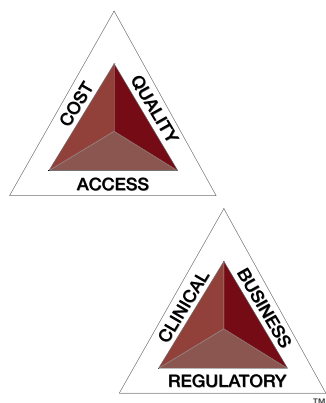


AMERICAN HEALTH & DRUG BENEFITS®

SUPPLEMENT



Pharmaceutical Research & Development in a Value-Based Healthcare System

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S154 Research and Development in the Current Healthcare System: An Overview

Thomas McCarter, MD, FACP

S156 What Constitutes Medical Evidence in the Era of Comparative Effectiveness?

Nirav R. Shah, MD, MPH, FACP

S161 New Government Policies: Opportunities for Supporting Research and Development

Kip Piper, MA, FACHE

S164 Drug Discovery and Development in a Value-Driven Healthcare System

Matthew Sarnes, PharmD

S168 A Hypothetical Case: Current Drug R&D Process

Michael F. Murphy, MD, PhD

These articles are based on live presentations at the Academy of Managed Care Pharmacy annual meeting held April 2009.

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Mission Statement

American Health & Drug Benefits is founded on the concept that health and drug benefits have undergone a transformation: the econometric value of a drug is of equal importance to clinical outcomes as it is to serving as the basis for securing coverage in formularies and benefit designs. Benefit designs are greatly affected by clinical, business, and policy conditions.

This publication provides benefit design decision makers the integrated industry information they require to devise formularies and benefit designs that stand up to today's special healthcare delivery and business needs.

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New Government Policies: Opportunities for Supporting Research and Development

Kip Piper, MA, FACHE

We are going through dramatic and fundamental changes in the way the marketplace works, and these changes will affect critical healthcare elements, such as pricing and coverage, as well as innovation. There is a sea change occurring in Washington that can be described as a shift from a private sector focus to a very public sector focus, which will affect our perceptions and lead people to draw conclusions that are not necessarily based on reality.

Government-Run Public Plan

This sea change presents a true challenge for all drug manufacturers, as well as for payers and purchasers in public programs and in private health plans. Everybody is struggling with this change. The major policies that will likely affect innovation are listed in **Table 1**. Of these, a government-run public health plan is the most contentious issue in healthcare reform. Proponents of such a “public plan” propose a federal government health plan to compete with commercial plans not only in terms of the Medicare, Medicaid, and State Children’s Health Insurance Program populations but particularly in the employer-sponsored health insurance market.

The projections of the postreform market suggest that commercial plans would dry up fast, because of the significant advantages the government has in setting reimbursement, regulating prices of drugs and devices, and mandating provider participation. Because the federal government can print money and operate in deficit mode indefinitely, a public health plan would not need to maintain reserves for claims payments or buy reinsurance. Even if a government plan uses buying power and does not use federal regulatory power, what happens when as a buyer, the government decides to throw its weight to get lower unit drug prices? That would inevitably result in tight formularies, cost-shifting to self-insured employers and commercial health plans, and a long-range disincentive for innovation.

Like any health plan, the government plan would

have to create a formulary. And to generate even more savings than the private sector achieves through competition, the government would have to be more draconian about what it covers, which would likely result in something akin to what the US Department of Veterans Affairs does—a very limited formulary and being very circumspect about adding newly approved products, even high-priority products that go through a relatively quick US Food and Drug Administration (FDA) approval process because of the potential impact for patients.

Federal Regulations

Congress is currently very interested in new federal regulations about advertising, business, and marketing practices. Much of this is based on the avalanche of state-level legislation. Further government regulation of drug prices will likely build on recent reforms to average sales price (ASP) and average manufacturer price (AMP). This backdoor approach to regulating prices will provide new opportunities for policymakers to use the mechanics of ASP and AMP to directly set and influence prices.

There is also strong interest in extending best price or mandatory rebates (which has been in Medicaid since 1991) to the Medicare Part D drug benefit. This is one way in which the government could execute the concept of federal “negotiation,” which from the government’s perspective would avoid the need to have a formulary and therefore to decide what is on or off the formulary. The federal government could simply use its regulatory power, instead of its buying power, to mandate best price in all or part of Medicare Part D. If it does, at least half of the US market would be subject to best price, fundamentally changing manufacturer pricing and revenue practices and likely increasing private sector prices. However, Congress and the Obama administration are sorely tempted by the projected federal savings of \$150 billion over 10 years from extending Medicaid-like rebates to all of Medicare Part D. Medicaid best price is probably also going to be strengthened, which provides a temptation for policymakers to get the savings from that practice, regardless of any potential unintended conse-

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Table 1 Key Policy Changes that May Affect Innovation

1. Public health insurance plan
2. Public plan in Medicare Part D
3. Federal negotiation of drug prices
4. Comparative effectiveness research
5. Pathway for biosimilars
6. Federal regulation of advertising, business, and marketing practices
7. State regulation of advertising, business, and marketing practices
8. Limits on authorized generics
9. Further regulation of prices (eg, ASP, AMP)
10. Extension of Medicaid Best Price to Medicare Part D
11. Deeper Medicaid Best Price
12. Increased FDA-CMS collaboration
13. Medicare payment reforms (eg, bundling, gain sharing)
14. National health reform (various), including need for budget savings

AMP indicates average manufacturer price; ASP, average sales price; CMS, Centers for Medicare & Medicaid Services; FDA, US Food and Drug Administration.

quences in terms of innovation or long-term access.

There is an increasing level of collaboration among the FDA, the Centers for Medicare & Medicaid Services, and the Agency for Healthcare Reform and Quality. These federal bodies have different responsibilities, but as the government becomes the monopsony in American healthcare, there will be more opportunities for Congress and the administration to exercise policymaking power, which will lead to more collaboration across the spectrums of research, product regulation, coverage, and reimbursement.

As the government becomes the monopsony in American healthcare, there will be more opportunities for Congress and the administration to exercise policymaking power.

The Game Metaphor

Applying the game metaphor to policymaking in government can help us understand the evolution of the business environment in the United States from the 1980s through the 1990s to today, and how this can affect regulations and policies that, in turn, will have great effect on innovation and the marketplace. Three games—checkers, poker, and chess—illustrate funda-

mental strategies akin to the business environment that affect innovation and its evolution to today's environment (Figure).

In the 1980s, the market environment was very linear, moving 1 product at a time, much like checkers. We thought of products in separate terms. Payers saw different things in individual products or in individual parts of the formulary. New products required relatively low investment compared with today, in terms of innovation, involving relatively low risks and a low level of regulation. Most decisions, including business negotiations, were made behind the scenes, and the rewards were fairly consistent and predictable.

The environment in the 1990s is best epitomized by poker, in which each person, for the most part, is playing the other player. Similarly, in these years buyers and sellers were playing against each other. Payers and sellers were making financial bets, largely without regard to the underlying value of the products ("cards"). The 1990s were marked by innovation in pricing methods, in marketing practices, and in deals within the supply chain, but not by the value proposition. When products mattered most, the market and the dealmakers emphasized novelty, not value. The risks were moderate and scalable.

Now the new environment is akin to chess. Manufacturers and health plans can no longer think in a linear way. They cannot look at drug benefits or at a product they offer in isolation; they have to understand how all their different activities in the marketplace are affecting everything else (ie, other activities or services). Increasingly it is becoming a transparent game, where everybody can see everyone's moves, as in chess. Payers and manufacturers have to play the entire board, maximize the value of their pieces, think multiple moves ahead, and play defense and offense at the same time, thus creating a far more complex setting for strategy and decision making. However, the new chesslike marketplace does create opportunities to support innovation.

The Value Proposition

Historically, the business environment evolved from relatively modest but steady innovation—occasional leaps in benefits, fairly linear—to deal-making in pricing and marketing in a more aggressive and short-term play. Until recently, novelty ruled. Showing novelty is required for securing a patent. However, novelty is the quality of being new or different—novelty does not mean better. Value is a separate proposition entirely.

The new emerging environment is no longer opaque; it is increasingly transparent and is about risk-taking,

persuasion, positioning, and ultimately trying to demonstrate value.

Just like in chess, today's environment is about trying to maximize the resources, the value of the piece, and the value and the positioning of that piece on the board, similar to advancing the value and the positioning of manufacturing products, or the benefits that a health plan offers. In the 1990s, many plans were criticized for ultimately managing finance. Now, public programs and private health plans ultimately have to manage and to provide value in care management; that is a fundamental shift.

We are moving away from an environment focused on novelty of products to one dedicated to the value of products.

Now we have another significant transition in the marketplace. Previously, private sector players served as the primary drivers and buyers. We are steadily moving to a much more complex and politicized environment, where the public sector is the regulator as well as the principal buyer. We are moving away from an environment focused on novelty of products to one dedicated to the value of products and ultimately the value of health-care services (Table 2).

This transformation is moving the power base, the basic structure, and the decision-making tools and strategies toward payers and purchasers. We are moving toward an environment of increasing transparency in prices and in performance of providers, particularly physicians and hospitals. It is a transition from the market-driven business practices—negotiation, contracts, deals, concessions—between buyers and sellers and into business practices that are increasingly rule- or regulation-driven, in which the government says what can and cannot be done, and where the government is setting basic parameters within which the business practices (ie, providers, health plans, employers, manufacturers) must operate.

The effectiveness of the approach in which manufacturers were trying to persuade customers and prescribers about specific products has been diminished considerably. Ultimately, we are moving toward a world in which manufacturers must persuade and partner with federal and state policymakers, opinion leaders, and health plans to protect access, reward innovation, and ensure appropriate coverage and payment policies.

Figure Evolution of the Business of Innovation

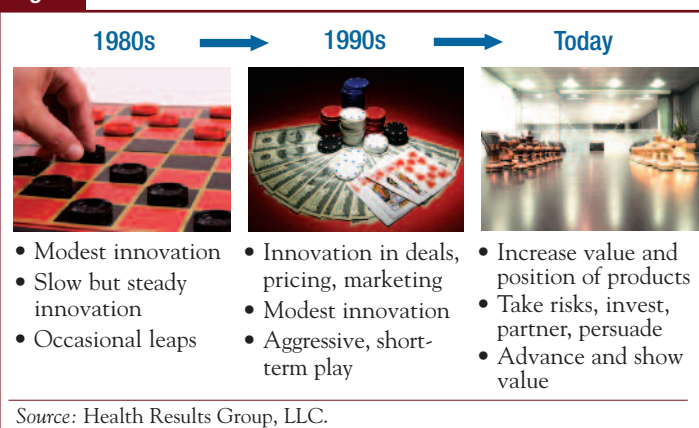


Table 2 Transformation of the Market

That was then	This is now/future
• Private sector as driver, buyer	→ • Public sector as driver, buyer
• Novelty of products	→ • Value of products
• Physicians and manufacturers (supply-side players)	→ • Payers and purchasers (demand-side players)
• Opaque prices and performance	→ • Transparent prices and performance
• Market-driven business practices	→ • Rule-driven business practices
• Sales and marketing	→ • Research, comparative effectiveness
• Persuading consumers and prescribers, direct-to-consumer advertising	→ • Persuading federal and state policymakers, key opinion leaders, plans

Source: Health Results Group, LLC.

Conclusion

Today's environment is moving from a sales and marketing approach, where the emphasis was on trying to influence through sales and marketing efforts, to a world that is research- and evidence-based, the world of comparative effectiveness analysis. These dynamics are affecting all players in the marketplace, albeit in different ways. These are some of the basic changes we can anticipate in the near future in terms of policymaking and the interactions in healthcare; and these are perhaps made clear metaphorically by applying the rules of checkers, poker, and chess to the evolution of the business environment. ■