DEcision-Maker Commentary

Thirty Years of Media Coverage on High Drug Prices in the United States—A Never-Ending Story or a Time for Change?

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A B S T R A C T

In recent years drug prices have increasingly become a topic of debate for patients, providers, payers and policy makers.

To place the current drug price debate into historical context, we searched the New York Times and Wall Street Journal from 1985 – 2015 and found that concerns about drug prices have commonly featured in the press over the study period with recently stronger calls for change.

Price levels, types of innovations, stakeholder responses, and strategies to address high prices discussed in the media suggest that concerted efforts are required to enable affordable and high-value innovations.

Keywords: drug prices, media, New York Times, US, Wall Street Journal.

Introduction

The introduction of a number of breakthrough, highly effective, and high-cost specialty medicines over the past few years has stoked the fire of the long-running drug price debate. The prices of these specialty medicines—above $100,000 per treatment course—have resulted in widespread outcry among patients, providers, insurers, and members of the Congress and the Senate. More such products will come to the market as 700 specialty products—including immune therapy and gene therapy—are currently in the drug pipeline. But does the recent debate’s renewed vigor signal a watershed moment? Or is it merely a rehashing of an often-revisited grievance that will be forgotten as “business as usual” goes on?

To put these questions into historical context, we used LexisNexis Academia—a database of legal, news, and business sources—to determine how often the New York Times (NYT) and the Wall Street Journal (WSJ) featured articles including the term "drug pricing" from January 1985 through 15th of November 2015. We excluded articles covering stories outside of the United States as well as blog entries. In total we found 926 articles (549 in the NYT; 377 in the WSJ with a peak of 75 articles from both journals in 2015) including the term. For the purpose of analyzing the media releases, we assigned each article to one of four categories: 1) increase in drug prices, 2) innovation, 3) stakeholder’s response, and 4) strategies. In the case in which articles discussed more than one of the topics, we classified them under the dominant theme of the article. In Figure 1, we present the data (as number of media releases per 5 years) per category over time to illustrate how media debate on drug pricing has changed throughout the past 30 years.

Increase in Drug Prices

The concern of increasing drug prices has been a steady topic over the past 30 years (see Fig. 1: NYT, December 28, 1985).

In the late 1980s, media coverage on high drug prices centered on the novel AIDS treatment zidovudine (AZT) costing $10,000 per patient per year. A peak in media coverage is noticeable in the mid-2000 due to the launch of new cancer medicines such as bevacizumab (Avastin) for metastatic colon cancer and trastuzumab (Herceptin) for breast cancer, with a price tag of $100,000 per treatment course. More recently, reported prices have reached a new high. For example, ivacaftor (Kalydeco), indicated for a rare condition, cystic fibrosis, is priced upward of $300,000 per patient per year (see Fig. 1: NYT, March 23, 2008). Since early 2014, media releases are dominated by the launch of new very effective but at the sometime very expensive high-volume drugs such as the hepatitis C treatments, with sofosbuvir priced around $84,000 for a treatment course (see Figure 1: WSJ, April 1, 2014) and more recently the cholesterol-lowering drugs PCSK9, with Praluent priced around $14,600 per patient per year. However as those medicines are indicated for millions of patients their impact on public health budgets is tremendous and brings a new urgency to the debate.

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In addition, most recent concerns about steep increases of generic prices have dominated the debate on drug pricing. Repeatedly, it was reported that drug price increases have far outpaced inflation—the most recent estimates report a 75% increase since 2007 [1]—and that launch prices (adjusted for inflation) of 58 cancer drugs approved between 1995 and 2013 have increased by 10% (about $8.500) per year [2].

Innovation

Since 2000, media coverage on the launch of breakthrough innovations (such as orphan medicines) is increasing. This can be traced back to the Food and Drug Administration’s approach to increase access to innovative drugs through regulations such as priority review, accelerated approval, fast track review, and breakthrough designations.

These innovations contribute to the drug pricing debate due to their high prices and the combined volume of their use, impacting health care budgets. The number of personalized treatments targeting specific genes or the immune system of small numbers of eligible patients per molecule—like ivacaftor for the treatment of about 2150 patients globally with a specific variant of cystic fibrosis—is rapidly increasing; in 2011, molecules were approved for 22 orphan or rare diseases, each with between 50,000 and 200,000 patients. In addition, new, costly molecules treating millions of patients (such as the new hepatitis C medicines and the new cholesterol-lowering products) are increasingly being launched, leading to heightened concerns about budget impact and sustainability of systems.

Voices in the media are raising the question of why innovations that were developed with funds from the National Institute of Health (funded by American tax payers’ money) should cost two to three times more in the United States than in Canada or Europe (see Fig. 1: NYT, October 23, 2003). In 1995, the National Institute for Health dropped a provision ensuring that drugs developed with government funds are sold at reasonable prices because the clause presumably drove industry away from potentially beneficial scientific collaborations [2].

Stakeholder’s Response

Throughout the past 30 years, high drug prices have been on the political agenda of senators and of the Congress representing a politically sensitive topic (see Fig. 1: WSJ, December 17, 1999). In the 1980s, patients’ voices prompted the pharmaceutical industry to lower the price of the first high-priced HIV drug. In the years to follow, the voices of retirees, represented by the American Association of Retired Persons, advocated for the implementation of the Medicare Part D drug benefit and are reflected in media coverage peaks between 2000 and 2004 (see Fig. 1: WSJ, April 10, 2000). Most recently, however, responses to high-cost medicines seem to be changing, with new stakeholders taking action: in 2012, clinicians at a major cancer center have declined using a new cancer chemotherapy due to its price (see Fig. 1: NYT, November 9, 2012); in 2014, Express Scripts, one of the largest pharmacy benefit managers, announced plans to exclude from its formulary 70 high-priced medicines that it deemed to be low value (see Fig. 1: NYT, December 22, 2014); in addition, state
Medicaid directors suggested in a joint statement options to address prices of expensive new pharmaceuticals [3]. In June 2015, the American Society of Clinical Oncology proposed a value framework for comparing the relative clinical benefit, toxicity, and cost of cancer treatments (see Fig. 1: NYT, June 22, 2015).

**Strategies**

Throughout the past 30 years, various stakeholders implemented and suggested different strategies to cope with high-priced medicines: 1) industry offered to reduce drug prices (see Fig. 1: WSJ, September 19, 1989) as well as to distribute discount cards; 2) states and federal government agencies mandated drug price discounts for the Medicare Part D program, initiated lawsuits against pharmaceutical companies for overcharging for medicines, and mentioned importing of lower-priced drugs from abroad as well as legal changes to allow for price negotiations and price controls (see Fig. 1: WSJ, April 19, 2007); more recently, states have introduced pharmaceutical cost transparency bills requiring the pharmaceutical industry to justify drug pricing [4]; 3) payers have typically responded to the introduction of expensive products by limiting access through prior authorization, mandating the use of generics, implementing different co-payment tiers, and shifting an increasing proportion of costs to patients, through higher insurance premiums and coinsurance, co-payments, and deductibles. The establishment of a buyer consortium through which they could negotiate lower prices was also debated in media; 4) patients shopped for cheaper medicines abroad or opted to forgo treatment; 5) in 1993, experts mentioned the implementation of cost-effectiveness analysis and price control regulations as possible ways forward. More recently, however, experts more strongly call for ways to assess the overall value of a product. They point to examples from Europe and Canada where decision makers use multiple tools to negotiate prices, such as value-based (health technology assessments, pharmacoeconomic analyses), reference-based (international and therapeutic price referencing), and risk-based (managed entry agreements) approaches. As is the case in Europe and Canada, authors suggested using quality-adjusted-life-years—a measure of the state of health of a person or group that defines benefits of products in terms of length and quality of life—to assess benefits of a product compared to its price [5].

**Discussion**

Our media search on “drug pricing” over the last 30 years showed that high prices of medicines have been a hot topic for a long time. US policymakers have historically been reluctant to embrace price regulations, instead relying on market forces to set prices. In addition, a drug’s value is not routinely considered. US drug prices are among the highest worldwide and contribute to devastating consequences of care for patients as medical expenses remain the most common cause of personal bankruptcy [6].

Our optimistic belief is that the recent groundswell of opinion regarding high drug prices, in combination with a changing environment, constitutes a “watershed moment” for legal and policy innovations that provide payers the tools to ensure patient access to effective treatments at affordable prices while continuing to incentivize much-needed innovations. We suggest future research to build on our brief summary of media coverage of drug prices over time. Questions to address include the following: What factors and which stakeholders have prompted media coverage? Which policy and program actions have followed increasing media discussion of drug prices? How can media coverage contribute to a critical and constructive multistakeholder dialogue of health technology innovations’ benefits and costs?

In his 2015 State of the Union address, President Obama committed to invest in basic and clinical research for personalized and precision medicines. We strongly advocate for additional funding of policy research to explore the financial impacts of innovations on patients, providers, payers, and the system as a whole and to develop evidence for innovative pricing and reimbursement strategies. We believe that there will not be one single approach to pricing and paying for innovations but rather multifaceted approaches that will need to consider not only safety, efficacy, and cost but also the overall societal value of innovations. For true change, in our opinion, all stakeholders need to act in concert to develop strategies that ensure investment in R&D and guarantee long-term affordable access to needed innovations.

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New French Coverage with Evidence Development for Innovative Medical Devices: Improvements and Unresolved Issues

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A B S T R A C T

We describe here recent modifications to the French Coverage with Evidence Development (CED) scheme for innovative medical devices. CED can be defined as temporary coverage for a novel health product during collection of the additional evidence required to determine whether definitive coverage is possible. The principle refinements to the scheme include a more precise definition of what may be considered an innovative product, the possibility for device manufacturers to request CED either independently or in partnership with hospitals, and the establishment of processing deadlines for health authorities. In the long term, these modifications may increase the number of applications to the CED scheme, which could lead to unsustainable funding for future projects. It will also be necessary to ensure that the study conditions required by national health authorities are suitable for medical devices and that processing deadlines are met for the scheme to be fully operational. Overall, the modifications recently applied to the French CED scheme for innovative medical devices should increase the transparency of the process, and therefore be more appealing to medical device manufacturers.

Keywords: coverage with evidence development, innovation, medical device, reimbursement.

Introduction

In all health care systems, coverage decisions tend to be based on the best available evidence, with the aim of ensuring that resources are judiciously allocated [1]. This may result, however, in a binary “yes” or “no” approach that is biased against innovative and promising technologies for which few clinical data are available. This situation has applied to many innovative medical devices released to market in the European Union. European Union regulations concerning premarket evidence are currently inadequate, and there is often a lack of appropriate data to support the ability of new devices to respond to the expectations of policymakers in the context of a reimbursement process [2,3].

In France, device manufacturers can request the health authorities to reimburse medical devices via two routes [4]. First, reimbursement can be obtained if the characteristics of the device match an existing generic definition on the list of devices qualifying for reimbursement. In such cases, the manufacturer can automatically register the device without the need for any additional evaluation by the national health authorities. The second route available, particularly if the manufacturer is producing an innovative product and wishes to charge a relatively high price, is to apply for reimbursement to the National Committee of Medical Devices and Health Technologies (CNEDIMTS) [5]. This committee initially assesses the expected clinical benefit of the device to determine whether it is sufficient to merit reimbursement. It then evaluates the added clinical value of the device in comparison with existing technologies or alternative treatments [4,5]. In most cases, too few data are available to accurately assess the expected clinical benefit. Consequently, more than half the applications submitted to the CNEDIMTS each year are finally rejected or withdrawn because of a lack of data [6].

Several countries including France have acted to prevent the exclusion of promising technologies due to a lack of clinical evidence, by introducing the Coverage with Evidence Development (CED) scheme. This provides patients with provisional access to a new device while the necessary evidence is acquired to determine whether definitive coverage is warranted [1,7]. Five years after the introduction of the CED scheme in France, however, only two medical devices have benefited: a high-intensity focused ultrasound technique for treating prostate cancer and a retinal prosthesis system to treat patients with severe retinitis pigmentosa. In view of this relative failure, it was generally agreed that there was a need to reform the CED...
scheme. We describe here the history of the CED scheme for medical devices in France. We then present the modifications recently applied to this scheme by the French government. Finally, we discuss the potential improvements following these changes and the issues that remain unresolved.

**History of the French CED Scheme for Medical Devices**

Conditional coverage for a new drug was first tested in France in 2003 [8]. It was agreed that risperidone would be reimbursed provided that the company performed studies to determine whether it improved patient compliance. In 2007, the CNEDIMTS proposed the creation of a CED scheme for innovative devices for which the committee was unable to determine the expected clinical benefit. As part of the initial project, the manufacturer was required to conduct a clinical trial on the basis of conditions defined by the CNEDIMTS itself. This early version of the scheme was never implemented. Two years later, a new project was launched, in Article L. 165-1-1 of the French Social Security Code [9]. This article, in application since March 2010, laid down the rules for a new evidence generation scheme for promising health products or procedures. On the basis of technological intelligence or applications for reimbursement, the CNEDIMTS could select eligible innovative devices; however, device manufacturers were not allowed to directly request the inclusion of their products in the CED scheme. The committee would issue an expert opinion that was then transmitted to the French Ministry of Health for a final decision. If the decision was positive, the Ministry of Health subsequently defined the conditions of the clinical trial. The requirements covered the number of patients, indications for use, funding period, and hospitals conducting the study. To our knowledge, over the past 5 years, several medical devices have been designated as eligible by the CNEDIMTS, in addition to the two cited above, yet the Ministry of Health has neglected to make any clear decisions. Consequently, a lack of innovative products is not the result of the CED scheme failure, but perhaps a lack of political will, possibly due to economic reasons.

<table>
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<tr>
<th>Table 1 - Conditions required for clinical or economic studies submitted to obtain coverage with evidence development in France.</th>
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<td><strong>Conditions required for the clinical/economic study</strong></td>
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<tr>
<td>1. The study must be able to collect additional data required for assessment of the expected clinical benefit of the device. Studies should be comparative unless there is either no relevant comparator or for ethical reasons.</td>
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<td>2. Ongoing studies with the device must be presented to assess the relevance of the new study.</td>
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<td>3. The feasibility of the study must be considered reasonable in terms of both the protocol and the estimated budget.</td>
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**Recent Modifications to the French CED Scheme**

In February 2015, a new decree came into force, modifying Article L. 165-1-1 [10]. This decree defines four criteria that must be met for a new device to be considered innovative: 1) the medical device must be novel and not simply an updated version of an existing product used for the same indications; 2) the medical device must only recently have become available on the market and not have been previously reimbursed by the French national health insurance agency for the indications concerned; 3) the available clinical data for the product must have clearly established the potential risks for patients and users; 4) the available clinical and/or economic data must have shown that the product is likely to a) provide significant clinical benefit for an unmet or insufficiently covered medical need or b) decrease health care expenditure due to its cost-effectiveness, although only if the device is at least as effective as the standard treatment.

Device manufacturers can now apply directly for the inclusion of their products in the CED program, either independently or in partnership with a hospital. For eligibility, applicants must submit a clinical or economic study project plan that meets three essential conditions (see Table 1). The application is still submitted to the CNEDIMTS for assessment, as well as simultaneously being submitted to the Ministry of Health. In addition to the study project, the applicant is asked to estimate the budget required to carry out the study and must make a formal commitment to provide the national health authorities with full access to the data collected. The decree specifies that the study data can be used by the Economic Committee for Health Products & Services (Comité Economique des Produits de Santé [CEPS]) during future price negotiations.

Finally, the decree introduces processing deadlines. The CNEDIMTS now has a maximum of 45 days to check the completeness of the submission and deliver an opinion on the admissibility of the application. The commission subsequently has a maximum of 30 days to confirm the suitability of the proposed study for the collection of additional data required to determine the expected clinical benefit of the product. The duration of the study and the number of patients to be included must also be validated. At the same time, the Ministry of Health determines whether the estimated budget is reasonable. Once both assessments have been completed, the Ministry of Health must confirm its final decision within 30 days. Finally, the funding required for the study is provided entirely by the French national health insurance agency.

**Improvements and Unresolved Issues**

In a previous study, we concluded that improvements to the French CED scheme were required to ensure that the process is fully operational [11]. The recent modifications have partly resolved the issues we raised. First, the transparency of the process has increased, by setting criteria that clearly define an innovative device. Before the new decree, it was left entirely to the CNEDIMTS to determine whether a new product could be considered innovative. In addition, device manufacturers can now directly request the inclusion of their products in the CED scheme, as is already the case in other countries, such as Germany [12]. These modifications will probably have a major impact on the market access strategies of medical device companies, who will now consider this coverage option for their products. The French CED scheme is also potentially appealing to device manufacturers because full funding is offered and the reimbursement of study expenses is not requested even if results do not provide conclusive evidence. This is a major strength of the scheme because the collection of supplementary evidence can often result in the manufacturer making a loss in other countries [13,14]. We believe that the French CED scheme offers a great opportunity for small- and medium-sized enterprises (SMEs) with insufficient resources to manage large-scale clinical trials. In France, where 94% of medical device companies are SMEs, the new CED scheme can be regarded as a major support to innovation in this sector, in addition to the research and innovation tax credit recently implemented. In addition, the data collected can be reused in other countries for future reimbursement applications or finding new markets. From the point of view of health care providers, the scheme is likely to improve access to...
innovative treatments for unmet medical needs and avoid excessive financial risk for devices with little available evidence. The funding of CED projects, however, may become a critical issue in the long term if the number of applications significantly increases. Therefore, substantial and sustainable funding for future studies will be required, particularly if high-quality evidence is to be obtained [15]. To date, the Ministry of Health has not indicated how many CED projects will be annually funded or whether a maximum budget will be set. Furthermore, the CEN-DIMTS and the Ministry of Health will need to devote additional resources to ensure an adequate follow-up of all CED projects.

The possible involvement of hospitals in the scheme is a positive aspect. The early involvement of clinical investigators is likely to favor the successful establishment of future projects. Indeed, French hospitals have experience in hospital-based research programs funded by the Ministry of Health for non-reimbursed innovative devices, which are successful largely due to the involvement of the end users [11]. Partnerships with hospitals are also desirable for SMEs as they frequently require guidance in the design of clinical trials, which is increasingly offered by French university hospitals [16]. However, although randomised controlled trials are considered to be the gold standard for decision-making, the use of a randomised design is not always feasible for medical devices [14,17]. This standard is difficult to achieve with medical devices, for many reasons, including "learning curve" issues, frequent product modifications, and difficulties enrolling patients [18,19]. The French national health authorities should therefore consider alternative methods better suited to medical devices, such as Bayesian methods or tracker studies [20,21].

Finally, the new processing deadlines for the CNEDIMTS and the Ministry of Health should reduce bureaucratic delays, which were perceived as too long by device manufacturers. This will ensure that the process is completed in a more timely and transparent manner. Other countries have recently reformed their CED schemes, with the introduction of faster processing times, such as in the United Kingdom [22]. Nevertheless, the decree does not state whether the time frame will be also limited for pricing negotiations with the CEPS at the end of the study. In addition, the decree does not declare whether the manufacturer can expect a "premium" price on the basis of additional evidence generated and how these data can affect the CEPS price decisions. The primary intent of the scheme, however, is to provide as much evidence as possible to the CNEDIMTS to establish the added clinical value of the device. The CEPS decisions are then largely based on the conclusions made by the CNEDIMTS, which is potentially very positive provided that most uncertainties have been removed.

In conclusion, we feel that the recent modifications to the French CED scheme for innovative medical devices represent a step in the right direction, particularly with respect to greater transparency. The scheme now shares many features with other CED schemes worldwide. As recently stated by Olberg et al. [12], there may be an emerging international standard for CED [12]. It remains to be seen, however, how CED projects will be funded in the long term, how hospital partnerships will be set up, whether national health authorities will consider alternative study methods, and whether the new processing deadlines will be met.

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