



# Can We Make Medicines Affordable?

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I've read more than my share of official reports decrying the current state of our ailing healthcare system. Indeed, it's tantamount to an occupational hazard. Rarely have I read such a scathing, even damning, public report from an irrefutable source such as the National Academies of Sciences, Engineering, and Medicine. I therefore wish to discuss that consensus study report, titled "Making Medicines Affordable: A National Imperative,"<sup>1</sup> which was first released at the end of 2017 and was prepared by a panel of healthcare experts. My goal is to highlight some of the political and cultural underpinnings of the report, and to make a special reference to a potential plan moving forward.

I have surely promoted existing dogma that, although expensive, the nation's outlay for pharmaceuticals was only approximately 10% of the total healthcare bill. It turns out that I was wrong. Today, because more than 50% of all people in the United States routinely use prescription drugs, and 15% regularly use 5 or more drugs,<sup>2</sup> it has become clear that if we include prescription drugs dispensed through hospitals and clinics, the total personal healthcare bill is now closer to 20%.<sup>1</sup> This was a true eye-opener for me. Why is this the case?

According to the report, "The U.S. biopharmaceutical enterprise has evolved into a supremely complex amalgam of regulators, developers and manufacturers, retailers, insurers, wholesalers, physicians, employers offering benefits, and intermediaries, including organizations referred to as pharmacy benefit managers. The role of the latter is to support the overall pharmaceutical enterprise, providing such services as negotiating prices, establishing formularies, . . . and handling administrative functions."<sup>1</sup>

The panel notes that this process is further being complicated by the recent development that some smaller pharmacies got together and now use their own set of intermediary entities to handle their interactions with pharmacy benefit managers. Further complicating the process is that "some pharmacy benefit managers operate their own mail-order and retail pharmacies. Not surprisingly, the system is rife with potential conflicts of interest."<sup>1</sup>

As a result, this incredibly complicated and nontransparent environment sets the list price for drugs with very

little relation to the true resources used to produce the specific drug. In other words, although the pharmaceutical industry contends that its burden of research and development (R&D) leads to such high prices, the accumulating evidence, according to this comprehensive report, does not support this contention. Although we all support the notion of a patient-centered system as it relates to the biopharmaceutical enterprise, it has become clear, even to me, that we have lost sight of the core goal for this critically important industry.

Returning to the claims about R&D, the report maintains that "it is particularly difficult to determine the profitability of intermediary firms in the biopharmaceutical business chain, let alone to assess the appropriateness of that profitability. Many of these entities are, for example, owned by parent firms or are privately held and make little detailed financial data publicly available."<sup>1</sup>

Finally, the market that biopharmaceutical companies actually sell their drugs in is characterized by the absence of competition because of distortions "in the application of the patent protection process; concentration throughout the supply chain; limitations on foreign competition; the imbalance between the negotiating power of suppliers and purchasers; the opacity of prices; the lack of information on product efficacy; the separation among decision makers, payers, producers, and consumers; and the convoluted structure of the supply chain."<sup>1</sup>

From my perspective, this report is damning of the marketplace itself, making quick work of the canard perpetuated regarding the total cost of pharmaceuticals, the overwhelming investments in R&D, and the highly efficient functioning of the drug supply chain. The facts speak otherwise.

As a result, then, what did the expert authors of the report call for in terms of reforms that may tackle these stunning accusations laid at the feet of the pharmaceutical industry itself? A side aspect of this entire story, according to the Committee Chair who wrote the preface to the report, is that the nation's "overarching moral issue remains unresolved."<sup>1</sup> He asks, "is access to health care—including prescription drugs—a fundamental human right? And if it is not, who is to decide, and based on what criteria, which individuals are to be denied ac-

cess to the drugs and the care that they need? But if health care is a right, who is to pay its costs?”<sup>1</sup>

We have not resolved this issue, but despite this failing, the report does offer many realistic and achievable steps that we may take to reform this vital part of the US healthcare system.

The following points represent some of the report’s key recommendations:

1. The report does not endorse price controls, and rather recommends other steps to promote competition and make drugs more affordable. It specifically recommends that the patient’s share of the cost be calculated as a fraction of the net purchase price of drugs—after rebates and discounts—rather than the manufacturer’s list price. This is a benchmark that is widely used and must be changed.
2. The panel concluded that because of the opaque nature of the drug-pricing system, the government should require pharmaceutical companies to issue annual public reports showing the list prices for their drugs, the amount of any rebates and discounts, and the average net price of each drug sold in the United States.
3. The US Department of Justice and the Federal Trade Commission should vigorously deter brand-name pharmaceutical companies from paying other manufacturers to delay the marketing of lower-cost generic drugs and copycat versions of biotechnology drugs. This is sometimes called the “pay to delay” strategy.
4. The panel suggests that Congress should eliminate the tax deduction that pharmaceutical companies take for the cost of advertising prescription drugs to consumers, and that the industry should reduce or eliminate direct-to-consumer advertising of prescription drugs.
5. The federal government should limit pharmaceutical manufacturers’ ability to give away coupons that reduce consumers’ out-of-pocket costs for brand-name prescription drugs. Although seemingly counterintuitive, pharmaceutical manufacturers tend to use coupons to promote the use of branded expensive drugs when less-expensive alternatives are available.
6. The National Academy of Medicine called on Congress to establish limits on the total annual out-of-pocket drug costs for Medicare beneficiaries so they would not have to spend more than the current out-of-pocket threshold of approximately \$5000 annually.
7. The report’s panel noted that tax credits and other financial incentives available for the development of drugs to treat rare diseases should not be extended to widely sold drugs. Inexplicably, dozens of widely used

medicines have received a designation as an “orphan drug” and then have achieved blockbuster success, with more than \$1 billion in annual sales.

8. Doctors and hospitals should work collaboratively to further tighten restrictions on visits to offices and clinics by drug company sales representatives. They should work harder to curb the acceptance and use of free drug samples and other inducements. I have not seen a drug representative in my clinical office in more than 15 years, so perhaps we have made progress on this final recommendation.

This list of 8 recommendations will clearly gore more than one person’s ox in the fight to reduce the overall price of pharmaceuticals.

In summary, I believe that the background political and cultural music is reaching a crescendo, and this report, coming as it does from the National Academies of Sciences, Engineering, and Medicine, is part of the increasing, and now nearly deafening, cacophonous call for reform. Indeed, other experts who have long supported the pharmaceutical industry have broken ranks and essentially endorsed many of the findings of this report, including calling for a “bona fide rate regulation review body that can meaningfully evaluate the information presented by drug companies.”<sup>3</sup> I hope we don’t have to go that far.

As Editor-in-Chief of *American Health & Drug Benefits* and as a researcher, policy analyst, and practitioner, I have interacted with scores of pharmaceutical companies and literally thousands of hardworking, intelligent, and reflective members of the pharmaceutical industry worldwide. In a word—I get it, but I think we are at an important crossroad: I am joining the voices calling for self-reflection, evaluation, and action.

I applaud the members of the National Academies of Sciences, Engineering, and Medicine and the hard work in creating this watershed report. I do not think I could say it any better than the author of the report’s preface, who noted, “In the end, drugs that are not affordable are of little value and drugs that do not exist are of no value.”<sup>1</sup>

As always, I am interested in your views, and you can reach me via e-mail at david.nash@jefferson.edu. ■

## References

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