THE**PULSE**

THE WHARTON HEALTH CARE JOURNAL

THE PRICE OF ADMISSION: EVOLUTION OF PATIENT ACCESS TO HEALTH CARE

SPRING 2008 - Including interviews with: FDA Commissioner, CEO of UPenn Health System and Executives from Merck, Humana and McKesson

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FROM THE EDITORS

After three years of publication under the name of "Wharton Health Care Leadership Exchange," we are pleased to present our readers with a new name, look and feel in the magazine's fourth year of publication. Each year, the Wharton Health Care MBA students publish the magazine in conjunction with the annual Wharton Health Care Business Conference. Despite these superficial changes, our mission continues to be to create a forum, in print, for the exchange of ideas on the most challenging and topical issues in the health care industry today, and to share that exchange with both attendees of the Wharton Health Care Business Conference, as well as others who could not attend the event. However, in choosing a new name, "The Pulse," we hope to emphasize our intention of presenting the issues that are most relevant and timely to health care for our readers.

Our changes to the physical manifestation of *The Pulse* correspond with a year promising to hold significant change in our industry, culminating in the 2008 presidential elections. This year's focus for the publication was inspired by the debates surrounding us in the fall of 2007, whether on television and in our newspapers or on campus and in the classroom. We witnessed that health care, in general, was one of the most hotly debated topics across the platforms of each presidential candidate with proposals ranging from sweeping changes calling for universal coverage to incremental adjustments to the current employer-centric system. Therefore, this year, *The Pulse* focuses on the predominant theme underlying those political debates, that is, how will patients' access to health care evolve in the future? Indeed, we were most interested in how politics intersects with the decisions business, government, and academic leaders make that touch all aspects of the health care industry.

Our editorial team, comprised of seven health care MBA students, had the unique opportunity to discuss this question in depth with experts across the health care value chain – from authorities on health care policy and reform to leaders in the provider and physician space to executives representing the pharmaceutical, insurance and health care services industries. We learned how various health care policies are impacting the selection and training of the next generation of physicians and how this evolution may impact the care delivered across the health care system. In addition we explored how the national debate on access to care is being influenced indirectly by different sources, including the debate over children's health insurance as well as important changes to universal insurance and access at the state level. Finally we discussed with industry leaders how the current political environment shapes their businesses and what is in store for the future.

We hope our readers benefit from the ideas discussed and observations debated in this year's publication as much as we learned in putting together the viewpoints and opinions from our distinguished panel of health care leaders.

***The Pulse* Editorial Staff**

WHARTON HEALTH CARE ORGANIZATIONS

Central to the Wharton Health Care Management student experience is each individual's ability to shape and participate in a number of dynamic student-run initiatives. We have highlighted some of these activities below. For more information about the Program and its student-run initiatives, please contact June Kinney (kinneyj@wharton.upenn.edu).

Wharton Health Care Management Program: The Health Care Management major builds on the established strength of the management core to provide expertise in the unique elements and issues of the health care industry. A Wharton health care major is unusually well-qualified to respond to the many critical problems now faced by hospitals, government agencies, group practices, pharmaceutical and biotechnology firms, insurance and managed care organizations, and consulting firms. The Health Care Management major differs from others at Wharton in that: (1) students must choose the major at the time of application to Wharton, and (2) it integrates academic and professional development, helping students to obtain summer and permanent positions in all parts of the health care sector, including consulting firms, biotechnology, pharmaceutical firms, hospitals, insurers, and government agencies. The department also sponsors a mentor program and links students to the Wharton Health Care Alumni Association.

Health Care Club: The Health Care Club organizes professional and social activities for all Wharton graduate students who are interested in exploring opportunities in the health care industry. Members share their knowledge and perspectives in addition to interacting with current industry leaders to develop an understanding of the issues facing hospital, physician, managed care, pharmaceutical, biotechnology, and medical device organizations. (http://clubs.wharton.upenn.edu/whcc/)

Wharton Health Care International Volunteer Project: The WHIVP is designed to give Wharton Health Care Management students the opportunity to participate in service projects for health care systems with limited resources and severe health problems. WHIVP has worked closely with numerous organizations including BroadReach, Aravind Eye Hospitals and Doctors of the World. Student teams have worked on a wide array of projects such as a microfinance project in Kenya, optimizing resource allocation of a satellite eye hospital in Tamil Nadu and developing a business plan for a health care facility in Tanzania. (http;//clubs.wharton.upenn.edu/whivp/index.htm)

Wharton Health Care Business Conference: Since 1996, the Wharton Health Care Business Conference has brought together leaders from industry, academia, and government to engage in discussion and debate about the future of health care. This year's conference, held February 21st and 22nd in Philadelphia, addressed the evolution of the many sectors of health care – the new business models and technologies characterizing the biopharmaceutical space, how IT is transforming health care delivery, and the political and international factors driving change in venture capital and corporate finance. The two-day annual event draws over 600 attendees from across the nation. (www.whcbc.org)

Penn Biotech Group (PBG): The Penn Biotech Group is a cross-disciplinary club with a mission to promote careers related to the biotechnology and medical device industries through practical experiential learning. The club draws members and expertise from graduate programs at Penn, including The Wharton School of Business, the School of Engineering and Applied Sciences, the Law School and the School of Medicine, as well as the larger life sciences community of Southeastern Pennsylvania. Members participate in consulting engagements with local life science companies, business plan writing and company formation, public equity investment reports and stock pitches, an interactive lecture series, social networking events, and career preparatory and advisory events. (www.pennbiotechgroup.com)

Wharton Health Care Board Fellows Program: The mission of the Wharton Health Care Board Fellows Program is to cultivate and enhance learning relationships between Wharton's Health Care Management Program and the non-profit health care community. The program allows HCM students to attend board meetings of local non-profit organizations, under the sponsorship of a board mentor. For the 2007-2008 term, four students were matched with the following organizations: A Chance to Heal Foundation, American Heart Association, Chestnut Hill Health Care Foundation, and the Children's Hospital of Philadelphia. (http://clubs.wharton.upenn.edu/whbf/)

SECTION ONE
ECONOMICS 101: SUPPLY AND DEMAND FOR HOSPITALS AND PROVIDERS

The growth of technology has fueled a tremendous rise in the demand for health care in the midst of a physician shortage. Hospital and health care providers must make new decisions on how to meet these demands while controlling costs, achieving the highest standards of quality, and providing increased patient access to care. Health care policy has played a significant role in shaping the landscape, but many challenges remain. We spoke with three leaders in the medical field to find out what factors have led us to where we are today and what new changes must be made as we move forward. Ralph Muller, CEO of the University of Pennsylvania Health System, outlines the political landscape surrounding the health care system and provides a layout of future initiatives impacting academic medical centers and patients' access to health care. Dr. Joel Katz, Internal Medicine Residency Director at Brigham & Women's Hospital, breaks down the major policies impacting resident physician training and why so many physicians are shying away from primary care. Robert Ruiz, University of Michigan Medical School Admissions Director, provides an inside look at how medical school admissions committees make decisions that impact the next generation of physicians.

RALPH W. MULLER - CHIEF EXECUTIVE OFFICER OF UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM

Ralph Muller is Chief Executive Officer of the University of Pennsylvania Health System – a $2.7 billion enterprise that includes three owned and two joint venture hospitals, a faculty practice plan, a primary-care provider network, multispecialty satellite facilities, home care, hospice care, and long-term care.

Prior to joining UPHS, he was, from 1985 to 2001, the President and CEO of the University of Chicago Hospitals and Health System. In 2001-2002, he was a Visiting Fellow at the Kings Fund in London, U.K.

In 1985-86 Mr. Muller also served as the Deputy Dean of the Division of the Biological Sciences at the Pritzker School of Medicine at the University of Chicago. Previously, he had been Budget Director at the University.

Before joining the University, Mr. Muller held senior positions with the Commonwealth of Massachusetts. His career with the Commonwealth included serving as Deputy Commissioner of the Massachusetts Department of Public Welfare, where he was the operating officer responsible for the state's major welfare programs, including Medicaid.

Mr. Muller received his bachelor's degree in economics from Syracuse University and a master's degree in government from Harvard University. Mr. Muller has served and currently serves on the boards of several national, regional, and local health care organizations and is active in local civic affairs. He is a Director of the National Committee for Quality Assurance (NCQA) and a Commissioner-Elect of the Joint Commission (JC). He has served as Commissioner on the Medicare Payment Advisory Commission (MedPAC), Chairman of the Association of American Medical Colleges (AAMC), Chairman of the Council of Teaching Hospitals and Health Systems (COTH), Vice Chairman of the University Healthsystems Consortium (UHC), and as Chairman of several UHC study projects. He is former Chairman of the Board of the National Opinion Research Center (NORC).

He is a Fellow of the American Association for the Advancement of Science.

He and his wife, Susan, have two children: Peter, a 2001 graduate of Duke, is a MBA student at Wharton, and Elisabeth, a 2004 graduate of Penn, is a law student in New York City.

WHAT KEEPS YOU AWAKE AT NIGHT? THOUGHTS FROM A HEALTH SYSTEM CEO

PULSE: With the upcoming presidential election, what initiatives do you see coming forth at the state and national levels?

RM: As the presidential campaign proceeds, the candidates are outlining their prescriptions for reducing the uninsured population. The plans differ on the extent to which they rely on government-based versus private market-based solutions to improving access to healthcare. Among the states, Massachusetts and California have received the most attention. However, there are about 10 states that are moving to provide more access to health care. I tend to be skeptical about how much the access issue can be solved on a state level, as it requires more of a national solution. Therefore, I'm looking forward to seeing what kind of mandate comes out of the presidential election. With a year remaining until the election, Iraq still is the biggest political issue. However, health care is likely to be a primary domestic issue and may even rise to the top of the list for voters.

Efforts to increase insurance coverage have been going on since the 1940s. In 1948, Truman's efforts were unsuccessful; in 1965 there was an expansion of access with the creation of Medicare and Medicaid; and then in the '80s to '90s the efforts came short with the most significant attempt being the Clinton health plan in 1993. It will take an election that results in a national mandate to change this trend of efforts that fall short.

There has recently been much debate regarding SCHIP (State Children's Health Insurance Program), a program which has helped to expand access to care for children over the last 10 years. Right now, you see conflict. The President does not want the government taking over financing of health care and the Congressional Democrats respond by pointing out that there are children who need insurance. It is difficult to broaden insurance coverage if expanding SCHIP is victim to the President's veto. That being said, I think we're going to see increased coverage at the federal level when a compromise is reached.

A family's health care insurance costs about $12,000 per year. Many lower-income people can't afford if that insurance is not provided by the employer. So there has to be a subsidy for those

people. Who's going to pay for it? An employer who is paying an employee $20,000 a year will not add another $12,000 in insurance costs. So it's not going to come from the employer unless the employee's salary is a reasonable amount higher.

If a Democrat wins the presidential election, I believe there will be an expansion of coverage. There will be 50-60 votes in the Senate for SCHIP expansion but no presidential veto. I think we'll see some mild expansion of Medicare coverage, perhaps by beginning coverage at age 62 rather than 65. However, even the Democratic candidates propose that working adults be covered mostly by employers rather than by government. Even with these efforts, until we migrate into a system where the incremental coverage is by government, we won't have universal coverage. Over the next few years, we are going to see this ongoing debate regarding employer vs. government-based insurance.

The fact that health care is expensive means that increased coverage is going to require raising taxes. We have the money as a country to do so. We spent money expanding Medicare to cover prescription drugs. We are spending $200 billion a year on Iraq. While the Iraq spending won't go down to zero, there's enough money to pay for expansion of health care coverage. But is there a political will? About 20 - 25% of uninsured adults include undocumented immigrants. There is no current willingness to use tax dollars to cover this population. While there will not be universal health care anytime in the next four years, it could be achieved with a major presidential campaign focused on that theme. A campaign like that will not happen in 2008, but it might by 2012.

The state efforts come down to the same set of issues. Who's paying for coverage? Most governors do not want to raise taxes. The states must have a balanced budget, compared to the federal level where government can run a deficit. Federal payments for Medicare Part D and the Iraq war are run on deficits, not through increased taxes. Coming up with the money to provide insurance without raising taxes is therefore far more difficult for state governments.

From the providers' perspective of responsibility for the uninsured, I refer to the old saying that "the drunk looks for his lost keys under the lamppost because that's where he can see." Similarly, most people tend to look to hospitals for coverage because hospitals provide it, although lack of insurance has more to do with physician payments. Physicians cannot afford to take care of the uninsured because they have no way to compensate financially. So far none of the policy initiatives require physicians to take on responsibility for providing care to the uninsured. Current law requires all hospitals to provide emergent care to those in need, regardless of insurance. At Penn, our hospital provides the second largest amount of charity care in the state, well over $60 million a year. That becomes a safety net for the population, although through emergent care. As a hospital, if we provided total care to everyone, we'd be swamped. So we, like other hospitals, provide charity care on an emergent basis.

PULSE: What recent policies, laws, or mandates have impacted your role as CEO of the Penn Health System?

RM: There are a couple of broad changes. One is the decline of managed care. It grew aggressively in the 1990s and then there was a political backlash leading to a decline over the last 10 years. The insurance products that are being offered today provide more choice for patients. This provides an advantage to an academic medical center like our hospitals with many excellent, well-known physicians. HUP (Hospital of the University of Pennsylvania), for example, is not the low-cost provider, mainly because of training programs, our use of high technology, and treatment of many acutely-ill patients. These factors make it 20-30% more costly at HUP than at a community hospital 30 miles outside of Philadelphia. If insurance programs forced patients to use a low-cost provider, it would be a more difficult environment for a place like HUP to thrive. However, in the choice system, people will not put up with being told they must use the low-cost provider. They want access to top hospitals like the University of Pennsylvania, University of Chicago or University of Michigan. A lot of economists would like to see more price competition, but the U.S. population has shown over and over again that they want access to their choice of doctors and if it costs more money they are willing to bear that cost. One exception to this is that people with lower incomes and with little or no insurance just don't have that same access to care.

The second factor with large impact is the ongoing advance of technology. Most advances come from companies such as Johnson & Johnson

or Boston Scientific in fields like cardiology or orthopedic surgery. Those advances whether in cardiac procedures or knee replacements create new technologies that are better for patients but are also more costly. This growth of innovation in the U.S. has advantaged academic medical centers because these are the locations where young physicians train and access new technologies. Our doctors perform minimally invasive surgery using robots and prevent major heart attacks with the newest cardiac stents. For these reasons, the fact that the U.S. health care system is so focused on technology is advantageous to academic medical centers.

A third significant thrust is towards quality measurement. Faculty at UPHS (University of Pennsylvania Health System) are among those leading the evolution of measuring quality. The measurement of outcomes and quality is much more difficult in health care than other industries. If they were easier to measure, there would have been a Consumer Reports in health care just as there is for digital electronics or automobiles. Since patients present to the hospital with varying medical conditions, it makes it difficult to measure of the effect of the care provided. The quality movement will be very active over the next 5-10 years and academic medical centers will be in the forefront of that movement. Hopefully, these efforts will help us to increase performance.

PULSE: You mentioned publishing departmental results and ratings for patients to measure quality of care. Recently there has been talk about publishing individual physician ratings, possibly even a "Zagat" rating starting in New York for patients to review when choosing a provider. What are your thoughts on this idea and how do you think it will impact patients' choice of care providers?

RM: It is hard for patients to answer questions evaluating physician care except on specific issues such as "can I get an appointment on a timely basis or does the doctor explain treatment options well." It is more difficult for them to evaluate who is the best electrophysiologist or surgeon. The typical Zagat ratings for a restaurant address questions such as "is the service friendly?," "do they seat me on time?," or "what's the quality of the food?" That's why patients focus hospital complaints about matters like parking, food, and bills. They are less able to evaluate the quality of care they receive. So the Zagat rating will be limited in terms of its impact on health care because it'll focus on factors that are not ultimately why patients go to the doctor. One may complain about the quality of food at HUP, but ultimately a patient is here because of the top experts to treat cancer. Patients can evaluate hospital parking and food because that's what they know how to judge. While these matters are important, patients will not be able accurately to measure quality of care or whether the doctor made the right diagnosis. Organizations such as foundations (e.g. Robert Wood Johnson Foundation), non-profit quality evaluators (e.g. National Committee for Quality Assurance), government agencies (e.g. Agency for Health Care Research and Quality) or insurance companies (e.g. Blue Cross) are able to better evaluate these criteria.

PULSE: You mentioned how innovation and technology are advantages for academic medical centers. HUP has been on the forefront of implementing technology such as the Electronic Medical Record. However, many people worry about potential violations of patient confidentiality and specifically HIPAA laws. How does HUP take steps to avoid situations like this?

RM: When patient information is in electronic form, it is potentially less secure than on paper because it can be accessed without actually having a physical copy. On the other hand, it can be tracked to exactly who is accessing the record. For example, a couple of years ago when President Clinton was in the hospital in New York for a cardiac procedure, 30-40 people inappropriately accessed his file. These people were electronically identified and then reprimanded or discharged. The electronic system figuratively captures a fingerprint when someone accesses it. On the other hand, when someone sees a paper file, there's no way to trace who saw the information. So there's more potential for abuse with an electronic system but there is also the promise of maintaining confidentiality because of this tracking capability within electronic systems. There are opportunities to provide better care if a physician can immediately access a diagnostic test, image or medical history. With so much potential for advance, we have to handle security issues.

With regard to medical privacy, people worry about, for example, the secrecy of their medications, psychiatric history, and sexual history. These are sensitive personal issues and many worry that an employer might wrongly use this information.

There are major companies like Google or Yahoo that have to find ways to be confidential or they can't conduct their business. Security protection will likely develop outside of health care, as with these companies (e.g. people have to keep email confidential). With the whole world moving towards being electronic, these issues have to and will be solved. Otherwise business models of companies like Google will not survive. The same protection will migrate to health care and the Electronic Medical Record.

PULSE: The Veteran Affairs (VA) System has done a good job of implementing a national electronic medical record (EMR) system. Do you see something like that happening with all other hospitals or do you think Government regulation or subsidies are necessary for this to expand?

RM: The VA system has been highly commended and rightfully so. Their EMR system has been in place for six to seven years and they have offered their software for free to non-VA hospitals, but no one has picked it up. Why has this not migrated from the VA to other hospitals? Part of it is that there's no billing system integrated within the VA's electronic medical record because VA care is paid for by the government. For this VA system to work in other hospitals, it needs to incorporate a billing component. The VA system was a major step forward for patient care but in the U.S. payment system, the lack of a billing component has prevented migration to other hospitals.

So far there is not a similar robust software package for the private sector. We do have a system here at HUP, which is different from the one used by Thomas Jefferson, which is different from the one used at Johns Hopkins or at the University of Michigan. There are five or six major systems throughout the country but no conformity to one major platform. It will take governmental initiatives for this to happen. It will be a slow process because of the large cost. To give you an idea about the cost, the EMR system UPHS is implementing will cost about $50 million. If tomorrow the government requires a different standardized system which costs $50 million, we don't have those funds available. The potential cost for 5,000 hospitals in the U.S. is considerable. For the VA, their health system was in disarray prior to the implementation of EMR and the government took steps to markedly improve care. The fact that the rest of the hospitals across the U.S. are not on a uniform system means that there's going to have to be some type of governmental regulation to push in that direction. It will not happen purely from market forces.

PULSE: Looking forward there has been talk about expanding patient access to care, but there has been a steady supply of physicians in the U.S. Do you feel that there will be a worsening shortage of physicians and what changes do you think will happen to better this situation?

RM: There is a shortage of physicians being trained in U.S. schools. Right now, 2/3 of physicians are coming from U.S. medical schools and 1/3 are from elsewhere. The U.S. schools are not going to dramatically expand anytime soon and if they did, it would take a long time to have an impact since physician training takes 8-10 years. So a good portion of physicians will come from elsewhere in the world, which is a problem for other countries since they are losing physicians. For example, Penn has an international program in Botswana where the physicians are paid $18,000 a year. Unless a physician has a real attachment to Botswana, they are very likely to come to the U.S. or Europe where they would get paid at least $100,000. Whether you look at Israel, Russia, etc. physicians are paid much more in the U.S. So we are going to continue to be a big magnet for physicians from other countries. I don't think we will have shortages in large urban centers like New York or Miami, but instead the rural areas of Minnesota or Iowa. Today, medical school enrollment is 50% women and many people are meeting their spouse in medical school. These physician couples have an easier time finding two jobs in urban areas than rural areas. So I believe we'll have a physician shortage for quite a while.

In terms of addressing the shortage, market forces will make nurse practitioners, physician assistants and others take on larger roles in primary care. Exactly how medicine responds will be tied to innovation and technology. I'm surprised there hasn't been more development in fields like radiology. Telemedicine has been with us for 30 years but it just hasn't taken off. Now with robotic surgery, you can sit in an OR in the U.S. and do a case in Africa. While you still need some staff in Africa, it doesn't necessarily require the lead surgeon to be there. I think technology will increasingly allow physicians to conduct interventions from afar.

JOEL T. KATZ - DIRECTOR OF INTERNAL MEDICINE RESIDENCY PROGRAM

Dr. Joel T. Katz is the Director of the Internal Medicine Residency Program at Brigham and Women's Hospital in Boston, Massachusetts. He is an Assistant Professor of Medicine at Harvard Medical School, an Infectious Disease Consultant at Brigham and Women's Hospital, Vice Chair for Education for the Department of Medicine, and the Marshall A. Wolf Distinguished Chair of Medical Education. Previously, Dr. Katz has served as director of both residencies and clerkships in medicine at Allegheny General Hospital and Medical College of Pennyslvania/Hahnemann School of Medicine.

The focus of Dr. Katz's clinical practice and research is on immunocompromised patients with infections or suspected infections, particularly recipients of solid organ or bone marrow transplants. His major administrative activities concern innovation in post-graduate medical education, including the recent development of novel combined training programs in internal medicine, global health equity, adult genetics.

Dr. Katz has an interest in using humanities to improve medical education. He is director of the Harvard Medical School course entitled, "Training the Eye: Improving the Art of Physical Diagnosis", in which students hone their physical diagnosis acumen through the study of fine arts at the Boston Museum of Fine Arts. He has received numerous teaching awards including the Louis Sudler Award at Johns Hopkins, the Dean's Special Award for Excellence in Teaching at MCP/Hahnemann, and the Best Clinical Teacher Award at Harvard Medical School.

Dr. Katz received a BA from Earlham College, and his MD and Masters in Medical Illustration from The Johns Hopkins School of Medicine.

HEALTHCARE IS CHANGING FAST. IS RESIDENCY TRAINING KEEPING UP?

PULSE: What recent policies or issues have made the biggest impact on residency programs?

JK: I think that restrictions on Graduate Medical Education (GME) funding have significantly limited the options residents have during their training. Residents have less flexibility to pursue non-traditional careers because these restraints impact what they can do with their elective time. For example, lack of appropriate funds may hinder residents from traveling to international settings to provide care. For many programs, it's meant that residents have less of an opportunity to participate in activities that place them in contact with the poorest and most needy patients. At Brigham, we've tried to overcome this situation by using philanthropic funds, but even this is limited and the trend is likely to get worse.

Inequitable income distribution among physicians is another funding issue that has driven many residents into highly specialized areas of medicine rather than primary care. This problem affects young physicians who may want to work in underserved and rural communities. The residents at Brigham tend to be very altruistic and mission-focused, and many ultimately do practice in primary care. However, nationally the income disparity between primary care and specialized fields has had a huge impact on career choice and ultimately on patients' access to care. I have seen many residents enter internal medicine with the goal of practicing in primary care, but quickly become discouraged and choose to specialize.

In Massachusetts, the introduction of a state-wide universal health care program has thus far had a positive impact on residents and their training. Patients who are the most marginal and thereby the most likely to fall through health care gaps, now have better access to preventive and general medical services. It's still too early to tell, but my hope and expectation is that this will be beneficial to society and to medical training in the long-run. A potential detriment of universal health care that I am keeping my eye on is the trend of private insurance companies to increasingly place restrictions on the role that residents can play in providing care. Over the last few years, we have begun to see a shift towards the faculty caring for privately insured patients and the house staff (residents) providing care exclusively to the

under- and uninsured. While this is a valuable role for them, the problem will be if universal insurance further restricts the house staff's role in longitudinal care.

A second problem associated with universal health care is that a large portion of Massachusetts' population is undocumented immigrants who still do not have equal access to health care. I fear it's going to become harder and harder for these patients to receive preventive and general medical care.

PULSE: You mentioned the increasing tendency for residents to pursue specialized training. Are there any initiatives at Brigham to encourage residents to pursue a career in primary care?

JK: Yes, Brigham has two primary care tracks within the internal medicine residency program, and they have slightly different goals. Nationally, the number of primary care applicants has been steadily decreasing over a number of years. My early review of this year's applicant pool suggests that this trend is continuing. My understanding is that a number of prominent primary care training programs in the country have shutdown because they didn't think they could consistently attract enough residents.

One of our primary care programs is co-sponsored with Harvard Vanguard Medial Associates (HVMA), which, incidentally, I graduated from. It is one of the few programs in the country that is embedded in both an academic institution and a staff-modeled health maintenance organization (HMO). The goal of this program is to teach residents not only how to provide care to individual patients, but to also look at how to evaluate and plan care for large populations of patients. For example, interns in the program might study how to make institutional decisions about formulary blood pressure medication choices and screening guidelines that translate into national guidelines. The program includes specific courses on decision science, management, and epidemiology. The majority of physicians graduating from this program either pursue a career in primary care or general internal medicine research with a focus on health services research. One of the distinguished graduates, for example, is Dr. Kevin Volpp who is a professor at Penn and at the Wharton School of Business.

The other primary care program is through our Division of General Medicine (DGM). The major theme of this program is health equity, and residents learn about and care for a more traditional underserved patient population. Residents attracted to this program are those typically interested in trying to understand and address barriers to health care access. Many physicians from this program are conducting research in this area, and also tend to continue their clinical practice in this population. Both of these programs are fulfilling an important mission that can be easily overlooked in large academic centers.

However, the challenges of having a satisfying practice within an extremely underserved population have driven some physicians to either pursue a specialized fellowship or a research-oriented career.

I'm very concerned about the future of primary care. I'm sure it will evolve in ways which we can't predict. But it's certainly alarming to me that there is a declining desire to enter this field of medicine. Inequitable reimbursement is, of course, at the heart of this vexing problem.

PULSE: Many feel that there will be a worsening shortage of physicians. Some medical schools have increased class size and there are even new medical schools forming. Are residency sizes increasing as well or are these students filling the spots that were previously left empty?

JK: This is a very complicated issue. In 1980, the Graduate Medical Education National Advisory Committee (GMENAC) predicted that there would be a significant surplus of physicians in the United States. This prediction created one of the driving forces for the current prediction of a worsening physician shortage. At that time, the Government enacted policies to limit the number of medical school positions and to restrict the number of international medical graduates entering the United States. Funding of medical education was capped to limit hospitals from increasing the number of residents they trained. These actions were very effective and probably helped cause the shortage we face today.

Residency programs such as the one at the Brigham have increased residency size by a few spots compared to 10 years ago, but not by much. Our ability to increase enrollment is limited by both the the Accreditation Council

for Graduate Medical Education (ACGME) and reimbursement caps established by Medicare legislation. Furthermore, starting a new program can be very difficult because of issues involved with reimbursement policies and accreditation organizations.

Currently, U.S. medical graduates fill about 2/3 of the residency positions in the country and the rest are filled by internationally trained U.S. graduates, foreign medical graduates, and now increasingly osteopathic graduates who want to pursue traditional careers. My sense is that U.S. medical school enrollment is growing for two reasons. First, they want to address the potential physician shortage. Second, expansion will allow U.S. medical schools to retain students that would otherwise be trained internationally. There are a number of new medical schools in the U.S., and several more forming over the next few years. The American Association of Medical Colleges (AAMC) has recommended increasing medical school admissions by 15% over the next decade, and many medical schools have responded by increasing class size. If this truly addresses our need for primary care physicians, I think it would be wonderful. However, a potential problem could arise if the students that would have been educated internationally and gone into primary care are now being educated in the U.S. and are shifting to more specialized fields. We have to be careful because if this occurs, our efforts may actually be worsening the problem.

PULSE: Many political initiatives may lead to increased health care coverage, allowing more patients to regularly visit physicians. Do you feel the increased patient load will benefit residents through increased exposure or hinder them by adding additional work to their current loads?

JK: The number of patients is increasing in most areas and stable in others, while nationally the number of residents is essentially fixed. Moreover, the acuity of patients is increasing, as is the aging of the general population. Due to strictly enforced ACGME rules, the number of patients that can be admitted by a single resident is capped. To compensate for these trends, many academic medical centers are moving toward new models of caring for patients that don't involve house staff. There are many models to do this and I think it's a step in the right direction. Currently, there are plenty of interesting patients for residents to provide care for and learn from, but they don't necessarily need to take care of every patient. If hospitals adequately support training, this situation will have a positive impact, because it gives me the opportunity to choose the most valuable patients for residents from an educational perspective.

PULSE: So you see it more of an advantage because of the flexibility as a program director to choose which patients residents provide care for?

JK: I sure do. If you look at the numbers nationally, the majority of patients are not taken care of by house staff. Academic medical centers are bit different and I think the care in either situation can be excellent. It's important to make sure that the residents are seeing patients that provide a balanced experience. For example, we have a partnership with Faulkner Hospital, which is a nearby community hospital. Our residents spend 1/3 of their time at this hospital, thereby allowing exposure to this older, generally single-system disease patient population. I think partnerships like this have become more common and increasingly beneficial.

PULSE: The mandate requiring residents to work no more than 80 hours a week has now been in place for several years. From your experience, what impact has this policy had on residency training?

JK: The ultimate goal of the 80 hour work week was to improve patient care, physician safety, and resident education. Studies suggest that well rested interns provide better care and that well rested physicians are less likely to be involved in car accidents. The piece that is much less clear is the long-term impact of these rules and its effect on residents' sense of professionalism, career satisfaction, and their ability to provide longitudinal care. While the rules have certainly been beneficial overall, some of these subtle effects are still unknown pieces of the equation.

It's taken a significant amount effort to find the right balance between the ideal educational experience and work hour restrictions. The main problem with the current policy is that the rules are inflexible and arbitrary. While well-intentioned, it does not provide program directors with the flexibility to remodel training programs that are both safe and educationally sound. I do feel that overall the 80 hour work week has been beneficial, but I'm hopeful that in the near future, accreditation organizations will allow more room to

explore alternative guidelines.

PULSE:With the change in the hours per week, many programs are shifting from overnight call for senior residents to the use of a "night float" system. Can you speak to the rationale of this system and whether Brigham and other hospitals nationally are following this trend?

JK: A "night float" system is basically a method of dividing long stretches of care among day- and night-time physicians, rather than have extended on-call shifts for 24 to 36 hours at a time. Some of the first studies involving the use of night floats were actually conducted at Brigham about 20 years ago. Most teaching hospitals are now using this system, at least to some degree, including Brigham and Women's Hospital. I think the challenge with night float systems is to make them both safe and educationally rich experiences. It's important to prevent the voltage drop off that occurs when one patient is passed from resident to resident multiple times. We need to make sure residents feel they are really responsible for their patients and that they are not merely shift-workers. At Brigham, we have a system in which the residents provide care during either the day or night, while interns work during the day and stay overnight. This allows intern to spend valuable time carefully interviewing and examining patients, and thinking through the patients' management, without feeling rushed to leave. We monitor for fatigue, and provide adequate back up if needed. At Brigham, we have tried at least four or five iterations of this system and have just now found one we are comfortable with.

ROBERT F. RUIZ - DIRECTOR OF UNIVERSITY OF MICHIGAN MEDICAL SCHOOL ADMISSIONS COMMITTEE

Robert F. Ruiz was appointed Director of Admissions at The University of Michigan Medical School in 2004. As Director, he is responsible for the entire selection process for new students entering the medical education program. Additional efforts particularly focus on medical student recruitment and development, community outreach and issues of diversity within medical education. Director Ruiz has pioneered work in admissions known as "Data Driven Admission Decisions." Director Ruiz has researched and written in areas of diversity based admissions, emerging technologies for recruitment, as well as extensive work in the areas of operational efficiencies within higher education.

Prior to his appointment at Michigan, Director Ruiz was Vice President for Application Services for the American Association of Colleges of Osteopathic Medicine. While in this post, he developed and executed a strategic plan, vision and mission for the American Health Careers Application Service which included the management of two national, centralized application services. Director Ruiz previously held the post of Director of Admission and Student Recruitment at the Oklahoma State University College of Osteopathic Medicine where he created an electronic data management program to maximize admission outcomes. Director Ruiz garnered honors while serving as Regional Director, Senior Counselor, and Assistant Director of Undergraduate Admissions at Tulane University where his work centered on segmented marketing and enrollment management.

Director Ruiz has held numerous roles with the American Osteopathic Advisory Council on Minority Affairs, American Medical College Application Service Advisory Group, Association of American Medical Colleges, Association of American Medical Colleges, American Association of Collegiate Registrars and Admission Officers, National Association of College Admission Counselors, National Association of Advisor for the Health Professions, American Medical Student Association, Student National Medical Association, American Osteopathic Association, Michigan State Medical Society, as well as many regional and local affiliations.

Director Ruiz holds a BA in Sociology and Spanish and an MA from the University of Michigan. He has completed Doctoral work in Higher Education Administration at Oklahoma State University.

UP FOR THE CHALLENGE? THE NEXT GENERATION OF PHYSICIANS WILL BE…

PULSE: What recent policies or issues have made the biggest impact on your role as Director of Medical Student Admissions at The University of Michigan?

RR: The biggest policy for Michigan has been recent state legislation, specifically Proposal 2, an amendment to the Michigan constitution which makes it forbidden for our institution to consider race or gender in the admission process. This has required us to substantially rethink the way we conduct admissions, offer scholarship awards, and has had an impact on the diversity of ethnic minority groups and gender. For example, one of the things we were very proud of was to have a class with an even balance of men and women. Under this new Michigan law, we don't have the ability to create that. So it's definitely disappointing in that regard. There are other states such as California and Texas who have had similar laws passed recently. So while I'm talking about Michigan specifically, it's the case that this is a trend and there are five to six states this year that may also adopt similar laws.

Another big issue, although it has not yet been significantly impacted by policy, is debt. Over the last 5-10 years, we have seen an explosion of debt accumulation. A recent published report showed that the current trend is not sustainable. In other words, even at the projected incomes physicians make, it's going to be very difficult for them to pay off their loans with the rising cost of debt. In that regard, in terms of admissions, it does force us to rethink the issue of financial aid. How much financial aid should we make available if we are really serious about trying to address this debt issue?

There's another issue on the horizon, which is a criminal background check. As the U.S. increasingly demands public safety, background checks began with physicians and have now backed up into the medical student admissions process. We're seeing a sweeping trend where the national association has strongly recommend that every medical school in the United States conduct a criminal background check on all applicants. So there really is a shift towards the common good to make sure the people we are admitting are good citizens.

Those are the three top issues that have really forced us to rethink how we conduct the medical school admissions process. In general, we have begun to rethink our overall approach to the admissions process. Traditionally there was heavy weight, as there is still, on MCAT scores, the science GPA, and science majors. I think increasingly we are seeing a shift towards humanities majors and if you will, a more well-rounded candidate. There's certainly more of a receptive climate today for the anthropology major who wants to go to medical school than there was five or six years ago.

PULSE: You mentioned that the State of Michigan's Proposal 2 Act limits the admissions committee from considering race or gender. Is that related to the recent Supreme Court Decision regarding affirmative action?

RR: It is related, but independent of the Supreme Court Decision. That decision affirmed the rights of institutions to use race and gender in the admissions process. So that remains in many states the federal law. In Michigan, a petition drive led to a state amendment that prohibits this with some rare exceptions such as where federal grants/ programs are involved.

PULSE: What actions have you actually taken since the Proposal 2 Act was passed?

RR: Well, obviously we are following the law in terms of compliance. But we really have stepped up our outreach programs, which are still permitted by law. We do this because diversity is very important to us in terms of ethnicity and gender. Although we are not allowed to take this into consideration in the admissions process, there are steps we can take to target specific groups at stages prior to admission and financial aid. So we really work hard to make these programs much more inclusive.

The other thing that has happened is a move towards the holistic review of applicants. We really look beyond grades and scores, to see what applicants have accomplished, the circumstances and context from which they accomplished it, and the distance they've traveled. The good news is that we've done that for quite a long time in our admission process so while that hasn't actually changed, we probably have placed a larger emphasis on it.

PULSE: In terms of rising debt, are there programs in place or in development to help subsidize or reduce medical school tuition costs?

RR: On a national and more global level there are several scholarship programs like the one through the military services. However, these programs haven't been very attractive to students mainly because they come with long-term commitments. So while there is a national effort, I'm not as hopeful about those programs.

If we don't start doing something, we run the risk of medicine becoming a profession for those who can simply afford it rather than those who are better qualified. At Michigan, we are fortunate because we have a Dean who recognized this situation very early on and has worked very hard to make adjustments to help students. Some medical schools, including ours, cap tuition rate increases. That doesn't mean that tuition rates won't increase, but that the percentage increase is capped at say 4-5%. Now that's good news for the students. The bad news is that someone still has to cover that cost and it usually ends up being the medical institution, which takes away from putting resources into another area. The Dean of Admissions at Michigan Medical School has been very forthright about developing a process whereby sometime in near future we hope to have every student who comes to medical school receive a four-year full tuition scholarship. To give you some perspective, about 10 years ago we had probably about $50,000 in scholarship funds per year. This year we have nearly $2.5 million. So I think the Dean has done a great job in going back to particularly alumni and helping them understand this debt burden, thereby increasing donations towards future scholarship awards to make medicine accessible to applicants who are qualified and need help affording it. Otherwise, we really do run the risk of pricing out people from this field and I'm sure that none of us wants to be in that scenario.

PULSE: You mentioned that you're looking more holistically at candidates including increasing applicants with a humanities background. Since implementing this goal, have you seen a change in the diversity of medical student involvement in activities such as research, global health, or community service?

RR: Certainly as we look for more diverse student perspectives, we would hope to see that translate into more activities and involvement, and we've

found this has been the case. Take for example, our summer research program at Michigan. Last year, the largest number of students, approximately 50% of the class, participated in that program. Not only do we see increased numbers of research projects but there are many topics in addition to basic science such as public health, environmental health, public policy and public advocacy. So I think we have an institution of students who can provide contributions in a variety of ways. There are several examples of expanding diversity in involvement. For example, take international rotations. Among the class that recently graduated, about 40% of them did at least one international activity, compared to just 10% about 10 years ago. Certainly we have far more active student organizations here today than we did 10 years ago. For example, the kinds of community service projects are in greater number than in previous years.

So I think this is all very healthy. As we look for a more diverse student body, we've seen some evidence that this has resulted in an increase in the various types of activities students participate in.

PULSE: There has been recent concern over a shortage in the supply of physicians in the United States. The State of Michigan asked all medical schools to increase their class size, however the University of Michigan decided not to make a change while the other two schools in the state did. In addition, a fourth new medical school is forming in the state. Can you discuss The University of Michigan's reasons for not increasing class size and if the formation of new medical schools is a trend you expect to see continue?

RR: There's a lot of debate over this topic. There are some data that show that there is a tremendous physician shortage. We are seeing a large growth both in schools increasing class size and the formation of new medical schools. However, there are a number of people who have questioned, but not necessarily discounted these assumptions in physician shortage. The assumptions come from a dataset that led to a surplus prediction in the mid-90s. So I think the truth probably lies somewhere in the middle. But at least at the University of Michigan, we have not yet committed towards a full size expansion. We are looking into all the factors that play into this. It's not just the issue of class size, available clinical clerkships, or facility size. It also involves post-graduate training with residency positions.

So we've made a decision not yet to expand the class because we're not sure exactly what the issues are. And I don't say that lightly. Two years ago, this medical school along with the others in the state participated in a commission to thoroughly analyze the workforce data to get a grasp of how many physicians there are in the state, what is their demographic, how many are likely to retire, and how many physicians we'll need to replace. But I think there's still some question regarding these factors. So because the data was not eminently clear about a shortage, we've decided not to expand the class size at this point. However, this issue is under constant review.

The second issue is quality of education. A rapid expansion means you have to have more people to teach, more to mentor, and more to precept. Our facilities are just not prepared to handle that. And we don't want to send students out to other places where we don't have quality control over the educational process.

The third and limiting factor is our clerkship size. The reality is that we are at capacity. We don't want to get in a situation where we end up with 10 students to one attending. We'd much rather have it smaller, where it's a meaningful, smaller proportion.

So if you're not careful you can diminish the educational experience. All that being said, we recognize the service element of our institution and certainly want to be responsive to the demands of the state.

So could we expand in the future? I think it's entirely possible to expand to some degree, but I don't think it'll be anything close to doubling the class size. However, nationally we are certainly seeing an explosion in the number of medical students.

The flip side of that coin is the issue of physician distribution. What types of medicine are they practicing and where are they practicing? These are really big challenges that I'm not sure have been fully addressed at the national or local level.

In summary, the entire situation of class size is very complex. And until we are comfortable with the data and able to control quality, we are not going to make any drastic changes.

SECTION TWO
ELECTION YEAR POLITICS AND REFORMS

The upcoming 2008 presidential elections have the potential to yield significant health care reform in the U.S. However, significant barriers to positive change still remain. The media spotlight is on universal versus privatized health care, affordability and cost containment, and improved access to care. We tackled these expansive topics by speaking with key opinion leaders regarding the main challenges to health care reform, the heated political debate on the children's health insurance program (SCHIP), California's initiatives towards developing a universal health policy, and the influential federal regulatory environment. Dr. Arthur Caplan, Chair of the Department of Medical Ethics and the Director of the Center for Bioethics at the University of Pennsylvania, provides forward-thinking ideas to effectively create sustainable change, including leveraging our nation's equal opportunity mentality to enact universal children's health insurance. Dr. Mark Pauly, a Bendheim Professor in the Department of Health Care Systems at the Wharton School of the University of Pennsylvania, also weighs in on the children's health insurance debate while providing a framework to achieve more equitable access to health care given an ever evolving political climate. Dr. Mark Smith, President and CEO of the California HealthCare Foundation, assesses the ongoing political debate over Governor Schwarzenegger's attempt to create a universal health care plan in California by taking a look at health care issues on both a state-wide and national level. Dr. Andrew von Eschenbach, Commissioner of the FDA, speaks about the regulatory environment for pharmaceutical, biotechnology and medical device companies, and provides insight on the evolving role of the FDA.

DR. ARTHUR CAPLAN - CHAIR OF THE DEPARTMENT OF MEDICAL ETHICS AND THE DIRECTOR OF THE CENTER FOR BIOETHICS AT THE UNIVERSITY OF PENNSYLVANIA

Dr. Caplan is currently the Emmanuel and Robert Hart Professor of Bioethics, Chair of the Department of Medical Ethics and the Director of the Center for Bioethics at the University of Pennsylvania in Philadelphia.

Born in Boston, Caplan did his undergraduate work at Brandeis University, and did his graduate work at Columbia University where he received a Ph.D in the history and philosophy of science in 1979.

Caplan is the author or editor of 29 books and over 500 papers in refereed journals of medicine, science, philosophy, bioethics and health policy. His most recent book is Smart Mice Not So Smart People (Rowman Littlefield, 2006).

He has served on a number of national and international committees including as the Chair National Cancer Institute Biobanking Ethics Working Group, the Chair of the Advisory Committee to the United Nations on Human Cloning, the Chair of the Advisory Committee to the Department of Health and Human Services on Blood Safety and Availability, a member of the Presidential Advisory Committee on Gulf War Illnesses, the special advisory committee to the International Olympic Committee on genetics and gene therapy, the ethics committee of the American Society of Gene Therapy, and the special advisory panel to the National Institutes of Mental Health on human experimentation on vulnerable subjects.

He writes a regular column on bioethics for MSNBC.com. He is a frequent guest and commentator on various media outlets.

Caplan is the recipient of many awards and honors including the McGovern Medal of the American Medical Writers Association and the Franklin Award from the City of Philadelphia. He was a person of the Year-2001 from USA Today, one of the 50 most influential people in American health care by Modern Health Care magazine, one of the 10 most influential people in America in biotechnology by the National Journal and one of the 10 most influential people in the ethics of biotechnology by the editors of Nature Biotechnology. He holds seven honorary degrees from colleges and medical schools.

DR. MARK PAULY - BENDHEIM PROFESSOR IN THE DEPARTMENT OF HEALTH CARE SYSTEMS AT THE WHARTON SCHOOL OF THE UNIVERSITY OF PENNSYLVANIA

Mark V. Pauly is Bendheim Professor in the Department of Health Care Systems at the Wharton School of the University of Pennsylvania. He is Professor of Health Care Systems, Insurance and Risk Management, and Business and Public Policy at the Wharton School and Professor of Economics in the School of Arts and Sciences at the University of Pennsylvania. Dr. Pauly is a former commissioner on the Physician Payment Review Commission, a former member of the advisory committee to the Agency for Health Care Research and Quality, most recently a member of the Medicare Technical Advisory Panel, and an active member of the Institute of Medicine. He is a co-editor-in-chief of the International Journal of Health Care Finance and Economics and an associate editor of the Journal of Risk and Uncertainty.

THE YELLOW JAUNDICED BABY: WILL OUR KIDS GET US UNIVERSAL COVERAGE?

PULSE: You have previously spoken publicly regarding the novel idea of creating health care reform through children – that is, mandating health care insurance for our nation's younger generation in order to set the stage for future improvements. Would you expand on that notion and explain why you think it's an effective tool for sustainable health care reform?

AC: If you look at American attitudes about what they think is okay in terms of the government taking their money away from them, I think children are seen as something that they really want to support. Children are a group that they want to back. Children don't have a lobby, so that's a problem. But, the good news is that they have a lot of moral heft in American society. So, I think it would be more powerful if politicians would re-couch their arguments about SCHIP (State Children's Health Insurance Program) and other programs, and say look, no competitive capitalist society can consider itself fair and equitable unless it allows all of its citizens to get to the point where they can compete – and the only way that they can do that is if children have sufficient health care to minimize their disabilities and maximize their chances of being healthy to enter into and compete in the market.

So this is a condition for capitalism. It's not a condition for what some liberal's vision is or what some dreamy utopianism is. It's a hard-nosed picture about what you need to have a competitive market. And what you need is to have educated people – people who have meals and housing – you need people who are healthy. And that seems to me to be essential to have a fair market. This also makes some cost sense, because if you invest in some of these kids, you'll get better health habits, and better health across their lifespan. So I'm pretty sure it's going to turn out to be cheaper to go with kids.

So you have a dual pronged ethical argument: They deserve it because that's how you create equal opportunity and it's prudent because that's how you're going to get better savings on where you spend your health care dollars. You can add in a third arm – we're not that far from getting it done. So that it's not like we have to start from no kids and get to all kids. Right now, in most cases 50%, 60%, 70% of kids have something… you can get this through and finish it up in a way that is doable. And I think from the ethics of health care, setting achievable goals, which people can see are possible, has a lot of power, as opposed to single payer systems, which I'm not against, but I don't see how we're going to get there from where we are now.

PULSE: Do you feel making health insurance a requirement is an effective tool in bettering our nation's health and do you feel that such a mandate is achievable?

AC: I think mandating insurance is doable. I think it works in automobile insurance coverage to the point where there is even a fee charged for uninsured people who were supposed to be insured by state mandate. I think you could basically say you have to get your insurance through one of these programs or you have to get it through your employer or there has to be a pool of people who aren't in those categories who have to be able to buy affordable insurance. There would have to be a basic package, bare bones minimum stuff, but required by law that it has to be sold by all insurers.

I'm no fan of getting your health insurance through work, but that's going to take a long time to change. It should be changed. It's stupid and it doesn't make any sense at all. It's really accidents of history that link up health care access to employment. Unions wanted that coverage to draw people to unions in the U.S. Employers like to use it as a perk to compete against other businesses, but having your employer buy your health insurance is just goofy. So, I'm in favor of just paying for it out of your pocket or out of your taxes, getting rid of this corporate health department thing, but you are going to need to get purchasing pools, so I think that could be done by this mandate idea. Again, think about it like automobile insurance – you can buy the basic package or you can get your glass insured or you can get your paint job insured or you can get full coverage for every occupant…however, the bare bones plan is one that just has to be sold by anybody who wants to sell automobile insurance. And it probably does get subsidized off of the other luxury or voluntary types of charges, but that's okay.

While I think you could do it, I don't see much political will to do it, and that's probably because

of the system – there are about 55% - 60% of Americans who do pretty well in the system, and I don't think they want to change it. And there are 40% that rattle around at any given time with trouble – but the majority is protected enough that they are not so interested in losing what they've already got to help the 40% come in. So politically you have to convince them that they don't have to give up anything to get the 40% on board. That's the only way it's going to work.

MP: I'm in favor of mandating it for everybody so that you're required to have at least some basic minimum health insurance. No, I don't think the amount you mandate has to be uniform. In some ways and ironically, it should probably be more generous for lower income people. If Bill Gates wants to get by with a catastrophic policy, that would be okay with me. I won't stay up late nights worrying about that, but I would be concerned about a low income person with a very high deductible policy. The reason for mandating it is in part because it's humane, but also and related to that because we are concerned about the well-being of our fellow human beings. When they don't have health insurance and they need health care, people are motivated to at least do something for them.

I think mandating insurance is achievable. I would rely on the most efficient parts of the U.S. government, which are the Department of Treasury and the Internal Revenue Service. I'll probably have to qualify a bit for people who are undocumented — but for people who have a social security number and are working, the IRS knows about them. The requirement would be that you provide evidence that you have health insurance. If you don't attach that to your income tax form, then you pay an extra charge which would in my view just conveniently be what the premium would be for the basic insurance we want you to have. So that's easy to say, of course, and it's a little harder to enforce because it requires sometimes a kind of painful judgment that a family that is stressed in other ways would have to give up money for health insurance. But if you believe in the value of health insurance, either the family is deserving of help in which case they should get a bigger subsidy, or if the tax payers aren't willing to pick up a bigger subsidy, then logic seems to say [the family] should pay. Somebody's got to pay.

PULSE: Democrat party critics argue that the liberals are playing off emotions by shamelessly presenting images of needy children in the media to support their plea, while Republican party critics argue that conservatives dismiss SCHIP expansion because they want to maintain their politically lucrative corporate alignment with private insurance companies. Is SCHIP merely a pawn for the upcoming presidential election?

AC: No, I think it's a real issue. I do. I think playing on emotions is okay. I think having an adherence ideologically to the market as a better way to deliver is okay. That is, in my view, the best way to do this is with kids. Because I think, if the parents are incapable of signing up for the free program in Pennsylvania, the chance that they're going to perform well in the marketplace to get their kids health care is not strong. So I'm a skeptic that the market can deliver universal access when many players in the market are too impaired. But, that aside, I think the kid issue is and should be the battle ground.

I think the possibility of drawing alliances from organized medicine, dentistry, nursing, teachers' unions, and putting together a package of political will to bring in kids is very strong. Whereas on the adult side, when trying to go universal, you are ignoring so many vested interests that it's very tough to say everybody's going to get that basic plan and now we're competing against you. It gets tricky to take trillions of dollars that are being spent on health care and take it away from people. They don't like it. But if you get a fire going with the kids program, then you have some chance of showing how savings then might be redistributed to more useful things.

I mean, everybody knows that we spend too much on administration in the American health care system. On the one hand, that's hard to get rid of too because that's a lot of employment – so it's many jobs for people that would go out the window if you did away with it. On the other hand, administrative costs are not what anybody, I think, wants to spend money on. So if SCHIP could come in federalized and almost have no bureaucracy requirement, you get to see another example of relatively efficient health care delivery. I think we should use the VA as an example of that too – it's pretty efficient and doesn't cost much to administer. Neither does Medicare – these are low paperwork systems because they're universal, standardized. You're in by qualifications, not by some paperwork admission.

MP: I think both of those arguments are bogus. On the one hand, states have the freedom under SCHIP to administer the insurance through the private sector. I'm on the board of a private insurer, I should probably say that. It's a non-profit and an HMO to boot, but I mean we'll do anything if you give us money. So, private insurers would be perfectly delighted to write whatever coverage the state would want. The only thing that's an issue here — it's not the fact, it's the price — whether there's going to be federal matching or not. For a lot of states, New Jersey excepted because they're not in financial difficulty, the idea that somehow they can't help their own children because they can't get the federal government to come up with the money is a little bit ludicrous, especially those rich states. New Jersey actually is a rich state in terms of income per capita, so if we had to pick on somebody we'd pick on Connecticut. So, both the "you hate children" and even the "creeping socialism" arguments are really bogus arguments. The people's republic of Vermont might choose to have a single state run policy, but other than that you'd need an experiment to see what worked better. My perception is that some people trust the government and distrust the private sector. For other people it's the other way around. If I was designing it for my state, I'd want there to be post office and a Fed Ex of children's health insurance so we could decide which one would give you better service with your subsidy voucher.

PULSE: SCHIP is coming into renewal right now and Congress has yet to make a decision in regards to expansion. The Democrats are advocating a stronger, more aggressive expansion plan while the Republicans are in favor of an economically more conservative maintenance type of continuance. First, do you feel SCHIP has been successful in bettering the health of our nation's children? Second, what do you feel is the ideal expansion?

AC: Yes, I think the data is in: the SCHIP has been a success. I think SCHIP should be basically shifted towards a program where every kid is in without any qualification requirement, like what we have in Pennsylvania. To me, you're basically in. It cuts down on administrative costs. And I think the argument here is one of equal opportunity – that kids can't protect themselves, kids can't earn their health care, kids often require specialized health care because they're kids, or they're adolescents…but they are still special vulnerable populations. And while some Americans hate the idea of handouts to people they see as quite capable of working to get their health insurance, no one can argue that about a kid. So, the moral argument has always seemed to me, expand the SCHIP program Pennsylvania style – cover everybody, make it a lean package, but get everybody in.

In a peculiar way, I think this is the battle that's likely to unfold for the first four years of the next president. I don't think it's going to get settled this year – I think it's the stocking horse for general health insurance. If the Democrats can't win this issue, cannot win with SCHIP, they're not getting any farther with any other health issue. If they can win this issue, then there's a chance that they can then swing around and say, well we've covered all kids, now let's think about other populations to expand to.

MP: I think we have the direct measure, which is how many children have some kind of health insurance and that's definitely improved. I don't think I've ever seen any data that actually tries to turn that into a measure of improvement in health. It's hard to believe that there isn't an improvement, but I can't quote chapter and verse on it. Part of the debate about SCHIP, in fact there is pretty good data for this: poor children who don't have health insurance, their health suffers. The debate though is not about covering poor children; it's about increasing the subsidy further up the distribution of income. What the impact of insurance coverage is on children of the middle class is something I don't know much about and is something that I don't know that we have as good evidence about.

In regards to expansion, I think it does go back to what the citizens and states are willing to do. There are not some tablets of gold upon which the rules are written. One issue obviously is: how do you feel about raising taxes? Taxes will be paid by the middle class. It's also kind of tied in with the tobacco tax. As fewer and fewer people are smokers I guess the main concern there is whether that's a stable funding source. What if people stop smoking or more generally, if the rate of growth in the cost of this program continues to grow like it has in the past? The tobacco tax revenue is not going to grow at that rate. So tying it to a particular tax like that seems like less of a good idea than tying it general revenue taxes. It'd be a little less gimmicky, I guess.

PULSE: The Congressional Budgetary Office estimated that approximately 25-50% of children who have enrolled in SCHIP switched from their previous coverage through a private plan. Therefore, critics argue that the plan is not effective in significantly decreasing the number of uninsured children. If this statistic is accurate, are you concerned and do you feel it de-values the SCHIP program?

MP: It devalues it if you think of it just as a program for getting insurance to more kids. In the sense that the budgetary cost of the program per newly insured child is higher than it would be if no crowd-out existed and the only families that covered their children under SCHIP were families that previously had no insurance for the kids. What you said there is not quite right, you'd still get more kids covered with 25-50% crowd-out, it'd just cost more per kid. So partly, that's a question getting back to the voters and the tax-payers, what's it worth to them? There is a different way to look at that though, which is to note in a way what is kind of wrong with the SCHIP approach. So at lower-middle income levels, that's where most of the fuss is; above 200-300% [of the poverty line] most kids have private insurance. So you know if you start offering subsidized public insurance, there's bound to be crowd-out, just because there is a non-trivial minority of children who are uninsured, but the majority of children are privately insured. So, my ideal arrangement, although it would require much higher governmental budgetary cost, would say whatever we think the appropriate subsidy is for a family at 250% of the poverty line, let's make that available for that family to get insurance for its children regardless of how it gets the insurance. So, if they get it through signing up for an SCHIP program that's fine. For the family that was already getting insurance through their job and taking a lousy job just so they could have insurance coverage for the kids, I think they deserve a bigger subsidy than the people who were formerly irresponsible and hoping against hope that their kids wouldn't get sick....I've been trying to think about writing this as reframing it as effectively a kind of tax cut for the lower middle class, which I personally think they ought to have anyway. It's almost like saying you get this tax cut, unless you don't have your children insured in which case we don't give you the tax cut. That's maybe a different way of thinking of it, than thinking of it as a subsidy. So, the problem at least with the typical government-run SCHIP arrangement, a lot of families who are at the exact income level won't make the switch. They won't make the switch and that's not really fair. So they don't get any subsidy or they get a very small subsidy that comes from taxes. Then there's another set of people that look exactly the same in terms of income, children and so forth, and their children get quite a substantial subsidy. But if the insurance policy offered by the SCHIP plan is not really a good policy, it's like you're bribing people to take what could be very lousy insurance especially if it's low on the physician reimbursement side. That's not a good thing either. I'd much prefer a uniform tax credit or uniform subsidy if I was God and of course had the power to raise taxes because that's going to cost more money. But I personally think it would be worth it in terms of equity and probably in terms of reducing distortion. Because I said, kind of bribing people to take public insurance which maybe far inferior to the private insurance that the kids already have. So, I guess that leads to my fundamental view that, although I hate to say this, but I hope we don't do much about SCHIP because it's a Band-Aid and a patchwork. All those things really ought to be part of the economy, like a graded program to subsidize health care equitably for people of given income levels regardless of their personal situation.

PULSE: With child health outcomes, such as immunization and death rates, differing significantly from state to state, it has been argued that the total federal funding level is not the issue, but rather the allocation across the states. If those states with worse health outcomes received a larger portion of the provisions, then perhaps they would reach the effectiveness levels of other states. Do you feel state allocation is a key factor in the success of SCHIP?

AC: That's possible – I haven't seen the numbers on that, but it is possible. I mean, there are programs I'm sure that are sitting on pots of money that don't use them. I can't imagine the Minnesota SCHIP is completely spent out. And, you know, I'm not sure if they are always so grandly efficient. These are classic economic failure situations. It reminds me of the Philadelphia parking authority where they take in a lot of ticket money but they don't seem to have any excess except to pay the people in the program.

MP: I agree with that. SCHIP is sort of peculiar because technically, it was a capped entitlement, but the states are now behaving as if it were open ended and they should get funding at the

same ratio. And what happens both for SCHIP and for Medicaid is that the richer states provide better benefits than the poorer states to their poor people, which seems sort of upside down and backwards. The simplest explanation for why that's true, at least if you wanted it to be more uniform, would be that the state spending share in high income states is too low; it overestimates their spending. You could go either way, but I would prefer to raise the state share in the high income states. That would seem to be a reasonable thing to do. Then, that would relieve some of the burden on the federal tax payers, which could draw the federal budgets of deficit. A lot of state budgets are actually in pretty good shape, but it would also avoid offering excessive incentives to richer states to provide benefits that then are much better than otherwise equally measurable poor people would face in poorer states. My own research suggests that there are adverse consequences on insured people of having a lot of uninsured people in your community. That's a worse problem in Texas than it is in Minnesota. Partly, it would be that way anyhow, but partly the structure for matching for Medicaid and at least apparently for SCHIP is skewed to offer excessive incentives for spending for high income states who probably don't need that kind of temptation and are kind of leaving the poor states behind. Of course, the problem is not only for poor people. So, we've developed a system that helps the rich to get richer because they end up getting a lot of federal dollars because they're spending a lot even though the matching rate is lower.

PULSE: Do you have any final thoughts you would like to share with our Readers?

AC: There's an old political adage – something I've learned in American politics – which I call the jaundiced yellow baby syndrome. When you go to a Congressional hearing, and you want to get Congress to spend money on something in health care, there are three things you can do. You can bring in a celebrity to testify that they have the disease, or know somebody with the disease, or have thoughts about the disease. You can bring in experts which is sometimes effective. Or you can bring in a yellow jaundiced baby.

So, you bring the yellow jaundiced baby to the hearing and say, "Now look, we have to have a liver transplant or we've got to do something about MRSA, or something has to happen," and then the sickly child is displayed. In a way, the uninsured child, the sick child who has a preventable illness, is the jaundiced yellow baby of health policy. You want to use the access problems kids face because it works. I've seen it work. If you bring in fifty people with mental illness, I'm not sure that Congress is going to do anything about that except say, well that's creepy, and I don't like it, and I'm not going there. Or 50 people who are alcoholics. But you bring in 50 sick babies right in front of them face to face, it's hard to say, well there's nothing we should do. But if you can get them to do something, then you can usually bang out some type of compromise between conservatives and liberals on these things. But if they don't have the agreement that something must be done, then it doesn't matter what all the detailed plans are. Nothing is going to be done. They have to agree that they need to do something. So, I'm a big fan of the jaundiced baby approach and using that symbolically as a key weapon in the fight to get health insurance.

DR. MARK SMITH - PRESIDENT AND CEO OF THE CALIFORNIA HEALTHCARE FOUNDATION

Dr. Mark Smith is the President and CEO of the California HealthCare Foundation. The Foundation is an independent philanthropy with assets of $800 million, headquartered in Oakland, California and dedicated to improving the availability of high-quality, affordable health care to Californians, with particular attention paid to the needs of the underserved in the state.

Dr. Smith received a BA in Afro-American Studies from Harvard College, an MD from the School of Medicine at the University of North Carolina at Chapel Hill, and an MBA with a concentration in health care administration from the Wharton School at the University of Pennsylvania. As a board-certified internist, he is a member of the clinical faculty at the University of California San Francisco and an attending physician at the Positive Health Program for AIDS care at San Francisco General Hospital. He is a member of the Institute of Medicine and serves on the board of the National Business Group on Health.

Prior to joining the California HealthCare Foundation, Dr. Smith was Executive Vice President of the Henry J. Kaiser Family Foundation and previously served as Associate Director of the AIDS Service and Assistant Professor of Medicine and of Health Policy and Management at Johns Hopkins University. He has served on the Performance Measurement Committee of the National Committee for Quality Assurance and the editorial board of the Annals of Internal Medicine.

Presently, Dr. Smith is working closely with Governor Schwarzenegger's administration to address the need for California's uninsured population.

UNIVERSAL ACCESS … WEST COAST STYLE

PULSE: What are the main areas of focus for the California HealthCare Foundation?

MS: We have three main programs. One is "Better Chronic Disease Care," because chronic disease is such a big part of both suffering and expense of health care. Second, is a program we call "Innovations for the Underserved," in which we try to find ways to do things better, faster, cheaper, and more accessibly for underserved people. That includes both delivery of care and streamlining of insurance products. And the third is what we call "Market and Policy Monitor," and it's used to help stakeholders, policy makers and the public have a better understanding of most of the things that are happening in the health care market, and important policies like the expansion of insurance coverage. We also put out a number of publications, including two daily publications, California Healthline and iHealthBeat. We do some other things, but those three programs that I've talked about, "Better Chronic Disease Care," "Innovations for the Underserved," and "Market and Policy Monitor" are the bulk of our actions.

PULSE: I understand you've worked closely with the Governor's administration, and that in January of 2007 he introduced a plan to reform the state's health care system. What are the primary objectives of the Governor's plan?

MS: The Governor's plan, and the Governor, it must be said, is working with the legislative leadership, which is from the other party, the Democrats. Even as we speak, they are continuing to negotiate this and are trying to find a way to cover people in California who aren't covered, to do so in a way that's accessible, and in a way that shares the responsibility among a number of payers. So, our staff has tried to provide a common, analytical framework which policy makers can use to discuss, debate, and propose their alternatives. The reason that's important is because in these kinds of discussions, often people can wind up using different numbers and arguing over the numbers, rather than over the policy. And so, we think it is particularly noteworthy because in this debate in California, which is far from over, we've heard very little debate about whether provision A or tax B would raise $2 billion or $9 billion. They agree it will raise $2 billion, or it'll raise $9 billion, and they could argue about whether that's a good thing or not,

but let's not waste time arguing over the numbers. That's one of the contributions that we've tried to make here, and I think it has been a largely successful one.

PULSE: Is everyone going to be required to have insurance or will there be some exemptions?

MS: Ah, well, that's a big debate. The governor's original proposal was that everyone be required to have insurance, and that those who couldn't afford it would be subsidized so that they could afford it. Of course, one's definition of affordability is in the eye of the beholder. And that's one of the things that is being debated now. You'll note that in Massachusetts, a proposal that was debated, passed, and signed, originally aimed to have everyone buy insurance, but it has now been amended to exempt, so far, 20% of the people because it was thought that they couldn't afford insurance. And many of the proposals that are going around now are arguing over exactly that. So it is way too early for me to decide or try to predict how that will come out. I think there are two things that most people agree on. One is that there's no such thing as universal, voluntary anything. If you want everybody to have health insurance, you're going to have to force some people, who would not otherwise buy it, to do so. So I think that's clear.

The second thing that's clear is that there are large numbers of low income people for whom, forcing them to buy insurance with the current insurance products at the current rate, would pose an undue economic hardship on them. And so you can't say that everybody is going to have to buy insurance unless you can also assure them that there will be affordable products available for them or that they will be subsidized. Now working out those details of what's affordable, how much to subsidize, and where the funding for that subsidy will come from – those are the items that are under heavy debate in this state and many other states.

PULSE: How will this plan in California to change the health care system be financed?

MS: Well, there are a number of proposals for that. In the Governor's original plan, the sources were to be a fee on doctors, a fee on hospitals, some contribution from employers, and some contribution from individuals or employees who would be required to have insurance. The current debate has stripped out the doctor contribution, which proved to be quite unpopular with doctors as one might imagine, and continued the contribution from hospitals because the hospital association actually supported that proposal once they figured out that in the end they would get more money under this approach than they are getting now.

And there are various other sources of income being debated, so the Democrats have proposed a much higher fee coming from employers, which as you might imagine employers have resisted. They have also proposed a new tax on tobacco products, which one might imagine the tobacco companies and some others would resist. The Governor has countered with a proposal to privatize the lottery, which is supported by some and opposed by others. And so, the negotiations that are going on now are really around the two points that you've raised, which is "what is the definition of affordable, in terms of people who will need to be subsidized, and where will those subsidies come from?" Those are the two key questions.

PULSE: What is the current status of the plan?

MS: The current status is that there is a special session of the California legislature in session that is debating two questions. One is water policy in the state, which if you've ever seen the movie China Town, is perhaps as contentious, long standing, and divisive of an issue in California as health care. And the other is health care. A compromise bill passed out of the committee [on November 15]. It is likely that if an agreement is reached between the Democratic leadership and the Governor, that a proposal with the general outlines of what I just talked about would be adopted, but the funding mechanism, because of the vagaries of the California Constitution, would require a vote by the people, and so, we have this strange situation where the legislature might pass, on the Governor's side, an agreement about a general approach on how to do this, but it would have to be a ballot initiative in which the voters would approve the funding mechanism. And that raises the prospect of competing ballot initiatives by various people who have a different idea about what ought to be done. Or, I suppose some people would think that nothing at all should be done. So, we're expecting that over the next year and a half, in California, there'll be a lot of intense public debate and lots of jockeying by interest groups, because no matter what comes out of this legislative session,

it is by no means assured that an agreement will be reached. But even if one is reached, it will be an agreement that in order to be enacted, would have to go before the people. And the California ballot initiative process is famously unpredictable and messy. So we'll see. If you interview me again about this time next year, I'll have much better information than I can give now.

PULSE: I know earlier you mentioned Massachusetts and its plan. What is the initial feedback on how that plan is going? And how do you see the events in Massachusetts influencing California's debate?

MS: First, I think the passage of the bill in Massachusetts really stimulated forces in this state, and many other states, to take a fresh look at what states could do, and there was a lot of initial optimism. Now that a year has passed and a plan is settling in to execution, I think a couple of things are clear. First of all, as I said, the initial promise of their plan, which is that everyone will have coverage, has gone away as they've already exempted 20%. The enrollment of people who are required to pay full freight and get the subsidy, I think it's fair to say it's going quite slowly, and I'll be amazed if by July 2008, there aren't big discussions about either exempting more people, or raising the more or less symbolic contribution from employers, or raising taxes.

The other two things that have to be said about Massachusetts is that Massachusetts started out with a very favorable situation, in that it is a relatively small state, and that there are more uninsured people in California than there are people in Massachusetts. And second that their rate of uninsured was relatively low. They had a long history of an uninsured pool that was being paid to hospitals under a Medicaid waiver that was going to expire if they didn't do something, and so what I'm saying is that they started with a "best case scenario." I think that it is still too early to tell just how effective this plan will be in reaching people who are uninsured. So I think after some initial optimism, some of the hard business is now underway, and it's frankly too soon to tell what its successes will be. I will point out that this is not the first time that Massachusetts has passed a law promising universal care. It fell apart once before. But, that doesn't mean the Massachusetts plan isn't going to work, but what it does mean is that we have to be very careful about mistaking a press release or a passage of a law for the actual achievement of that law's intent. And several months is way too early to judge the success of these enterprises, which have tended to whither under the inexorable increase in cost in the past. Everybody is "in" when the talk is of expanding coverage, but when it comes to cost control and keeping that coverage affordable, all of a sudden, the room empties out really quickly. And so I think that's a big issue. The biggest problem I think with most of the efforts to expand coverage is that the coalition for expanding coverage is a lot bigger than the coalition for restraining costs.

PULSE: So moving on to the bigger picture then, how do you see the national debate over health care, with the upcoming presidential election, influencing the situation in California?

MS: I think the lesson we've learned from past efforts is that it probably doesn't help to wait until this problem is solved from Washington. I recently read a recap in the LA Times of their editorials on health reforms over the last 50 years and there was one statement in 1972 that said "all observers agree that in the next two years, Congress will pass universal health care coverage." That was 35 years ago. So, some of these same issues that one confronts on the state level about power of stakeholders, and difficulty of control of costs, are true at the national level as well.

One of the problems of trying to do this on a state basis is that the levers that are important in financing the system aren't controlled from the state. I will point out just two; Medicare and Medicaid. So, most hospitals get somewhere between 60 and 75% of their funding from a combination of Medicare and Medicaid. Nobody in California has any control over the Medicare budget or policy whatsoever. So, trying to build a system in California that is stable, and that includes stable financing for all the players here, when a significant proportion of that financing comes from outside of the state and is not under the control of the state, makes these things very difficult to do at the state level. Further, the bigger and more complicated and heterogeneous the state, the harder it is. And that makes California the hardest of all, perhaps.

So I think the good news, if you will, is that no one can run for President these days without having to say what he or she would do about fixing the health insurance system. And that has not always been the case. But, even those who have more conservative, less ambitious plans are forced

by the exigencies of this problem to articulate what their view is, what their plan is, and what their policy is. So I think that figures well because whoever gets elected will have gotten elected with at least, to some extent, a mandate of what he or she will do about health insurance. But, as a participant in the Clinton health care reform of the early 90s, I've got the scars to prove that just because you want to do something, doesn't mean you can necessarily get it done.

PULSE: One final, rather broad question. If there is one reform you would like to see in the health care system to promote access to care, and you may have touched on it, what would the reform be?

MS: Wow, one reform, that's a great question. Well, I'll give you two. One is, I think we've got to work very hard at our incredibly byzantine system of state-by-state micro-regulation of health care providers, facilities and institutions. In many areas, we have many people who are over-trained. We have doctors doing things that nurses should do. Nurses doing things technicians can do. We have technicians doing things that patients can and should be doing for themselves. And yet we can't ever get out of that because we have such a bizarre and byzantine system of regulation, all of which is supposedly in the name of protecting the patient, but most of which, in my opinion, is really more about protecting the providers than the patients. So, there are all sorts of things we could do in our system that we could do cheaply and simply, but that we do expensively and in a complicated fashion. That doesn't mean that there won't be things for doctors and nurses and technicians to do, but my opinion is that if we are ever going to have money to do the complicated, expensive thing, it will only be because we do the cheap, simple things cheaply and simply. And I think one of the reforms has to be to loosen up that state-by-state, incredibly mind-boggling, nitpicking regulation of who does what, where they can do things, and what has to be present in the places where they're done, etcetera, etcetera, and etcetera.

The second reform that I think is important is for the government to help create a system of standardization, both of technology, its format, and its languages, so that we can move information and clinical data far more efficiently and rapidly. I'm not a big fan of thinking that the way you will solve shortages is by training more and more people who require 13-15 years of training, then require very high salaries to compensate them for that training. I think the answer is in making the whole process more efficient. And a lot of that has to do with information technology. I think there are opportunities here for the government not to dictate what everybody does, but to set the standards and the rules, which is what it does in lots of other fields, and let the private sector with its capacity for innovation help us solve this access problem.

ANDREW C. VON ESCHENBACH, MD- COMMISSIONER OF THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Andrew C. von Eschenbach, MD, is the commissioner of the U.S. Food and Drug Administration and was formerly the director of the National Cancer Institute (NCI). Dr. von Eschenbach was President-elect of the American Cancer Society at the time of his appointment to NCI. A nationally recognized urologic surgeon and oncologist, Dr. von Eschenbach previously served as executive vice president and chief academic officer of the University of Texas M.D. Anderson Cancer Center in Houston, and held the Roy M. and Phyllis Gough Huffington Clinical Research Distinguished Chair in Urologic Oncology. Himself a cancer survivor, Dr. von Eschenbach's contributions to scientific literature include more than 200 articles, books, and book chapters. Many influential organizations have recognized his leadership and accomplishments, including the American Medical Writers Association, the American Urological Association, the Lance Armstrong Foundation, the American Radium Society, and "The Best Doctors in America" publication. In 2006, Time Magazine chose Dr. von Eschenbach as one of the 100 most influential people to shape the world.

A native of Philadelphia, Dr. von Eschenbach earned his medical degree from Georgetown University School of Medicine. After completing his residency in urologic surgery at Pennsylvania Hospital in Philadelphia, he was an instructor in urology at the University of Pennsylvania School of Medicine. He also served as a Lieutenant Commander in the U.S. Navy Medical Corps.

STEERING THE COURSE: HOW THE FDA IS NAVIGATING NEW DIRECTIONS FOR HEALTH CARE

PULSE: How has the regulatory environment for the pharmaceutical and medical device industry changed over the past 10 years? What have been the major drivers of these changes?

AvE: The change process is profound and radical, and it's not just affecting the pharmaceutical and medical device industry. It's affecting the entire domain of health, health care delivery, and health care products. The fundamental reason for this is that we're really going into an entirely new reality as it relates to health and health care. It's a reality that's based on what I describe as the molecular metamorphosis. So, the point of this, from a high level perspective, is that we have been practicing medicine in the past, in a model where all we could do was observe the manifestations of disease. Once we moved into the era of genomics and molecular medicine, we're now beginning to understand the fundamental mechanisms that are responsible for those diseases. So, we're not only observing, we're understanding. And those insights have created an entirely new portfolio of products that are able to impact disease or, more importantly, impact the preservation of health. So, what you're seeing in the pharmaceutical and medical device industry is a radical transformation that is a direct result of the progress that has been made in science and technology that's given us an entirely new and different perspective on the purpose of those products – how they impact human life, health and disease. So, we're seeing that from the regulatory perspective. We're seeing science as it relates to genomics, science as it relates to new fields like nano-technology, and we're beginning to recognize that science is leading all of us to a very different place.

PULSE: How do you foresee the regulatory environment progressing over the next decade?

AvE: I think the regulatory environment is going to be an entirely different reality in the next decade than it has been in the past. First of all, you have the impact of what I just eluded to – the impact of radical transformation that is occurring by virtue of advances in science and technology. You have that coupled with the fact that we are now seeing the impact of that science and technology, especially information technologies, that cause us to have to address issues with regards to

globalization, and, if you will, to recognize as author Thomas Friedman did, that indeed The World is Flat. We are now in a global market place rather than in a local or national market place. So, we have to look beyond our borders. We have come to the realization that things are no longer made in the USA or made in any other part of the world. They're more often than not assembled in a given location, while the parts and components come from a whole variety of places. You look at some of the parts and pieces that go into many of the cardiovascular devices and you find wires in the leads are coming from one country, and the batteries are coming from someplace else, and the software is from an entirely different place, and somewhere in Boston they put that all together. It creates an entirely new environment in which we have to work. The complexity of the products is increasing.

Think of miniaturization and what implications that has – as these devices get smaller, their complexity increases. You look at combinations of drugs and biologics that become solutions to problems. There is a rare patient that's taking one medication. There's a rare disease that's going to be cured by one single pill. There are no magic bullets. You're beginning to see the integration of diagnostics and therapeutics into these multiplex platforms. And that's going to be even more revolutionized by advances I alluded to earlier, such as nanotechnology. Nanotechnology is going to have a dramatic impact on some of these issues. Finally, the regulatory environment is going to be influenced by virtue of this molecular metamorphosis in which the future of health care is not going to look anything like the past than a butterfly looks like a caterpillar. You have to see medicine thru a prism where it's going to personalized, much more predictive, much more preventative, and much more participatory where patients are going to be actively engaged on a continuous basis in their care, rather than episodic recipients of care. So, you're going to see the environment dramatically and radically change.

I think one of the big challenges that you're focusing on at a school like Wharton is how to put this into context of the reality that all of this is embedded in a business model. Without the business model, without the entrepreneurship, without the financial return on investment, etc, you don't have viable, sustainable progress. So, there is in fact a need to rethink the models. Companies have built models around finding the blockbuster, magic bullet drug and are now realizing the need for change, much like the computer industry did. There is always somebody who is going to make a microprocessor. There is always going to be some company out there making a CD-ROM. But the fact of the matter is that as a consumer I could care less about your microprocessor or your CD-ROM. What I want is for you to put that all together into a laptop. I want the laptop. Patients are going to want solutions to their problems, and those solutions are almost invariably going to require the sharing of intellectual property from a variety of sources that put a drug, a vaccine, a monoclonal antibody, and a diagnostic platform together. They want someone to suddenly say, I have the solution for the detection, intervention and modulation of Alzheimer's disease.

PULSE: Some argue that personalized medicine is the wave of the future for the health care industry as the block-buster model continues to falter for pharmaceutical companies. How large an impact does the FDA believe personalized medicine will have on both the regulatory environment and the health industry as a whole? Is the FDA taking measures to promote the development of personalized medicine studies or is it reacting to industry changes?

AvE: The real important issue for the FDA is that the FDA has to be a bridge and not a barrier to this new future. We have to be creating a regulatory pathway that actually facilitates this kind of progress. So, I see the FDA's role as not being passive or simply waiting until somebody arrives on our doorstep with a new innovation or new product, and then we have to make a regulatory decision about it. But actually, we need to be out in the front helping to provide the kind of leadership that will enable us to understand what the new future will look like, and how to facilitate and create a regulatory pathway that is going to promote the discovery and development of those products. We need to provide leadership on how that can be brought to patients in the most efficient and effective way, while still ensuring that those interventions are appropriate, effective, and at minimal risk. So, I don't see us standing by as spectators. I see the FDA taking a very strong leadership role.

We've done some things like our Critical Path Initiative, which is intended to bring this new science and these new tools of technology into this regulatory pathway and process. To work

proactively on the front end by engaging with developers and discoverers, and helping to align that in a way that those products are coming into the regulatory pathway with us knowing as much as we possibly can about them at the molecular level so we can make better decisions about them. What we've done over the past year with the exploratory IND process is intended to provide that kind of leadership. I think we have to do a number of things along those lines. Patients have always wanted personalized medicine. I practiced medicine at the University of Texas M.D. Anderson Cancer Center for 26 years. Every patient who came in to see me with cancer knew that there was chemotherapy, knew that there was surgery, knew that there was radiation. What they wanted to know was what was best for them. Patients expect personalized medicine. So, this is not a new concept. What is new is that for the first time we actually are beginning to have the tools to really do that. I mean, my mother-in-law has always known that suggestion, "Take two aspirin and call me in the morning," can't be right for everybody. We all can look around, see our differences, and realize how can two aspirin be exactly right for everybody? Well, it's not. Be we never had the tools to figure that out. Now you can look at people from a genetic profile and recognize that they have different genes for the metabolism of aspirin.

We've just done a study, in terms of our leadership position, looking at a blood thinner, warfarin, and how to use genomics to appropriately dose that drug so that you get the right amount of drug for the right patients and you get the right outcome. We know that everything you put in your mouth has a potential benefit and a potential risk. You can take one aspirin tablet and it can have a benefit and it can have a risk. So, there is no drug that is ever guaranteed 100% safe, no drug that is guaranteed to be 100% effective. In the past, we have relied on a trial and error approach through clinical trials to try to figure out what the right balance is. How much of this drug gets me a good effect without unacceptable side effects. Warfarin happens to be one of those kinds of drugs where that range is very narrow. It's very easy to under-dose it, and it's very easy to over-dose it. You just don't have that much room on either side. With aspirin, you've probably got a fair amount of latitude, but you don't with a drug like warfarin.

So, from a Wharton School point of view, what's the problem with warfarin? Well, the problem with warfarin is that you've got a model that has a great deal of waste built into it. There's going to be a distribution curve in which many patients are not going to get enough warfarin, in which case they are going to have clots and will continue to have strokes and pulmonary emboli. So, you've got a huge cost associated with that because you haven't given the appropriate amount of med. Then you have on the other end of the curve a group of people who are taking too much so they are not forming any clots at all. They bleed – they bleed from their stomachs, and they just have a huge variety of problems. So there again you have huge costs.

So, when you look at our health care system, and you ask, 'What's one of the fundamental problems with health care?' it's the same way the Japanese looked at the problems associated with building an automobile. The biggest problem as it related to cost was waste. The cheapest way to build a car is to build it perfectly in the first place. The best and most effective cost model in medicine is to get the right patient the exact right amount of drug to get the exact right outcome. The quality goes up. It's optimal because the patients are getting optimal care, and the waste goes out of the system because you don't have complications. The most costly drug is the one that doesn't work or the one that kills you. I think these are parts of the story of where we are going with personalized medicine – how we are going to use modern science to make better decisions, better regulatory decisions, better medical decisions, and how we can provide optimal solutions to patients' problems.

PULSE: In what ways, if any, will your regulatory forecast be impacted by the outcomes of the 2008 presidential elections?

AvE: I don't think that politics is going to affect the outcome of what we have been talking about. I think the fact of the matter is this process is underway. It's not being driven by politics. It's being driven by science and technology. And that progress is going to continue. So, the drivers of change are in place, and politics is not going to alter that no matter who gets elected President. Having said that, who gets elected President will have a great impact in terms of where this process goes, with regards to its pace and its direction. I think it is extremely important that whomever the next president is that they recognize that this process is occurring. It is underway, and there are with it both challenges and opportunities. And this

country is going to have to address its leadership responsibility in that process in terms of where is it going to go. Is the U.S. going to continue being a leader or follower? Because you know what, it isn't like this is a secret! And it isn't like the rest of the world doesn't know what we're talking about. Europe is making huge investments in this area. I've just been in China and I happen to know their Minister of Health – he's a world renowned CA researcher, member of our U.S. National Academy of Science and Institute of Medicine – you think this is a secret to him?! So, everybody in the world knows where this is all going in terms of the drivers. What the world is looking for is who is going to lead? And I think the outcome of the next election is important as it relates to leadership and the future direction, but it isn't going to change that this process is occurring. It is occurring, irrespective of a presidential election.

PULSE: Does the FDA publically support one direction over another?

AvE: No, the FDA is here to support the science and to support the process of which science can help lead us to this better place. The FDA is only here for one reason and there are millions of people out there whose health and welfare are dependent upon getting access to the things we are responsible for regulating, including the food that they eat, as well as the drugs that they take, and the vaccines that they are giving to their newborns, and on and on. So, our job is to play our role and do our part. But the rest of it is in someone else's hands.

PULSE: Regulations on the medical devices industry have been increasingly tightened in recent years. Do you anticipate this trend to continue?

AvE: I'm not sure I agree with your premise. I think if we look at our own criteria and our legal basis upon which we've made pre-market approvals or clearances of 5, 10Ks, or PMAs, etc, nothing has changed. We haven't changed the rules. I think what has changed is the tools with which these devices are being developed and made, and the tools with which we are able to make regulatory decisions have constantly and continuously improved. The science and technology we have been talking about has resulted in major changes in these devices as it relates to their complexity. That has put us in the position of having to take a more sophisticated approach to the regulation. Earlier in the conversation I alluded to the concept of miniaturization. You might say a pacemaker is a pacemaker. But you know, that is just not true, because a small pacemaker is fundamentally different from a big pacemaker. You know why? Because the distance between the wires inside the pacemaker gets smaller, and when the distance gets smaller, the possibility of internal short circuits by virtue of the fact that electrons can now jump from one wire to another wire is different. So, can you apply the same regulatory process to a small pacemaker as you would to big pacemaker? The answer is no, you can't. Now, you might turn around and say, well, the FDA has changed the rules – it's tightened up its regulatory approvals of pacemakers. No we haven't. We're still applying the same regulatory rules. What's changed is the science. Just as the science made it possible to make a small pacemaker, we've got to use the science to make sure that a small pacemaker is not going to be subject to short circuits or problems of insulation, or that sort of thing. We're seeing bare metal stents now becoming drug eluting stents. We haven't changed the rules. The product is different. Pacemakers are now biventricular. We've got laparoscopic surgeries now going through robotic surgeries. Robotics introduces a whole new level of complexity into approval. So, I think we are still on the same foundation we have always been, which is that our decisions are based on science and they are based on a risk-based regulatory framework that says we will look at the benefits, we will look at the risks, we will look at the balance between the two, we will look at the need that this is intended to address – we will put that all together into an equation and render a decision. That hasn't changed at all.

PULSE: The cost of drug therapy and other technologies has come under increasing scrutiny. What role should the U.S. regulatory agencies play in terms of overseeing manufacturers' attempts to measure outcomes related to cost effectiveness?

AvE: First of all, I want to make it clear that the FDA has no role, nor should it have a role, in the pricing of drugs. I don't believe that is an appropriate area for a regulatory agency like the FDA to be involved in. That's not to say that the FDA should not be involved in consideration as it relates to cost. Where our regulatory process addresses that appropriately, we have to be thoughtful and mindful. There are a variety of ways in which we actually do that. One of which is, for example, as it relates to choices. So, with regards to generics – generic drug approval is

an important part in giving patients access to choices in the market place, and that has an influence on cost. Now, does that mean the FDA is involved in the marketing and pricing of drugs? No. But FDA is acting responsibly to be sure that people have options and that those options could result in people having access to those drugs at lower cost. One other way I believe the FDA could appropriately affect cost is to look at the regulatory process itself.

As I indicated earlier, we are taking an approach of being engaged in the total lifecycle of the products we regulate. We're no longer sitting here passively waiting for an application to arrive, then when we make a decision, that drug goes into the market place and that's the end of our responsibility. We are looking at our responsibility as being engaged in the total lifecycle, from discovery and development all the way through delivery. So, on one end we're engaged in much more post-market surveillance. Post-market surveillance involvement is going to help us understand the appropriate use of those drugs in the real world, in large diverse populations. We'll be able to start providing better information, better labeling as it relates to how those drugs should most appropriately be used. That gets us back to that model of waste where if we can continuously improve the utilization of a drug and eliminate many of the adverse events that are associated with that drug that has a reduction as it relates to cost. The more efficient and effective the regulatory pathway is, and the more guidance that we can provide, the more it might result in more affordable drugs. Our recent renegotiation of our prescription drug user fees and our medical device user fees provide resources for us to be much involved in pre-market consultations. We can work with companies to help them reduce the risk involved in some of that early development. Everybody talks about the funnel. You start off with a thousand and you wind up with one coming out the other end of the pipeline. But I think the tools of science and technology will now help us to understand these drugs and human beings in ways that will allow us to make better choices even before we subject large populations of patients to clinical drugs, to drugs that don't ultimately work, and we'll be able to be much more predictive about which ones will work. I think the FDA has to play a role in that. What will that do? That will reduce the cost of development. That then translates into more options and lower costs available to patients with a wide variety of conditions. If we can do this, then I think we have really fulfilled our mission to protect and promote the public health.

PULSE: Do you have any additional thoughts you would like to share with our readers?

AvE: I have a real affection and appreciation for Wharton. Specifically, I think it's a great tribute to all of you that you are focusing on this issue of health and addressing it in a way that doesn't simply focus on excessive health care costs, or how much of our GDP is being spent on health care, etc. Instead, you're stepping back from it all and asking more fundamental questions: In what direction is health and health care going? What are the drivers and what are the implications? Maybe we ought to be rethinking the whole equation rather than looking at one piece of it. I think it's a great storyline and something that we can't quite capture in a brief interview – it really requires an ongoing conversation. So, my hope is that this will be the beginning of a conversation. I hope I accomplished at least one thing with you today, and that is at the end of this interview I've created more questions in your mind than I've actually answered. I hope you all go forward rethinking the entire system and creating new, unique solutions.

SECTION THREE
SURVEY SAYS: EXECS FROM PHARMA, HEALTH CARE SERVICES AND INSURANCE WEIGH IN

Different players in the health care industry uniquely influence how patients access care, from the obvious and direct delivery of health care to more subtle interactions involved in everything from financing the care to providing various technologies or tools to enable that care. As we enter the final months before the 2008 presidential elections, it is clear that the current political environment could re-shape how these industry players influence patient care. The pharmaceutical industry is evolving in terms of how drugs are developed and promoted. Insurance companies are impacted by the debate surrounding payment for care, which could ultimately influence how their businesses interact with customers. Companies in the health care services space are using information technology to connect all of the players across the health care continuum to efficiently deliver care while potentially playing a unique role as a facilitator of change. We asked three health care leaders, representing the pharmaceutical, service, and insurance sectors, to share how the current political environment shapes their businesses and to give their vision of what the future holds. Adam Schechter, President of Global Pharmaceuticals at Merck, discusses the evolving value proposition of the pharmaceutical industry and the progress towards a new commercial selling model. Marc Owen, Executive Vice President at McKesson, describes how information technology can improve access to care and how the services sector is uniquely positioned to create value because it connects the different pieces of the health care system. Carol McCall, Vice President at Humana, Inc., examines the potential impact of the upcoming presidential elections on the insurance industry with insights into how patients' interaction with the system could evolve.

ADAM H. SCHECHTER - PRESIDENT, MERCK GLOBAL PHARMACEUTICALS

Adam Schechter is President of Global Pharmaceuticals at Merck & Co, Inc. In this role, he has commercial, P&L, and strategic responsibility for the Company's current and future portfolio of prescription medicines for the treatment of chronic and acute diseases. He also has operational responsibility for the U.S. Pharmaceuticals business.

Prior to his current role, Mr. Schechter was President of the U.S. Human Health Division. He served in a number of different roles before that, including Vice President/ General Manager of the U.S. Joint Venture with Schering-Plough Pharmaceuticals, Vice President, Arthritis & Analgesia Franchise Business Group, and Executive Director of both the A&A and New Products Franchise Business Group and New Products/Licensing. His experience also encompasses product management and sales.

Mr. Schechter serves on a number of boards and other organizations, including the National Pharmaceutical Committee, the Philadelphia CEO Chamber of Commerce, the Health Care Leadership Council, and the Merck/ Schering-Plough JV Boards. He also serves as co-chair of the Merial Animal Health Board.

Mr. Schechter earned his BA in biology at LaSalle University.

THE COMING PARADIGM SHIFT: RETHINKING THE PHARMACEUTICAL SELLING MODEL

PULSE: How would you describe the role of pharmaceutical companies in the health care system historically?

AS: Historically, the primary focus of pharmaceutical companies has been to develop new medicines that address important, unmet medical needs and thereby improve the health and well being of patients. To do this, companies in our industry invest billions of dollars every year in studying the safety and efficacy of their medicines. Through that process, we compile extensive information on our medicines that we then communicate to medical professionals around the world.

In the future, I believe pharmaceutical companies will continue to search for new medicines that improve health and will continue to study the safety and efficacy of their medicines, but the way we communicate information about our products and their value will change as we move forward.

We also will have to show how new drugs compare to existing therapies, and to show the value that they bring into the marketplace. We will need to convey the value of those innovations to a broader array of health care stakeholders than we do presently. And, we will need to broaden our communication to include not only medical professionals, and consumers where appropriate, but also to payers of all types around the world, including governments, managed care organizations and hospitals.

PULSE: What are some threats to the future of pharmaceutical companies?

AS: There continue to be many external factors that we must watch and adjust to – and how we respond as companies and as an industry will determine whether we meet those challenges and create opportunities in doing so. For instance, governments and payers are demanding more value, and consumers are becoming more involved in their health care. If we as companies, and as an industry, can successfully show that the 10% of the U.S. health care dollar that goes to prescription drugs provides real value and real benefit, that's a win-win situation.

Even though the industry invested a record amount of more than $52 billion on discovering new medicines in 2006, there are fewer breakthrough products coming out of the industry's labs and coming to market each year. And for the new drugs making it to market, it is becoming harder to show the value of new products above and beyond the existing options, including some generic medicines available today. That's a big challenge.

And overall, there is increased public scrutiny of our industry, and that means we have to work even harder to communicate the value we bring to the health care system.

PULSE: How do you plan to show this value going forward to consumers and to health care professionals?

AS: First, we have to continue to invest in the research and development of truly innovative products. Without new, first-in-class medicines that show significant value to our customers, it will be very difficult to be successful moving forward.

Factoring in external input from a wide range of customers very early in the development stages is also critical to delivering products that offer value. At Merck, we have created "early product development teams" charged with really understanding the perspectives of health care professionals, payers, as well as patients. Very early in the development of our medicines we are "building in" the types of benefits and kind of value our customers tell us they are looking for.

Once we develop products reflecting external input and delivering the value customers want, then we have to commercialize our products very differently than we've done in the past in order to truly meet the needs of our customers.

Right now, our industry focuses on the individual parts of the health care system. We develop programs designed to meet the needs of physicians, the needs of hospitals or the needs of managed care organizations. I believe in the future, we have to look at all of our customers and how they interact and how they work together. This understanding will help us better communicate the value of our medicines across our very different, but very important, and very interrelated customer segments.

PULSE: Given that there are so many external forces that you can't control, such as the FDA approval process, how do you influence the speed of R&D?

AS: First, any efforts to increase speed and efficiency in R&D must be conducted without sacrificing safety or efficacy. One example of how we're speeding development is by using high throughput screening. When you see how quickly we can look at different molecules today versus 20 years ago, it is remarkable. Another example is the use of new ways of compiling data from our trials. If you have all of your data electronically coordinated you can get the results of your studies faster than before and can be much more efficient.

When you start to think about the new information, databases, and technologies we have today, you really can begin to understand how we can be much more efficient than in the past.

PULSE: The current promotional model is very sales-force focused, and we were wondering what you see as the major challenges with that model.

AS: I believe that there will always be an important role for sales representatives to play in terms of communicating information to health care professionals. On the other hand, I don't believe that the best way to do that in the future will be to continue with the current model.

Today we discuss both the benefits and the risks of our medicines, but do it very systematically through what I call a "frequency" model, where multiple representatives talk with the same customers about our products. In the future, we will have to work more closely with our customers to understand what is important to them, what information they need, and also to understand the best way to get that information to them in an appropriate way.

There are some physicians who don't see professional representatives today. However, they do go on the internet, they do read journals, they do seek information on our products. So for those physicians, we have to find a better way to utilize technology to provide them with the information they value. There are other physicians who still count on the representatives to bring them information and like to see and spend time with representatives. In those instances, we have to provide representatives with significantly better

ways to communicate information above and beyond the product to help physicians improve their patients' health and outcomes.

I believe that all of the constituents in the health care system are ultimately trying to improve quality of care and the length and quality of life for patients. With that in mind, I believe we can help physicians, payers and consumers achieve those goals. Together, we need to focus on how we can bring the best care and value to the patients. In short, we must have a much more interactive discussion with our customers over time, rather than one that is only product-focused.

PULSE: Are you doing pilot studies right now? How are you actually going about trying to create this new type of commercial model to address some of these issues you've been talking about?

AS: It starts with bringing in customer input very early on in the development of our products, which we are doing. Once we launch our products, we are using multi-media and multi-channels, including professional representatives, e-technologies and other ways to best meet the needs of our customers and communicate important information to them.

In addition, we have a very significant pilot underway at Merck to which we've dedicated over 700 of our people. What we are doing in that pilot is organizing ourselves, and the way we work, around our customers. In the past, we focused first on product, and delivering product information. Now, we are changing the hierarchy to focus on our customers first. We are developing a deep understanding of our customers and their needs in order to develop ways that we can better interact with them and provide value in helping them improve patient health.

PULSE: Can you give us a better understanding, when you're talking about this new model, of what is actually happening on the physician's end and the sales force end? How is this actually being implemented?

AS: Traditionally companies have organized around a specific geography or around a product or set of products. What we're saying is let's first organize around customers. Organizing around the customer allows us to build a better understanding of the needs of that customer and therefore foster a more productive and valuable relationship. We are encouraging our professional representatives to be experts on understanding their customers, in addition to being experts on understanding our products.

We are also developing new solutions to help our customers, and to help our customers work together to improve quality of life and patient care. A good example of that is helping providers help their patients on compliance with recommended or prescribed treatments. For example, to help the physician communicate to the patient the importance of his or her compliance with recommended diets or exercise programs or drug therapy. At the same time, we also want to work with payers to encourage their beneficiaries to be compliant. If we can develop solutions that improve the quality of care and improve patient health by making sure that all of the players in the health care system are working together, that is a very different model than what we have today.

PULSE: Would you say that it essentially helps them do their jobs better as well?

AS: We are trying to help them improve patient health, help them interact with their patients in a different way, and help them to achieve the results that they are seeking for their patients. I believe that by working together with a common goal, to improve human health, we can all do our jobs and serve patients better.

We recognize that our customers have unique needs, but we also want to find ways to work with them so they can work together for better patient health.

PULSE: Anyone who has worked with physicians is familiar with the challenges of incorporating any kind of change into the clinical space, specifically with regard to information technology. I know when pharmaceutical companies look to the future, a lot of the changes are around incorporating some sort of IT improvement, such as being able to go online and get information. In addition to the potential IT challenges, what do you see as some of the general challenges to implementing this new model?

AS: Over time, physicians, payers, and consumers are changing significantly in how they gain and process information. It is remarkable to think that 20 years ago, the internet and cell phones were

not widely used. Not every person is going to utilize the technology at the same time. You must have multiple offerings for physicians and other customers that best meet their needs.

To be innovative as a pharmaceutical company, we have to look out into the future and understand the technologies that exist and set the pace for change. We also have to realize that not everybody is going to move there at the same time. Therefore, we have to develop and make available multiple ways to meet the needs of our customers and provide convenience for the way they want to get the information. It is really fundamentally different from the way we do it today.

PULSE: The next thing that we were wondering is whether you think the first company that is able to successfully develop a model like this will have a competitive advantage in the marketplace. Does this provide incentives to companies to work towards such a model? Or do you think it might be positive for companies to be able to easily copy a new model, that it would benefit the industry as a whole?

AS: I believe the first company moving into this new model will have a competitive advantage. That is why we are moving so fast and spending significant resources to develop our new model at Merck. In addition, I realize that there are always companies that will try to replicate a model based upon proven success. One way you can continue to differentiate yourself is through truly understanding your customers and meeting their needs and through speed, agility, and continuing to look for the next innovation. I believe that one competitive advantage you have is getting to the new model first, and then continuing to innovate and to change that model over time. The key is to move to the new model quickly and then to continue to innovate and improve over time.

PULSE: It must be difficult to keep any innovative ideas secret, because you rely on the interaction with physicians, and the physicians are dealing with multiple pharmaceutical companies. So there must be a leak of information very quickly between the pharmaceutical companies and the health care professionals. Is that a fair concern?

AS: Competition is much more intense than it has been in the past, and it is much more difficult to keep a competitive advantage secret when you have the significant number of customers that we do in this industry. You can't roll out a new initiative slowly and expect that your competitors won't know about it. Once you begin to roll out a new initiative, you have to move quickly and you have to continue to innovate and refine your model over time.

PULSE: Going back to the current selling model, what effects do you think that has had on enhancing opportunities for increasing patients' health care outcomes within the existing health care system, versus the access that we hope they will have in the future with the new model?

AS: Let me take a step back and say I believe consumers trust their physicians and that consumers also trust their pharmacists and other health care professionals.

However, I think that consumers find it difficult to trust or understand the health care system that they are involved in overall. In general, I think that they are unhappy with the amount of time they receive from various health care professionals and that they are also seeking more information on their own.

To the extent that we in pharma can play a role in integrating the needs of our customers – of health care providers, consumers, and payers – and give them both product-specific information and resources that can help them improve patient outcomes, I believe that patients will become more satisfied overall.

If we can find ways to help our customers communicate with one another better, provide them with ways to increase compliance and offer other important initiatives, then together we can improve patient access and also improve patient outcomes.

MARC OWEN - EXECUTIVE VICE PRESIDENT OF CORFORATE STRATEGY AND BUSINESS DEVELOPMENT, MCKESSON

Marc Owen, Executive Vice President, Corporate Strategy and Business Development, joined McKesson in 2001. Prior to that, Owen was a senior partner at McKinsey, advising pharmaceutical manufacturers, healthcare providers, distributors and technology companies, including McKesson, for more than a decade. He was the founding partner responsible for establishing McKinsey's presence in Silicon Valley and a leader of McKinsey's Business Technology office globally. Owen was also president and chief executive officer of a small software company, MindCrossing. Owen, who was born and raised in Wales, was trained as a lawyer in the U.K., and also holds an MBA from Stanford University.

BACK TO BASICS: COMMON SENSE SOLUTIONS FOR ACCESS TO CARE

PULSE: Please describe your view on the most pressing issues facing patients' access to health care.

MO: First, I would start with a fundamental concept that often gets lost when we talk about health care. That's the fact that every health care system has to figure out a way to ration health care, and every system does it differently. The U.K. used to do it and still does to some extent through wait times and by deciding which drugs get covered and which don't. Other health care systems do it by giving you a base level of care; everyone is entitled to that base level and people who want more can buy more. The U.S. has historically rationed health care through the insurance system and by providing a safety net through Medicaid and emergency room visits, yet the result is that we still have 47 million uninsured people. It may not be the conscious way it was done, but this is the net effect of how we ration health care in this country.

As we look at potentially better ways to ration health care, we start with a few basic principles. First, we believe market mechanisms are the best way to do this, just as they are with any other good or service. Second, we think some of the restrictions of insurance need to be opened, such as regulations across state lines. And third, the tax system needs to be changed. Individuals should be able to buy insurance with pre-tax dollars, just as employers do today. We think that if you open up along these lines then you will open up access to health care. It will be a much better way to answer the question of how to ration health care and how to provide access to health care.

Beyond that we also believe there are ways, even within the current system, of trying to make sure that the right patients receive the right care in the right places. One of our businesses at McKesson is triage – basically, a patient calls a health line and will be advised (along a spectrum) to go to bed and take an aspirin, or to go to the emergency room, or to go see their doctor in the morning. The cost of different access points within the health care system varies tremendously starting with the emergency room as the most expensive, then the physician office, then the pharmacy, then basically what you can do by self-medicating from home. Today in our health care system, the right people don't necessarily end up in the right setting

of care. So even within our existing system there's a lot that can be done to improve access to care and reduce the use of the most expensive setting, the emergency room.

Our general theme across McKesson is that there is a spectrum of things that can be done to improve the health care system. There are policy things that can and perhaps should be done. There are also a lot of operational things that we know how to do, that the system already has in place, and that can improve the overall quality and efficiency of health care. If the health care system were a corporation then you would say there are certainly strategic policy things we can change, yet there is also a lot left to be done on the execution side.

PULSE: What are some of McKesson's product offerings that perhaps will address some of the operational deficiencies you previously highlighted?

MO: There are several opportunities to change quality and outcomes of health care. The first is adoption of accepted clinical practices. If you look at the numbers today, somewhere in the range of 55% of people actually get the care they should receive if their physician is following evidence-based best practices. There are a number of studies on variation in clinical care by doctors. Making sure we get clinical best practices and accepted best practices – these are not cutting edge, experimental technologies; this is basic blocking and tackling. For example, how you treat diabetics or asthmatics or cardiovascular disease. McKesson is doing a lot around getting those evidence-based protocols into the practice of medicine through our disease management programs (where we are the leading provider of disease management to Medicaid populations) or through the adoption of electronic medical records in the physician office which include those evidence-based protocols. Or through physician order entry for selecting and ordering lab tests and medications, for instance, and the evidence-based clinical guidelines that are embedded into our clinical systems for hospitals. Or in arenas like medication therapy management, which is a platform for allowing pharmacists to intervene properly when patients are taking multiple medications.

McKesson tries to close the gap and get that 55% up to a much higher number. We try to make it easy for clinicians to practice medicine in accordance with accepted guidelines. It's not that physicians don't want to practice in accordance with these guidelines, but it is an issue of making it easier to do that today by embedding those rules and guidelines into the natural work flow. The level of knowledge needed to practice in accordance with these guidelines is more than one person can reasonably keep in their head.

A second opportunity to improve the health care system is to address the $300 billion that is wasted in terms of operational or administrative inefficiencies. McKesson is very focused on this problem. Our solutions can be everything from eliminating paper prescriptions through e-prescribing or making it easier for patients to pay their bill through online billing or it could be through removing a lot of the back and forth that occurs between payer and provider by taking things like eligibility and lab orders or lab results and making these processes electronic so that you can go from a $25 transaction to $0.25 transaction.

A new McKesson entity called RelayHealth has been created to actually connect all the pieces of health care. Traditionally the payers and the providers were all disconnected and what we have tried to do is create a network – or connectivity – between all the pieces of health care in the same way our core pharmaceutical distribution business makes the physical transfer of medicines between a supplier and retailer easy; we have been focused on that physical connection side for 175 years. Now we are building a "parallel" system around the flow of information. Today, roughly $1 trillion worth of medical and pharmaceutical transactions go through our systems, from traditional financial claims to eligibility authorizations to electronic prescriptions. We do 8.5 billion pharmacy transactions alone, per year. We are trying to build the network that, for example, Kaiser has built – because it is a completely closed model, everything is connected. We want to enable anyone who wants to be a virtual Kaiser to be that, by putting together the pieces in that way.

We also have a company we acquired, our original RelayHealth, which allows physicians to conduct e-visits with patients. For example, if a mother with two children has one child who comes down with an ear infection, then instead of having to take two kids to the doctor's office, and if this is a doctor they have dealt with before, then the mother can simply go online and answer a

structured set of questions. The doctor can provide the diagnosis online, write the prescription online and send the prescription electronically to the pharmacy. All the mother has to do is pick up the prescription at the pharmacy. This is an example of a $30-$40 medical visit, rather than a $100 office visit.

As another example, we've used a similar network to launch a lab results delivery service. So if you are a hospital lab or outsource lab and you do a set of tests, and then you need to get results back to the patient, primary care physician or specialists who treat this patient, our network allows these orders and results to flow electronically. So when the primary care physician sees the results and wants to make them available to the patient they just click on a box and the patient is told. Again, the doctor's office doesn't have to make the phone call and say "your lab results look fine" or copy them and put them in the mail. McKesson's products are making these kinds of things much more efficient.

PULSE: What challenges do you face when introducing new and innovative products or technologies to your customers in the health care industry, especially given the changes in behavior you are introducing into the system?

MO: There's a perception that health care is backward in adopting technology. I would argue that that's a misplaced perception. Part of what's going on here is that the technologies that mainstream corporate America adopted 10-15 years ago were around the PC and enterprise resource planning systems. Many of those technologies were not very well suited to health care. Newer technologies, like ubiquitous wireless technology, RFID, portal technology, and web-based technologies, are simply better suited to health care. The health care industry is actually adopting these newer technologies quite quickly. Let me give you a few examples of the challenges to technology adoption. People have always talked about the challenge of getting physicians to adopt technology, particularly around adoption of physician order entry. One of the things we discovered as we went through building our business, is that if you start with relatively simple things and don't try to make the big changes in workflow and the big changes in technology at the same time but rather do it incrementally we found you get better benefits.

For example, we have a physician portal that will allow a physician to sign off on medical records, allow the physician to view images, allow the physician to see his or her schedule, or to see lab results on line and so on. We first introduced the ability to sign-off on medical records. That started the physician adoption because it saved time. They didn't have to go, for example, to the basement of the hospital to find the record and sign-off on it. They could do it online from their office or from home or wherever. We started to introduce that portal technology and get the physician used to using that technology and then we added the capability to view images, and then we added scheduling through that portal once they were used to using it. And now McKesson gets in excess of 3 million log-ins per month on that portal. Once that's in place, then the last step is physician order entry; by that time the physician is very used to doing a lot of their practice online. The last piece of physician order entry is the biggest change in behavior but it is a much easier thing to change because you are not introducing them to the technology at the same time as the change in workflow.

PULSE: Do you face any challenges from a cost perspective in terms of convincing your customers of the economic value of these products?

MO: There are two challenges that you're always going to deal with in health care. The first challenge is that the provider community in US health care, with a few exceptions, is largely a cottage industry. You have 550,000 doctors and about half of them are in practices of two or fewer doctors. You have 5,000 hospitals and many of them are not-for-profits and many of them are units of one, two or three hospitals. The result of this dynamic is that IT departments and technology expertise are simply not there to drive adoption. If you think about other industries it's easy for Goldman Sachs and Citigroup or BP or Shell to adopt technology because they have hundreds, if not thousands, of people in their IT departments. But most health care providers have one or maybe two people in a small department driving their IT, and the level of sophistication and the ability to absorb more is limited. What we're finding over time is that – and we will see this as an increasing trend – software as a service and introduction of simpler technology that reduces total cost of ownership are good levers.

The second challenge in health care technology adoption is the fact that the people who get the benefits from something are not always the same people who pay for it. For example, the payer may get big benefits from e-prescribing but you are asking the doctor to make the investment. One of the roles that McKesson plays is to act as the intermediary to help make that market work. If there is an incentive that a physician needs to adopt that technology and the payer should be paying that then there is a mechanism for doing that by having someone sit in between who can say – "if you, the payer, have this problem because you are getting all these paper prescriptions that are illegible and you, the doctor, are frustrated because you are getting all these calls to your office about illegible prescriptions" – If the payer is able to provide incentives to the physician to adopt technology properly, then you can do this.

We've had numerous examples over the years of health care businesses that are all about making that market work so that the right incentive can be put in place for the person adopting when the benefit is going to someone else. There are many businesses in health care that are so-called network businesses where the payer is going to say "why should I pay for it when there are no physicians adopting it?" and the physician is saying "no payer is willing to give me incentives, so why should I do it?" Some of these businesses require more time to take hold in health care because you have to build the critical mass. You have to get enough payers on board and you have to get enough physicians or patients on board.

McKesson is the only company that actually sees all the players and pieces of health care. Every manufacturer is a customer, every payer is a customer, virtually every hospital is a customer, nearly 35,000 pharmacists are customers, 250,000 doctors are customers. Because we see all of health care we understand how a payer thinks, and we understand how a hospital thinks, and we understand how a pharmacy thinks. We can see their economics and realize that there would be benefits to both sides here if we could solve this problem and then we could get a customer who is a payer and a customer who is a provider together and say – "why don't we help solve this problem together?"

CAROL J. MCCALL, FSA, MAAA VP, RESEARCH AND DEVELOPMENT INNOVATION CENTER HUMANA INC.

A fellow of the Society of Actuaries and a member of the American Academy of Actuaries, Carol has almost 20 years of experience in the healthcare field. She has served as an actuary for a number of health plans and as an actuarial consultant with Milliman.

In non-actuarial roles, while serving as Humana's CIO, she designed information strategies to transform data from being mere 'exhaust' from its business into something that could be used in new ways. As Humana's Vice President of Pharmacy Management, she was responsible for managing the strategy, operations, contracting and clinical programs for $1 billion of pharmacy spending by Humana's members. Ms. McCall was also Executive Vice President for Allscripts Healthcare Solutions, creating e-prescribing, electronic health record and clinical decision support solutions for physicians and their practices.

Carol re-joined Humana in 2002 to launch their Center for Health Metrics, part of Humana's Innovation Center. She introduced novel techniques into the field of healthcare prediction, leading teams to create new methodologies in knowledge discovery and computational health intelligence to predict future health, severity and healthcare behavior. These models, along with other innovations in predictive modeling and advanced visualization, have become integral components of Humana's consumer-centric strategies.

She is currently Humana's Vice President of Research and Development where she continues to advance Humana's capabilities in computational health intelligence, creating new ways to characterize, understand and engage consumers. She also leads Humana's Health Service Research Center, a partnership with the University of Miami, focused on health services and outcomes research, pharmacovigilance studies, biomarker research services, and wellness and health behavior strategies that improve patient experiences and outcomes.

Carol is also a member of the National Committee on Vital and Health Statistics (NCVHS), a congressional advisory committee to the Secretary of Health and Human Services on national health information policy, and serves as a member of its Quality Workgroup. She also sits on the board of the University of Miami / Humana Health Services Research Center, is a member of the HRP Scientific Program Board and a member of Icosystem's Industry Expert Panel.

CUSTOMERS ARE KING: HELPING PATIENTS ACCESS CARE

PULSE: What implications do the upcoming political elections have on the health care industry, particularly the insurance industry?

CM: I get the sense people are ready to address the issue of health care reform and in particular, access to health care. When people talk about reforms which address access issues, it's usually based on the idea that a key barrier to access is health care financing, which eventually turns into issues about health insurance, who has it and how it gets paid for. So, I see insurance reform being one of the first issues that people address.

Insurance reform can take a variety of forms and while there are different proposals out there, most have elements which include individual mandates, portability of coverage, and guaranteed issue of insurance. But for reform to work well, there are other things you need to have, too, such as risk adjustment mechanisms, rating boundaries and/or restrictions and perhaps some sort of reinsurance pool for truly catastrophic claims, because no risk adjustment mechanism is perfect. These latter elements create important protections, for individuals, from extremely high insurance rates, and for payers, from disproportionately higher risk pools, which also remove any incentives payers might have to try and cover only healthier people.

One of the more obvious consequences of such reform would be a change in the employer's role. Today, many employers actively manage the health insurance options available to their employees. I think reform would accelerate the decline of employers playing this role, though it has been central for many years.

A much bigger impact will be to the insurance industry itself because reform will fundamentally alter the basis on which payers do business and compete. The first consequence, because of rating restrictions and risk adjustment, is to place boundaries around existing business models, restricting a payer's ability to profit from risk selection and risk management. As these business models change, it will force companies to seek new ways to thrive. The second consequence, because of guaranteed issue and portability, will be to change the value proposition payers must offer. When consumer-customers can come and go as they please, they will surely test the value

they think they're getting.

Taken together, though, these consequences hold the possibility that reform could fundamentally change the nature of the relationships between payers and their consumer-customers. Rather than a two or three year relationship, which was interrupted because the employer changed payers, there can be relationships that last for decades. Payers will become interested in people's overall health, not just their health care needs. More important than even the reforms themselves, is the potential for a paradigm shift in the way things are today which can be tremendously valuable. But it will only happen if reform is done correctly.

PULSE: Do you see the mandates being pushed through some states such as Massachusetts and California significantly impacting the national debate? Do you think the individual mandates under consideration by the states are good for health care reform?

CM: The states have a long track record of serving as labs, in a way. One of the silver linings of having insurance regulated by the states is that individual states can try things where it wouldn't be easy to reach consensus at a national level. Everyone can learn from these "experiments" and find out what works.

It would be difficult to accomplish what we've been discussing for reform, though, if it were to continue to be regulated only at the state level. We need the ability to regulate entities by a single set of comprehensive rules as opposed to always being state-by-state where everyone requires something different. This fragmented system adds tremendous cost and administrative burden and gets in the way of relationships with consumers because what I can do for person A who, lives in Illinois, can be fundamentally different from what I can do for person B, who lives in Florida. There have been discussions from a regulatory perspective, of finding ways to charter entities at a national level. It would be analogous to banks, with two paths to being chartered, so you could be a national player or an individual state player.

I also see the current Medicare Part-D prescription drug program (PDP) as a kind of national experiment. It actually uses many of the mechanisms that would be used within broader insurance reform. PDP's use of risk adjustment mechanisms on a massive scale has taught us a lot we can use as we go forward into broader reform. It removes the ability and incentives for payers to profit from risk selection and they become equally incented to attract and retain customers who are less healthy and those who are healthier than the average.

But the long term nature of the health care debate needs to move beyond issues of access. The real conversation shouldn't be about whether people have access to care. It should be about what kind of care is best and what the best choices are for them. To do that, we need the ability to answer those questions. But we can answer those today, not because we're focused on access but because we lack the appropriate feedback mechanisms from data and analysis to actually know the answer. And it's here that we need something new. We need research that actually understands which treatments work best and compares their effectiveness. We can use our current reform as a leverage point to do this kind of research by requiring minimum data sets as a part of reform. If we don't, we're missing a big opportunity. Before we can have true pay for performance or begin to measure whether a treatment has been successful, we must first define success and have the ability to know success when we see it.

PULSE: We talk about improving access to health care as a big theme in the current political debates, but another issue in the debate is cost. What has Humana done to reduce costs, for example, if patients already have broad access to care, and create solutions to more actively engage the patient in their health care?

CM: Part of health engagement is getting people to think differently about health. One way to do that is through benefit design. We have a variety of innovative designs which we started creating back in 2000. By offering more choice in benefit designs, we got away from the Model T world of health benefits. We introduced more choice and different designs, as well as personal care accounts, health savings accounts, and alternative financing arrangements for people with high deductible plans. These latter plans include lines of credit which help people if they have unexpected expenses. Let's say you consider yourself to be relatively healthy and decide you want a $5,000 deductible plan. But then something unexpected happens, and you find yourself with $4,500 of

expenses. It's something you knew might happen, which you'd decided you could afford to pay, but perhaps not all at once. This way you don't have to write a check for the entire amount but can pay it over time. This kind of "peace of mind" benefit can make high deductible health plans much more accessible and appealing to people. It gives them the assurance that if something does happen, they can pay for it without having to write a check for the full amount. The idea behind these innovations in benefits is to broaden people's view, from the narrow world of "what's my co-pay" or "what's my co-insurance," to a broader view of how they actually finance maintaining their overall health.

There are other innovations in benefit design that make people become more aware of the true cost of health care and help them make different choices. One in particular, uses an allowance for prescriptions instead of using co-pays. Rather than, say, a $10 or $20 co-pay for drugs, it provides allowance which pays up to that amount for a prescription, where people keep the difference for things under the allowance. Unlike copays, which hide the actual price of medications, people become exposed to the full price and learn to identify and compare opportunities to save money. It's a subtle shift in design, but we've seen a big impact on behavior.

For other types of health engagement beyond benefit design, we create innovations in everything from personalized reward programs, to clinical services programs focused on helping people better live with chronic disease, to health games and personal mobile coaches. We've started a company called Sensei, which delivers a personal mobile coach for diet and fitness on your mobile phone; helped create Health Miles, an activity-based reward programs; and launched companies like Green Ribbon Health that focus on helping people with chronic disease. We create a continuum of programs that extend from prevention and healthy activity to severe chronic conditions. What they all have at their core is the idea of finding new ways to engage people in the creation and maintenance of their health.

PULSE: In what other ways will the patients' access to health care change in the future?

CM: There are two other areas I'd like to talk about. They go back to the first part of the conversation about reform and what you could do if there were requirements around minimum data sets. If something were included as part of reform, imagine what could be done! One area in particular is pharmacovigilance and drug safety. Here, the health care system has done a poor job embracing the idea of "do no harm." There are millions of serious adverse drug events every year, which are estimated to cause more than 5% of all hospital admissions. Given the way clinical trials are conducted, it is very difficult to identify more rare events, meaning, these events are rare in the clinical trial itself but not as rare in the broader population. And so it's with this as a backdrop that we're pursuing a very explicit strategy around post-marketing surveillance of drug safety in partnership with University of Miami. With Humana's data, we will be able to look at new drugs and monitor which ones are leading to adverse events. We will also be able to see how new drugs react with existing ones and the context in which adverse events happen. The information in the data we have becomes a kind of signal or divining rod for high-risk situations that can be used to identify when people are at risk. Communicating this risk has a tremendous value to the broader population as well as insurance players like Humana.

The second area that we are pushing forward in is personalized medicine. Personalized medicine is emerging out of a convergence of forces that come from completing the mapping the human genome and the maturing of technologies that can harness that information, and the pressures on drug manufacturers. Given what is happening to the business models of drug manufacturers, whose blockbuster strategies are losing steam, there is a significant interest in new approaches to pharmaceutical interventions. Rather than a one-size fits all approach to drugs, personalized medicine promises a more laser-like focus of niche therapies, including biomarker diagnostics, which allow doctors to predict, diagnose, and assess treatment efficacy in ways that simply weren't possible before. The research to create these products is done by others, but Humana facilitates this by enabling studies to be conducted with volunteer participants from Humana's membership.

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Universal Access … West Coast Style

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Customers are King: Helping Patients Access Care

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The Yellow Jaundiced Baby: Will our Kids get us Universal Coverage?

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