Access to Medical Innovation

Obstacles & Opportunities

Peter J. Pitts

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Table of Contents

1. Executive Summary

Healthcare innovation saves lives, saves money, promotes economic growth, and provides hope for hundreds of millions of people (both patients and care-givers) in the United States and around the world. But innovation isn't easy.

There are many roadblocks beyond those of discovery and development. The complicated and conflicting dynamics of politics, perspectives on healthcare economics, of friction between payers, providers, manufacturers, and regulators, the battle for better patient education, and the need for a more forceful and factual debate over the value of innovation all create the need for a more balanced and robust debate.

The public policy essays in this paper present some of the key obstructions to maximizing healthcare innovation. The Center for Medicine in the Public Interest is dedicated to addressing these problems head-on and providing practical opportunities to overcome them. Specifically:

- The importance of understanding and rewarding incremental innovation.
- The price/value debate. Rather than focusing on the short-term costs of healthcare, what are the long-term benefits to both patients and society? We will examine this issue through the lens of the Solvadi debate.
- Value-based insurance design. How a more personalized approach to reimbursement matches up well with advances in personalized medicine.
- The dynamic and distressing link between co-pays and outcomes and how this relationship must be understood and recalibrated.
- The urgent need for transparency in insurance choices within the Affordable Care Act in order to provide the right medicine to the right patient at the right time in a transparent and affordable manner.
- How to reach best clinical practice more swiftly through electronic pre-authorization and the increasing empowerment of physicians.
- Addressing the problem of medication compliance through innovative approaches such as apps and more user-friendly patient education.
- How "the story of innovation" can be more clearly and powerfully communicated to various constituencies so that we can narrow the "misperception gap."
- Rather than playing the "blame game," how we can advance healthcare innovation by working together to advance the public good.

Shortly before his death, I had the privilege of a private meeting with Nobel laureate Joshua Lederberg. We talked about the state of applied science, the prioritization of development science, biomarkers, and a host of other future-oriented issues. At the end of the meeting he put everything into perspective in a single sentence. He leaned over the table and said, "The real question should be, is innovation feasible?" Let's hope so. Innovation equals hope.

-- Peter J. Pitts, September 2014, New York City

2. Innovation Nation

In 1950, Americans spent about 5 percent of their income on health care. Today the share is about 16 percent.[1] According to Harvard University economist N. Gregory Mankiw, "many pundits take the increasing cost as evidence that the system is too expensive. But increasing expenditures could just as well be a symptom of success."[2]

And he hits a homerun with a clear, concise, and common sense explanation. "The reason Americans spend more than their grandparents did is not waste, fraud and abuse, but advances in medical technology and growth in incomes. Medical science has consistently found new ways to extend and improve lives. Wonderful as they are, they do not come cheap."

Change is not required," wrote marketing guru W. Edwards Deming. "Survival is not mandatory." If we learn nothing else from BP's recent un- pleasantness, it is that being able to identify an obvious problem (e.g., when oil is gushing un- controlled into the Gulf of Mexico) is one thing. Identifying a potential problem is tougher. Toughest of all, however, is designing a solution that addresses a need early in the curve. Consider Alzheimer disease, a health care oil spill of draconian proportion. As Gina Kolata wrote in the *New York Times*, "The failure of a promising Alzheimer's drug in clinical trials highlights the gap between diagnosis—where real progress has recently been made—and treatment of the disease."[3] Recent significant steps forward in early diagnosis of the disease are important, and also frustrating, because there is still precious little that can be done when this devastating condition is identified either late in the game or in its nascent stages.

There are some tough but important basic principles when it comes to innovation in health care technologies.

Innovation is slow. As any medical scientist will tell you, there are few "Eureka!" moments in health research. Progress comes step by step, one incremental innovation at a time. Biopharmaceutical companies more often profit by improving existing molecules and making processes more efficient than by revolutionizing the whole field with new miracle products. Discontinuous innovation is the wonderful exception to the rule.

Innovation is hard. Today it takes about 10,000 new molecules to produce one FDA-approved medicine. This observation itself is disconcerting, but, further, only 3 out of 10 new medicines earn back their R&D costs. Moreover, unlike other R&D-intensive industries, biopharmaceutical investments generally must be sustained for over 2 decades before the few that make it can generate any profit.[4]

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[1] http://visualeconomics.creditloan.com/100-years-of-consumer-spending/
[2] http://economistsview.typepad.com/economistsview/2007/11/mankiw-beyond-t.html
[3] http://www.nytimes.com/2010/08/19/health/19alzheimers.html?_r=0
[4] http://www.innovation.org/index.cfm/insidedrugdiscovery

Innovation is expensive. The costs of development also continue to escalate. In 2003, researchers at Tufts Center for the Study of Drug Development (CSDD) estimated the costs to bring a new medicine to market to be $802 million. More recent authoritative estimates are well over the $1 billion mark, going as high as $1.7 billion.[5]

Innovation is under attack. From accusations of the "me-too" variety, to questionable schemes to replace pharmaceutical patents with a prize system, life for innovator pharmaceutical companies is rough and tough. Israel Makov (formerly the Big Abba of generics giant Teva) once told me that he wasn't really in the pharmaceutical business, but rather "in the litigation business," and he made this comment before the reality of biosimilars.

Nonetheless, innovation is important. This is true for more than just biopharmaceutical industry profits. In the United States, increases in life expectancy resulting from better treatment of cardiovascular disease from 1970 to 1990 have been conservatively estimated as bringing benefits worth more than $500 billion a year. In 1974, cardiovascular disease was the cause of 39% of all deaths. Today it is about 25%. Cerebrovascular diseases were responsible for 11% of deaths back then. In 2004 they caused 6.3% of deaths. Kidney diseases were linked to 10.4% of deaths and now are associated with 1.8%.[6]

As Harvard University health economist (and health care advisor to President Obama) David Cutler has noted: "The average person aged 45 will live three years longer than he used to solely because medical care for cardiovascular disease has improved. Virtually every study of medical innovation suggests that changes in the nature of medical care over time are clearly worth the cost."[7] Innovation must not be only about medicines. We have to embrace innovative technologies for medical records and prescribing. We need innovative clinical trial designs and molecular diagnostics so that we can develop better, more personalized medicines faster and for far less then the current $1 billion-plus delivery charge. We need innovation in access and reimbursement policies that rewards speed to best treatment rather than lower-cost patients per hour.

Do we want a health care system that is cost-based or patient-centric? Should end-of-life care be rationed? If so, by whom and by what measure? And if we decide not to pay for new medicines, the clear signal to the pharmaceutical industry is "cease research and development for new treatments for killer diseases."

These considerations lead to the conclusion that we must start taking innovation, both incremental and discontinuous, seriously, which means spending more on harder developmental R&D (with concomitant higher investment risks). Currently, lip service is being paid to the need for more robust comparative effective- ness—

[5] http://csdd.tufts.edu/
[6] http://www.washingtontimes.com/news/2008/may/12/health-care-realities/
[7] Ibid

although this is a battle yet to be either defined (comparative effectiveness, cost effectiveness, or clinical effectiveness?) or fought (do we need a US version of NICE?). It will indeed be a battle royale. In the words of Frederick the Great, "L'audace, l'audace, toujours l'audace."

According to Yale economist William Nordhaus, "The social productivity of health care spending might be many times that of other spending. If this is anywhere near the case, it would suggest that the image of a stupendously wasteful health care system is far off the mark."[8]

When it comes to health care reform, this is not even the end of the beginning. We need to keep our eye on the prize, that is, innovation that focuses on creating a chronic health care culture that embraces prevention and prophylactic care. We will not survive as a nation of obese, hypertensive diabetics. Rather than wasting time on Beltway spin, redoubling our efforts on innovation is far preferable.

3. Sovaldi and the Price/Value Debate

Expensive new drugs often get fingered as the culprit to rising US health-care costs. The truth is closer to the reverse.

First off, it's hard to see how pharmaceuticals can be a major driver of costs when they're just over 11 percent of the total US health-care budget.[9]

But more important is that even extremely pricey drugs still save money if used right.

Consider Sovaldi, which has a 90 percent cure rate for Hepatitis C, a disease affecting over 3 million Americans. A three-month treatment cycle of the new drug costs upward of $84,000. On the market for just a few months, Sovaldi has already clocked in a record-shattering $2.3 billion in sales.[10]

Some are calling foul, accusing the drug's developer — Gilead Sciences Inc. — of exploitative pricing. "The company in this case is asking for a blank check," says Karen Ignagni, president of America's Health Insurance Plans. "It will blow up family budgets, state Medicaid budgets, employer costs and wreak havoc on the federal debt."[11]

That's 100 percent wrong — the exact opposite of reality. New, better medications are actually the best and swiftest way for this country to cut down on our health-

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[8] www.econ.yale.edu/~nordhaus/.../health_nber_1.doc
[9] http://www.ashpmedia.org/AJHP/DrugExpenditures-2014.pdf
[10] http://www.nytimes.com/2014/07/24/business/sales-of-hepatitis-c-drug-sovaldi-soar.html
[11] http://www.reuters.com/article/2014/05/28/us-usa-healthcare-hepatitisc-insight-idUSKBN0E80AZ20140528

care expenses. By more effectively combating disease and improving patients' lives, drugs reduce long-term medical costs and bolster the overall economy.

Consider one pre-Sovaldi "best practice" treatment for Hepatitis C, the drug Pegasys. This requires one injection a week for 48 weeks — and very few patients see the treatment through to completion, so much of that treatment, both physician time and drug cost, is wasted. Nor is it that much cheaper: At about $7,000/month, the full course of treatment is over $70,000 — barely less than cost of the three months needed for Sovaldi to work a cure.[12]

And the price of not using Sovaldi is very high. One in three patients with the Hepatitis C virus eventually develops liver cirrhosis, and managing these patients is costly. A "routine" liver transplant (where the liver is from a cadaver) costs close to $300,000; a "living donor" transplant is even more expensive.[13]

Thanks to Sovaldi, a pill that cures the disease when taken once a day over 12 weeks will eradicate the need, the risks and the costs of liver transplantation. Such radical innovation deserves to be both lauded and rewarded.

And Sovaldi's costs will come down. The initial price of such breakthrough medications reflects the huge R&D costs required to bring the drug to market, not avarice.

As Food and Drug Administration official Dr. Janet Woodcock noted of the Sovaldi controversy: "We may have to put a big down payment down now to get something really good."[14]

It's remarkable that some large insurers have the chutzpah to complain that curing 3 million Americans of hepatitis C will bankrupt health-care systems. Data recently published by the PwC Health Research Institute suggests the reverse. The study shows that the use of Sovaldi will actually drive down overall spending within a decade. According to the authors, "The challenge may lie in targeting the patient most in need of the more expensive course of therapy."[15]

In short, drugs aren't the cause of rising health-care costs — they're the solution. Demonizing new treatments distracts from the real problem in the US biopharmaceutical industry: top-down cost-centric policies that focus on the near-term, short-changing long-term patient outcomes, and so endanger "sustainable innovation" by denying fair reimbursement for high-risk investment in R&D.

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[12] http://www.drugs.com/clinical_trials/pegasys-proven-effective-hepatitis-c-latino-patients-according-article-new-england-journal-medicine-6620.html
[13] http://www.healio.com/gastroenterology/curbside-consultation/%7Ba8b9ec89-2c79-4696-a702-84e9fad15233%7D/what-is-the-likelihood-t
[14] http://www.focr.org/news/inside-health-policy-fda-drug-chief-drug-cures-progress-could-require-down-payment
[15] http://www.pwc.com/us/en/health-industries/behind-the-numbers/specialty-drugs.jhtml

(Research and development costs big even if a drug never makes it to market — and most don't.)

New treatments are a bargain. Disease is always much more costly.

Unfortunately, under ObamaCare health plans are sticking more people with a bigger share of drug costs — a strategy designed to discourage use by the people in greatest need and direct outrage away from insurers to drug companies.

Breakthrough drugs could generate huge new savings in the US economy — but only if federal regulators don't smother them in the womb with expensive and unnecessary legal hurdles. Left unencumbered, domestic medical innovation will generate the new treatments to improve lives, stave off disease and cut down on long-term health-care costs.

If we don't reward risk-taking on behalf of human health, both will shrink.

4. What about "value-based insurance design?"

Consider value-based insurance design, and then consider Section 224 (c) of HR3200, "Encouraging the Use of High Value Services." The public health insurance option may modify cost sharing and payment rates to encourage the use of services that promote health and value."[16]

The Pink Sheet points out a recent paper sponsored by the National Pharmaceutical Council as "adjust[ing] out-of-pocket costs based on an assessment of the clinical benefit value - not simply the cost - to a specific patient population." The overall goal is "getting more health out of every health care dollar."[17]

And they continue:

"A shift to value-based insurance would provide some interesting opportunities for drug manufacturers to develop and present evidence of their products' value. A permanent comparative effectiveness research program, which is being considered as part of health care reform legislation, also could become an important source of information on value."

It's important to consider VBID in the broader conversation of clinical effectiveness and more specifically HTA modeling a la QALY – because that brings you into the direct path of VSLY – the value of a statistical life year. According to Dr. Frank Lichtenberg of Columbia University, for a healthcare technology assessment scheme (such as the NICE model) to yield valid decisions in practice, it is necessary to have reliable estimates of:

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[16] http://thomas.loc.gov/cgi-bin/query/z?c111:H.R.3200:

[17] http://www.sph.umich.edu/vbidcenter/registry/pdfs/NPC_VBIDreport_7-22-09.pdf

ΔCOST
ΔQALY
and VSLY (Value of a Statistical Life Year)

and his main point is that the devil is in the details.

Lichtenberg believes that incorrect estimates of some or all of these key inputs are often used:

ΔCOST is frequently overestimated
ΔQALY and VSLY are frequently underestimated

And due to these estimation biases, health technologies that are truly cost-effective may often be rejected as cost-ineffective.[18]

Per the recent debate over the utility of new cancer treatments, he makes a very interesting point -- that even though, over the past 30 years, the U.S. Mortality Age-Adjusted Rates for cancer have remained relatively constant -- (leading to such mainstream media headlines as Fortune Magazine's *"Why have we made so little progress in the War on Cancer?"*[19] and NEJM articles like "The effect of new treatments for cancer on mortality has been largely disappointing"[20] -- the often ignored reality is that *5-year relative survival rates, for all cancer sites, have increased from 50.1% in 1975 to 65.9% in 2000.*[21]

Lichtenberg cites two crucial studies, pointing out how health care economists must seriously reconsider the outdated estimates of a QALY:

Viscusi and Aldy: The value of a statistical life for prime-aged workers has a median value of about $7 million in the United States

Viscusi, W. Kip and Joseph E. Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World," The Journal of Risk and Uncertainty, 27:1; 5–76, 2003.

and

Murphy and Topel: The value of a life year is $373,000.

Murphy, Kevin M., and Robert H. Topel, "The value of health and longevity," Journal of

[18] http://www.stockholm-network.org/downloads/events/Lichtenberg.pdf
[19] http://fortune.com/?s=why-were-losing-the-war-on-cancer%2F
[20] http://www.nejm.org/doi/full/10.1056/NEJM199705293362206
[21] http://www.researchgate.net/publication/46555895_Are_Increasing_5-Year_Survival_Rates_Evidence_of_Success_Against_Cancer_A_Reexamination_Using_Data_from_the_U.S._and_Australia/file/e0b49521388f04d272.pdf

Political Economy, 2006.

Attention must be paid.

5. The Co-Pay Catastrophe

In the current national health care debate, let's hope we never hear the words, "As Georgia goes, so goes the nation."

Since 2005, Georgia politicians have been conducting a dangerous penny-wise, pound-foolish experiment with its state health program by hiking co-pays for brand-name prescription medications.

The results of that policy have been sicker, less productive state employees. These Georgians end up consuming more and costlier health care during the course of their lives, as their neglected conditions worsen.

The lesson here is that higher co-pays discourage patients from getting the treatment they need — especially when they reach upwards of $100.

Just consider what Daniel M. Hartung of Oregon Health & Science University calls the "co-pay effect."

Professor Hartung and his colleagues analyzed the effect of even a small co-payment — $2 for generic drugs and $3 for brand-name drugs — for those pharmaceuticals that were available to Oregon Medicaid enrollees in 2003.[22]

The co-pay fees were not required for patients who were unable to pay. The researchers examined pharmacy claims data on about 117,000 Medicare enrollees with conditions like depression, schizophrenia, respiratory disease, cardiovascular disease and diabetes.

They found that the patients' overall use of prescription drugs decreased by about 17 percent after the introduction of the co-pay policy.

It should come as no surprise that any policy that encourages patients to stop taking their prescription drugs is a recipe for disaster.

There is already a growing national trend of Americans not adhering to their prescribed drug regimens.

A study by Wolter Kluwer Health found that fewer and fewer Americans are even bothering to fill their prescriptions. [23]

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[22] Hartung DM, Ketchum KL, Haxby DG. An evaluation of Oregon's evidence-based Practitioner-Managed Prescription Drug Plan.*Health Affairs* 2006;25:1423-32.

In fact, during the fourth quarter of 2008, American patients neglected to fill 6.8 percent of their brand-name prescriptions — a 22 percent increase when compared to the previous quarter.

This practice — often known as prescription drug "non-adherence" — can have serious repercussions on a patient's health.

For example, hypertensive patients who do not take their prescribed medicines as directed suffer 5.4 times as many poor clinical outcomes as those who do.

And poor outcomes are 1.5 times more common for heart disease patients who do not take their meds regularly. This adds an additional $100 billion to $300 billion in health care costs each year.

The trend has been perpetuated by the fact the Americans with private health insurance have found themselves paying more for prescription drugs in recent years.

Why? Because insurance companies are paying less. In 2000, people under 65 with private health insurance paid 37.2 percent of their prescription drugs costs out of their own pockets.

Many Americans mistakenly believe that this increase in out-of-pocket expenses is the result of higher drug costs. The data reveal otherwise.

In fact, the growth in prescription drug co-payments outpaced the growth rate of prescription drug prices four to one.

It's easy to see why plans to increase the co-pays for Medicare beneficiaries will also have serious adverse effects on the health of our seniors, as well as on our health care system as a whole.

Unable to afford their prescriptions, many Medicare enrollees will begin treating strict obedience to their drug regimen as a luxury, not a necessity.

As more and more seniors choose to abandon their treatment, health care outcomes will suffer, as prices soar even higher.

Making health care decisions based solely on cost is a losing strategy over the long term for both the state and for the health of its residents.

But maybe those are the kind of shortsighted, budget-driven results you get when cost-over-care bureaucrats run your health plan.

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[23] http://www.wolterskluwerhealth.com/News/Pages/Symposium-Focuses-on-Disparities-in-Cardiovascular-Disease.aspx

6. Therapeutic Innovation is the Great Emancipator

Referring to the Model T, Henry Ford famously said, "Any customer can have a car painted any color that he wants so long as it is black." That worked out fine – until there was competition. Choice is the great emancipator. The same is true when it comes to healthcare – and a lot more important.

When it comes to the Affordable Care Act, patients can access any medicine they need -- as long as it's on the exchange formulary. Sure, the ACA limits the degree to which insurers can charge higher premiums for sicker patients, but ObamaCare plans found a way around these rules: impose higher out-of-pocket costs for all or most specialty drugs. High co-pays effectively remove choice from the system for many patients.

The breakdown of Silver plans (the most popular category) is particularly revealing. In seven classes of drugs for conditions from cancer to bipolar disorder, more than a fifth of these plans require patients to shoulder 40 percent of the medicine's cost. And 60 percent of Silver plans place all drugs for illnesses like multiple sclerosis and rheumatoid arthritis in the "formulary tier" with the highest level of cost-sharing.[24]

Nearly every Silver plan across the country, in fact, puts at least one class of drug exclusively in the top cost-sharing tier. In effect, this leaves patients with a given condition — whether HIV or Crohn's disease — without a single affordable treatment option. Silver is the new Black.

And those signing up for Silver plans don't know what's going to hit them until they access the healthcare system. It's time, at least, for that to change. It's time for exchange transparency.

The American Legislative Exchange Council (a forum for state legislators and private sector members to collaborate on model legislation that members can customize and introduce for debate in their own state legislatures) has drafted the "Exchange Transparency Act." Whatever your position on ObamaCare (or, if you prefer, the Affordable Care Act), it makes a lot of sense. If there's nothing to hide then there shouldn't be a problem.

Exchange Transparency Act

Summary

Requires health plans offered through a state-based health exchange to provide specific information in order for consumers to draw meaningful comparisons between plans.

[24] http://www.healthpocket.com/healthcare-research/infostat/prescription-drug-coverage-and-affordable-care-act#.U_sp9UgQGiw

Model Policy

Section 1. Title. This Act shall be known as the "Exchange Transparency Act."

Section 2. Form of Information Available to the Public and Disclosures Required of Health

*Insurers***.** The following information about each health plan offered for sale to consumers shall be available to consumers on {insert state-based exchange website} in a clear and understandable form for use in comparing plans, plan coverage, and plan premiums:

(1) The ability to determine whether specific types of specialists are in network and to determine whether a named physician, hospital or other health care provider is in network;

(2) Any exclusions from coverage and any restrictions on use or quantity of covered items and services in each category of benefits;

(3) A description of how medications will specifically be included in or excluded from the deductible, including a description of out-of-pocket costs that may not apply to the deductible for a medication;

(4) The specific dollar amount of any copay or percentage coinsurance for each item or service;

(5) The ability to determine whether a specific drug is available on formulary, the applicable cost-sharing requirement, whether a specific drug is covered when furnished by a physician or clinic, and any clinical prerequisites or authorization requirements for coverage of a drug;

(6) The process for a patient to obtain reversal of a health plan decision where an item or service prescribed or ordered by the treating physician has been denied; and

(7) An explanation of the amount of coverage for out of network providers or non-covered services, and any rights of appeal that exist when out of network providers or non-covered services are medically necessary.

Section 3. Enforcement. The {insert state insurance commissioner} may impose fines on any entity failing to meet the requirements of this act.

What's the ETA of the ETA? Stay tuned.

7. Preauthorization: Prescriptions and Proscriptions

News that Blue Shield of California will no longer pay for Avastin to treat breast cancer, though "exceptions may be considered on a case-by-case basis," makes a nationwide survey by the Coalition of State Rheumatology Organizations (CSRO) big news. The survey shows broad dissatisfaction with the insidious practices of

preauthorization and step therapy – specifically the ways in which it impacts the ability of physicians to treat patients.[25]

(Prior authorization, also known as pre-authorization, pre-certification or prior notification, is an extra set of steps some insurance carriers require before determining whether they will pay for a medical service or prescription medication. The physician, or other medical provider, is required to obtain approval from the insurance carrier before the carrier will agree to cover the cost of the medical service or prescription medication. Step therapy, also referred to as "fail-first," requires patients to 'fail' on one or more less costly medications before the health insurance carrier will agree to cover a more expensive medication, even if a physician thinks it is a better option for the patient.)

"Rheumatologists around the country have increasingly voiced their concerns about the impact of health insurance protocols such as prior authorization and step therapy on patient care," said Reuben Allen, CSRO Executive Director. "These practices are stripping rheumatologists of the ability to direct the most appropriate and effective courses of treatment, which causes patients to suffer delays or outright denials of proper medical care. Individualized treatment plans that can restore, enhance, and preserve quality-of-life over time are essential to rheumatology patients and their struggle against autoimmune and destructive arthritic disorders."

Specific findings of the CSRO survey include:

Nearly 99% of rheumatologists surveyed say they have had to alter treatment plans including changing prescription medications to accommodate restrictions imposed by patient health insurance carriers;

91.5% of survey respondents say prior authorization has a **"**negative" to "very negative" effect on their ability to treat patients;

Nearly 97% of rheumatologists surveyed agree**,** "There should be enforceable legislation to regulate restrictions that insurance companies place on health care providers in regards to treatment modalities they prescribe for their patients;"

Nearly 98% of survey respondents agree that decisions about what medications are best for a patient should be made by the patient's own health care provider and not by the health plan or insurance company;

Nearly 73% of respondents say they are only **"**sometimes" or "rarely" able to easily determine what procedures will be covered by a patient's health plan at point-of-service;

52.2% of rheumatologists surveyed say they have considered re-establishing their

[25] http://www.csro.info/

practices as fee-for-service only because of prior authorization constraints.

Currently, prior authorization and fail-first protocols are primarily paper-based, and non-standardized. Each insurance carrier has its own set of requirements, which can vary among plans, even within the same carrier's portfolio of coverage options. To meet prior authorization requirements physicians must complete a time-consuming series of faxes, phone calls, emails, input of data into insurance carrier web sites and, in some cases, letters.

In response to the survey, CSRO also announced its recommendations to policymakers in addressing prior authorization protocols by ensuring that:

Prior authorization should be standardized and improvements in the current process can be made by the adoption of a universal prior authorization form;

Electronic prescribing platforms are provided on neutral and open platforms that do not advance the commercial interests of any particular participant (e.g., health insurers, hospitals, pharmacy benefits managers, pharmaceutical companies, etc.) to the potential detriment of the patient;

Adjudication of prior authorization requests occurs within a reasonable time frame (hours as opposed to days or weeks); and communication between physicians and payers should be on a peer to peer basis;

Electronic prescribing platforms include access to information about all FDA-approved medications and medical services without restrictions;

Complete, up-to-date information about prior authorization and fail-first criteria is available through electronic prescribing platforms at point-of-service;

Prior authorizations should not be required on a repeated basis. It should only be necessary with a change in medication dictated by a change in clinical status;

Prior authorization should not be necessary for low cost medications; for example, prednisone and methotrexate.

"Physicians are responsible for the administrative costs associated with meeting prior authorization and fail first requirements.

"Prompt diagnosis and specially tailored treatment can improve the long-term outcomes of patients with rheumatologic diseases," said CSRO's Allen. "State legislatures and insurance commissioners should take appropriate steps to ensure that patients suffering from chronic rheumatic diseases and chronic pain do not have to needlessly suffer."

8. **What about Adherence?**

Advancing adherence requires innovation of a different kind

When it comes to medication adherence, is knowledge power? Or is that even the right question. Perhaps patients, and healthcare professionals (and payers and regulators) also need to learn how to share knowledge. When it comes to medication adherence in the 21st century, the medium is the medicine.

Are package inserts, hard copy med guides, brochures and "starter packages" still the best way to make important healthcare information "sticky?" Were they ever?

Zig Ziglar once said, "If what you're doing isn't working, try something else. If what you're doing *is* working, try anything else." While there are certainly success stories and validated methodologies in the battle for better adherence/compliance, we're losing the war. It's time to reconsider what we're doing.

Consider the National Council on Patient Information and Education's report, Accelerating Progress in Prescription Medicine Adherence: The Adherence Action Agenda: A National Action Plan to Address America's "Other Drug Problem."[26]

The report advocates for an expanded investment in patient/provider education and engagement tools to help clinicians implement best practices for medication adherence and counsel their patients on the importance of following treatment plans.

Will the tried-and-true ways enhance safe use or drive positive therapeutic outcomes? Or do today's patients (also known as consumers) want their healthcare intelligence the same way they're getting enlightenment and orientation on all the other things they want and need to know about the daily details of their lives? In short, on tablets and smart phones.

"Human action can be modified to some extent, but human nature cannot be changed." Those are the words of Abraham Lincoln and they pretty well sum up a major issue in American healthcare – adherence/compliance. There's a lot to be done. There are a lot of good ideas. There seems to be a lot of commitment. But more than the better angels of our nature are required.

What are the issues we are trying to impact? There are six and they are linked: Sub-optimal patient outcomes (The Big Kahuna), sub-optimal physician metrics (pay-for-performance), lower healthcare costs (for payers), sub-optimal profits (for pharmaceutical companies), impact on safe use programs – specifically in reducing medical errors and, lower healthcare costs for society

Some think that (as with REMS), the FDA should insist that new drugs have adherence/compliance plans that can be monitored and improved through iterative

[26] http://www.bemedicinesmart.org/Medication_Adherence_Fact%20Sheet.pdf

learning. Should sales reps (or, better yet, MSLs) "detail adherence/compliance programs and share validated tools for adherence/compliance "triage?" The only thing that's currently on the table is that the FDA has promised to make MedGuides more user-friendly. (We can do better.)

All these are important, but what we really need are solutions that impact social conditioning … and that means using innovative platforms such as social media -- and specifically apps.

Not apps that are medical devices (although they too play an important role), but apps that remind, cajole, educate, praise, and assist patients in their quest for better health. Apps are at the nexus of safe use, treatment outcomes and patient satisfaction. And it's not science fiction. And as Philip K. Dick wrote, "Reality is that which, when you stop believing in it, doesn't go away."

At present, there are some 17,828 healthcare and fitness apps and 14,558 that can be deemed "medical."[27] Dr. Janet Woodcock, the director of FDA's Center for Drug Evaluation and Research said that the use of social media by healthcare companies is important because social media "is where the people are." And that's not just Facebook and Twitter and YouTube -- also true when it comes to apps.

According to a national survey by Adherent Health Strategies of 2,216 patients (age 18+ who take at least one prescription medication per day) show that whether you're a Millennial or a member of the Greatest Generation, you're using apps via a smart phone or a tablet.[28]

And when it comes to medication management, only 4% of the sample preferred a web site that was brand specific and only 8% want manufacturers' programs sent to them via e-mail.

Will our socio-economic "technology gap" lead to a more pronounced "adherence/compliance gap?" It's an important question. That's why it's crucial we remember there is no one-size-fits all solution. But that's mustn't mean we disregard the reality of the growth and pervasiveness of apps, *mobile* apps. Let's face it, when it comes to mobile phones, any gap is rather narrow.

Apps for adherence/compliance are "safe use" apps. Apps that can be "prescribed" by physicians to their patients are the wave of the present. Adherence/compliance "app-ens" and patients, physicians, payers, pharmaceutical companies – and society benefit.

As Walter O'Malley (the man who moved the Brooklyn Dodgers to Los Angeles) once opined, "The future is just one damned thing after another."

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[27] http://www.burrillreport.com/printer_article-facing_an_adherence_and_compliance_gap.html

[28] http://www.adherenthealth.com/whatsnew/index.php

9. Communicating Innovation

Ian Read (Chairman and CEO of Pfizer and the current Chairman of PhRMA) recently published a piece on LinkedIn under the title, *Why Society Needs a Vibrant Pharmaceutical Industry: Improving Patients' Lives.*[29]

Towards the end, Read writes:

I recognize that there are differing views when it comes to society's perception of the pharmaceutical industry. Many believe we are more focused on making profits rather than finding cures for patients, even though the industry has a long-standing commitment to providing patients access to needed medicines through many different programs globally. There is also a perception that we do not operate in an open and transparent manner when it comes to our clinical data and financial relationships with healthcare providers. This view lingers despite the significant steps that have been taken to increase transparency, even in the face of the current debate that rages over an individual's right to privacy.

As an industry we are working diligently to improve our standing in society. We understand that we have a great responsibility. We are at the center of society's desire and expectation for delivering potential cures and new lifesaving treatments. We will continue to fulfill that vital purpose.

Patients are waiting and we are working hard every day to earn their trust.

Fine sentiments and well-crafted words – but working hard alone isn't enough to earn trust. Pharma must work hard *to do the right thing*. What does that mean?

Mr. Read offers the following:

Over the course of the past 50 years, this industry has tackled some of the leading causes of disease and life-threatening illnesses.

For example, today the number of people who have died from heart attacks and strokes has declined. In 2008 around 16 percent of the U.S. adult population was taking a statin to reduce cholesterol. This translated into 60,000 fewer heart attacks, 22,000 fewer strokes and 40,000 fewer deaths.

An article published in 2010 by the Journal of Health Economics found that from 1988 to 2000, improvements in cancer survival created an estimated 23 million additional life-years over this period.

And according to the World Health Organization, immunizations save an estimated 2.5 million lives every year. For every $1 the U.S. spends on childhood vaccinations, we save $10.20 in disease treatment costs.

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[29] https://www.linkedin.com/pulse/article/20140612143605-322581966-why-society-needs-a-vibrant-pharmaceutical-industry-improving-patients-lives

Consider that pharmaceutical innovation has accounted for 73 percent of the total increase in life expectancy between 2000 and 2009 across 30 developing and high-income countries.

Those are, by any measure, extraordinary accomplishments. Why then is the biopharmaceutical industry so roundly pilloried in the press and so low in the general view of public opinion? *Working hard*, it seems, is not enough.

The genesis of Mr. Read's philosophy began (at least publically) this past April (2014), PhRMA held its 14th annual meeting in Washington DC.

During his inaugural remarks as incoming PhRMA board chair Read shared his concern about the industry's failure in getting the message out about "the value we generate." His key message, "We need to fix the misperception gap."

Specifically he talked about the industry's need to broaden the conversation from the economic performance of biopharmaceutical companies to the value that accrues to society and called for a "dialogue with society." Bravo.

He asked, "Where are the headlines?" They're not about societal value – and they need to be. There's a strong story to tell. It's not happening. And it needs to, because minus that narrative, nothing the industry wants to make happen (with government being a focus since the meeting was in Washington, DC) will be possible.

Read called for "industry speaking for itself." After all, if you can't be your own best advocate, you're suspect in the minds of many – and rightfully so. He spoke to "better ideas and clarity" versus "more tactics."

They were the right words – but what's happened since that fine oration? One thing that comes to mind is the debate over the price of Sovaldi. Another is ASCO's decision to get into the comparative effectiveness game. Both of these issues are tailor-made for a Read-led discussion on price vs. value. And neither has generated a regular and robust response from either industry or it's trade association.

That's not to say there hasn't been a debate. The Center for Medicine in the Public Interest (www.cmpi.org) has been writing and speaking with both force and frequency on these issues as have other public policy institutes (aka, "think tanks") and thought leaders across the healthcare policy spectrum.

But there has been precious little in terms of by-lined commentary from pharmaceutical executives – especially of the C-suite variety.

To achieve Ian Read's noble goal of "dialogue with society," there needs to be a… dialogue. And it can't only be via third party groups – as worthy and invested in the debate as they are. Pharma must speak for itself. Can you quote any useful answers from the folks at Gilead relative to Sovaldi pricing?

Pharma must embrace a new paradigm. Rather than focusing on traditional ROI (Return on Investment), they must now also consider Return on Integrity.

Integrity comes in many forms. Honesty. Virtue. Morality. But it also means (in more common parlance) "doing the right thing." It means not waiting to be told to do it or waiting to see what others do first. Integrity means being principled and, as my father used to say, "A principle doesn't count until it hurts."

The current risk-averse position of many in pharma does nothing if not reinforce the general perception that the industry only cares about profit. Mr. Read's words hit the nail on the head – *change is required and we must drive it!* But the gearbox has remained firmly in neutral.

For there to be Return on Integrity, integrity must first be demonstrated – publically demonstrated with names attached. This is especially true in the age of social media where the public is watching and commenting. And nature abhors a vacuum.

Read called for "industry speaking for itself." After all, if you can't be your own best advocate, you're suspect in the minds of many – and rightfully so. He spoke to "better ideas and clarity" versus "more tactics." That's a foundational shift and a timely one. Innovators win when the discussion is about the future.

10. Innovation: Keeping our eyes on the prize

The US healthcare system may be broken, as such sages as Michael Moore suggest, but it's not likely to be fixed as long as our domestic debate remains stuck on the cost of prescription drugs. Meanwhile, Alzheimer's Disease, obesity and diabetes are becoming national epidemics. Talk about sicko.

Imagine American healthcare spending as a dollar bill divided into 100 pennies. How many pennies do you think represent spending on prescription drugs? Sixty? Eighty? Wrong. The answer is 11.5 (with just under 9% being spent on innovative, on-patent medicines). The other 88.5 represent everything else—from doctor visits and hospitalization to administrative charges and insurance.[30] (If this is news to industry professionals, imagine how enlightening civilians might find it.)

Put another way, which is the bargain: a hospital stay at about $7,500 a day, or innovative medicines that help keep you healthy and productive? Clearly, fewer cents make more sense.

Yet these and many other facts backing pharmaceuticals as a sound healthcare investment have been twisted to suit the agendas of politicians, pundits, and other competing stakeholders. It goes relatively unreported that insurance companies continue to increase their monthly premiums without really explaining why. The industry claims its costs are increasing because prescription drug costs are busting their budgets. But prescription drugs account for only a small part of monthly insurance-premium hikes. From 1998 to 2003, insurance companies increased

[30] http://www.innovation.org/index.cfm/insidedrugdiscovery

premiums by an average of $104.62 per person. During that same period, drug costs rose by $22.48. [31]

Still, it's true that a majority of Americans with private health insurance are spending more for drugs—not only because they're taking more but also because their insurance is paying less. And it's no surprise that with rising pharmacy co-pays—the only healthcare costs that many of us actually see and feel—we tend to swallow the lie that increased healthcare costs are Big Pharma's fault.

Should we blame "Big Insurance"? Out-of-control out-of-pocket expenses cause many patients to stop using prescription drugs for controllable chronic conditions. The unfortunate result is that visits to the ER have jumped by 17 percent and hospital stays have risen 10 percent.[32] And a new Integrated Benefits Institute study shows that when employers shift too much of their healthcare costs to employees, the companies lose more than they save, through absenteeism and lost productivity.[33]

Should we blame our skewed priorities? American healthcare often works miracles when people become very ill, but it needs to do a better job with preventive care. Equally to blame is the fact that we spend a disproportionate amount of our healthcare budget for end-of-life care.

But rather than tangle up the already volatile healthcare debate in ethical arguments over whose life is worth more, it would be smarter to shift the focus to keeping people healthier longer. Earlier diagnosis and care are crucial to the future health of both Americans and American healthcare—and pharma has a starring role here.

Why? Because prevention is our first line of defense. Now is the time to promote prevention, so that we have the funds to invest in promising treatments for conditions like cancer and Parkinson's disease. We are on the cusp of a pharmacogenetic revolution that will finally make personalized medicine a reality.

We cannot afford, in terms of dollars or lives, to continue the blame game. In order to deliver on the promise of affordable and quality healthcare for all citizens, all the players in the healthcare debate must work together. At the end of the day, we should unite against our common enemy—disease.

And our most potent weapon in innovation.

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[31] http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Review-of-Insurance-Rates.html
[32] http://www.cdc.gov/nchs/data/nhsr/nhsr007.pdf
[33] http://www.ibiweb.org/community-events/detail/more-evidence-that-improving-health-can-improve-productivity

11. About the Author

Peter J. Pitts

President, Center for Medicine in the Public Interest

Former Associate Commissioner, US Food and Drug Administration

- Associate Editor, Therapeutic Innovation & Regulatory Science (official DIA journal)
- Executive Advisory Board, the Galien Foundation
- Editorial Advisory Board, Food and Drug Policy Forum
- Advisory Board, Journal of Commercial Biotechnology
- Editorial Advisory Board, The Patient Magazine
- Board of Advisors, Digital Health Council
- Washington Drug Letter, Editorial Advisory Board
- Briefings on Drug Safety, Editorial Advisory Board
- Scientific Advisory Council. Animal Health Institute

Peter Pitts is President of the Center for Medicine in the Public Interest. A former member of the United States Senior Executive Service, Peter was FDA's Associate Commissioner for External Relations, serving as senior communications and policy adviser to the Commissioner. He supervised FDA's Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, Office of Executive Secretariat, and Advisory Committee Oversight and Management. He served on the agency's obesity working group and counterfeit drug taskforce and as a Special Government Employee (SGE) consultant to the FDA's Risk Communications Advisory Committee.

His comments and commentaries on health care policy issues regularly appear in *The New York Times, The Los Angeles Times, The Washington Post, The Wall Street Journal*, *The Financial Times*, *Health Affairs*, *The Boston Globe*, *The Washington Times*, *The Chicago Tribune, The Chicago Sun Times*, *The San Francisco Examiner*, *Investor's Business Daily*, *The Baltimore Sun*, *The Economist, Nature Biotechnology, The Journal of Life Sciences the BBC World Service, Fox News,* and *The NewsHour with Jim Lehrer*, among others.

He has given healthcare policy presentations throughout Europe, Canada, and the United States, as well as in Russia, China, the Philippines, Malaysia, Saudi Arabia, Lebanon, Israel, Turkey, The United Arab Emirates, Jordan, Kenya, South Africa, Egypt, Algeria, Ukraine, Taiwan, Japan, Brazil, Mexico, Vietnam, and Columbia.