Public Opinion: Can Pharma Chart a New Course?

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As the high cost of drugs continues to erode public opinion, experts ask whether price controls are the best, or only, way to improve access to medicines and regain the public's trust.

Pharma has come a long way since the late 1980s, when Roy Vagelos, then CEO of Merck, promoted the image of an ethical and compassionate industry by makingivermectin, its treatment for river blindness, available to countries around the world at no cost. At the time, the late Sen. Edward Kennedy called the act "a triumph of the human spirit" (1).

Since then, as direct-to-consumer advertising took off in the United States, the industry's image began to change. Bolstered by media coverage of conflicts of interest in promoting products to physicians and first-hand accounts such as Jamie Reidy's book, Hard Sell: Confessions of a Viagra Salesman (2), the pharma sales representative began to eclipse the devoted researcher in public perception. As regulators and academics pointed out the need for pharma to control manufacturing costs (3), spending on manufacturing and quality were dwarfed by industry spending in other areas. The millennium's first decade saw criticism over pharma's expensive political lobbying and its clinical trial and patent extension practices, by physicians including Harvard Medical School professor Marcia Angell.

Negative publicity reached a high point in 2015, when former Turing Pharmaceuticals CEO Martin Shkreli increased prices for an anti-infective from $13.50 to $750 per pill (4); and in 2016, when Mylan first came under fire for cornering the market on EpiPen epinephrine (5) auto-injectors and increasing prices by more than 500% over a nine-year period; and Valeant Pharma executives were charged with fraud (6). That same year, the Project on Government Oversight questioned FDA's ties to the industry through the US Prescription Drug User Fee Act and its scientific independence in approving new rare disease therapies, and also drew attention to pharma's connection with patient advocacy groups (7).

Deteriorating public trust

Over the past 15 years, US public opinion polls have continued to reflect decreasing public trust in the industry, a trend that has been exacerbated by questions of corporate culpability in the opioid addiction crisis. In 2015, a Kaiser Health Tracking poll found that 72% of US citizens saw drug costs as unreasonable, with 70% believing that drug companies put profits before patients' lives, and 25% saying they found it difficult to pay for treatments their physicians had prescribed (8).

In October of 2019, a year that saw outcry over pricing for insulin, continued shortages of crucial commodity drugs, and Congressional hearings on the topic of drug pricing, a Gallup poll...
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found pharmacy to be the least-trusted industry in the US (9). In December 2019, an international group of researchers launched the Pathways to Independence project in the British Medical Journal to explore how evidence of a drug’s therapeutic value might be gauged more scientifically, divorced from all commercial interests (10).

Demands for government action
As the public and special interest groups have demanded government action on pricing, a number of proposals would impose limits on pharmaceutical prices, or bring them in line with the prices that patients in other countries pay. Other suggestions have called for establishing an independent US government agency focused exclusively on pharmaceutical pricing (11). While it is not certain that any of these proposals will be voted into law, some observers ask whether both sides of the pricing debate are missing the point. Exploring some of these issues is The Great American Drug Deal: A New Prescription for Innovative and Affordable Medicines, which will hit bookstore shelves on January 20, 2020 (12). Author Peter Kolchinsky is a doctorate-level scientist and founding partner of RA Capital Management, a Boston-based investment fund that focuses on forming and funding biotech companies that are developing new medicines, medical devices, and diagnostics. He shared insights with Pharmaceutical Technology.

Distinguishing between innovation and patent extension
Kolchinsky says he wrote The Great American Drug Deal in response to misunderstandings about drug pricing and innovation costs. “Companies that we are working with and funding to develop new drugs never intended for those drugs to be unaffordable to anyone. They want patients to benefit from their inventions,” he says. But these small innovators would be hurt by sweeping price controls, he says.

One problem is that, when the public and Congress look at the drug industry, they see a single, abusive business model when there are really two distinct models, Kolchinsky says. One model drives innovation and needs to be preserved, while the other takes advantage of society and must be reformed. In the first, companies develop new drugs with the hope of marketing them for a period of 10-15 years before they go generic. In the second, they extend the lives of older drugs with new patents, often by making minor upgrades, some of which do not add much value, or simply by exploiting regulatory loopholes so that they can keep harvesting branded revenues. Efforts to reform the industry should largely be focused on the second model, Kolchinsky says, and aim to prevent unjustified patent extensions rather than imposing direct price controls on all drugs.

Pharma’s social contract
Kolchinsky uses the concept of the “biotech social contract” to explain what should be expected from innovators, the industry, and society. Public policy should reward innovators for the period during which their drug is patented, after which, Kolchinsky says, a process called “contractual genericization” should be used to prevent companies from engaging in frivolous patent extensions.

Under contractual genericization, all drug companies would have to enter into a contract with a dedicated government agency at the time they file for approval of a new drug. They would not be able to get approval without signing that contract, which would ensure that the drug becomes inexpensive once the initial patent period has expired, Kolchinsky explains. “If a company were to make a legitimate, useful but straightforward upgrade to the drug after it launches, it could then apply for and receive a deferral of the contractual genericization date, permitting six more months of branded revenues, analogous to the way that FDA awards six months’ additional patent exclusivity in exchange for running pediatric trials,” he says. In addition to bringing about contractual genericization, Kolchinsky believes that legislation should focus on insurance reform and ensuring that patients’ out-of-pocket costs are minimized or even eliminated. “Insurance companies have increasingly been shifting costs on to patients, which has intensified public outrage,” he says.

The international price index
One form of price control that is currently being discussed is use of an International Price Index (IPI), requiring that companies set US prices to be comparable to those they charge in European countries. Marc Rodwin, professor of law at Suffolk University in Boston, who has studied the way that European markets measure cost effectiveness and set prices, sees this approach as having potential benefits. Rodwin’s research has focused on practices in France (13), where the government sets a maximum price based on comparing the value of a new drug to that of its closest equivalent treatment. If a company doesn’t like the price, it can walk away, although that rarely occurs, Rodwin says.

In order for international price benchmarking to work, however, the US would have to consider off-list discounts, Rodwin says. Kolchinsky believes that syncing US drug costs to either list or net prices in other countries would lead to higher prices. “If drug companies have to charge the same for a drug in US and Europe, they will simply export the US price to Europe. In some cases, Europe will refuse to pay, denying patients treatment. With less revenue and profits from Europe, companies would be forced to make up the difference by charging the US more, thus raising the global price and further reducing Europe’s participation,” he says, noting that this view was corroborated by the US Congressional Budget Office’s own analysis (14).

Drug pricing agency
Kolchinsky’s big idea in The Great American Drug Deal is the introduction of the concept of contractual ge-
nerization to ensure that all drugs go generic without undue delay.

But Rodwin counters, "Ending abusive patent extensions would at the margins (of the pricing problem) be toxic to innovation. The key question is: Must purchasers pay any price that a drug developer says it wants?"

Taking NICE's approach

Rodwin believes that the idea of a separate government agency focused on pricing could work in the US, but he wants to see it negotiate for launch prices, an approach that Kolchinsky insists would be toxic to innovation. Rodwin says, "The UK developed the National Institute for Health and Care Excellence (NICE) over time, and the US could develop its own approach. It already has a physician payment assessment commission for Medicare."

"If a pricing agency were established, it could first establish the principle that they have the ability not to purchase a drug if it’s not worth it, and to use existing resources to establish value. If the federal government established that principle for its own purchasing in the Veterans Administration, Department of Defense, Medicare and Medicaid, the private sector might choose to piggyback on that," Rodwin says.

"If Medicare were to develop a thoughtful way to assess a pharmaceutical's value like the approach that is used by NICE, or if it developed a system that incorporated the approach used in France (i.e., one that allows for the added value of a new drug), large private insurance companies might choose to use this methodology, and we wouldn't have to change US systems in one fell swoop," Rodwin says.

Even on a limited basis, he says, adopting these approaches could work. "If we could incorporate some of these changes, just for Medicaid and Medicare, which account for nearly half of the market, it would have a substantial impact on government spending and on individual copayments," he says.

The danger of losing R&D incentives

Kolchinsky argues forcefully against attempts to control launch prices or deny patients access to innovative therapies. "The cuts we can make are in what we spend on old drugs, but we can't cut the incentives for new ones or the response will be a predictable and swift reduction in funding of work to treat any disease that the price-setting government agency appears to undervalue," he says. As an example of what might go wrong, Kolchinsky points to the dearth of industry investment in antibiotics (15), which has prompted a call for establishing incentives for discovery and development.

Using the BARDA model

If an independent pricing agency is established in the US, Kolchinsky thinks it should be structured, not like NICE but like the US Biomedical Advanced Research and Development Authority, which stockpiles biodefense vaccines and guarantees that developers and manufacturers make a specific profit for their highly specialized products.

"Such an agency could hold the genericization contract on every drug, guaranteeing that its price would drop to, say, twice the cost of production after initial patents expire. It could modestly extend that date to reward a useful upgrade of the drug after it is launched (e.g., moving from a twice-daily to a daily dose)," says Kolchinsky.

There would still be room for drugs to go generic the conventional way, he explains, through competition amongst several generic versions, but if the price didn't drop low enough due to competition, the contract would serve as a backstop and the original manufacturer would either have to provide it at the guaranteed low price or else transfer the contract to another company that would honor it.

"If multiple companies were interested in the contract, they could bid for it. But at all times someone would be accountable for making the drug and selling it at a modest, yet still profitable price. As a last resort, if a non-profit company wanted to manufac-

ture the drug, the government could contract with it to make the drugs that nobody wants to make, many of which are in short supply," Kolchinsky explains.

Clearly, the debate over high US drug prices promises to continue. But perhaps, as Kolchinsky suggests, it's time for all stakeholders — industry, insurers, and the government — to consider obligations, not only to the present generation but to future generations of patients, and to redefine the social contract and the roles they each should play in it.

References

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