

Guest Article

Will Healthcare be Rationed or Rational?

A Case for Supporting
Comparative Effectiveness
Research

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PMN83-02



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This article is part of the March 2009 issue of *Pharma Marketing News*.

For other articles in this issue, see:

<http://www.news.pharma-mkting.com/PMNIssueMar09archive.htm>

Published by:

VirSci Corporation

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Newtown, PA 18940

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“Health Care – Rational or Rationed?”

That was the title of a talk delivered back in 1996 by Dr. George Poste, former head of Research for SmithKline Beecham (pre-Glaxo). I found the talk fascinating because it was probably the first time someone had suggested to me that the future of the biopharmaceutical industry wasn't a straight path, but was actually likely to be a choice among several paths leading to very different looking worlds. Given the debate that is now occurring about health care reform and the “R word” (rationing), the title of Poste's presentation seems very timely once again.

All Health Systems Ration Care

Before I continue, let me make a very important point. All health care systems “ration” care in some way and always have.

In 1963, the then head of the UK's National Health Service, Enoch Powell said “there is virtually no upper limit to the amount of health care an individual can consume.” That's as true today as it was then.

As a result, some sort of mechanism has to exist to allocate the scarce resource of health care supply to all those who would like to consume it. That's not a matter of political ideology, it's just economics 101.

We ration care in the US today using one of the most capricious and inequitable means possible—ability to pay. As cost shifting to consumers has

accelerated over the past decade, we've seen the effects of this as year-on-year sales growth for prescription products has dropped on more or less a straight line since 2000 (see Figure 1, below).

Pharma 2020

A few weeks ago, the consulting firm PriceWaterhouse Coopers (PwC) released its own vision for the industry's future entitled “Pharma 2020: Marketing the Future, Which Path Will You Take?” (see box, pg 3).

The PwC paper describes a world just over ten years from now in which pharmaceutical sales and marketing has been radically transformed. Most of the large sales forces that are currently par for the course in the drug industry have vanished and have been replaced by smaller teams that feature members with strong medical backgrounds.

The marketing skills needed to succeed also look much different in an environment where collaboration between payers and biopharmas is the norm, compounds are reimbursed on the basis of the value they bring to the market, and the concept of a pharmaceutical “brand” includes not just molecules but a suite of services designed to ensure that all the needed partnerships can function successfully.

Evidence is, or Will be King

In many ways, this is the preferred world that George Poste sketched out in that talk I heard thirteen years ago. It's a highly rational environ-

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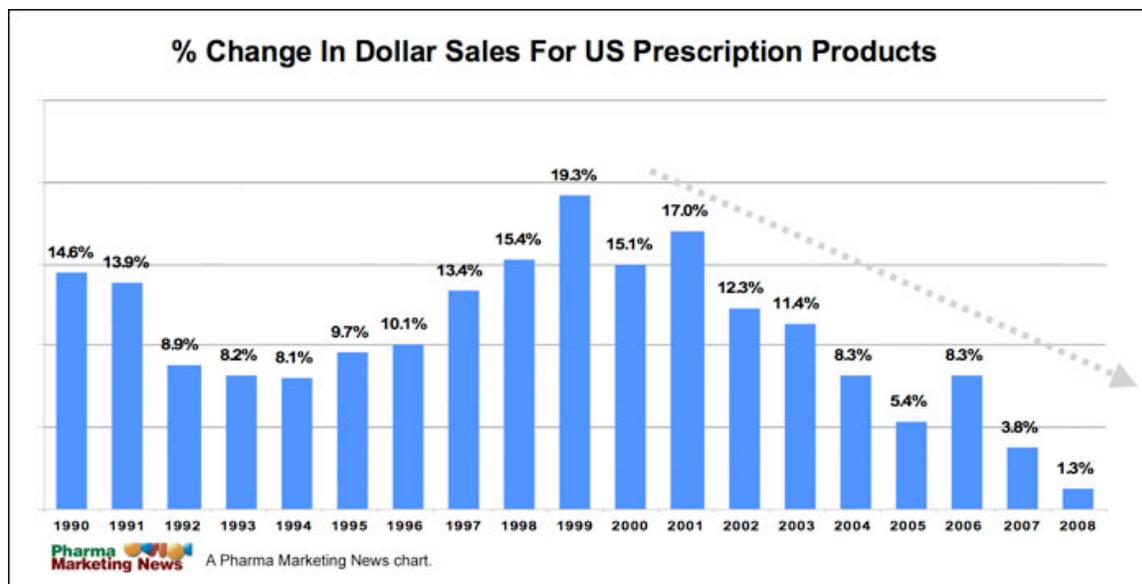


Figure 1: Percent Change in Dollar Sales of US Rx Products (1990 through 2008). Source: IMS National Sales Perspective, January 2006, 2007, 2008, 2009.

ment where evidence is king and features a health care system that is both willing and able to pay premium prices for greater demonstrated value (see "Value-based Pricing": PMN Reprint#76-04; <http://tinyurl.com/4chyy2>).

Poste's world features something very much akin to "comparative effectiveness review" (CER), which is much discussed these days in the face of the \$1 billion-plus appropriation contained in the American Recovery and Reinvestment Act (ARRA) to set up such a function here in the US.

Many in the biopharmaceutical industry are recoiling in horror at the thought of even a quasi-governmental body passing judgment on the value of their products (see "PhRMA Statement on the Comparative Effectiveness Council," pg 4).

The "R" word is thrown around in an attempt to reduce support for such an effort. Of course this conveniently overlooks the point I made about rationing earlier. It also overlooks a critical question: What alternatives exist to CER for making the scarce supply of health care fit the demand?

The Current Path is Untenable

If you've been following the press coverage of the past few months, you've heard a lot of pundits suggest that escalating health care costs will bankrupt the US. That's not much of an exaggeration. For example, according to the Congressional Budget Office (CBO) the Medicare program has an unfunded liability of over \$30 trillion dollars between now and about 2050—that's well over twice the annual GDP of the entire country. That means benefits have been promised to retiring baby boomers that the current tax base won't support.

If health care costs continue their historical pattern of growing 2%-2.5% faster than the overall economy, the CBO says we would need to have a marginal tax rate of 92% to close the funding gap.

While Medicare may be the most visible problem in health care funding, it's by no means the only one. The amount employers spend on health care benefits is now roughly equal to the amount they earn in profits, and continues to grow at unacceptable rates.

Consumers aren't immune either. Health care costs now reportedly produce a personal bankruptcy about every 30 seconds in this country. Large numbers of Americans are being pursued by medical collection agencies, and many are "under-insured." There are simply no funds available to keep feeding the accelerating costs of health care,

and unfortunately, that also affects research-based biopharmaceuticals.

The point of this is that the evidence based, rational world contemplated by both George Poste and the more recent PwC monograph may look very threatening for those currently working in pharmaceutical sales and marketing roles, but the more important question is, compared to what?

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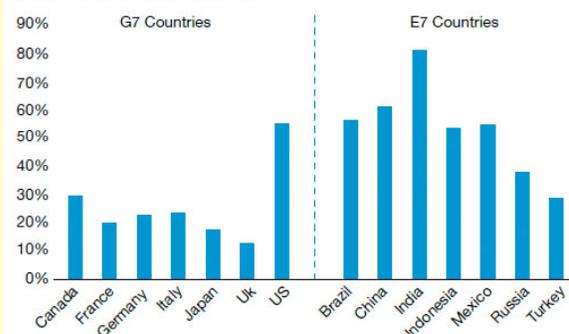
Pharma 2020: Marketing the future - Which path will you take?

This is the third paper in the Pharma 2020 series, published by PricewaterhouseCoopers. It outlines a confluence of dynamics that lead to a new marketing and sales system with a smaller, more agile and smarter sales force. The pharma industry is no longer being rewarded for incremental innovation, me-too products and selling the most pills. Companies will need to demonstrate that their brand adds value to patients and they will have to offer a package of products and health services that the market not only wants and needs but is willing to pay a premium for. The paper highlights some very strong facts related to the need for Pharma to change its marketing and sales functions in order to sustain future growth and performance.

This report outlines in some detail what those changes in the business environment will be and provides pharma companies with indicators of organisational and operational structure that could influence their success and readiness to compete.

Find it here: <http://tinyurl.com/b5sb5x>

Figure 1: Private expenditure on health as a percentage of total healthcare spending in the G7 and E7 countries



Source: World Health Organisation, "World Health Statistics 2008"

It's been obvious for some time now that we're facing more and more restrictions on traditional pharmaceutical promotional activities. The new PhRMA code, the appellate court decision regarding data-mining laws, the "DC Safe Act" the increasing numbers of hospitals and medical groups that are limiting rep access, and the myriad of state legislative efforts underway all point in the same direction:

The standard methods of selling and marketing prescription products will be less and less available to the industry in the future.

Future Scenarios

I've had the opportunity to do a lot of scenario-based strategic planning, both during my time in corporate life and as an independent consultant. This very useful approach looks at assorted alternative futures and forces you to think about how you'd be successful in a wide variety of potential environments.

To do scenario-based planning right, it's important to first identify those factors that are both very important in terms of business impact and inherently unpredictable. These are termed "drivers."

Drivers can then be combined in various ways to produce a set of alternative futures in which a firm might have to operate. Good scenario exercises will often use from five to ten different drivers, so the number of scenarios generated can be almost infinite.

Triumph of Reason

Three different archetypes for the biopharmaceutical industry almost always emerge. We've touched a bit on the first one already—let's call it "**The Triumph of Reason.**" This scenario is characterized by evidence-based medicine, widespread use of health care information technology to support real-time comparative effectiveness review, and value-based reimbursement for innovative biopharmaceuticals are its hallmarks.

As noted above, this environment seems deeply threatening for many in industry because it represents such a steep change from where we are today. But before rejecting this one as too "dangerous," it's important to think about the alternatives.

Consumer Chaos

Another option that invariably emerges is an extension of the path we've been on for most of the past decade. Let's call this one "**Consumer Chaos.**" This environment involves acceleration of the trends toward shifting costs and decision-making authority to consumers.

There's plenty of evidence to show that the average consumer is a very inferior decision-maker when it comes to health care. Consumers tend to cut back on all sorts of care, both necessary and unnecessary, in equal proportions.

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PhRMA Statement on the Comparative Effectiveness Council

Washington, D.C. (March 19, 2009) — Pharmaceutical Research and Manufacturers of America (PhRMA) Senior Vice President Ken Johnson issued the following statement today regarding the Federal Coordinating Council on Comparative Effectiveness Research:

"The economic stimulus law made an important footprint in the health care debate by providing significant funds for government-sponsored comparative effectiveness research (CER). PhRMA has long supported well-designed CER because when used correctly, it can serve as a tool to help improve patient outcomes and medical decision-making.

"To help ensure that CER is used to promote patient health and improve the quality of health care in the U.S., it is critical that the new Federal Coordinating Council listen carefully to input from all stakeholders throughout the process, particularly physician and patient input because, ultimately, they will be ones most impacted by the Council's recommendations.

"As the Administration continues to implement this initiative, we expect it will be done with transparency, openness, accountability and public input in how research priorities are set and how studies are ultimately communicated and conducted.

"We look forward to working with members of Congress and the Administration as a long-term framework for comparative clinical effectiveness research is established."

This tendency, significantly exacerbated by the poor economy, has been one of the leading contributors to the slow down in the sales growth for patented medications over the past several years.

In the absence of solid data on the value of novel biopharmaceuticals that a well-run CER process should yield, the problem is likely to get worse. As a result, product selection decisions will increasingly default to lower cost options.

Extend the trend out just a bit further and you're faced with a world in which sixty or seventy million people are completely uninsured with many of the remainder living with very skimpy coverage. Generic utilization rates in this situation probably exceed 80% and perhaps 30%-40% of all prescriptions go unfilled.

The only people who can actually afford innovative medications in this scenario are probably those making six-figure incomes (roughly 20% of the US population today). The effects of such a scenario on the research-based biopharmaceutical industry are probably best described as "the death of a thousand cuts."

Big Brother Arrives

A third option involves a backlash of major proportions, and we'll call this one "Big Brother Arrives." Take the numbers of un- and under-insured up a bit further, especially if that population contains a high proportion politically active Baby Boomers, those who are becoming "power users" of health care.

It's not hard to imagine an electoral mandate for the Federal government to "fix" the health care cost and access problem. This may sound far-fetched, but opinion research surveys consistently show that a majority of Americans think health care is a right, not a privilege, and that it's primarily the Federal government's job to make sure everyone has access to care.

Once again, in the absence of an objective means to determine value, about the only choice available is to slam the care delivery system and its suppliers (including the biopharmaceutical industry) with price controls. This is probably every industry executive's worst nightmare, and the negative ramifications for sales and profits are obvious.

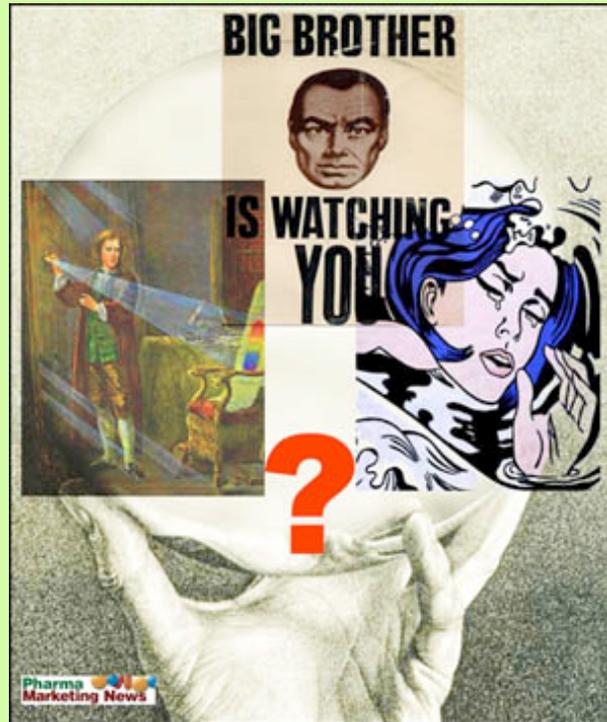
Blended Models

There are some blended models that could emerge as well. One of the options I find plausible is a government run, price controlled "Safety Net" system that would cover primary care, generic

medications, basic chronic disease care and catastrophic hospitalizations. People with more money could "trade up" with their own money to better standards of care.

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Which Future US Health Care Scenario is Best for Pharma?



- A. "The Triumph of Reason"
- B. "Big Brother Arrives"
- C. "Consumer Chaos"
- D. "Safety Net"
- E. "PhRMA's Platform"

Or something else?

TAKE THE SURVEY HERE:

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After you complete the survey, you will be able to see a summary of responses to date. No comments or other identifying information is included in the summary.

Your comments are confidential (anonymous) unless you specifically provide your contact information at the end of the survey and allow us to attribute comments to you personally.

This is much like the health care system we see today in Australia and there are elements of it emerging in parts of Europe as well. This two-tier system also wouldn't necessarily be especially attractive for many research-based firms.

Badly Done CER

All this seems to show a potentially fatal paradox for the biopharmaceutical industry. By fighting against the evolution of CER, something immeasurably worse might be made more likely.

The only real threat of CER is to have it done badly, by people whose only interest is in reducing costs. Admittedly, that's a very real possibility.

Many believe that's the goal of CER-like activities such as the Oregon Drug Evaluation and Review Program (DERP) that supports many state Medicaid formularies today.

The answer for this concern is not to become "abominable no-men" opposing CER in any form. If that strategy succeeds something more dire becomes increasingly likely. If it fails, industry has a high probability of being excluded from the discussion about the right way to conduct such an analysis. That increases the probability of the very thing most executives would like to prevent—a badly run process.

Best Course of Action

The best course of action, in my opinion, is to accept that the way pharmaceutical products are marketed and reimbursed is going to change under just about any plausible set of circumstances one can imagine.

Then it becomes a question of identifying the "least worst" option available. Most are "blunt instrument" forms of rationing without any good means to determine value. Whether that rationing is done by consumers at an individual level or by the Federal government for large swaths of the population these are ugly choices. Compared to them, "rational" health care as imagined by George Poste back in 1996 or more recently the folks at Pricewaterhouse Coopers looks downright attractive.

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