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Have an article to contribute or words of wisdom for the Philosopher’s Corner?
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EDITOR’S LETTER

I’ll be brief because this quarter’s edition is chock full of content which spans the spectrum of problems and opportunities in the healthcare arena, both in the U.S. and around the globe. Without planning a theme-based issue, it seems a pattern has developed nonetheless. Our contributors advance our knowledge and provide solutions in a recurring refrain around:

• patient engagement
• innovation through collaboration
• prevention and taking a proactive approach
• a plea for both a whole-person, whole-system, and more global view
• the promise and challenges of new technology

We also gain insights from outgoing WHCMAA president, Jay Mohr WG’91, in the Philosopher’s Corner and learn about the Board’s goals from incoming WHCMAA president, Jeff Voigt WG’85.

Lastly, we remember and honor Bill Kissick, the George Seckel Pepper Professor of Medicine of the University of Pennsylvania School of Medicine who taught many of us who were students in the program in the 1970s – 1990s, who died in June.

Much appreciation goes to our sponsors, Duane Morris, Locust Walk Partners, and Bristol Myers Squibb. And, as always, thanks to Jeff Voigt (the “executive sponsor” from the Board) and Gabriela Sanchez who provides administrative support, and finally to you, our readers, without whom the WHQ has no life.

So spread the word outside the Wharton community, keep on reading, continue to contribute articles, and be vigilant about letting us know what you think and want from the WHQ.

Z. Colette Edwards, WG’84, MD’85
Managing Editor

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The opinions expressed within are those of the authors and editors of the articles and do not necessarily reflect the views, opinions, positions or strategies of The Wharton School and/or the University of Pennsylvania. Publication in this e-magazine should not be considered an endorsement. The Wharton Healthcare Quarterly e-magazine and WHCMAA make no representations as to accuracy, completeness, currentness, suitability, or validity of any information in this e-magazine and will not be liable for any errors, omissions, or delays in this information or any losses, injuries, or damages arising from its display or use.
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Fellow Alumni, Friends and Colleagues:

I very much look forward to serving as President, in working with the alumni, faculty, and students of the Wharton School, the university as a whole, and the alumni board over the next two years. The board’s goals, all of which reflect learning from each other, “giving back,” and fostering and maintaining relationships, include:

• **A dedication to lifelong learning.** We have begun to build stronger relationships with the Wharton faculty with the goal to provide additional content to the alumni. This alignment of the faculty’s interests and our experiences has already been manifest by (1) contribution of articles to the *Wharton Healthcare Quarterly*, (2) webinars such as Amanda Starc and Scott Harrington, State Exchanges, (3) live roundtable discussions with the faculty on the issues we are grappling with in the working world, (4) faculty outreach to us (i.e., Dan Polsky and Skip Rosoff – State and Federal Policy Making, December 2012); and participation in alumni conferences (Mark Pauly – October 2011; Skip Rosoff – October 2012).

Further, we will continue to seek input and participation from you. We encourage you to work through the Board in developing content relevant to you. If you would like to host a webinar or regional event, let us know – we would be happy to help.

• **Giving back in a meaningful way to the school.** We have instituted a $15,000 Kissick/Alumni scholarship to a deserving first-year MBA to support learnings outside of the school. A significant increase over prior scholarship funding was accomplished by combining Kissick and alumni monies. The recipient of the 2013 award is Ross Stern. Ross will be presenting on his summer internship at the Center for Medicare and Medicaid Innovation at our October 26, 2013 Alumni Healthcare conference. Our goal is to increase our “giving back” over the next few years. We intend on providing additional specifics on this increased “give back” at the 2013 Wharton Healthcare conference.

• **Increased participation from affiliate members/University of Pennsylvania schools.** The alumni board has now built an infrastructure for outreach to other Penn schools and alumni (medicine, nursing, law, bioengineering, dental, veterinary, Wharton undergrad, etc.) involved in the healthcare field in order to be inclusive, to learn from each other, and to provide a platform to engage in a “family” of alumni activities. This also means our being involved in some of their alumni activities. This “more inclusive” initiative will be rolled out over the next couple of years, and we will continue to update you on its progress.

• **Sustainability.** Our goal is to ensure what we build upon over the next couple of years continues to exist and thrive into the future. It is our association, so let’s make it the best it can be.

• **Member engagement.** Most importantly, we will be seeking inputs and involvement from you in making our association as impactful as possible. The education, experiences, and knowledge we have gained are likely unparalleled, compared with any other US healthcare graduate program. The sum of our experiences and knowledge is much greater than the individual parts – so let’s continue to build on sharing our experiences and relationships. In my humble opinion, the Wharton Healthcare Program (including LDI, faculty, and alumni), is the most impactful (to the business of healthcare) of its kind around the globe. We ask you to communicate with us regularly so we can continue to enhance the membership experience. Lastly, here is an organizational chart with several areas where we need your help (i.e., volunteers). Feel free to contact us via the contact information appearing on the organizational chart.
THE PRESIDENT’S DESK  continued

The following alumni are to be congratulated on their election to the Board: Colette Edwards WG’84, MD’85; Peter Fishman WG’07; Molly Harper WG’04; John Harris WG’88; Phil Heifetz WG’96 (re-elected); Amanda Hopkins Tirrell WG’85 (re-elected); Fran Kelleher WG’84; and Michael Rovinsky WG’85 (re-elected).

We owe a debt of gratitude to the following Board members who are stepping down as of 7/1/13: Jay Mohr WG’91, Geoff Meyerson WG’07, Michael Palladinetti WG’06, and Rich Caligaris WG’92. All have given their time and effort to the association - volunteering on your behalf for the good of the association. Each has done their part in building our association to where it currently stands. Most especially, I would like to thank Jay Mohr, outgoing President. Jay built a strong foundation from which the association will continue to grow. Fortunately for us, Jay is not fading off into the sunset and will continue to participate in the association - as the Chair of the 2013 Alumni Conference (slated to be a great event) and in events in and around the Boston area.

We have a very strong executive team: Ryan Berger, Vice President; Maureen Spivack, Secretary and; Tom Kupp, Treasurer. Maureen and Tom have been gracious enough to “re-up” for their respective positions. It is going to be an absolute pleasure working with each of them.

Lastly, if you have questions related to the above, feel free to contact me at: meddevconsultant@aol.com; 201-251-8204(w). We look forward to serving you and in building upon what is already a very strong association.

Respectfully,

Jeff Voigt (WG’85)
President, WHCMAA
Here, There, Why Not Everywhere?

Normally there would be a continuation of the previous column in this space, but I had the opportunity to be part of a presentation at Penn Dental over the May Alumni Weekend. Together with Dr. Myron Allukian, Jr. D’64 (an eminent figure in dental public health), I spoke on the question “Has Dentistry Failed the American People?” A provocative question for sure, intended to be so, and one that rightly could be – should be – starkly asked of healthcare in America in general.

I began my examination of the question with one of two contradictory yet equally valid statements.

1. Dentistry has failed the American people because, as part of overall healthcare in America, it has mirrored the same principal overall failings, namely lack of cost control; persistent, and, for some socioeconomic groups, increasing disparities in access to care with consequent worsening oral health status; and quality of care that is of a presumed, but in actuality, an indeterminate, level.

2. Dentistry is failing the American people because it is not part of overall healthcare in America, it is not following the trajectory the rest of healthcare is taking. What do I mean by that? The Affordable Care Act, apart from its widely recognized feature of universal coverage, is really an attempt to “bend the cost curve” by encouraging such new delivery structures as ACOs – that integrate and coordinate the care they provide, emphasize comprehensive preventive primary care, and are held accountable financially and relative to health outcomes through the delivery of high quality, evidence- and value- based care rather than reimbursement based on the volume of services provided.

Change is in the works through such funding as Round Two of awards up to $1 billion recently announced by the Center for Medicare and Medicaid Innovation (itself a creation of the ACA) “for evaluation of projects from across the country that test new payment and service delivery models that will deliver better care and lower costs for Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) enrollees.” Or, as stated by Alice Rivlin of the Brookings Institute, who recently testified before the House Subcommittee on Health, the reforms taking place in Medicare through the ACA are “big enough to move the whole American healthcare delivery system away from fee-for-service reimbursement, which rewards volume of services, toward new delivery structures, which reward quality and value.”

So now that the train appears to have already left the station, the question arises “Is dentistry on board?” At first blush, it would appear so, as the ACA, the most significant piece of federal health legislation since Medicare, has a number of specific provisions for dental care (unlike the original Medicare legislation, which contained no dental coverage at all, due to lobbying efforts by the American Dental Association at the time, but did include podiatry - a situation of “foot” but no “mouth” in this disease). They include:

- extension of Medicaid and CHIP dental coverage
- inclusion of children’s coverage in Essential Health Benefits (EHBs)
- prohibition on cost sharing for certain pediatric oral health services, e.g., oral health assessments and fluoride supplements
- establishment of a Prevention and Public Health Fund
In Every Issue

WE INTERRUPT OUR REGULARLY SCHEDULED PROGRAMMING TO BRING YOU... continued

- reimbursement review through MACPAC (Medicaid and CHIP Payment and Access Commission)
- emphasis on prevention and treatment (caries management, 5-year oral health education program, school based sealants)
- expansion of oral health training programs and residencies

The above provisions are all important, but essentially are extensions of what currently exists, or should exist, e.g., having an up-to-date and informative surveillance system.

For innovation in the delivery of dental care, one has to look at two other provisions in the ACA:

- a 15-site demonstration project in alternative dental care delivery models, each site funded at $4 million
- establishment of the National Healthcare Workforce Commission, with dental workforce issues among its priorities, and whose overall purpose includes “(1) developing and commissioning evaluations of education and training activities to determine whether the demand for healthcare workers is being met, (2) identification of barriers to improved coordination at the Federal, state, and local levels and recommend ways to address such barriers, and (3) encouraging innovations to address population needs, constant changes in technology, and other environmental factors.”

Dental workforce issues and the organization of dental care have been, and will be, a continuing theme with me, as my previous columns have underscored that dental public health objectives (fundamentally centering upon cost, access, quality) cannot be achieved through the existing private, solo practice, fee-for-service, “business model” to which traditional dentistry adheres.

So with innovation in payment and service delivery models being given such high priority, where do those two innovative provisions now stand? In a word, nowhere. The demonstration project failed to get funding in the Senate Appropriations Committee after lobbying by the ADA. The Healthcare Workforce Commission, while also authorized in the ACA with members named in September 2010, has not met and has been advised by the Government Accountability Office “not to work or be seen to be working,” as the Commission has no funding as part of “a broader political struggle, and in the gridlock between Congress and the administration,” according to Dr. Richard D. Krugman, the Dean of the University of Colorado Medical School and a member of the Commission.

The healthcare train has left the station, and dentistry isn’t aboard. I am reminded of the adage, “Everyone is for health reform... provided he doesn’t have to change what he’s doing.” That applies to providers, as well as to patients. In the absence of meaningful, substantive reform, however, we will not see a bend in the cost curve, nor will we see better care. Instead, and more trenchantly, what I think we will see is what Colin Gordon said in Dead on Arrival: The Politics of Health Care in Twentieth-Century America: “The central problem [is] the persistence of a fragmentary system that defer[s] health policy to private interests and squander[s] a quarter of its resources on the administrative task of sorting the insured from the uninsured.”

But need that necessarily be the case? That failure once, or twice, or thrice, or however many times, means failure forever? The “business” of medicine is changing. Some thoughts on the “business” of dental care next time.

Stay tuned for further developments...

To contact Harris: hcontos@alumni.upenn.edu
THE PHILOSOPHER’S CORNER

Life Lessons:
If I knew then what I know now, I would have:

- pursued entrepreneurial ventures earlier in my career.
- given more of my time to philanthropic organizations.

Favorite Quotes:

1. Brevity is a virtue.
   - Unknown
2. Humility is not thinking less of yourself; it’s thinking of yourself less.
   - CS Lewis
3. Effective leadership is not about making speeches or being liked; leadership is defined by results not attributes.
   - Peter Drucker

Recommended Reading:

- The President’s Club, Michael Duffy and Nancy Gibbs
- Killing Lincoln, Bill O’Reilly
- Give and Take, Adam Grant
- American Nations: A History of the Eleven Rival Regional Cultures of North America, Colin Woodard
- The Hard Way, Lee Child

This month’s philosopher Jay Mohr. To learn more about Jay, click here.
ALUMNI NEWS

Josh Stein WG’12

Josh is enjoying continued traction with AdhereTech, the company he co-founded while an MBA student at Wharton. AdhereTech has created patented smart pill bottles that improve medication adherence. These bottles automatically measure the number of pills in the bottle in real-time and wirelessly transmit this HIPAA-compliant data to the cloud. If a patient hasn’t taken his/her medication, our service reminds them via phone call or text message.

AdhereTech is beginning trials this fall with The Walter Reed Army Medical Center, Weill Cornell Medical College, The University of Michigan, and other incredible partner institutions. AdhereTech is the winner of the 2013 Healthcare Innovation World Cup and PILOT Health Tech NYC. The company has been featured in The Wall Street Journal, Fast Company, Wired, and TEDMED.

The AdhereTech team is always interested in engaging with passionate people in the healthcare field - especially fellow Wharton grads. If you would like to learn more, please contact Josh at j.stein@adheretech.com.

Sam Holliday EAS’01,WG’09

Sam Holliday, Vice President, Population Health Services, was recently elected to the Executive Committee of the HIMSS EHR Association.

Click here for the press release.

To contact Sam: samholliday@greenwaymedical.com

Rohit Mahajan WG’08

Saviance Technologies has recently become a Gold Category Corporate Member with Healthcare Information Management Systems Society (HIMSS). This coveted membership brings with it an increased responsibility of leading change in Healthcare IT through active involvement and participation, collaboration, and knowledge-sharing in the healthcare sector. As a member of this recognized organization, Saviance will work to bring about forces that influence public policy impacting the national health IT agenda, educate colleagues on industry trends, market developments, and help physicians make meaningful use of IT. The Saviance professional talent is consulting on the latest technology stack such as Social, Mobile, Cloud and Analytics (SMAC stack) and on the global R&D focus on developing patient care and community portals, collaboration applications for driving innovation, big data consulting, developing ICD-10 transition strategy, and designing interoperability of systems.

To learn how Saviance can add value to your enterprise, please contact Rohit Mahajan at: rohit.mahajan.wf08@wharton.upenn.edu

Clifford Jones WG’07

Clifford Jones, recently presented at Health Datapalooza IV on the main stage.

Read more: http://online.wsj.com/article/PR-CO-20130610-907089.html

To contact Cliff: cliff@allazohealth.com
Yehong Zhang, WG’00, PhD’89, BA’85

Dr. Yehong Zhang became the CEO of a transformational joint venture between Merck and Simcere Pharmaceutical Group in China. This is a heavily profiled joint venture with the goal of facilitating healthcare reform.

To contact Dr. Zhang: yehongzhang1@gmail.com

Tom Davis WG ‘87

After a 15 year run ending with the acquisition of Coventry by Aetna, I am setting out on a new route. I have resigned my roles as President of Coventry Pharmacy Management, the Georgia health plan, and Head of Integrated Marketing/Digital Commerce. The next step is a family bicycle trip in France. After that I hope to find an organization that aligns member, provider and payer interests on a local or regional scale. With any luck that will be in Atlanta.

To contact Tom, email rowtomdavis@gmail.com

Cecile A. Feldman, DMD, MBA SAS ’80, Dent ’84, GWH ’85, GDent ’85

Cecile Feldman, Dean of Rutgers School of Dental Medicine, reports “The New Jersey Medical and Health Sciences Education Restructuring Act resulted in most of UMDNJ’s health science schools becoming part of Rutgers, The State University of New Jersey. This restructuring has been written about in all major newspapers. It is the largest, most complicated restructuring in the history of our nation.”

(You can look forward to learning more in a future edition of the WHQ, as Cecile has agreed to contribute an article in an upcoming issue.)

Cari Kraft WG’85

Cari Kraft, Wharton Undergrad ’85 and President & CEO of Jacobs Management Group, has teamed up with The Healthcare Sales & Marketing Network (the leading website for healthcare sales & marketing professionals) and a custom publisher to launch Healthcare Sales & Marketing Magazine (HS&M).

HS&M is the first digital publication (online, iPad, droid, kindle) to cover all aspects of selling & marketing in the pharmaceutical, biotechnology, and medical device space. The goal is to take complete advantage of the digital opportunity, embedding rich media such as videos, interviews behind articles, and presentations. We are also including a “news” function which will be updated every time the magazine is opened, so it will always be fresh and current. Our first task was to build an Editorial Board of top sales & marketing leaders, and we are honored to have the direction steered by leaders from companies such as J&J, BD, Biomarin, & WellDoc.

If you are interested in getting involved in the magazine, please e-mail me at ckraft@jacobsmgt.com. A few slots are available for industry leaders on the Editorial Board, and I am always looking for great content to direct towards our Editor.
ALUMNI NEWS

Z. Colette Edwards WG’84, MD’85

Z. Colette Edwards has been selected to participate in the 2013 NIH scholar program in translational health disparities.

In May she wrote about “superfoods” for the Her Health column of Her Mind magazine and has been asked to chair the Career Development Subcommittee of the Visiting Committee of the Harris School of Public Policy at the University of Chicago.

Elayne Howard WG’76

Elayne was elected to the Board of Directors of People’s Emergency Center, whose mission is to nurture families, strengthen neighborhoods, and drive change in West Philadelphia. In addition, Elayne will be speaking on “Volunteers: Paper Cuts & Licking Envelopes, Productive Ways to Use Volunteers for Fundraising” on July 25 for the Association of Fundraising Professionals, Greater Philadelphia Chapter.

For more information about Elayne, click here.

Kevin McNally WG ’76

Kevin McNally recently retired after 31 years with the New Jersey Department of Health. At the time of his retirement, Kevin was Executive Assistant to the Assistant Commissioner responsible for the Division of Public Health Infrastructure, Laboratories and Emergency Response. During his time with the Department, Kevin had the opportunity to participate in responding to the major public health challenges of our era, from the HIV/AIDS epidemic of the 1980’s through to the response to Hurricane Sandy last fall. While he is no longer with the State, Kevin is not yet ready to retire completely from the public health field, and will be exploring opportunities to use his skills and experience in service to the health of people and their communities.

First WHCMAA Innovations Webinar a Success!

On May 22nd, WHCMAA presented a new webinar-based initiative to showcase some of the most promising healthcare innovations from our alumni. 24 people signed up for the lunch time webinar, which featured three alumni-led startups: 1Doc Way (Samir Malik, Wharton UG ’08), Somnarus (Maria Merchant, WG ’08), and AdhereTech (Josh Stein, WG ‘12). Each speaker presented a brief overview and then took questions from the audience. The presenters also received valuable feedback and had an opportunity to connect offline with alumni who could serve as mentors or investors.

The next free Innovations webinar is scheduled for 12PM EST on Wednesday September 18th. Please save the date, and consider participating as a mentor or advisor to our innovators. If you haven’t already done so, you can sign up by sending an email to whcmaainnovations@gmail.com indicating your areas of interest.
WHCMAA: KISSICK/ALUMNI $15,000 SCHOLARSHIP WINNER CHOSEN

The Wharton Healthcare Management Alumni Association (WHCMAA) recently chose a first-year MBA student for its prestigious Kissick/Alumni $15,000 scholarship. The scholarship is meant for a deserving first-year healthcare MBA student whose outside-the-classroom educational experience relates to having a “business building/social and intellectual capital/health policy impact or contribution.” These types of educational experiences can include: entrepreneurial ventures; providing services/products to the less fortunate; contributing to intellectual capital (such as performing research for a nonprofit and publishing on these findings); and working for a state/federal agency as a health policy analyst (e.g., Medicare). In most of these instances, there is no payment for these services. The scholarship is named after William Kissick, PhD, who played an integral role in developing the Wharton HCM program and had been deeply involved at the national level as one of the pioneers of the Medicare program.

This year’s recipient is Ross Stern. Prior to Wharton, Ross worked as an associate on the health care team at Summit Partners, a growth equity firm headquartered in Boston, where he sourced and executed investments across a wide range of healthcare subsectors. Ross began his career in Cowen and Company’s health care investment banking group, focusing on mergers and acquisitions, as well as public and private financings for companies in the pharmaceutical, biotechnology, and medical device sectors. Ross serves on the Alumni Board of Directors for The Hopkins School and volunteers with Minds Matter, a not-for-profit organization whose mission is to prepare accomplished high school students from low-income families for college. Ross graduated from Bowdoin College with a B.A. in Economics.

Ross will be working this summer at the Center for Medicare(597,809),(831,907) & Medicaid Innovation. The department operates within the Centers for Medicare & Medicaid Services and has been tasked with developing, testing, and implementing innovative care delivery models to reduce domestic healthcare expenditures and enhance the quality of care for individuals receiving public healthcare benefits.

The majority of Ross’s time will be spent within the Innovation Center’s Seamless Care Models Group, working with both the Accountable Care Organizations and the Advanced Primary Care Initiatives teams. He will be broadly focused on analytical and data-driven projects, leveraging his quantitative healthcare finance background. The Accountable Care Organizations team designed, and is currently running, the widely known Pioneer ACO Program that is working with 32 of the country’s most sophisticated health systems to test the impact of different payment arrangements on care improvement and cost reduction. The Advanced Primary Care Initiatives team is tasked with evaluating how the patient-centered medical home model can improve quality of care, promote better health, and lower costs. The care delivery and payment models the Innovation Center is developing will likely serve as the foundation of future healthcare payment reform as the country transitions from a fee-for-service system to a value-based payment model.

Taking an active role in this transformation will be an incredible learning experience. This position will allow Ross to work closely
WHCMAA: KISSICK/ALUMNI $15,000 SCHOLARSHIP WINNER CHOSEN

with key constituents of the healthcare system and government, while gaining significant exposure to healthcare policy design, implementation, proof of concept testing, and how each of these elements relates to the federal government’s broader healthcare decision-making process.

We congratulate Ross on being the WHCMAA scholarship recipient and will be asking him to present on his experience at the upcoming Saturday, October 26, 2013 WHCMAA conference to be held in Huntsman Hall.

To contact Jeff: meddevconsultant@aol.com; 201-251-8204(w)
DRUGS FOR RARE DISEASES: RAVICTI FOR UREA CYCLE DISORDERS AS A CASE STUDY

INTRODUCTION
The development of drugs for rare or ‘orphan’ diseases has received increasing attention from drug manufacturers, third-party payers, and the public. Typically, the spotlight has been on macroeconomics, with a sometimes harsh or critical focus on price. Here we tell the ground-level story of just one drug, glycerol phenylbutyrate (Ravicti™ or HPN-100), recently approved for the treatment of urea cycle disorders (UCDs), which are estimated to affect ~2100 individuals in the US. We tell it as seen through the eyes of the key protagonists, including (1) the patients and families who live with UCDs and participated in the clinical trials (CL), (2) the Patient Advocacy Organization (PAO), in this case the National Urea Cycle Disorders Foundation (NUCDF) (CL), (3) the lead academic physician in the trials, who is also a Howard Hughes Investigator at Baylor College of Medicine and an investigator in the NIH-funded UCD Consortium (UCDC) (BL), (4) one of Hyperion’s venture backers (BS), and (5) those at Hyperion responsible for the drug’s development (KD, MM, BFS) and commercialization (CN).

THE DISEASE – UREA CYCLE DISORDERS (UCDs)
UCDs are genetic disorders caused by mutations in one of the six enzymes or two transport proteins critical to the function of the urea cycle, which is responsible for detoxifying ammonia and removing it from the bloodstream. UCDs are estimated to affect about 1 in 14,000 births.

There are 6 different UCD subtypes, each corresponding to defects in different genes, some of which may have many different mutations. Thus, unlike some inherited disorders such as sickle cell disease, which involve one or very few mutations in a single gene, UCDs affect all populations independent of race, ethnicity, and geography.

UCDs may be diagnosed anytime from shortly after birth to adulthood. Signs and symptoms may include failure to thrive, chronic episodes of vomiting and drowsiness, an avoidance of high protein foods, hyperactivity, and episodes of disorientation, combative, and stroke-like symptoms. While newborns with severe mutations usually become catastrophically ill within 48 hours of birth, more mildly affected patients can go undiagnosed or misdiagnosed until later in childhood or even adulthood. The diagnosis might only be recognized when triggers or stressors - viral or bacterial infection, surgery, high protein diet, excessive exercise or certain medications – cause an increase in the production of ammonia in the body, resulting in severe illness. If left untreated, UCDs may cause brain damage, coma, and death.

As with most metabolic disorders that result in toxic accumulation of a substance in the body, a urea cycle disorder leads to accumulation of ammonia upstream of the enzymatic block. Elevation of ammonia in the blood and brain (hyperammonemia) is the most important clinical feature of UCDs and can cause severe and irreversible neurological damage. Prevention of hyperammonemia and management of hyperammonemic crises are primary goals of treatment.

THE CHARACTERS AND SETTING
Patient and Family Perspective
The UCD community had an enormous stake in the success of HPN-100, as it was called during the clinical trials. While the 1996 approval under the Orphan Drug Act of sodium phenylbutyrate (Buphenyl®) was a huge milestone, adults and families of children...
DRUGS FOR RARE DISEASES: RAVICTI FOR UREA CYCLE DISORDERS AS A CASE STUDY

with UCDs have struggled ever since with its burdens, which often lead to non-compliance and sometimes life-threatening complications. Its obnoxious smell and taste, akin to butane lighter fluid, are such that UCD children commonly develop behavioral and eating disorders, and many require gastrostomy tubes so they can take the drug without having to swallow it. Adults with UCDs sometimes take up to 40 tablets per day and often become non-compliant due to its nauseating effects.

The social burden is enormous. Several-times daily administration may require trips to the school nurse or work breaks until the nausea or vomiting pass. Equally difficult are the risks from the high sodium content, to which some UCD patients are particularly sensitive. Some young adults have struggled to the point where they decided that a life tethered to sodium phenylbutyrate was not worth living. The potential for a nearly tasteless, less burdensome treatment would be life-changing and potentially life-saving.

PAO Perspective
Patient advocacy organizations (PAOs) such as NUCDF representing rare genetic disorders drive research focused on the unique needs of their communities. In order to attract and influence development of new treatments, NUCDF has forged close relationships with UCD researchers and clinicians that enable it to foster and help orchestrate and coordinate cooperative research networks. NUCDF must understand the nuanced convergence of agendas and develop a set of principles that unifies, organizes, and guides development.

NUCDF is focused on assuring the process is patient-centric. Successful collaborations require a culture of transparency and trust that enables the partners to make fully informed decisions and facilitates a collective approach to overcoming barriers, problem-solving, communicating results, and driving the development process. Despite the success of the UCD patient and medical community on many fronts, its prior experience with drug companies left it mistrustful.

Development: Company Perspective
Approval requires a determination by the FDA that a drug is effective, which typically requires two late-stage trials or ‘pivotal’ trials, and that the drug’s safety profile will translate into a favorable risk-benefit for patients. “Orphan” diseases (defined by the FDA as affecting ≤ 200,000 Americans) pose a problem, in that the number of patients available to participate in clinical trials required to demonstrate effectiveness and safety is limited. There are no specific guidelines pertaining to orphan drugs, and the challenge for the FDA is to ensure patients suffering from a rare disease have access to potentially useful treatments without compromising quality. This is particularly problematic for “ultra-orphan” diseases such as UCDs, which are estimated to affect just 2,100 Americans, about half of whom are diagnosed and one quarter of whom are treated.

Venture Capital Perspective
Investing venture capital in early, development stage drug companies is risky. Recent analysis has shown more than half of all VC-funded companies fail to return their invested capital at exit. High failure rates, capital requirements, binary regulatory risks, commercial risks and uncertain investor ‘exits’ have made VC investments in drug development increasingly unpopular.

Moreover, unlike other sectors where dramatic improvements in information technology have driven down the cost of starting a company, the costs of drug development may be increasing. Recent studies indicate it costs large pharma companies up to $4B for each new approved drug.
DRUGS FOR RARE DISEASES: RAVICTI FOR UREA CYCLE DISORDERS AS A CASE STUDY

Lack of the occasional, but seductive stratospheric return from development stage drug companies, along with widespread apprehension regarding the long, challenging, and unpredictable nature of clinical trials and FDA review, has led many VC firms to shun biopharmaceutical investing. Indeed, the proportion of overall investment in early-stage biopharma companies at their first round of VC financing declined dramatically between 2006 and 2012 (Figure 1).

![Figure 1: Percentage of US biopharmaceutical VC investment in first sequence companies as a percentage of all VC investment in biopharmaceuticals. Derived from PricewaterhouseCoopers MoneyTree, January 2013.](image)

Physician-Investigator Perspective
Ammonia control in UCD patients is challenging, as it varies considerably due to dietary intake, age-related changes in protein requirements, or illness, which can accelerate breakdown of body protein and ammonia production. Decreasing ammonia production by restricting dietary protein, often to the minimum required for growth and development, is the cornerstone of UCD treatment. However, dietary protein restriction is insufficient for the most severely affected UCD patients, and pioneering work by Drs. Saul Brusilow and Mark Batshaw led to the discovery of new approaches to disposal of precursor nitrogen. They discovered certain compounds were conjugated by the body to form nitrogen-containing products that were excreted in urine, thereby providing an alternative pathway for nitrogen excretion and a potentially lifesaving “buffer” for UCD patients with defective urea synthesis. The best example of this is sodium phenylbutyrate.

The approval of sodium phenylbutyrate was a ‘game changer.’ However, its disadvantages, including taste, salt content, and gastrointestinal intolerance, may affect patient compliance and, thereby, risk of hyperammonemia. This factor, compounded by the relatively short duration of action of phenylbutyrate, constituted an unmet need for UCD patients.

Glycerol phenylbutyrate offered the potential for slower absorption and more sustained ammonia control. Moreover, its physical properties as an odorless, sodium-free, and nearly tasteless liquid offered advantages in tolerability. However, performing robust clinical research in rare diseases is challenging.

It was in this setting that the development program was begun.
DRUGS FOR RARE DISEASES: RAVICTI FOR UREA CYCLE DISORDERS AS A CASE STUDY

THE PLOT

Physician-Investigator Perspective
The collaboration between NIH-funded academic investigators belonging to the UCDC, the NUCDF, and Hyperion evolved as a model. The intellectual and organizational infrastructure funded by the NIH Urea Cycle Rare Disease Clinical Research Center (RDCRN) was critical to the drug’s development. NIH resources did not directly fund development, but the collaboration between the NIH-funded UCD RDCRN network of academic investigators and the company evolved as an outstanding example of how NIH resources can be effectively leveraged to address an important unmet need for patients with a rare disease.

PAO Perspective
Hyperion’s leadership understood the critical difference between the ‘who’ vs. the ‘what.’ They did not repeat the internally-entrenched, ‘silied’ approach of prior companies, but rather understood the need to partner with the most important stakeholder in the drug’s success – the UCD community.

PAOs often serve as the “moral authority” to help ensure patients’ lives and well-being, not dollars, are the bottom line. NUCDF partnered with Hyperion at all stages, from protocol design through enrollment and interpretation of results. NUCDF:

- provided guidance with respect to the ‘enrollability’ of the protocols, i.e., a design such that patients and families could actually participate and comply
- recommended the most experienced and diligent clinicians to serve as Investigators to help ensure optimal patient care and collection of the highest quality trial data
- provided insight on non-medical barriers to enrollment. UCD patients are widely dispersed, and the burden of travel with chronically ill children can severely impact participation. NUCDF helped identify solutions to minimize the burden of trial participation.

Once the protocols were finalized and ready for enrollment, NUCDF used its reach and influence to help mobilize the community. The transparency of the communication with the company addressed NUCDF’s concerns that full attention was paid to the safety, concerns, and needs of participating UCD families.

The impact of NUCDF was particularly visible at a critical juncture in the development program, when the FDA signaled the need for data from UCD children under age 6. NUCDF worked with the investigators and the company to develop the protocol. It then mobilized families with young children ages 2 months - 5 years such that the trial was fully enrolled in just two months – an astonishing feat – with a waiting list! Throughout, NUCDF was included in advisory and investigator meetings, was provided real time access to non-blinded trial data, and consulted regarding the development of the new drug application (NDA).

Venture Capital Perspective
Despite the negative chorus of opinions, a recent study has shown that over the past decade biopharmaceutical companies generated better returns and fewer failures than companies in other sectors, including information technology, software, and the Internet (Figure 2).10

However, unlike Internet companies such as Google and Facebook, where 100x returns have created popular legends, few if any biopharma companies ever yield such stratospheric gains. Thus, in spite of the emerging consensus that biopharma investing is a “binary risk” business, actual data shows the sector is far less ‘lumpy’ and dependent for return of capital on “lottery ticket” outliers.
Successful VC-backed biopharma companies have exited at median values of ~$100M, with only the top decile exceeding $400M of exit value. Therefore, VC biopharma investment must be scaled to allow a 3-5x return of invested capital for the majority of companies below the top decile. This reality implies a total investment of $25-75M prior to exit. Thus, VC firms cannot generally finance companies requiring massive clinical trials (e.g., for cardiovascular drugs) and, instead, seek investment opportunities in areas where clinical trial sizes may be smaller, the development time quicker, effective barriers to entry higher, and FDA review potentially more supportive.

While orphan drug companies face the same technical risks as non-orphan companies, the benefit of not having to enroll thousands of patients and the upside of extended patent life have been strong attractants of venture capital, resulting in clinical and financial successes in previously neglected areas. Big pharma and public equity markets have often rewarded investors in these companies with acquisitions and IPOs that have helped raise the capital necessary for orphan drug development and commercialization and allowed significantly better investment returns versus other drug categories. It is the confluence of these factors and the large unmet medical need that has allowed companies developing orphan drugs to buck the trend of declining VC investment, and it was in this context that the decision to invest in Hyperion was made.

Company Perspective: Development
The FDA provided considerable input into the development of glycerol phenylbutyrate, and the pivotal trial that was conducted under a Special Protocol Agreement, i.e., a written agreement with the FDA that the results of the trial, if successful, would be accepted as evidence of efficacy. The New Drug Application (NDA) was substantial and included a complete set of non-clinical (i.e., animal) studies, as well as information from a total of 10 clinical trials (including 6 in UCD patients which collectively involved 23 clinical sites, > 50 Investigators and Sub-Investigators, and 13 referring metabolic specialists, and enrolled >100 UCD patients ages 2 months to > 70 years of age, representing ~15% of all the UCD patients in the US previously taking sodium phenylbutyrate).
DRUGS FOR RARE DISEASES: RAVICTI FOR UREA CYCLE DISORDERS AS A CASE STUDY

The NUCDF and UCDC were involved throughout the development program, providing critical input on trial design so as to maximize scientific value while minimizing barriers to recruitment and retention, making families and physicians aware of the trials, encouraging enrollment, and collaborating in the interpretation of trial results and their timely communication at scientific meetings and through publications. This collaboration was a critical success factor. Also important was the collaboration with NUCDF and Investigators, which allowed for ‘real time’ presentation of clinical trial data at scientific meetings and through publications.13,14,15,16,17,18

Company Perspective: Commercializing Ultra-Orphan Drugs
The investment and operational requirements of commercializing drugs such as glycerol phenylbutyrate differ dramatically from those for more common diseases. Orphan drug designation is not necessarily a short-cut to approval, and the investment is often substantial, > $100 million in this case. Given the limited size of the affected patient population, prices are necessarily high, and private insurers as well as public payers are often unfamiliar with the disease. Companies must therefore invest in a variety of programs to achieve profitability while ensuring affordable patient access.

The commercial introduction of Ravicti in March of 2013 includes the establishment of a dedicated distribution channel (specialty pharmacy) and a ‘high-touch’ call center to interface with payers and assist patients and physicians in securing reimbursement. Free drug will be made available for the uninsured, and financial support has been given to an independent non-profit organization which specializes in providing financial assistance to patients with high out-of-pocket expenses, such as those with insurance that includes a ‘specialty tier’ requiring co-insurance versus a fixed co-pay. Given the long distance some patients must travel to the ‘center of excellence’ at which they are treated, this same non-profit organization has established a program to provide funding and concierge travel support such as were provided to patients and families who participated in the clinical trials. Adherence and compliance support programs delivered via the web, telephonically, or live, via nurse case managers, will also be implemented.

Successful commercialization of a product for patients with a rare disease requires exquisite attention to affordable access and patient support, with particular attention to the unique needs of the affected patient community. Hyperion is therefore building on the relationship established during development with physicians, their staff, the UCDC, and NUCDF to solicit feedback regarding the appropriate and necessary support services critical to the successful transition of Ravicti from an investigational to a commercial drug.

THE RESOLUTION
FDA Approval and Takeaways
Glycerol phenylbutyrate (Ravicti™) was approved on February 1, 2013 as chronic treatment for patients with most UCD subtypes down to 2 years of age. Its approval to age 2 would not have been possible without the rapid enrollment of children ages 2 months through 5 years, such that these data were available for FDA review as part of the 120-day NDA safety update. As a condition of approval, Hyperion agreed to several post-marketing requirements that will require substantial additional investment, including trials in UCD children < age 2 years and a registry of approximately 10 years duration. Ravicti is a success story and, while allowing for the importance of good fortune, its success was not just a matter of luck. Rather, its successful development and approval was the result of several critical success factors including the following:

- a drug addressing a sufficiently important need that it was a ‘call to action’
- data-driven VC investors with the courage to buck conventional wisdom and invest in a development-stage biopharmaceutical company
public-private collaboration among the key stakeholders, including the patient (NUCDF), investigator (e.g., UCDC) community and company (Hyperion) throughout the drug's development, including the design and execution of the clinical trials and interpretation and communication of the results.

The final takeaway may be that approval does not represent the end, but rather the end of the beginning. The collaboration that enabled Ravicti’s approval is the same one required for its fully informed use and the long-term benefit of the UCD community.

References


DRUGS FOR RARE DISEASES: RAVICTI FOR UREA CYCLE DISORDERS AS A CASE STUDY  
continued


I’M NOT SICK - DOES THAT MEAN I’M HEALTHY?

“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”
The World Health Organization’s Constitution

A colonoscopy or mammogram will only make you healthier if it finds an abnormality. A stress test will only make you healthier if you have underlying heart disease. Banners, slogans, and pamphlets will only make you healthier if you take personal action.

In recent years, all eyes and many dollars have shifted toward education and preventive measures to improve egregious health conditions around the world. Yet, right here in the United States, we continue as self-inflicted, disease-stricken people in alarming numbers. Our health — and health care system — is headed into a black hole. Our quality-of-life outcomes are woefully subpar given our resources and technologies. For the first time in history, lifestyle diseases like diabetes, heart disease, and some cancers kill more people than communicable ones. And despite the cries for more “preventive medicine,” expensive screenings and early detection do not provide an actual solution.

A small percentage of the population will thrive with wellness visits, screening modalities, and multimillion dollar health campaigns. But while preventive medicine — as it is currently being implemented — may find disease earlier, it will not make us healthier. Only proactivity and personal accountability will do that.

Experts say two-thirds of all cancers, three-quarters of heart disease, and the vast majority of type 2 diabetes can be prevented by behavioral and lifestyle changes — things like a healthy diet, regular exercise, stress reduction, and adequate sleep. These positive lifestyle choices will make you healthier 100 percent of the time, with most changes costing little to nothing and requiring only a change in habits. We live in a society where the vast majority of our illnesses are preventable, yet we do not actively prescribe proper nutrition or effective exercise programs during routine patient visits unless the patient presents with a health condition such as diabetes or hypertension. With so much data available on the potential health improvements with lifestyle modification, why is there a disconnect between theory and practice?

It is time we progress from reactive health care — including “preventive,” which just means an earlier diagnosis — to genuinely proactive health care.

• Rx: food as the best medicine
• Rx: exercise to prevent modern chronic diseases
• Rx: stress management, which plays a central role in essentially all chronic diseases
• Rx: personal accountability for our own health

There are professionals readily available whose primary goal is to elicit and sustain improved health with nutrition, exercise, sleep optimization, stress reduction, and personal development. These are your local personal trainers, nutritionists, functional medicine doctors, and other integrative practitioners. For simplicity’s sake, we will refer to these practitioners as “health mentors.” Their primary goal is to create urgency and compliance in their clients’ health before they succumb to illness. It will be through the knowledge, dedication, and treatment plans of these practitioners in tandem with conventional medicine that patients learn to invest in themselves. Only then can large-scale improvements in societal health be made.

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Conventional medicine alone has not been effective against the rising tide of chronic disease; however, Tracy, a health mentor and an author of this article, has had the unique opportunity to see the outcome when physicians and health mentors forge an alliance. Here are seven reasons why it works.

- **Referral mindset.** A referral to any specialist denotes the condition is beyond the primary physician’s scope of expertise, hence creating a sense of seriousness and urgency. A condition is present that requires referral, hence improvement becomes a priority.

- **Improved physician/patient relationship.** When a third party supports compliance, the doctor/patient relationship relaxes. The patient does not see the doctor as a judge, but as a partner concerned about his/her well-being.

- **Engaging mentoring relationships.** The relationship between the patient and health mentor is a gratifying emotional journey. Improved health becomes a source of power and comfort. Embarrassment dissipates. The patient has a partner in health who continually motivates him, tracks progress, and changes the program as necessary.

- **Increased Wellness Visits.** Obese or feeble patients tend only to visit a physician when they have a critical health matter. As health becomes a priority, patients value wellness visits and preventive maintenance; hence less money is spent treating late diagnoses.

- **Increased Physician Productivity.** The physician who partners with a trusted health mentor trained in patient education and focused on lifestyle-related behavior change expands options for the patient while freeing clinic time for preventive modalities and diagnostic measures.

- **Amazing Results.** A 38-year-old man on chronic anti-hypertensives since the age of 15 is able to stop all medications after working with a health mentor on personal lifestyle changes for one year. A 42-year-old woman suffering from the ravages of probable rheumatoid arthritis notices improvement in range of motion, chronic fatigue and pain; thus the rheumatologist shifts her diagnosis to fibromyalgia as a result of her dramatic progress. A 14-year-old Crohn’s patient embraces dietary modification and an active lifestyle and spaces his doctor visits from weekly to monthly due to his decrease in flare-ups.

- **Trickle Effect.** When one person is motivated to adopt proactive health, the results trickle to others. A 34-year-old mother loses 85 lbs. and applies the principles at home. A husband and son lose weight and experience robust vigor from her nurturing. A wife working with a trainer loses 45 lbs. Menu changes and increased activity with her diabetic husband result in his requiring less insulin. He documents stable blood-sugar levels and realizes the simple effect of managing diabetes with daily habits.

Professionals from all perspectives must work together. We have the same goal: sustainable, excellent health for every patient, not just the absence of disease or infirmity. Only by working together can we build a cooperative network that will drive true, meaningful change in the system.
Imagine the results of working together.

We need visionaries and missionaries from all disciplines to fuse and forge a new health system where proactive health is as important as diagnosis and treatment. Together we can equip and empower our population to utilize both proactive and preventive measures to manage the diseases and conditions we now face.

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MHEALTH TECHNOLOGY: DESIGN AND DEVELOPMENT OF MOBILE INTEGRATED THERAPIES

As healthcare reform increasingly shifts the burden of patient management to the primary care setting, healthcare practitioners (HCPs) face a rapidly growing chronic disease population while their numbers struggle to keep up with demand. According to the American Academy of Family Physicians, there are about 353,000 primary care physicians in the United States, and the country will need an estimated additional 45,000 by 2020. The number of medical students entering family medicine fell more than 25 percent between 2002 and 2007. The need to create a new-to-the-world healthcare solution that supports the patient in all aspects of care is dire.

The primary care practitioner is well poised to be the central point-of-care, aiding a more holistic approach to the patient. However, the patient demand curve will quickly outstrip the supply of practitioners in even the best treatment models. An enhanced approach is necessary, one that enables patient self-management combined with efficiency tools for HCPs.

Products that offer this approach bring self-management, knowledge creation, and motivational tools to the patient, wherever they are and whenever they’re needed. For providers, they deliver new information and insights into the patient’s condition through the analysis of both patient reported information and data from traditional care. The HCP burden is then reduced as patients are appropriately supported between office visits, and the HCP can leverage clinical decision support derived from the patient’s medication, symptom, lifestyle, and biometric data to have more productive office visits. This merger of the traditional with support beyond the four walls of healthcare can be incredibly powerful.

Today, few products deliver on this promise, but going forward this new class of therapies will become increasingly integral to care. These mobile integrated therapies (MIT) will also require traditional controls and validations, such as FDA clearance, prescription authorization from a physician, and robust clinical evidence, so doctors can trust the products they prescribe.

Claims- and Risk- Based Framework
While the pros and cons of regulating mobile health “apps” are an ongoing debate, it is clear the FDA and the healthcare industry are moving to a regulated model that appropriately mimics the framework in use today for traditional medical devices. Specifically, the regulatory status of an “app,” or of solutions like MITs, is dependent upon:

- the manufacturer’s intended use of the device
- the clinical claims a manufacturer makes about the system’s features and benefits
- the level of risk to a patient’s health the system might introduce

These claims and a risk-based framework are critical to the design and development of the solution. For MIT, the clinical, behavioral, and technology claims are essential to organizing and executing the product development lifecycle. Layered on this framework is the reimbursement structure or business model from which the MIT will be launched. This structure may drive the development lifecycle requirements (e.g., a randomized controlled trial to prove clinical outcomes).

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In addition to clinical considerations, there are the technology claims associated with the platforms and devices on which MITs are supported (e.g., mobile operating systems, data-enabled device platforms, etc.). These technology claims can have a significant impact on the development lifecycle as the number of operating systems (OSes) and devices that must be supported increase.

User-Centric Technology Framework
Critical to developing an MIT that is successful in the market is a thorough understanding of the intended stakeholders (e.g., patients, clinicians, enterprise workers, and their use of technology). For example, it is important to understand the target patient demographic within the context of technology use characteristics of that target market. While smartphone penetration is increasing at a rapid pace in the U.S., the ongoing use of feature phones among many patient market segments may require a manufacturer to offer not only smartphone versions of their solution running on iOS and Android, but also versions running on J2ME for feature phones [Java 2 Micro Edition, a version of the Java programming language that was adopted by feature phone (non-smart phones/flip phones) manufacturers as the de facto operating system standard for these devices)].

The same is true in the provider market, where technology adoption varies significantly — from practices that have adopted full-fledged electronic health record (EHR) systems to practices that are best served with fax-based solutions.

Development Complexities
Market-based technology claims have a significant impact on MIT development complexity. Consider, for example, a patient demographic of older, chronic disease sufferers being served by primary care physicians. In many markets, both patients and HCPs will be best served by a mix of mobile handset support (J2ME, Android, iOS), coupled with a web-based solution and a mix of fax-, web-, and EHR-based implementations for the providers.

Given the large quantity of feature phones still in use (J2ME-based OSes) and the wide variety of Android devices, a single MIT must be designed and tailored for each platform, considering important factors such as:

- processor capabilities
- memory requirements
- screen resolutions
- screen orientations
- keyboard configurations

While the mobile web and capabilities of technologies such as HTML5 are evolving, many manufacturers continue to develop native OS platform solutions due to the increased capabilities and control native application development allows. A key concern and a focus of increased scrutiny is how these solutions maintain not only quality and safety, but also the security and privacy of all data contained in the system. Today, native apps often provide the greatest control over quality, safety, security, and data privacy and better enable manufacturers to provide the necessary evidence of compliance with all applicable regulations. Further, native design is a better fit for patient education and support, as native design has been shown to maximize patient engagement, whereas a one-size-fits-all design is more appropriate for transactional situations.

Validate Early and Often
Finally, as with all good product design and development, it is critical to validate designs early and often with target stakeholders. Developers are often surprised by the “mistakes” their customers make when using their products. A key preventive measure is engaging stakeholders as early as possible, even at
the paper and pencil sketch stage. These design iterations with customers throughout the product development lifecycle help safeguard against a manufacturer experiencing costly “gotchas” late in development that are both expensive and time consuming.

For MIT, this early and frequent validation is a multi-stakeholder and multi-technology activity. For example, an MIT product that is delivered to the patient on three mobile platforms and the web, plus a fax interface for healthcare professionals, requires functional validation across mobile, web, and fax modalities. Further, the design validation should take into consideration not just product functionality but also the environment and “workflow” of each stakeholder.

This early and frequent design validation is even more critical to ensure that all of the clinical, behavioral, and technology claims can be met, significantly increasing the likelihood that an MIT will deliver not only a delightful user experience, but will help improve the health outcomes of patients and the effectiveness of their healthcare team.

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References


From Patient to Partner — Engaging Patients in the Paradigm Shift to Population Health Management

This is the first in a series of three articles about engaging patients in population health management, exploring the ways in which providers can foster collaboration with patients in care management and the questions this work raises for the identity of providers in the future.

From Sickness to Health — Getting Everyone to Pitch In
The US must transform its costly, fragmented healthcare system to a new delivery paradigm — one that is integrated, takes accountability not just for illness but also for wellness, and one that provides better value for patients, providers, and payers. A recent study of chronic care patients in the US showed that, while regions ranked in the highest fifth of spending provided as much as 60% more care than regions in the lowest fifth of spending, the increased outlay resulted in negligible improvement of outcomes or patient satisfaction.¹

Care providers of all types are already working to redesign care models, improve quality, and slow the rise in costs in their centers of care. However, the kind of transformation we are talking about will require changes beyond what is happening in the provider realm alone — it requires changes in how patients and their caregivers participate in their care (when sick) and in their overall well-being (when healthy).

As healthcare moves toward population health management, it is becoming increasingly apparent that patients will be key partners in achieving the Triple Aim — improving the health of populations and the patient experience while reducing costs. Health systems joining this movement now can reap the benefits with payers’ pilot programs, and will win business and better manage their margins as the payment model evolves.

Defining the Goal — From Patient to Partner
As one of our clients has said, “This population health management stuff is great, but how can we get enough of our patients to do the right thing — especially when so many of those choices are deeply entrenched in their culture?” Building out robust, coordinated systems of care will require substantial work. However, population health management can only go so far without enabling patients to more actively engage in their own health.

Patient Behavior and Lifestyle Choices Drive Cost
We are slowly taking to heart that social factors are significant determinants of health and illness. In fact, McGinnis et. al. find traditional healthcare delivery determines as little as 10% of a person’s overall health.²
Numerous studies suggest more than half of health issues in the US can be attributed to lifestyle issues, from high stress and smoking to sedentary activity and improper nutrition, just to name a few. We face a significant shift in bridging the gap between how healthcare works today — accounting for only 10% of the “overall health” pie — and a system that can reliably deliver comprehensive health. We know changing individual behavior isn’t easy, so we set out to answer the question, “What might make it easier for people to take greater ownership of their health so they can successfully transform from passive patients to active partners?”

**Change = Behavior + Supports**

When we work with organizations, we help them spur widespread change by focusing on the level of practice — the different actions people will need to take to realize different outcomes. We believe practice change is based on two components, behavior and supports. Change depends on people understanding the new behaviors that need to be in place. Those behaviors require supports that make it easier for people to change their actions than to choose not to do so.

The “practice” of healthcare can be understood as a set of “behaviors” that becomes embedded in daily life, plus the “supports” that provide the appropriate resources to achieve the desired outcomes. Without those supports, new behaviors often fall flat. For instance, a home infusion agency we worked with needed to help patients administer medication on their own after several sessions with a nurse. Patients were having difficulty, and talking them through steps on the phone was coming up short. Some patients wound up going to the hospital for help, which often counted as an unnecessary
From Patient to Partner — Engaging Patients in the Paradigm Shift to Population Health Management

readmission. After reviewing the problem, infusion nurses developed a diagram with large, color photographs that walked patients through the procedure. The diagram supported the new behavior change, helping patients take the reins of their own care.

Similarly, an academic medical center set a goal to schedule follow-up appointments for as many discharged patients as possible. After some time, they saw no-show rates for those appointments approached 70%. When a team dug into the underlying cause, they saw the health system was scheduling patients into slots without their input. Some patients couldn’t make the appointments because they had to work, or their caregiver did, they couldn’t find transportation to the doctor’s office, or they didn’t know where it was. The health system had met their scheduling metric but hadn’t achieved better patient outcomes. Several units piloted a program where patients could advise when and where they could successfully get to a provider. Having the patient participate in setting up the appointment also reinforced the importance of the follow-up itself and, slowly, the appointment attendance rate rose.

The road to successful population management will require a paradigm shift not only for patients, who will need to be more active partners in their own care, but also for providers, as their roles change. The next two articles in this series will explore specific strategies for patient behavior change and discuss implications of the changes for providers and the nation’s health system as a whole.

For more information on this topic or related materials, contact CFAR at info@cfar.com or 215.320.3200 or visit our website at http://www.cfar.com.

References


An Eye-Catching Vision: Patients and the Cost of Advanced Technology

Overview
We have all heard about the looming crisis with the federal deficit and Medicare expenditures.

Is the technology transformation in cataract surgery a harbinger of complex challenges which will only become more common in the delivery of services to Medicare beneficiaries?

The Medicare fee schedule is based on the Relative Value Unit (RVU) system developed in the 1980s. Physicians are paid based on a system which values each component of a procedure. For example, the cataract surgery fee is based on the time to perform cataract surgery, the typical indirect costs (rent, malpractice, etc.), and the number of typical post-operative visits within 90 days.

The Medicare schedule varies by region based on indirect cost. A physician in New York is paid more than a physician in Nebraska because of overhead, but two physicians in the same area within New York receive the same reimbursement. However, the fee schedule does not differentiate by a physician’s skills or the technology utilized. The fee for cataract surgery is fixed regardless of how the cataract is actually removed (as there are multiple ways to do so). As demand for services increases (the population is aging), the fee per procedure FALLS. This pattern is counter to basic economics, which centers on the supply and demand curve for pricing. However, because the Medicare budget is relatively fixed for ophthalmology services (accounting for 3% of the Medicare budget), for each new unit of production, the reimbursement per unit declines the following year in order to stay budget neutral. With each passing year, reimbursement has declined for this service code, and such a trend can be expected to continue in the coming years.

For many years, the Medicare fee schedule failed to value new technology. In the early 2000s, patients who were younger than Medicare age were able to purchase “upgraded” or deluxe lenses, which increased their visual freedom and decreased their blurred vision. Whereas the Medicare fee schedule paid around $125 for any type of lens implanted, the new advanced technology lenses (also known as premium lenses) cost between $400 and $1000 more than Medicare would allow. So Medicare-age patients were deprived from receiving these new lenses. The lens manufacturers approached CMS with this conundrum and secured a “waiver” to allow Medicare patients to pay extra money out of pocket if they “elect” to have these lenses implanted at the time of cataract surgery. As a result, any manufacturer who develops and gets FDA approval for a premium lens may charge the patient extra for this elective technology.

Recently, ophthalmic device manufacturers created lasers for cataract surgery that can create corneal incisions, treat pre-existing corneal astigmatism, and “disassemble” the cataract before it is removed. Again, the capital cost and per use fee are significant and not covered by current Medicare reimbursement rules. Under current CMS guidelines, patients may elect to have this new laser technology at the time of cataract surgery only if it is used to treat pre-existing corneal astigmatism.

If you are a patient without pre-existing corneal astigmatism? You are out of luck! You could not even be offered this advanced technology because Medicare rules bar the surgeon from charging the patient extra. So the manufacturers again secured a waiver from CMS because not all patients have pre-existing astigmatism, and these patients were unfairly excluded from having access to this advanced technology. So what are the costs to the patient? The average “upcharge” to patients for getting a premium lens.

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An Eye-Catching Vision: Patients and the Cost of Advanced Technology  

continued

can range from $1000-2000, depending on the lens. The cost to have the laser perform parts of the cataract surgery range from $1100-1500, again depending on the technology used. Remember, this is in addition to what Medicare reimburses for cataract surgery.

So what does this mean for Medicare patients? As reimbursement rates for cataract surgery continue to decline, one can expect fewer and fewer cataract surgeons to offer traditional Medicare-reimbursed-only cataract surgery as they migrate to premium cataract surgery. Such a trend may be just fine for Medicare, as it will continue to save money by ratcheting down rates, with patients paying the difference if they desire the premium service.

Medicare will accrue additional cost savings with this new technology relative to patients who are not yet even covered by Medicare but who elect to have premium lens surgery before a cataract has even formed in the eye. Patients are pursuing this refractive lens exchange procedure in their mid-50's in their quest for “the fountain of youth” and spectacle independence. As more patients seek this service before coverage kicks in, Medicare will save money by not having to pay for future cataract surgery.

Access Issues – Patients and Physicians

Cataract surgery is the first procedure for which Medicare has allowed service providers to bill and collect more than the Medicare allowable (under certain conditions). Such a system will have the deleterious effects of creating access issues for the technology and a two-tiered model of cataract surgery services:

• Not all patients will be able to afford to pay for this “upgrade.” Patients who are covered by insurance but cannot otherwise pay for the “premium” services will not have access to either the premium lenses or to the laser to assist in the cataract surgery.

• Some patients may even experience longer waits or lose access altogether as cataract surgeons compete for the patients willing to pay for the extra services.

• Not all surgeons will be able to afford to purchase the laser, a concern raised by the American Academy of Ophthalmology. This technology will then be used only by the busier cataract surgeons with a sufficient volume of patients to pay for the costs associated with buying and maintaining the laser.

The “silver lining” in this stormy cloud? This may be the only mechanism available to allow patients access to technology that might otherwise be restricted by Medicare rules as reimbursement levels continue to fall. With healthcare delivery systems being reinvented under the Affordable Care Act, what lessons can be learned and which actions can be taken now to prevent the proliferation of this problem in the future?

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HINDSIGHT IS 20/20: NEED STRONGER SPECS AND YOU’RE ONLY 50? COULD BE CATARACTS.

Vlad was 38. Ann’s brother was in his early forties. Tessa was 43. I was 45.

In the fall of 2012, I was diagnosed with cataracts in both eyes; two months later, I had very simple surgery to remove them. The diagnosis came about eight months, three different types of contacts, four doctors, and approximately seven consultations after I first told my eye doctor the glasses with progressive lenses I’d been trying to wear for the past several months weren’t working.

“I just can’t see,” I said. “It’s like I’m looking through a fog.”

More than seven opportunities to diagnose me, all missed. At first glance, I fell far outside the profile of a typical cataract patient. But only at first glance, and first glances are often fuzzy.

What if one of the doctors had thought about my symptoms as if they didn’t belong to me, and looked at them as if they were happening to someone younger or older? Or what if I had done my research, pushed for answers, and asked questions? Would the diagnosis have happened sooner?

During a routine visit to my optometrist in March 2012, I told him that for a while I hadn’t felt I was seeing clearly, neither close up (I was already wearing reading glasses.) nor at a distance, regardless of the time of day. Plus, I was experiencing terrible glare, day and night, with halos around every light.

Overall, my vision was cloudy, blurry, foggy, filmy. Pick the adjective. He attributed it to a combination of getting older -- experts call it “age-related deterioration” -- and the effects of my RK (radial keratotomy) surgery 20 years earlier. Before Lasik, surgeons learned that making spoke-like incisions in a cornea to flatten it produces clearer distance vision. In 1993, I went under the diamond-tipped knife, and for the next two decades I had great distance vision, outside of some halos around lights, a result of the scarring. My reading vision had begun to decrease about three years earlier, and I’d been making do with over-the-counter reading glasses.

At this visit we talked about the usual options – progressives, bifocals, contacts, and reading glasses – but I perked up when he mentioned the possibility of doing Lasik on top of the RK. He wasn’t sure it was a viable option, but something worth exploring, so he gave me a referral to a Lasik surgeon.

This visit was the first of many missed opportunities for a diagnosis or further testing. I didn’t ask, and he didn’t offer. This scenario would be repeated by him and a variety of other doctors over the next half year.

The surgeon’s office is bright and cheery, and the doctor’s mood is just as optimistic. After reviewing the multiple measurements and pictures taken by his technician, he recommends performing PRK (photorefractive keratectomy, a version of Lasik) on my left eye and leaving the right one alone, for now.

I leave happy and call my mom.

“He was a great doctor, he knows Gerri [the doctor who did my RK], he was really positive,” I ramble. And as I drive home, I relate the details of the appointment. “I think it’s a good idea,” I tell her, “but...” “But what?” she asks. “I only have one set of eyeballs, and the idea of doing Lasik over RK is a little unsettling.” “Call Julian,” she says. My cousin is a professor and chair of the department of
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ophthalmology for a university in Georgia; we’ve called him over the years when someone in the family needs a second opinion. “Send the records to me,” he says. “I’ll have one of my associates review them.”

Several weeks later his associate and I are on the phone. He agrees PRK is a reasonable option, but as we’re about to end our conversation, I ask “If I were your daughter, would you recommend the surgery?” “I’d recommend she explore her options,” he says. So I did.

The first time I put on the stylish blue metal frames with the progressive lenses, I want to throw up. “It takes some people longer than others to get used to them,” the optician says. It does get easier, but my vision is always just a bit “off,” like I’m looking through salt water, and the halos and glare are worse. The optician tells me the prescription is right, so I head back to my doctor. He checks the glasses and agrees: “The lenses are slightly small for progressives,” he says, “but the prescription is correct.”

I continue to struggle and visit his office several more times in the next few months.

“Maybe you’re one of those people who just can’t wear progressives,” he says on one visit. So we move on to the next option, contacts. Over the next six months, I attempt to wear one contact lens and reading glasses. Three different types of lenses give the same results: too dry, too uncomfortable, not clear enough. Each time I end up back in his office, and we smile weakly at each other when he walks through the door. Eventually he follows “Maybe you can’t wear progressives,” with “Maybe you can’t wear contacts.”

By now, we’re both incredibly frustrated. Each time I leave his office teary, confused that he doesn’t seem to know what’s wrong, and mad at myself for not asking any real questions nor doing any research.

However, on the next visit, things are different; he sends me to a specialist in his office. This doctor has retired from the operating room, and now one of his primary roles is to consult on confusing, difficult cases, like mine. He dilates my pupils, and once they’re “ripe” it only takes him about 15 minutes to see the reason for my troubles. He peers at my eyes from all different angles and uses a variety of machines, then steps back to deliver the news.

“I think you have cataracts,” he says, the tone of his voice betraying his surprise. He leaves and returns minutes later with my doctor, who looks at my eyes in the low-lit room. Almost too close for comfort, his breath hot and minty, he agrees with the diagnosis.

A real diagnosis.

I want to scream with happiness, but instead I listen. I have posterior subcapsular cataracts. Of the three types of cataracts, these often start as small, opaque areas that form near the back of the lens, right in the path of light on its way to the retina. This type often interferes with reading vision, reduces vision in bright light, and causes glare or halos around lights at night. Exactly the symptoms I’ve been describing over and over.

The tests performed on older patients with these symptoms weren’t performed on me until after the diagnosis. I wasn’t asked the questions asked of older patients and the assumptions made of older patients were not made on me. Why? I can’t blame anyone for the delay, but I have to wonder.

I learned some interesting facts after my diagnosis, including the range of factors that can speed up cataract formation, such as long-term use of corticosteroids, eye injury, family history of cataracts,
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diabetes, smoking, and surgery for another eye problem. I’m not a diabetic and I’ve never smoked, but my mother had cataract surgery at 67, and, at 25, I had multiple surgeries to correct my vision.

I asked Sonny Goel, M.D., an ophthalmologist and the Executive Medical Director of LasikPlus Laser Vision Centers and Visium Eye Institute for his thoughts. “Your age,” he said firmly. “That’s what it comes down to. We just assume people your age don’t have them.”

Now that I’ve had my surgery and am seeing clearly again, I can reflect. What happened to me is a good teaching moment for both doctor and patient.

I trusted each one of the doctors, each time I was in an office or on the phone; their tone, the explanations, the letters behind their names, all gave me confidence in their abilities, even as I grew more frustrated with every interaction.

Early on we’re taught to have complete faith in our doctors, unless there is a real reason not to, and to believe they are exploring all possibilities with regards to our health. I was no different. I was certain that one of these educated, kind specialists would figure it out, and I just had to wait. Not again. My request for a new thought process for doctors and their patients is pretty simple.

Doctors, I understand your schedules are full; you see so many of us in a day. But when you can, take that extra minute or two to think about the person in front of you. Not just as a set of eyes, or a spleen, a liver, or a heart, but as a whole person. We are made up of those individual parts and every aspect of our being has an impact on other aspects. Please don’t assume each of us will fit into a specific set of criteria at certain stages of our lives, and that sooner or later we’ll go neatly into an established box of diagnosis and care. As I, and the others who developed cataracts generations before what is considered “normal,” will tell you, that isn’t always the case. If just one of my doctors had removed the “she’s only 45” thought implanted firmly in his brain, and instead looked in detail at my symptoms and my history, several months of aggravation could have been avoided.

At the same time, though, I could have done more. No longer will I sit quietly when it comes to my health, and I’d ask that others take this new direction with me. Patients, we need to do our part as well. Maintaining this level of faith in our healthcare professionals takes work; we must learn to be our own best advocates. Don’t assume a doctor will do all the work.

My friend Z. Colette Edwards, M.D., founder of Insight MD, a healthcare consultancy, and PeopleTweaker, a health, wellness, and executive coaching service, calls this “being a healthcare rebel.” To me, this means taking a more active role in the direction of your own health. As the owner of your body, you know when something isn’t right. Come to your medical visits prepared; do your research, and don’t feeling inadequate if you don’t understand something and need to ask questions. Keep asking till you get the answers you need.

If I’d taken my own advice, I might have been seeing clearly again much sooner.

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SIX STEPS FOR SURVIVING THE PERFECT STORM IN HEALTHCARE

The perfect storm healthcare forecasters have been predicting is making landfall. Deep budget cuts are suddenly being required in many hospitals - stunning many leaders. It’s like Hurricane Sandy – we were all warned about climate change, but seeing the actual devastation is astonishing nonetheless.

How hospital leaders respond to the massive change could make the difference between the survival of their organization or its demise. “Such change will be so transformational that by 2020 one in three hospitals will close or reorganize into an entirely different type of healthcare service provider” according to David Houle and Jonathan Fleece, authors of The New Health Age: The Future of Health Care in America (2011).

People in a workforce undergoing rapid change react with powerful emotions. Initially, they are swept up by the automatic fight-flight-freeze reactions that occur in stressful situations. The primary emotions that accompany stress responses are anger, anxiety, and depression.

Leaders may feel themselves caught up in the riptide of negativity that accompanies change. Blaming behaviors can occur. Some may accuse nursing of having too much fat in their budgets. Others could allege doctors are costing the system too much money due to their entitlement attitude – “I’ll show up when it’s convenient for me and expect that everyone else will cater to my demands.” The staff at the bedside will ask why their income is frozen and their co-workers are being laid off when no one in the C-suite seems to be suffering.

While negativity is to be expected, it does not have to prevail. It is possible to convert the energy contained in stress reactions into motivation to achieve a common goal. Understanding how to harness the power of the people within a system can provide hospitals with the tools needed to cope with rapid change cycles.

Our research, conducted in partnership with a major academic medical center over the past 8 years, has revealed 6 principles essential for transforming conflict into collaboration. This research is grounded in the recent emergence of positive psychology, the study of optimal functioning in individuals and organizations. It has been interwoven into organizational development research as well as studies by groups specializing in healthcare performance metrics. When leaders and staff learn to use these 6 tools they are able to achieve quantum shifts in their performance.

Our initial application of the PROPEL principles to a poorly performing unit resulted in job engagement improving from the 3rd percentile to the 87th in a national database. As expected, patient satisfaction increased by 50% in the 2 years following the intervention. Patient safety, NDNQI (National Database of Nursing Quality Indicators), and other metrics all rose as well, and improvements were sustained for years afterward. An unexpected benefit was that sick leave and FMLA dropped by 75%. The hospital calculated their overall cost containment for this unit of almost 200 FTEs as being over $800,000 per year.

PROPEL© is the acronym for the 6 elements our studies show are essential for building high-functioning hospitals: Passion, Relationships, Optimism, Proactivity, Energy, and Legacy.
Six Steps for Surviving the Perfect Storm in Healthcare

Here's a brief description:

**Passion** is the first principle that must be put into place. However, the passion must be collaborative v. controlling. Leaders become controlling when they are too fearful of failure, which inhibits their ability to focus on empowering people to succeed. Collaborative passion develops when organizations create a shared vision of their future by engaging all stakeholders. By identifying the values they have in common and specific behaviors that would be manifest if everyone were living by those values, groups with competing interests can align around a positive outcome they all are passionately committed to achieving.

**Relationships** that support collaboration are crucial to success because people must work together to accomplish positive outcomes rather than disengaging or sabotaging the efforts of the hospital. Gallup surveys have shown that in almost every organization one in every five employees admits to feeling so hostile they are actively behaving in ways that damage the organization. This statistic holds true for every age group, every profession, and every income level. In addition to those 20% of employees, Gallup reports more than 50% of people are disengaged – they do their job well enough to just get by and get their paycheck.

**Positive** organizational psychologists have studied high-performing teams and identified 3 defining characteristics: First, they have more than 5 positive interactions for every negative encounter. Second, they address problems by asking questions in order to develop a full understanding of the situation (rather than drawing their own conclusions and advocating for their solution). Third, they find out what other stakeholders need in order to forge win-win agreements the majority of people will support.

**Optimism** is required in rapid change cycles because setbacks will be inevitable during the trial and error process of figuring what new ideas will work out to be the best. Pessimists blame other people, imagine the problem spiraling out of control, and insist there will be permanent damage done. Optimists, on the other hand, believe setbacks are temporary, lessons will be learned from every situation, and progress is possible – so they keep their eye out for it.

**Proactivity** is the opposite of reactivity. People are at their best when confronting a challenge if they see they have strengths that will enable them to succeed. Organizations that identify and focus on cultivating people’s strengths increase job engagement by 73%.

**Energy** management is crucial for people’s well-being. Stress takes a toll, resulting in people missing work and becoming disengaged. Organizations that promote and support people taking care of themselves physically, mentally, emotionally, and spiritually have the largest percentage of employees who maintain high engagement.

**Legacy** involves making a meaningful difference in other people’s lives. Think about who helped you to be successful. Feel the gratitude well up in your heart. Better yet, reach out and tell that person. Then ask yourself how you could be a better mentor to the people who work with you.

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PART 1 - WHITE-BAGGING: WHITE KNIGHT OR VILLAIN?

In old movies, it was easy to tell the “good guys” from the “bad guys” because the good guys always wore white. In recent cinema, it hasn’t been so easy to tell the difference. Often, it is the “good guy” who ends up the villain and the “bad guy” who saves the day, always shocking the audience.

Surprisingly, this has become the case within Pharma – both with the development and prescribing of medication. For most of the 20th century, medicines were life-saving or life-changing, and the public heralded the pharmaceutical manufacturers that made them and the doctors who prescribed them. As we approached the 21st century, things began to change. Pharmaceutical companies started being depicted as greedy, unscrupulous organizations caring more about profits than patients. Lawmakers and the public demanded drug prices come down along with other healthcare costs, like reimbursement to doctors for drugs administered in their offices. These demands made Pharma consider things like copay assistance and free drug programs, and meant doctors considered letting someone else handle drug costs and reimbursement – all seemingly “good guys” for patients and society.

But is the story really this black and white? It's incumbent upon each of us to look beyond the superficial, to the motivations, implications, and unintended consequences of an action or event. Good guys do not always wear white, and what appears to be “bad” might just be good medicine.

In the following paragraphs, I will define, explore, and examine the unintended consequences associated with “white-bagging,” a seemingly beneficial and benign shift in the prescribing of specialty products.

Definitions Are Important
Most people associate prescriptions with retail pharmacies; my doctor prescribes me a drug, and I go to my local drug store and get it filled. But some drugs, like chemotherapies and treatments for rheumatoid arthritis, for example, have to be administered by a doctor in a healthcare setting. Traditionally, doctors bought these products from the pharmaceutical manufacturer directly or through a distributor. The doctor would buy the drug, administer it in his/her office, and then bill the patient’s insurance for reimbursement of the drug plus an administration fee. In this model, the doctor makes a small profit, which is used to cover the overhead of the office – the staff, the supplies, rent for the office space, etc. It’s not unlike any other business – doctors have to make money to stay in business, just like a mechanic or a restaurant owner.

This model worked well for many years until healthcare reform moved the topic of healthcare costs front and center. Now “doctors making money on the backs of their patients and the government” became a topic of discussion – “bad guys,” right? Next, sequestration hit, bringing down reimbursement rates for Medicare-insured patients – the largest group of insured patients for whom doctors administer these drugs – good move, right? Doctors were making too much money anyway, right? Not so fast.

On average, doctors were only making 6% profit on drugs administered to Medicare patients (~60% of their total patient population) and an average of 10-12% for commercially insured patients (~40%). Most businesses shoot for a 20-30% profit margin to cover overhead costs and make a small profit. So doctors were already below the market on target profit margin, and now it is even lower, making it difficult to actually cover their overhead costs.
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costs, much less clear a small profit. This situation is forcing them to consider alternatives, like sending Medicare patients away (a hotly covered topic in the national media), consolidating their practice into a hospital or health system instead of staying independent, and white-bagging drugs into their practice.

In white-bagging, instead of the physician buying a quantity of drugs and having them on hand whenever a patient presents and needs treatment, they send a prescription for the individual patient to a specialty pharmacy (SP) and wait for the drug to be shipped to their office. The SP contacts the patient’s insurance company to get the prescription approved and once approved, ships the drug to the physician’s office. In this model, the physician does not buy, but still administers the drug. This lowers the doctor’s risk, as he or she doesn’t have to spend a lot of money up front for these expensive medicines (average cost for a specialty product is ~$700/dose). Sounds like the good guy, right?

Blurred Lines
So where did white-bagging come from? The intent of the white-bagging model is to reduce payer costs associated with specialty drugs by ensuring proper utilization by physicians. SP’s have sold payers on the idea there are “inappropriate” patients getting on drugs, by potentially pointing to articles such as the one that appeared in Pharmaceutical Commerce, which estimated more than half of all cancer drugs were used for off-label purposes. SP’s have sold their services as a way to ensure only patients who meet the payer’s formulary criteria get approved and shipped the drug. There are a few flaws in this argument for most of the specialty drugs we’re talking about.

First, since these drugs are expensive and doctors don’t want to run the risk of giving an expensive drug to a patient whose insurance won’t cover it, the doctor’s office usually does a benefit verification either with the payer or through the manufacturer’s HUB for the product. This means there is already a mechanism in place to make sure only appropriate patients are getting started on these in-office administered drugs.

Second, a recent report published by Magellan Pharmacy Solutions/ICORE Healthcare showed that in fact, in the oncology space, the acquisition cost alone is about 17% higher when chemotherapies are distributed through the SP channel vs. under traditional buy-and-bill. In an interview about this report published in Specialty Pharmacy Times, Kjel A. Johnson, PharmD, Senior Vice President, Strategy & Business Development, Magellan Pharmacy Solutions, estimates the total costs to be 50% higher due to drugs sent to a doctor’s office but which are never used. These drugs can’t be used for another patient as the product is a prescription rather than just inventory on-hand.

Third, I would argue the real cost is even higher. What about the fees/rebates paid by the payer for distribution and management of drugs through the SP channel which add to the total cost of therapy? In traditional buy-and-bill, the manufacturer usually covers these costs through their relationship with a specialty distributor (SD) or Group Purchasing Organization (GPO).

In addition to payers, healthcare practitioners have also indicated some support of white-bagging. According to several data sets, oncology practitioners and oncology practice managers actually support the shift away from buy-and-bill. The reasons behind their support varied; however, it should be noted the trend started following the 2005 Medicare Part B reduction in physician reimbursement.

In 2005, the reimbursement structure of Medicare Part B was switched from Average Wholesale Price (AWP) to the lower Average Sales Price (ASP) to combat rapid increases in Part B drug spending. The implemented changes essentially reduced physician reimbursement, but not the cost of the drugs themselves. Oncology practice managers estimate a 10-30% reduction in revenue as a result of these changes.
PART 1 - WHITE-BAGGING: WHITE KNIGHT OR VILLAIN?  

continued

In a time of eroding physician reimbursement, white-bagging can be perceived to be an attractive alternative to traditional buy-and-bill because financial responsibility for drug acquisition is shifted from the physician to the SP. Without a doubt, reducing medical costs is a noble endeavor, but as I have already alluded, there can be unintended and unforeseen consequences associated with white-bagging. As we speak, the pros and cons of white-bagging are being vigorously examined and debated by physicians, payers, specialty pharmacies, manufacturers, industry associations and distributors alike. Each stakeholder group is trying to ascertain the potential impacts of the white-bagging trend.

In the next issue we will explore several of the potential impacts of white-bagging for physicians and the patients they treat.

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HEALTHY LIVING: INTRODUCING PREVENTION INTO HEALTH POLICY

In an attempt to identify what concerns and intrigues its constituents, the World Economic Forum surveys its CEOs across all sectors each year, asking their opinions on important issues. In July 2012, this survey was also sent to members of the Network of Global Agenda Councils, which is composed of relevant thought leaders from academia, government, business, and other fields. From the forward-looking survey specific to healthcare, we plotted responses to a set of issues regarding their level of impact and degree of satisfaction with existing global solutions. The map highlighted the need for action in the areas of financial sustainability of health systems, non- communicable diseases (NCDs), illness prevention, and technology-enabled health. Accordingly, we have been working with our partner organizations to improve the state of global health through a project in healthy living, aimed at introducing prevention of NCDs into health policy.

In September 2011, the Forum reported the global economic impact of the five leading NCDs – cardiovascular disease (CVD), chronic respiratory disease, cancer, diabetes, and mental ill-health – could total US$ 47 trillion over the next 20 years. The findings indicated the estimated cumulative output loss over the next 20 years represents over 4% of annual global GDP. Over half of all deaths today result from largely preventable, non- communicable diseases (NCDs) like cancer, cardiovascular disease, and diabetes. Obesity alone could cut five years off the average American’s life within the next few decades. By now, it is well understood NCDs will escalate due to lifestyle factors and the aging population. Although the prevalence of such diseases has been well documented in the developed economies, NCDs are a truly global problem.

In the developing world, NCD risk factors are soaring. Take China, where physical activity has declined by almost 50% over the past 20 years. Chen Zhu, the immediate past Chinese Minister of Health, stated at the Forum’s 2012 Annual Meeting of the New Champions in Tianjin that China is now the global diabetes leader. China alone now has approximately 100 million diabetics—about four times the total number of diabetics in the United States. India is not far behind. Although diagnostic and therapeutic advances will play an important role in controlling the consequences of NCDs, governments and societies must do their parts in combatting the burden of disease.

New York City Mayor Michael Bloomberg received much publicity and debate in 2012 for his proposal to limit the size of sugary drinks to 16 ounces or less at restaurants, street carts, and entertainment and sports venues. Denmark implemented a tax on foods containing more than 2.3% saturated fat, including dairy, produce, meat, and processed foods in late 2011 and planned to introduce a similar tax on sugar. However, in November 2012, the government reversed this policy, as the tax has inflated food prices and put Danish jobs at risk. These examples illustrate some of the difficulties in implementing public policies to stem the tide of NCDs. Solutions are likely only to occur through collaboration between private sector, public sector, and civil society. This is what we are trying to achieve through our Healthy Living project. What if we could change the trend of Healthy Living and create a community in which total well-being is enabled, supported and rewarded?

In reality, encouraging Healthy Living will be challenging. Many interconnected drivers of Healthy Living interact with each other
through a complicated network effect. For example, diet and access to professional preventive and diagnostic care are highly influenced by an individual’s environment and income. Effectively addressing Healthy Living in a sustainable and systemic way requires combining stakeholder efforts to enable conducive environments and to drive long-term behavior changes.

In the first phase of the project, the Forum has developed a Charter to bring together stakeholders for collaborative action to enable Healthy Living. The co-chairs of the project are Paul Bulcke, CEO of Nestlé, and Chris Viehbacher, CEO of Sanofi. The Charter was developed through extensive consultation with representatives from government, business, and civil society, and defines the mutually agreed critical elements of success:

1. Stakeholders take joint, concrete, economically-sensible, and evidence-based multi-stakeholder action for Healthy Living and NCD prevention/control to:
   - build awareness
   - improve the availability of (and access to) products and services
   - create innovative incentives and supportive environments
   - invest in professional capacity building
   - advance knowledge through science and research.

2. Constituents from across sectors work together effectively, transparently, and respectfully.

3. All organizations advance their own approach to Healthy Living.

4. Healthy Living actions are regularly monitored and evaluated.

The Charter was launched at the 2013 Davos meeting and will facilitate cross-sectorial action to change the course of Healthy Living. The Charter is supported by step-by-step guidelines, hands-on templates, and case studies presented in the Toolkit for Multi-stakeholder Action. With the commitment to monitoring, evaluation, and continuous learning, the quality and impact of efforts for Healthy Living will set a new standard and improve the lives of millions of people around the world. Together, constituents can deliver lasting change and real health outcomes.

In the next stage of the project, the Charter will be used to implement “demonstration projects” that validate it as a means for effecting change to reduce the burden of NCDs in specific regions. For example, in 2013 the Forum will be working with industry, governments, international organizations, NGOs, and academia to reduce the rates of diabetes in Indian school children as well as to decrease the prevalence of hypertension in Mexico. The belief is these demonstration projects will validate the Charter as a roadmap to impact NCDs. The approach can then be scaled up in a multi-regional way at a global level. In addition to these tangible implementation efforts, the Forum will serve as a platform upon which a very important and sensitive topic will be openly addressed.

Much scrutiny has been placed on the credibility of collaboration between governments and IOs with healthcare, food, and beverage companies to combat chronic disease. Some have claimed conflicts of interest will stifle any progress in such efforts. The Forum’s model is one of multi-stakeholder action, so it depends on the trusted collaboration of cross-sectorial actors. Through the project, the Forum will explicitly address the ways in which work by these constituents together can bring about positive change in a transparent manner. The need for such positive change is essential, and the world must try many ways in which to achieve it, no matter what the perceived drawbacks.

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