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Mending the broken social contract for pharmaceutical pricing and innovation

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The biopharmaceutical industry is under unprecedented assault by the public and

The net price of drugs — that's the list price minus rebates and other reductions — is being squeezed[2], and the pressure won't let up. Industry revenues are increasingly derived from a smaller number of orphan and gene therapies with limited competition and from a few specialty blockbusters for chronic conditions that patients are reluctant to switch away from. Those revenue streams are precarious, as are the ones that derive from successful but politically vulnerable strategies such as patent thickets and pay-for-delay arrangements[3] to keep out specialty generics and biosimilars.

The pharmaceutical industry's increasingly fragile revenue stream puts at risk the financing of innovation, since more than half of all research investment is funded by industry, with the remainder funded by governmental and philanthropic entities.

The industry has reason to be worried. The development of new products is not only its economic lifeblood but also its self-image as a solution rather than a problem. It is groping for an effective response.

In a recent and prominent effort, 215 blue-ribbon life sciences executives and thought leaders published an open letter[4] in STAT announcing their "New Commitment to Patients" and their corporate responsibility.

Related: [4]

A new biotechnology and pharmaceutical industry commitment to patients and the public [4]

The motivation is commendable. The action items, however, are remarkably weak. The core of the new commitment is to set launch prices based on "value to patients" and to subsequently raise prices in a manner that is "reasonable."

Not only do the key terms go undefined, but they lend themselves to a

continuation of the status quo. Which pharmaceutical firm is willing to say that its past launch prices did not reflect value and that its price increases were unreasonable?

That wasn't a commitment but a plea: I ain't been misbehaving, but trust me and I'll start behaving.

If the authors of the open letter ask too little of themselves, they also ask too little of the other inhabitants of the pharmaceutical ecosystem. Neither payers nor policymakers are asked to do anything but let the industry do what it wants to do. That is not enough.

The broken social contract

The innovation ecosystem is based on an implicit social contract binding industry, payers, and policymakers. That contract is in serious disrepair.

Pharmaceutical firms enjoy free access to tax-funded scientific and clinical research as well as to tax credits and small business innovation grants that offset part of their development costs. They enjoy patent and regulatory protections against competition for long enough to recoup their research and development expenditures. They benefit from tax-subsidized health insurance that reduces the normal consumer resistance to high prices.

These public policies make it possible for pharmaceutical companies to charge prices and earn profits in excess of those available in other sectors. But with these rights should come social responsibilities. The public expects drug companies to devote a substantial portion of their profits to research and to price their products in a manner that is affordable for patients and society at large.

The public also expects payers to facilitate, not impede, access to these drugs. It expects the government to keep industry and insurers true to their commitments

and to ensure that short-term affordability does not preclude long term innovation.

A new social contract

The social contract for pharmaceutical pricing, patient access, and innovation needs expanded commitments from all participants. Drug firms need to adopt new pricing principles, payers need new patient access principles, and policymakers need to expand alternative supports for innovation.

New commitments by industry: pricing. A new social contract will require drug firms to change their pricing principles, aligning them more closely with comparative clinical effectiveness and cost-effectiveness, as well as with prices charged in other nations. These principles are found in all the major legislative proposals in Washington. Given the intensity of the industry's lobbying, it is hard to imagine any one of the current proposals passing in the short term. But given the intensity of public sentiment, it is hard to believe that some variant of them won't pass in the long term.

The pricing principles of the future are simple. Launch prices must reflect value to patients, not as defined by the industry but as defined by independent third parties, such as the Institute for Clinical and Economic Review, using transparent methods and with input from patients and other stakeholders. Prices should be raised in the years after launch only if new evidence emerges of clinical and social contribution. The limit on unsupported price increases has long been adopted by payers in other nations, and by Medicaid and selected payers in the U.S. It strengthens the incentive for industry to pursue post-launch studies using clinical trials and observational real-world evidence.

New commitments by payers: access. The new social contract will bind not only the pharmaceutical industry but also insurers, employers, and pharmacy benefit managers. These buyers have been relying on formulary exclusions, prior authorization, and consumer cost-sharing to wrest price discounts from

manufacturers (and, unfortunately, often pocket the savings rather than pass them on to patients).

This has created extensive collateral damage in the form of physician frustration, patient non-adherence, and system-wide administrative costs. To the extent that drug manufacturers adopt new pricing principles, payers will need to adopt new principles of utilization management.

Related: [2]

Wholesale drug prices have been falling, and so have net prices [2]

As I argued in a Viewpoint article[7] in the Journal of the American Medical Association authored jointly with Scott Howell of Novartis Pharmaceuticals and Steven Pearson of ICER, payers will need to offer value-based patient access in exchange for value-based product pricing. Once prices are aligned with clinical value, payers will no longer be justified in maintaining today's obstacles to access. This will allow drug firms to obtain the normal business reward for lower prices through higher sales volumes, and thereby recoup some of the revenues they will lose from charging lower prices for each unit sold.

New commitments by policymakers: innovation. An industry commitment to pricing moderation will reduce the margins that heretofore have funded research and development investments. The new social contract, therefore, will require governmental and philanthropic organizations to expand alternative funding sources and non-financial supports. This can include:

- Expanded support for basic science and applied clinical research[8] funded by the federal and state governments and by philanthropic entities.
- Expanded tax credits for R&D[9], with especially generous credits for investments in areas of high need, such as drug-resistant infections and cardiovascular disease.
- Expanded direct public grants to support product commercialization, including the Small Business Innovation Research[10] and related programs for technology-based startups.
- Expanded innovation prizes[11] that reward achievement of important developmental milestones, following the model of venture capital investment but without diluting owners' equity.

- Targeted tax reductions[12] on profits obtained from patent-protected and other innovation-intensive products.
- Continued acceleration of market authorization through greater reliance on post-market data generation and real-world evidence[13].

Additional benefits from a new social contract

A new social contract that reduces the dependency of research investments on high prices and industry profits will create additional social benefits.

A greater reliance on alternative funding sources will encourage the industry to prioritize innovation for treatments that have fared poorly under the status quo. Today's reliance on prices and profits has pushed R&D investments into narrow therapeutic niches and induced the industry to shift away[14] from treatments for cardiovascular disease, diabetes, drug-resistant infections, and other major health challenges.

A change in the mix of incentives could cause a dramatic move in the direction of investment, as demonstrated by the 1984 Orphan Drug Act. This act, which combined research grants, R&D tax credits, accelerated FDA review, and extended market exclusivity protections, led to an explosion of innovation[15], highlighting the sensitivity of investment to incentives. A new social contract could target areas of special need using the Orphan Drug Act model but with less reliance on extended market exclusivity.

Compared to the price-based status quo, the new social contract could better support the U.S. life sciences sector in the context of global competition for knowledge-based industries[16]. The traditional method of financing pharmaceutical research and development through higher prices in the U.S. than in other wealthy nations does not differentially support domestic research, commercialization, and manufacturing. Foreign firms can repatriate the outsized profits they earn in the U.S. to the economic benefit of their home nations.

In contrast, most alternative funding sources favor domestic investment and

production. Governmental and philanthropic grants, tax credits, Small Business Innovation Research awards, and innovation prizes usually are directed at U.S. universities, research institutes, startups, and established firms, with spillover benefits that include increased employment, higher wages, manufacturing investments, and export revenues.

Conclusion

The U.S. pharmaceutical system needs a new social contract binding manufacturers, payers, and policymakers. Manufacturers need to reduce their prices in line with evidence-based benchmarks developed by independent third parties. Payers need to relieve physicians and patients of onerous utilization management and cost sharing. Policymakers need to expand non-price incentives for R&D, including research grants, tax credits, and innovation prizes. Physicians and patients will need to support this new social contract by selecting the most cost-effective options within the range of clinically effective treatments for their conditions.

Without such a realignment, the pharmaceutical will remain locked in the contemporary war of all against all.

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