annual reports, documents from the governmental auditor, published articles, and white papers from consultants and other informed observers. We also conducted interviews with individuals employed by the social security system, the CEPS, hospitals, consulting firms, pharmaceutical associations, and academia. These qualitative interviews were used to develop and refine our perspective that the French system uses decentralized market negotiations to inform its centralized regulatory pricing process.

We limited our analysis of biosimilar policy to the French approach to be able to discuss the actual processes used in depth, and thereby offer more detailed lessons for the US. Excellent surveys of approaches adopted by the spectrum of European nations, which of necessity had to sacrifice depth for breadth, have been published elsewhere.[21–25]

LIMITATIONS The data used in this study reflect the national tariff prices negotiated by the CEPS, using its scale as a single payer, rather than the local prices negotiated by hospitals. We thus could not measure the size of the gainsharing revenues obtained by each hospital from the shifts to biosimilars. However, our data do illuminate the main theme of the study, which is the effect of biosimilar competition, working through local hospital negotiations, on the tariffs paid at the national level. Each round of hospital price reductions sets the stage for another cut in the national tariff, and each cut in the national tariff sets the stage for another round of hospital negotiations.

Our utilization data represent the hospital ambulatory sector and do not include drugs administered in the physician's office or the patient's home. The majority of injections for Enbrel and Humira and their biosimilars are performed in these community settings. In contrast, all infusions for Remicade and its biosimilars are performed in the hospital ambulatory setting. The shift toward the biosimilars of Enbrel and Humira and away from the reference biologics is likely to be sustained in community settings because of the reluctance of community-based physicians to contravene the clinical choices of hospital-based specialists. Indeed, the French social security system explicitly uses hospital gainsharing as a tool to influence biosimilar use in nonhospital settings.[12]

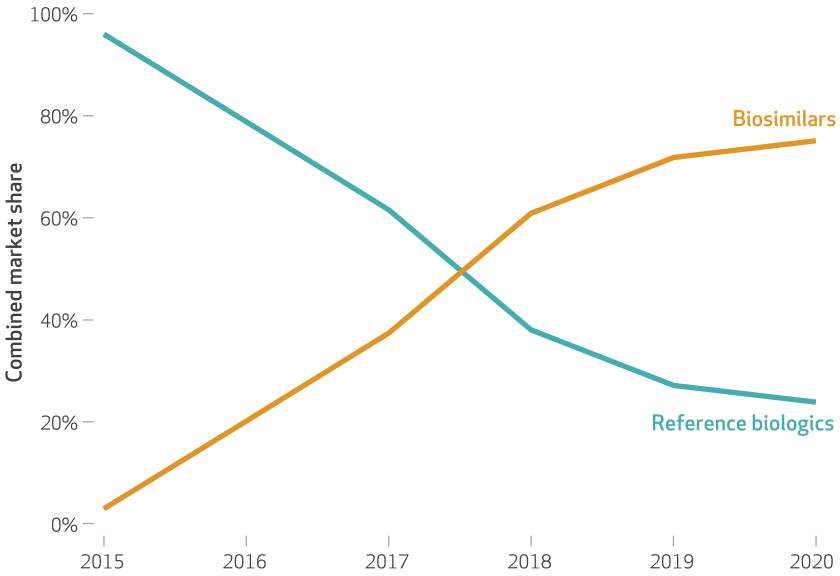
Study Results

TRENDS IN SALES AND MARKET SHARES Exhibit 1 presents the shares of the French hospital ambulatory drug market held by the three biologics and their biosimilars between 2015, the year of the first biosimilar launch, and January 2020. By 2019 the biosimilars as a group held an approximately 75 percent share of the hospital ambulatory market, defined in terms of volume of vials administered, which is close to the national goal of 80 percent biosimilar market penetration.[19]

The French market exhibits robust competition among biosimilars as well as between biosimilars and their reference biologics. Exhibit 2 shows trends in market shares for Remicade and each of its biosimilars beginning in 2015—the year the first biosimilar was launched. The first biosimilar to be launched, Inflectra, gained and retained the highest market share and had achieved 41 percent of the national market by January 2020. Each of the two subsequent biosimilar entrants gained approximately 18 percent of the market, whereas the fourth biosimilar had failed to gain any traction (0 percent market share) as of January 2020. The reference biologic Remicade itself suffered a dramatic fall in use and retained only one-quarter of the market by 2020.

EXHIBIT 1

Market shares for three reference biologics and their biosimilars used in hospital ambulatory clinics in France, 2015–20



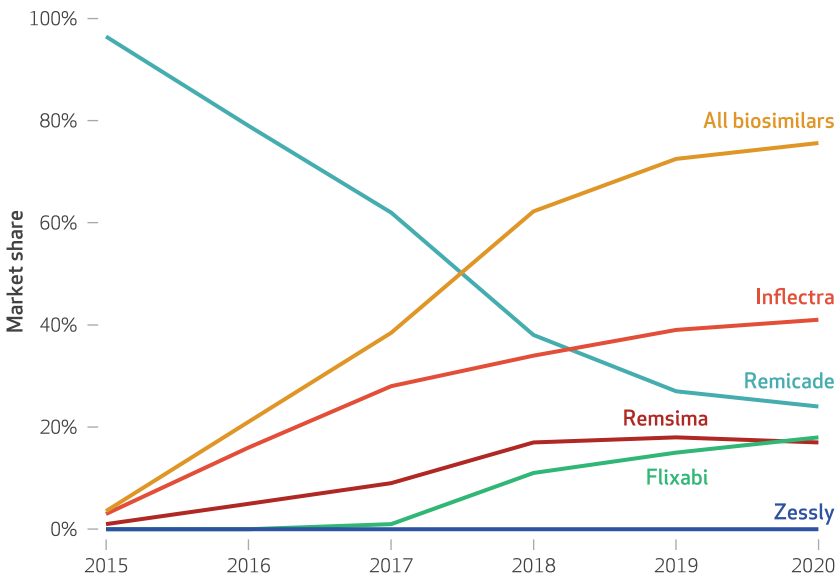
SOURCE Base Nationale ATIH du Programme de Médicalisation des Systèmes d'Informations et des Médicaments (proprietary data). **NOTE** Combined market shares for three anti–tumor necrosis factor biologics, Remicade, Enbrel, and Humira, and their biosimilars are shown.

Online appendix exhibits 1 and 2 show trends in hospital market shares for Enbrel and Humira and their biosimilars.[26] The growth in their biosimilar market shares was similar to that for Remicade, despite the fact that they are injected products used in both hospital and nonhospital settings, whereas the infused product Remicade is used exclusively in hospital clinics. The appendix exhibits represent use in hospital ambulatory clinics only, as comparable data on injections in private physician practices are not available.[26]

These changes in market shares occurred against a backdrop of overall growth in hospital ambulatory utilization but a reduction in spending due to the shift from higher-price biologics to lower-price biosimilars. As indicated in appendix exhibit 3, sales revenues for Remicade decreased from 276.4 million euros in 2015 to 33.8 million euros in 2019 under competitive pressure from the five biosimilars.[26] In contrast, the combined sales of the Remicade biosimilars increased from 6.7 million euros in 2015 to 59.5 million euros in 2019. Hospital ambulatory sales for Enbrel declined from 251.4 million euros in 2015 to 49.8 million euros in 2019, whereas those for Humira declined from 4.0 million euros to 730,580 euros between 2015 and 2019. Sales of their biosimilars rose from zero in 2015 to 36.8 million euros and 50.7 million euros, respectively, in 2019. These figures understate volumes administered for these latter two products, as the majority of injections are delivered in community-based physician offices rather than in hospital ambulatory clinics.

EXHIBIT 2

Trends in hospital ambulatory clinic market shares for Remicade and its biosimilars in France, 2015–20



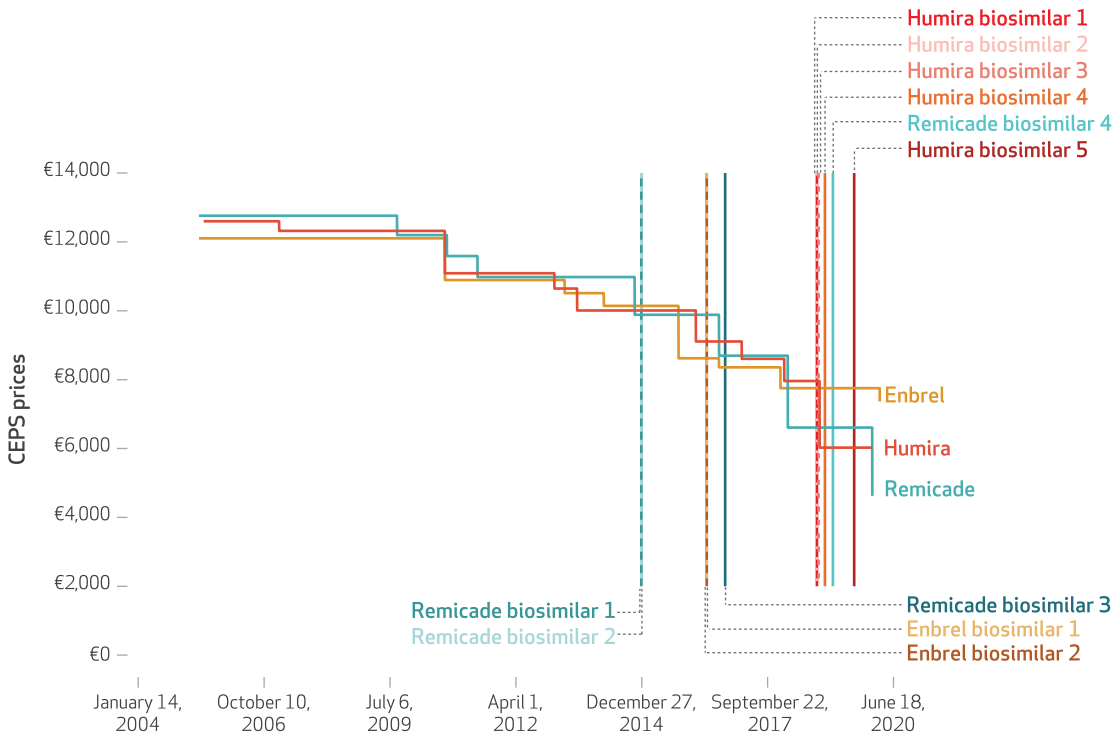
SOURCE Base Nationale ATIH du Programme de Médicalisation des Systèmes d'Informations et des Médicaments (proprietary data).

TRENDS IN PRICES AFTER BIOSIMILAR MARKET ENTRY Exhibit 3 presents the national tariffs for the three biologics and their biosimilars negotiated by the CEPS with drug manufacturers from 2004 to 2019, in the years before and after the introduction of competition from biosimilars. The first two biosimilars for Remicade were launched in France in December 2014, with a third launched in October 2016 and a fourth in February 2019. The two biosimilars for Enbrel were launched in May 2016. Four biosimilars for Humira were launched in quick succession in fall 2018, with a fifth launched in August 2019.

The CEPS did not wait for competition from biosimilars to achieve savings on the three reference biologics. It imposed price reductions in 2010–11 and again in 2013–14 before the launch of the first biosimilar. These reductions highlight the power of centralized single-payer purchasing and contrast with the US pattern of postlaunch price increases. However, the CEPS imposed much larger tariff reductions in the years after biosimilar market entry, during the period in which the hospitals were negotiating their individual price reductions with the manufacturers. The launches of the eleven biosimilars were accompanied by major tariff reductions in fall 2016, in spring 2018, and during 2019. The entry of a biosimilar for one biologic was associ-

EXHIBIT 3

Association between market entry of biosimilars and trends in prices for three reference biologics and their biosimilars used in hospital ambulatory clinics in France, 2004–20



SOURCE Base des Médicaments et Informations Tarifaires (proprietary data). **NOTE** Market entry for three anti–tumor necrosis factor biologics, Remicade, Enbrel, and Humira, and their biosimilars is shown.

ated with cuts in the national tariff for all three reference biologics. The differences between the tariff reductions imposed before and after biosimilar market entry reflect the use of the information from the decentralized hospital negotiations to identify manufacturers' readiness to offer price reductions.

Discussion

The advent of biosimilars initially stimulated optimism on the part of pharmaceutical purchasers, in both Europe and the US, that the resulting competition would lead to lower prices and reduced spending. This hope has been borne out in some European nations, but the US has not enjoyed comparable benefits. The development of the US Food and Drug Administration pathway for biosimilars was delayed for years after the European Medicines Agency had established its version. The manufacturers of some reference biologics have erected a thicket of secondary patents that impede the launch of biosimilars in the US. In contrast to the experience in Europe, public and private payers in the US have been slow to develop gainsharing incentives to drive biosimilar adoption. As of July 2020 biosimilars had gained only a small market share in the US against Remicade and had yet to be launched against Enbrel and Humira.[24] Market-share gains have been more impressive for biosimilars targeting oncology biologics that typically are administered for short courses of treatment, but the overall reduction in US drug spending attributable to biosimilars is only a fraction of the initial projections.

Some frustrated policy analysts have questioned relying on biosimilars to rein in spending on biologics. Mark Trusheim and colleagues and Nancy Yu and colleagues, for example, have declared the biosimilar strategy to be a failure and recommend direct price regulation of biologics once they lose patent exclusivity.[27,28] Those authors suggest that the government should mandate a large reduction in the price of biologics immediately after the lapse of the original patents. They do not offer a standard that takes into account the reservation price of the manufacturers. In contrast, the French approach, as described in this study, does seek to identify reservation prices, which are likely to vary instead of being uniform across products and over time.

There are several lessons to be gained from the French experience with biosimilars. Most obviously, even a centralized single-payer system has limited power to impose price reductions on drug manufacturers. Payers lack information on how low prices can be pushed before the manufacturer withdraws its product from the market. Insight into these reservation prices is of importance not only to ensure supply in the short-term but also to sustain a competitive market for the long term. Decentralized negotiations with manufacturers by provider organizations constitute multiple probes of these reservation prices. In France the CEPS maintains an interest in ensuring a competitive biosimilars market and encourages hospitals to contract for multiple biosimilar products instead of filling all of their needs from the manufacturer offering the lowest price.

The French approach to drug price determination generates a process in which the publicly visible tariffs negotiated by the CEPS and paid to the hospitals constitute a lagging indicator of the confidential prices negotiated by the hospitals and paid to the manufacturers. These hospital-negotiated prices in turn constitute a lagging indicator of the reservation prices below which manufacturers would reduce their sales efforts and ultimately withdraw their products from the French market altogether.

The French system allows and encourages hospitals to negotiate prices with drug manufacturers even though the CEPS has the legal authority to impose price reductions unilaterally. It thereby forgoes both the scale of the national payer and the sophistication of its extensive administrative staff to gain insights into reservation prices. It implicitly pays for this information by allowing the hospitals to retain half of the savings they negotiate (in terms of the difference between the national tariff and the hospital's negotiated rate) instead of mandating that all savings immediately be returned to the national system. The system is apparently willing to forgo these short-term savings in exchange for the information it generates on industry reservation prices.

Conclusion

Health policy debates in the US often portray a choice between decentralized market mechanisms and centralized regulatory mechanisms. This study suggests, however, that market and regulatory strategies can be complements rather than substitutes.

Even the highly centralized single-payer French system relies on decentralized hospital negotiations and competition from biosimilars to help determine prices for brand-name biologics. The price reductions obtained through decentralized negotiations and biosimilar competition then are translated into savings for the social security system through the regulatory authority wielded by the national payer. Reductions in the national tariff in turn reduce the shared savings available to hospitals, spurring them to negotiate another round of discounts with manufacturers.

When hospitals cannot negotiate further discounts, the national payer ceases to impose reductions in the national tariff. The national payer then has found the manufacturer's reservation price for the biologic in question and must seek further savings elsewhere in the health care system.

In its attempt to use biosimilars to obtain savings for the health care system, the US has pursued only one of the two levers used by France. It has encouraged market entry from biosimilars, albeit in the face of determined opposition from manufacturers. But it has not encouraged physician switching through gainsharing incentives, nor has it used biosimilar prices as benchmarks for the reservation prices of biologics. There are limits below which drug prices cannot be pushed without prompting market exits, but the US will never approach these reservation prices if it never seeks to find them. ■

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