Fall 2008 Volume 8, Issue 1

# TuftScope

The Interdisciplinary Journal of Health, Ethics, and Policy

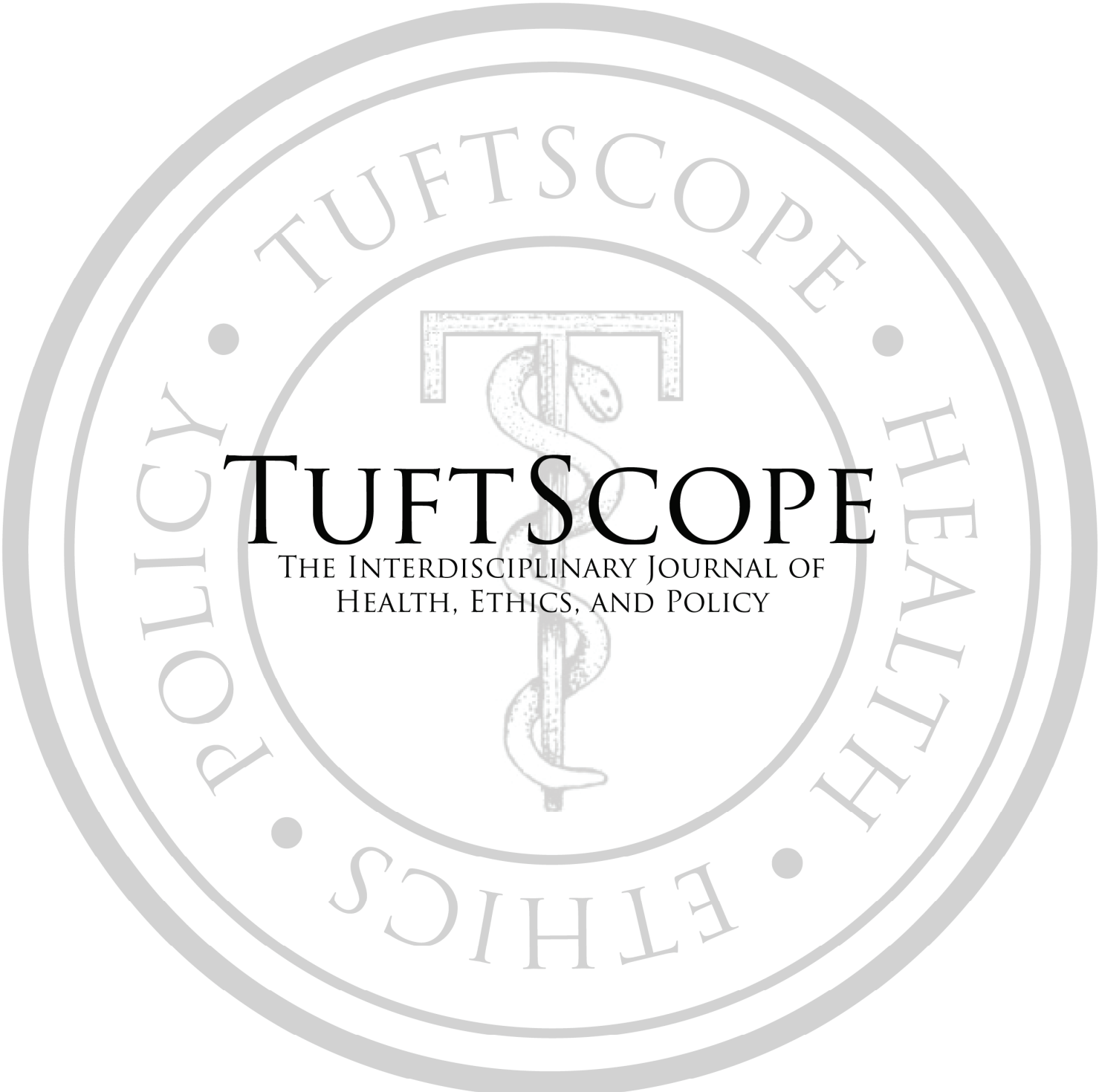
## Pharmaceutical Patent Laws:

### Are they necessary, or are they reducing access to important new drugs?

## Featured Articles



A Publication of TuftScope, the Student Bioethics Organization of Tufts University




# TuftScope

The Interdisciplinary Journal of Health, Ethics, and Policy

## Journal History

Since 2001 *TuftScope - The Interdisciplinary Journal of Health, Ethics, & Policy,* has provided an academic forum for discussion of the pertinent healthcare and biosocial debates in today's world. The Journal addresses different aspects of healthcare, bioethics, public health, policy, and active citizenship. It is operated and edited by undergraduate students of Tufts University, and advised by an Editorial Board composed of Tufts undergraduates and faculty. Today the Journal is one of the few peer-reviewed undergraduate published journals in the country.

## Publication Information

**Established:** October 15, 2001
**ISSN**: 1534-7397
**Publication/Archive:** Bi-annual (Open Access); Tufts University Digital Archives; TuftScope Website Archive

## Copyright Information



## Subscriptions

Subscriptions to the print edition of *TuftScope* may be obtained by filling out and mailing the "Subscriptions Form" on our website. Electronic delivery of *TuftScope* is also available.

## Submissions

Submissions on health, ethics, and policy topics from students, faculty, and individuals are welcomed in *TuftScope*. Both research papers and topic specific commentaries are welcomed. For more information please visit the "Submissions" page on our website.

## Contact

**Email:** TuftScope@gmail.com
**Website:** http://ase.tufts.edu/TuftScope
**Address:** Available on Back Cover.

## Editorial Staff



*©2008 TuftScope is published biannually in conjunction with Tufts University, Medford MA.*
*Founded in 2001, TuftScope receives funding from the Tufts Community Union Senate.*
*For more information, please visit http://ase.tufts.edu/tuftscope*

# Inside This Issue

## Commentary



## Interview



## Healthcare Review



## Opposing Viewpoints



## Featured Articles



## News



# Letter from the Editor

Dear Readers,

Thank you for reading this issue of *TuftScope*. Many of you may have noticed that this issue is very different from our previous issues. For the first time, we have chosen to concentrate on a specific bioethics issue. Our Opposing Viewpoints articles and Rachel Rizal's Feature Article highlight the delicate balance between access to drugs and fair compensation for pharmaceutical innovators. Opposing Viewpoints is a new feature that presents two sides to a current bioethics debate. I hope it will foster discussing within the Tufts community and beyond.

The bioethics and health-related issues discussed in this edition of *TuftScope* are pertinent to everyone's lives. While Tessa Novick and Allison Werner-Lin specifically present research on Asian and Pacific Islander communities in their article "Asian and Pacific Island Healthcare," she highlights a overall need for culturally sensitive healthcare. *TuftScope*'s own Margaret O'Connor considers improving healthcare quality in her article, "Pay for Performance: Persuading Providers Using Lessons from Home and Abroad."

This is an exhilarating time for a health and bioethics journal. The world of healthcare, bioethics, and health policy have changed rapidly in the recent months. With the election of Barack Obama, even more dramatic changes may be on the way. As an addendum to this issue, we have included a news section to keep you up to date with all of these changes.

In total, this has been an exceptional semester for *TuftScope*, both as a publication and as a student organization. We remain one of the few undergraduate bioethics journals in the nation. Our submissions and review process has become much more rigorous and selective, thus increasing the quality of our content. The *TuftScope* staff have amazed me with their dedication this semester, and I send them my thanks for helping produce our best issue yet. I invite all Tufts University undergraduates to join the staff. As an interdisciplinary journal, the quality of our publication relies on the diversity of interests and studies of our staff members. As always, I send gratitude on behalf of the entire Editorial Board to our faculty advisors for their guidance and expertise.

I hope you enjoy this issue!

Sincerely,

Cole Archambault
Editor-in-Chief

# COMMENTARY

## COMPLICATIONS WITH STUDENT HEALTH INSURANCE

*Aaron Marden**

In 1988, under the Dukakis administration, the Commonwealth of Massachusetts was set to take on healthcare reform by creating a universal health care law.[1] Unfortunately, the law was never fully realized. Only one aspect of this health reform, the Qualified Student Health Insurance Program (QSHIP), was preserved.[1] This will be the 19th year that Massachusetts requires every full-time and part-time (enrolled in ¾ of a full curriculum) student to be covered under some form of health insurance.[2] This mandate stipulates that a student may obtain health coverage as a dependant on his or her parents' plan, through an employer, or as an individual consumer on the private market. However, as many students are unable to find health coverage via these avenues, each university in Massachusetts must provide a student health plan (herein referred to as a "QSHIP plan") in which students may enroll.[3]

The website of the Division of Health Care Finance and Policy states, "One of the primary reasons for a mandatory student health insurance program in Massachusetts is to promote students' access to quality and comprehensive health insurance."[3] I believe the two words "quality" and "comprehensive" are perhaps the most comforting words you can say to an individual regarding his/her insurance; unfortunately the reality of QSHIP plans is that these two words are very poor descriptors of the current state of student health plans.

There are many problems with QSHIP plans, ranging from the customer service and underinsurance aspects that are features characteristic of the dysfunctional U.S. health care system to the annual benefit cap and per-service caps that are rather unique to QSHIP plans. Annual benefit caps are a rather straightforward feature of QSHIP plans; essentially, an annual benefit cap is the maximum amount that your health insurance will pay out in a given year, irrespective of the actual costs you incur. The current state law requires that QSHIP plans must place their annual benefit cap at $50,000 at a minimum.[3] If you are unfamiliar with the average cost of health procedures, surgeries, and other forms of health care, let me assure you that this cap is frighteningly low.

*** Author Contact Information:**
Tufts University, Class of 2009. Address correspondence to Aaron.Marden@tufts.edu

Per-service caps, often called internal caps, are the maximum payout for certain procedures covered by the plan. For instance, all community colleges in Massachusetts are under the same plan which implements a $50,000 annual cap.[4] Additionally, the plan includes a $1,500 cap on all outpatient services. [4] An outpatient service is a medical procedure, surgery, or test that does not require an overnight stay. Examples of these outpatient services, as described by the Bunker Hill Community College benefit plan, include medical emergency expenses, x-rays, injections, emergency ambulance services, tests, procedures, radiation therapy and chemotherapy for cancer, physiotherapy, and braces.[4] With this myriad of expensive procedures all limited to such a startlingly low benefit cap, it is easy to see how a purportedly "quality" and "comprehensive" QSHIP plan can provide students with little actual coverage, leaving him/her at great risk for accruing medical debt.

Sadly, the aforementioned shortcomings merely scratch the surface of the problems associated with student health plans. All health insurance providers are allowed by law to exclude coverage for certain procedures, and QSHIP plans are no exception. For the sake of continuity, I will continue with the community college health plan to illustrate two noteworthy exclusions (although there are many). First, the community college QSHIP plan offers no coverage for prescription medications. Consequently, a student must bear the entire financial burden of filling a prescription without any assistance from his/her insurer. This includes necessary antibiotics, birth control, medication for mental illness, medication for chronic illness, and any other substance that a physician deems necessary for the student. Given the high cost of drugs in our society, students may therefore be forced to choose between necessary prescriptions if they cannot afford to fill more than one at any given time.

Second, although preventative care is technically mandated by the QSHIP regulations, it is absent in many of the plans. For example, exclusion eight in the community college plans states that, "Immunizations, services and supplies related to immunizations, [and] preventative medicines or vaccines…"will not be considered covered expenses.[4] Furthermore, exclusion sixteen deems unnecessary, "routine physical examinations and routine testing;

screening exams or testing…"[4] This lack of preventative coverage highlights another major problem with student health insurance plans. Procedures which have been proven to detect diseases, syndromes, and conditions early, thus resulting in much more favorable medical and financial outcomes, are not available to students. The importance of prevention cannot be overstated, as it is responsible for considerable benefits to both individuals and the healthcare system in terms of improved quality of life and productivity and lower medical expenses.

The final problem I wish to highlight is that of poor customer service. This is a nearly universal problem at universities across the state resulting from a complex mix of students' lack of knowledge of the health insurance system, a certain level of unawareness at the university level, and the complicated language in which student health insurance plans are written. Often students are left on their own when filing claims to their insurer, interpreting the explanation of their benefits, and fighting (or reluctantly accepting) denied claims. In my limited outreach to students in Massachusetts, I have met dozens of individuals from Tufts University and beyond who do not know what benefits are covered by their plans, do not know how to fight a denied claim, or do not know how to prevent/resolve medical debt.

Students should not be expected to fully understand complex health insurance plans on their own. In fact, it should be fairly well understood that unless they have studied the system extensively they are likely to experience considerable difficulty navigating it. Despite the time that I have devoted to this issue, I still find it difficult to read through and fully comprehend the thirty-eight-page Tufts student health insurance brochure as it describes every type of health benefits offered and their associated maximums, co-insurance, co-pays, and deductibles.

In general, universities have fallen far short in their responsibility to educate students about their health plans and ensure that students have the skills and resources to deal with issues as they arise. Hardly any seminars, trainings sessions, or even optional lectures are presented by Tufts University (and many other universities) on their student health insurance plan. Nevertheless, Tufts University has resourceful, intelligent, and helpful individuals who work at their health clinic, and can help students with health insurance problems. However, most students have not been made aware of these options. Universities must inject themselves into students' health insurance education.

So what do the lack of preventative care, the woefully inadequate coverage of benefits, and the insured's lack of comprehension add up to? The most detrimental consequence of these insurance failures is medical debt, or debt that is incurred as a result of unpaid medical bills, which can lead students to bankruptcy and poor credit.

This insurance also encourages students to avoid care that they often need. Youth and the perception of invincibility already provide substantial barriers for many young adults to seek regular medical care. Applying a cost incentive to not get care, even when deemed necessary, has caused and will no doubt continue to cause students to avoid check-ups, screenings and medically-necessary procedures, as well as contribute to noncompliance with prescribed drug regimens.[5] Aside from the burden of suffering experienced by students who avoid care, delayed medical care will often result in costlier treatments (often coming from the student's pocket), intrusive medical treatments, and worse prognoses.

There are several potential avenues through which student health insurance plans could be improved. Presently, all but a few universities negotiate with insurance companies. Pooling students from across Massachusetts to create a large and relatively healthy pool of individuals could allow universities to bargain collectively for more comprehensive benefits at lower prices. Another solution may involve raising the mandated standards of QSHIP plans to ensure that the benefits students receive truly provide comprehensive and quality coverage. Finally, students could be made eligible for the newly formed state-subsidized Commonwealth Care plans. These plans are required to cover prescriptions plans and are banned from imposing any type of caps.

**References**

1. Rukavina, Mark, Pryor Carol, D'Amato, Stephen, and Stacey Beberman, "Not Making the Grade: Lesson learned from the Massachusetts Student Health insurance Mandate" The Access Project, May 2007. p.1
2. Division of Health Care Finance and Policy, "Introduction to QSHIP" mass.gov, Commonwealth of Massachusetts, 10-31-2008 <http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Consumer&L2=Insurance+(including+MassHealth)&L3=Additional+Insurance+and+Assistance+Programs&L4=Qualifying+Student+Health+Insurance+Program+(QSHIP)&sid=Eeohhs2&b=terminalcontent&f=dhcfp_consumer_qship_intro&csid=Eeohhs2>
3. Division of Health Care Finance and Policy, "Student Health Insurance Program" 114_6_3.pdf, Commonwealth of Massachusettts, 10-31-2008, <http://www.mass.gov/Eeohhs2/docs/dhcfp/g/regs/114_6_3.pdf>
4. University Health Plans, Inc., "Summary of Basic Insurance Benefits" Bunker Hill Community College Student Accident & Sickness Insurance Program Brochures, University Health Plans, Inc. 10-31-2008 <http://www.universityhealthplans.com/brochures_pdf/MassCC_SOB0809.pdf>
5. Illustrative of personal communications with a variety of students.

# INTERVIEW

## A DISCUSSION OF ALTERNATIVE MEDICINE WITH TUFTS LECTURER LAWRENCE E. WARNOCK

*Hyejo Jun*

In early October 2007, physicians, biomedical researchers, and alternative medicine practitioners, including chiropractors and Rolfers, who practice deep-tissue manipulation, gathered in Boston to discuss their shared organ of interest – fascia, the soft part of the connective tissue system. Akthough it was initially approached with skepticism, the conference ended with enthusiasm and in anticipation of another because it was one of the first attempts at dialogue between professionals who are usually never in the same room together.[1] Indeed, attendees encountered some "language" barriers, but these became less problematic once physicians and biomedical researchers realized they would be able to learn from alternative medicine practitioners, and vice versa.[2]

To extend an invitation to alternative practitioners to the fascia conference is telling of the increasing visibility of alternative and complementary medicine (CAM) in healthcare. The National Center for Complementary and Alternative Medicine, a branch of the National Institutes of Health (NIH), reported that at least 36% of Americans have used some form of CAM in 2004 in addition to or in place of conventional treatments.[3] CAM therapies include meditation, diet-based therapies, and those that require visits to licensed practitioners of fields including acupuncture, chiropractic care, and massage therapy. On the Tufts Medford/Somerville campus, Bodyworks is a sports massage class offered every semester through the Physical Education Department. The course is taught by a licensed clinical massage therapist, Lawrence E. Warnock, who was interviewed by TuftScope to highlight one portion of the emerging dialogue as an active practitioner of CAM.

This interview does not provide a comprehensive overview of massage therapy or CAM, but rather is designed to stimulate discussion on the increasing interactions between CAM and contemporary Western medicine within the healthcare system. Professor Warnock raises interesting points about what it would take for CAM to become integrated into conventional medicine, and why there may be an emphasis on healing rather than curing in CAM.

**Editors Note:** *Parentheses indicate an addendum to the transcript post-interview from the interviewee.*

***TuftScope (TS)***: How long has the Bodyworks course at Tufts been around?

**Lawrence E. Warnock (LW)**: This class has been going on about 9 years. A student of mine from Reading came to work here at Tufts in student activities and asked me to do some work at the end of the semester during reading period. Then someone asked me if I would apply to teach a course through the Experimental College and I did that for 2 semesters and it just blew up. The opportunity was offered to make it into a regular course.

***TS***: Where did you receive your education?

**LW**: I have my Bachelor's in clinical psychology and my masters in clinical rehabilitation counseling from Boston University (BU), worked on a research grant in Harvard, and went back to BU for my doctorate work.

***TS***: Can you tell me more about your professional background outside of Tufts?

**LW**: Primarily I am a clinical massage therapist. I started out as a rehabilitation specialist, and worked in the State Rehabilitation Commission for about 25 or so years, and ended my career as the Commissioner. I studied massage therapy when I was in graduate school and began to see the connection between bodywork and people with disabilities, pain, and paralysis, and other things. I try to put my massage background, my counseling background, and what I know about the body together. My practice is primarily clinical and I focus mostly on athletes and people with chronic and acute pain, more than just relaxation massage.

***TS***: Do you think that clinical massage specifically falls into the alternative or complementary category of medicine?

**LW**: I would prefer to see it as complementary. I believe that many people in the traditional medical world still see it as alternative, either or, but I see it as being a combination.

***TS***: Have you worked with traditional physicians?

**LW**: Yes, and I offer what I can to assist them in what they do. We can work together, we don't have to be competitive, and that has happened primarily in the area of trigger-point therapy.[4] It is an area the medical world can understand in terms of the language we both use and can see the value in.

***TS***: Why is that?

**LW**: Well, because one of the areas that trigger point therapy has been most successful in is in the area of pain management. There are several, well-known medical clinics around the country that use trigger point therapy as part of their pain management program. And if we can get doctors to look into that aspect of it, then what I do becomes much more plausible to them.

***TS***: Is trigger point a primary component of your practice?

**LW**: I do anything I need to do to help the patient but primarily my focus would be on trigger point.

***TS***: And where did you learn massage therapy?

**LW**: I first went to massage school (at the New England School of Massage) for a 600 hour program, (but the school doesn't exist anymore. In those days, massage training was mostly accomplished working with more experienced therapists, something I benefited from greatly. While massage school helps with basics, anyone who wants to excel quickly learns that experience, practice, reading, attending seminars, keeping up with research, and interacting with other professions is the real way to become successful in the pursuit to help others heal).

***TS***: If you can generalize, what is it about massage that is therapeutic? What is the physiological response?

**LW**: There are a number of responses. A number of benefits, I guess is more the term. Number one is increased circulation. When you're increasing good oxygenated blood to flow through the body you're cleansing and helping the body heal itself. You're also causing lymph to move through the body more quickly, and lymph is another cleansing agent of the body. You're also increasing the level of endorphins, particularly melatonin, serotonin, dopamine, and that's the stress management. If you can reduce stress in a person's mind and body you're helping a lot to their improve healing potential. And there are other benefits, increased flexibility and range of motion.

***TS***: Is reducing stress a major part of healing?

**LW**: Yes, I think so. Most of the research nowadays indicates that almost every disease or chronic condition has a stress element to it, and many have more than others. Fibromyalgia, heart disease, migraine headache, lumbar back problems, asthma, all those kind of disabilities and chronic conditions are very much related to stress. One of the areas that we work in now that we never did before with is cancer.

***TS***: Despite the benefits, why is it difficult for massage to become fully integrated into traditional medicine? For example, that you're teaching this course to unlicensed students who will practice on other students, does that make massage therapy less credible?

**LW**: I think what comes out of this class is more in the acknowledgement and the awareness that there are alternatives out there and adding some elements to their lifestyle that may have not been there before. That there are ways you can choose to do your own healing. But there's another part of it, too. Awareness has to do with a little bit better knowledge about the body, and awareness of what stress does to your body. In terms of getting the traditional medical world to buy into massage, I think that the way that's going to happen is it's going to be the consumer who almost forces it to happen. The traditional medical world is focused primarily on research and empirical data, and it's hard to quantify what a massage is. So if you can't see a trigger point on an x-ray, it's easy for the doctor to say it's not there. The way it's going to become bona fide, if you will, is the consumers are going to demand it. I think the reason this class has become popular has nothing to do with me per se. It has to do with I think an innate curiosity that students have and I credit the university for providing something like this.

***TS***: Where do you think massage, and CAM in general, should be? Should they be in hospitals, should they only be in holistic health care settings?

**LW**: I think they can be anywhere where people need to have someone to assist them in their healing. Hospitals, clinics, senior citizen places, anywhere where people can benefit from another person's clinical touch. And it's beginning to happen. MGH has an oncology massage program. So there seems to be lot of positive responses to massage.

I think once you experience it you will find some benefit in it if you need, if you want to. You can certainly put it down. I think the major difference between traditional and complementary medicine is that we see pain as a language that your body uses to tell you something is wrong. We can then trace that wrongness back to its origin rather than focusing on the site of the pain. And that's what the traditional world does; it focuses on the pain itself, by taking pills, masking it, cutting it out. Which isn't wrong, it's just not enough. Because I have

a counseling background, I find that it helps me interact with a patient beyond just the massage and teach them about their body. You can't expect that from all therapists, because it isn't really part of their job. But that's how I hope massage will become integrated.

***TS***: So how about people who contribute the results to the placebo effect?

**LW**: But you see, if you see it as the placebo effect, then I am saying to myself that I did my job because I got you to accept something. If you believed the placebo helped you get better, fine.

***TS:*** An article in Science magazine reviewed a conference last year on rolfing, where CAM practitioners, M.D.'s, and researchers came together to talk about fascia.

**LW**: Yes, fascia is something I've studied and it is one of the reasons why I have concerns about people who do deep-tissue massage. Fascia and the muscle connection is so sensitive that when you push into the fascia and you squeeze the muscle into smaller space you make the muscle get bruised and that's not good. I believe in working deep around a particular place if I need to but doing a full-body, deep tissue massage is buying into that "no pain, no gain" syndrome.

***TS***: Do you think the conference is a beginning step?
**LW**: Yes, I was there. That was a major breakthrough. It started out about 10 years ago, actually, when the American Massage Therapy Foundation called together a group of people who were scientists, clinicians, and educators. They spent four days developing an agenda for the integration of those kinds of experiences. And this fascia conference was one of the outcomes of that. To be able to sit around a table and talk about what I do and have a scientist try to quantify, that was amazing stuff. That kind of work helped the most when the NIH CAM program came into being, and now there is funding for research. And that's what is going to make a difference because the traditional medical world is not going to accept massage until there is some proof. So my attitude has always been let's show them the proof. Rather than fight it, let's try to find it.

**References**

1. The 2nd International Fascia Research Congress will take place on October 27-30, 2009 at the Vrije Universiteit in Amsterdam – for more information, please visit http://www.fasciacongress.org/2009/index.htm.
2. Grimm, David. "Cell Biology Meets Rolfing." Science. 318 (2007): 1234-1235.
3. National center for Complementary and Alternative Medicine. National Institutes of Health. <http://nccam.nih.gov>.
4. Trigger point therapy involves the manipulation of trigger points in the body, or hyperirritable spots considered common causes of pain.

# Healthcare review

# ASIAN AND PACIFIC ISLAND HEALTHCARE

*Tessa Novick* and Allison Werner-Lin, Ph.D.*

*Psychosocial needs of the Asian and Pacific Islander (API) population in New York City inhibit their access to primary healthcare. This study analyzes the disparities in API healthcare, and makes suggestions for reaching this underserved population. Six qualitative interviews were conducted with staff in the pediatric department of an urban, public hospital that sees underserved API immigrants with low socioeconomic status from the larger New York City area. Interviews examined care provider awareness of and ability to accommodate for API patients' psychosocial needs and barriers to care. Literature and interviews confirm that basic needs such as food and housing are often prioritized over health needs, determining health behavior and greatly inhibiting access to care. Health professionals do not have information on community resources or time to confront psychosocial issues. Community-based, culturally competent infrastructure providing information to connect patients, caregivers and services should be integrated into healthcare settings to improve overall health of API individuals.*

**Population studied.** From 2000 to 2005, the number of individuals in the United States who identified as Asian increased by over 2 million people, concentrating in certain urban areas like New York City.[1] In New York City, where 44% of all residents are foreign born,[2] immigration issues, including overall health and wellness, access to health care, and cost burdens, present major concerns. Immigrants from Asia and the Pacific Islands (API) have been identified as the second fastest growing minority group, increasing in New York City by 63.1% from 1999-2000.[3] API immigrants have a poverty rate of 10.2%—compared with the 7.8% of non-Hispanic whites.[4] They tend to live in concentrated and isolated areas with low-income work and overcrowded housing.[4] Residents of these neighborhoods generally have low educational attainment, limited work skills, language deficits, low earnings, lack of substantial employment, healthcare or affordable housing.[4] High school education completion is significantly lower than the national average, contradicting their reputation as highly educated "model citizens." They normally hold jobs in the restaurant and garment industries, resulting in neighborhoods with significantly lower than regional average wages[4]. Many live below or close to the poverty line, and are less likely to have health insurance; impoverished living conditions directly afflict the health of families, increasing barriers to social services and medical care.[5-7]

These characteristics of API immigrant communities are seen in New York City's Lower East Side, where 35% of the population identifies as Asian.[8] A policy initiative developed in 2004, Take Care New York assesses community health by measuring the presence of 10 key variables that substantially increase morbidity and mortality, all preventable with primary medical care. Take Care New York's most recent Community Health Report on the Lower East Side revealed that API immigrants are not accessing the primary care and social services necessary for basic health. In a community where one in four individuals lives below the poverty level, the Lower East Side ranked below average on half of these variables, including: (1) determining HIV status, (2) getting checked for cancer, and (3) making homes safe and healthy.[8] Further, one in four adults reported they did not have a regular doctor (which was average), and over one in four said they were uninsured or had been so within the past year.[8]

These statistics contribute to looming public health concerns that disparities in care for minority groups are mounting across the nation.[9] The API population's underutilization of basic health care is a national crisis because of their rapid growth. Previous speculation about this population looked toward traditional health beliefs and practices in cultural traditions as barriers to utilization of Western health services, but recent studies are proving this is not the case; a study examining API underutilization of health services in San Francisco reported that poverty status was one of the most consistent predictors of healthcare access.[10] Yet for this immigrant population, immigration history, language barriers, and cultural norms compound socioeconomic challenges,making the population especially difficult to reach. [11] Families prioritize basic physical environment needs like housing and food over health maintenance, preventing API immigrants from having a medical home with primary care. The aims of this study are to examine healthcare professionals' perceptions of the psychosocial issues that contribute to API immigrant patients' underutilization of primary health care. The information will serve as a needs assessment, investigating gaps in the API population-healthcare system interaction. From this, strategies for reaching API families can be explored.

**Understanding the needs of API populations.** The Charles B. Wang Community Health Center (CBWCHC), a local clinic in Chinatown, is spearheading the efforts of several

*** Author Contact Information:**
New York University. Silver School of Social Work, Class of 2008.
Address correspondence to tessanovick@gmail.com.

community organizations to research the exact health status of API populations, aiming to build a comprehensive understanding of their needs and how to connect them with medical care. For example, to address the significant presence of Hepatitis B seen in API neighborhoods across the United States, CBWCHC's Asian American Hepatitis B Program provides free screening and services at several local sites.[12] A 2006 report stated that during six months observed in 2005, 56.6% people screened said it was their first time being tested. Of this group, 14.8% had chronic HBV infection.[13] In other health areas, more research from the CBWCHC found that when practitioners began using the PHQ-9 to routinely screen this population for depression, 4.1% had clinically depressive symptoms that were never before addressed.[14] More alarming was the CBWCHC's report on API children with asthma. When school-based asthma allergy questionnaires (translated into Chinese) were sent home with 476 second grade students from four public schools in lower Manhattan, 48.1% of the children tested positively with no previous asthma diagnosis.[15]

It is important to recognize the significance of the tactics used by the CBWCHC to increase screening and reach more API individuals. The CBWCHC made Hepatitis B screening free, highlighting that cost of care and lack of insurance are major roadblocks. To identify and combat depression, clinicians used the PHQ-9 as part of every routine visit instead of just when the patient expressed concerns about their mental health. Asians traditionally do not respond to western interpretations of mental health, viewing such problems as indicators of hereditary weaknesses, imbalance between yin and yang, supernatural intervention, or just emotional exhaustion, and they may somatisize psychosocial concerns, underutilizing mental healthcare.[16] Asthma questionnaires enhanced screening efforts by sending home translated fliers, eliminating language barriers and the reliance on patients to actively seek services. Putting the information in their language seemed to have the most success in reaching API families.

These studies confirm the findings of Take Care New York's Lower East Side Healthcare Report: this population has chronic disease and health issues that are manageable and preventable, but they are not receiving the diagnostic or treatment attention that comes with having a primary care doctor or access to preventative care. This can aggravate symptoms until conditions reach detrimental states, and API individuals arrive in emergency rooms or urgent care sites. Yet even after emergency room and clinic visits, it is unclear whether API families will receive further check ups or education about managing chronic health conditions. Further, API immigrants are often unaccustomed to or confused by western medications and terms, and it is common for them to add their own traditional remedies.[17] This challenges hospital staffs to gauge how these families interpret their conditions, let alone know how they are treating conditions at home.[18,19]

API families are falling victim to the visible racial and socioeconomic disparities in access to and provision of healthcare.[20] There appears to be insensitivity in the system to the psychosocial and unique health factors faced by all minority populations, and specifically API immigrants.[12] Floating to the surface above these statistics is the continually debated question that follows all minority and vulnerable populations: what barriers are keeping them from accessing the care available? Are there simply not enough services? One theory suggests health care regulation efforts contribute to the neglect of needs and public attention towards API immigrants. Davies, Washington, and Bindman measured trends in public health reporting and explained that the way statistics are collected, analyzed and presented further marginalizes the experiences of vulnerable populations within the healthcare and social service system.[21] If a population does not have access to healthcare facilities they are not included when statistics are measured. This misleading absence from records diverts public attention instead of highlighting a need for supportive services.[21]

A different theory addressing ethno-cultural barriers suggests it is not a deficiency in services but a deficiency in the services' ability to accommodate for unique API needs. A recent study examined the Bridges Project, a community based organization that specifically targets the API population living with HIV/AIDS in New York City.[22] According to the report, the success of HIV/AIDS treatment was a result of the methods used by the Bridges Project to connect patients with available community services. Those clients who were undocumented and/or spoke an Asian primary language had a significantly lower receipt rate of services than English speaking documented participants.[22] When asked six months into the program about significant barriers that previously kept them from using services with which they were currently connected, the top three were that (1) the staff did not speak their language, (2) they were not sure where to go, and (3) the costs were prohibitive. Participants also reported confidentiality concerns: they feared what providers would say and that their HIV status, and possibly their immigration status, would be exposed.

The Bridges Project analysis revealed that low service utilization could indicate a lack of familiarity with where services are located, or that systems of care lacking in linguistic and cultural resources resulted in poor system recognition and failure to provide adequate medical treatment.[22] In other words—no cultural component means low service utilization. The staff spoke the appropriate languages, which enabled them to connect their patients with legal aid organizations, housing placement

services, ambulatory care services, and immigrant advocacy agencies. They also incorporated the use of traditional eastern medicinal treatments by developing an acupuncture clinic, an Asian food and nutrition program, and social events to address support needs. API families are often hesitant to seek help for fear that their medical conditions will somehow be revealed to their community; confronting the social stigmas of certain health conditions, which previously prevented some API families from seeking available treatment, reinforced confidentiality.[22] This could keep them from reaching critical services or even addressing health concerns altogether. Conclusions from this report further confirmed the indications of the CBWCHC clinical studies—that cost, language, knowledge of social service location and unique cultural stigmas must be addressed to successfully provide API immigrants care, and to help them find the services they need.

**Research methodology.** Many children in immigrant families are born in the United States and are United States citizens, eligible for federal health insurance and other public benefits like food stamps, WIC, and public assistance. Immigrant families are therefore more likely to visit healthcare settings for their children's issues, if at all. Children are seen in community or hospital clinics for general care, and sent to hospital specialty clinics for specific issues like asthma and developmental disorders. In New York City, urban public hospitals also act as a modern Ellis Island for the city's influx of immigrants, and are often one of the first stops for newly arrived individuals and families. However, because of tremendous demand, healthcare staff is generally not large enough and often lacks necessary funding to accommodate the patient population. Specialty clinics in public hospitals often receive API referrals from various community organizations and social service agencies in Chinatown and around the metropolitan New York area. Thus, to further explore the disparities seen in API access to and utilization of care, interviews were conducted with various providers who work with the API population treating children on a regular basis.

A semi-structured interview guide was created to elicit information about staff interactions with and perceptions of API patient needs, inquiring about the experience of communicating with and accommodating to the needs of API families. Six members of the pediatric health and allied health team of a large, Northeastern urban hospital that sees API children from around the metropolitan area were identified and approached to participate in this study. These individuals included social work and child life specialists, physicians from the pediatric developmental and asthma clinics, a department director, and a bilingual pediatrician working with API families. Each person approached consented to participate, and interviews lasted approximately 45 minutes. A set of core questions guided each interview, and included four main questions:

1. Can you describe the populations you work with (major health issues/presenting problems, etc.)?
2. What services do your patients typically use most?
3. What specific subgroups within this patient population are your department's services having trouble reaching? What has been challenging?
4. Is there a need you wish you could address, but have to push aside due to lack of time/funding/resources? What would be helpful?

**Results.** A basic content analysis of interview guide responses revealed characteristics and problems in the relationship between healthcare systems and API immigrants in NYC. These are presented below, categorized by the interview guide question. After the initial analysis, responses were compared with the TCNY and literature findings about the API population.

Interviewees described patients, mainly immigrants, many of whom are illegal with very low incomes. Major health issues for the entire population noted by all respondents included ADHD, developmental and language delays, obesity, asthma and diabetes. Physicians specifically noted the disorganized nature of patient homes, making it difficult to ensure that parents bring in their children for regular visits and correctly distribute medication. Parent depression and isolation is common, and many patients ask for help with housing, education, employment, legal status, and finding food.

Overall, patients ask health professionals for advice and advocacy regarding documentation and complicated legal issues. Families need help finding appropriate schools and special education programs. The physicians agreed that families sought referrals for schools and childcare, and many needed to know how to find after-school programs and other resources in their area. Families uniformly need help understanding and navigating insurance and public benefits. On top of chronic health conditions, patients come to their doctors for help with the daily tasks that prevent them from functioning in a novel environment.[23, 16] However, patient expectations for advice are not always satisfied; all interviewees reported they rarely know where to send families who ask for help with resources. Even if they could make suggestions for outside referrals, they do not have time to follow up with the families on these issues to ensure that social service connections were made.

Further, API patients are generally not receptive to support groups or educational services offered in the hospital. This may be a function of low self-efficacy regarding the health of their children, or alternatively, of low service utilization due to the absence of the ethno-cultural sensitivity. It is questionable whether these services are equipped to handle the language and cultural needs of this population, which is a fear that prevents

many API families and individuals from using social services.[22] One physician reported that API parents specifically underutilize the developmental, language delay, and behavioral services offered by the developmental clinic, and found that a significant cultural stigma regarding such issues prevents them from addressing disorders these clinics seek to treat.

Collectively, interviews indicated a need to provide information on where to find help with housing, immigration, health insurance, and other psychosocial issues. The short duration of a clinic visit gives insufficient time to address both medical and psychosocial concerns completely. Provider education about psychosocial and concrete services in the community is needed to enable discussions with families about the environmental and social needs that are inhibiting patient health, and multiple interviewees independently expressed the need for a consolidated resource of available social services in the city. They need a functional way to connect low-income immigrant families with services in their communities, and to efficiently follow up to ensure that referrals successfully address concerns.

Responses from the staff were consistent. Expression of psychosocial concerns was a dramatic trend in nearly every question, indicating that these families spend so much time trying to satisfy basic needs that health concerns are attended to secondarily. Providers are aware of the direct impact this has on health outcomes and on the unique cultural needs that keep families from seeking healthcare, and educational guidelines for healthcare professionals have recently been revised to incorporate the assessment of psychosocial issues. The Institute of Medicine's Proposal on Medical School Curriculum Reform states, "Identifying personal, familial, social, and environmental factors that may affect a patient's health enables physicians to provide better, more patient-centered care."[24] To this the American Academy of Pediatrics responded, "(t)he purpose of this statement is to reaffirm the commitment of the AAP to prevention, early detection, and management of behavioral, developmental, and social problems as a focus in pediatric practice."[25] In isolation, this genuine effort is substantial, but it counts on the ability of patients to actually access care; being trained and committed to the "early detection" and "management" of the psychosocial issues is not necessarily bringing these families into medical offices.

**Discussion and conclusions.** This study measured providers' perceptions of the psychosocial issues that prevent low-income, API immigrants from pursuing primary care and other health services. Findings from this investigation, which concur with the TCNY findings, reveal three main issues surrounding the interaction between healthcare and the API population that providers should address to reach these individuals. First, API immigrants experience tremendous barriers when trying to satisfy basic needs. Language difficulties prevent them from working through red tape of the city's many benefit programs, policies, and regulations. Located throughout the city are numerous immigrant advocacy groups and organizations that help with and provide legal services, public benefits, childcare, housing, and job training—the "outside system," but they continue to go underutilized.

Second, the extensive web of social and medical services in the city is complicated and scattered. Healthcare professionals do not have a knowledge of local, targeted resources to help patients.[27] Even if providers could make a suitable referral, it is difficult for healthcare staff to follow up, and to ensure the problems are adequately addressed.

The third substantial finding from this investigation reveals that API immigrant families use their children's pediatrician as an advisor on health issues and psychosocial issues. This suggests medical settings are ideal for addressing the needs of API immigrant populations. A study conducted by Johns Hopkins School of Medicine and the University of Connecticut School of Medicine surveyed parents in an urban hospital clinic for low-income children to determine whether they felt comfortable seeking advice from their child's doctor about psychosocial issues.[28] Of 100 parents questioned, 67% felt comfortable asking the pediatrician for help with needs like housing, childcare and job training, and of those, 70% expected doctors to actually provide referrals and advice. Families view their child's doctor as a part of "the system" who is able to listen to and advocate for them. Thus, an approach addressing the social problems of low-income families (especially immigrants) needs to be integrated into the medical setting where they receive healthcare.[28]

The challenges faced by API immigrants and providers can be addressed with a shift in the traditional medical care model to include infrastructure to connect and serve all constituents—care providers, social service agencies to help with afflicting basic needs, and providers. One approach to this is seen in the presence of Project HEALTH Family Help Desks in multiple hospitals nationwide. The Project HEALTH Family Help Desk serves as an interactive database that brings access to services into hospital waiting rooms. Families can walk up to the desk while they wait and meet a volunteer who will perform a quick analysis of their needs, screen them for public benefit eligibility, and help them find programs in their community. When a family indicates to their healthcare provider a need for resources, they are referred to the Family Help Desk where a well trained volunteer will provide the follow up, guidance and advocacy they cannot. The volunteers fill the gap in services that the present healthcare system does not support.

Yet, while the integration of information and referral services into healthcare settings is substantial, it may not com-

pletely address the needs of API families unless an ethno-cultural component is also included. If community based information and referral programs are placed in healthcare settings, several suggestions can be made to better reach API populations. Routine psychosocial surveys translated into Asian languages could be issued at the beginning of every doctor's visit as a part of regular paperwork, serving as publicity and providing the connection to attract API families in need to the service. Furthermore, the staff needs education about the various cultural traditions and languages that might determine API families' interpretation of services. Incorporating background knowledge of the unique psychosocial or health issues API populations experience into a separate screening test not recommended for the general population may also be helpful.[29]

To better serve Asian and Pacific Island populations, this study calls for culturally competent information and referral services to be placed in healthcare settings. This may ameliorate the API disparities in healthcare by addressing basic needs that act as barriers to adequate care. Further, such services may enable health professionals to discuss basic needs with API patients, providing complete and comprehensive care. More research is required to determine the services API populations specifically need, and what is difficult to find in their communities.

**References**

1. U.S. Census Bureau. American Community Survey: 2005. Washington DC: US Census Bureau, 2005. Available at http://factfinder.census.gov/servlet/DTTable?_bm=y&-geo_id=01000US&-ds_name=ACS_2005_EST_G00_&-redoLog=false&-mt_name=ACS_2005_EST_G2000_B02001.
2. Kim M, Van Wye G, Kerker B, et al. The health of immigrants in New York City. New York Department of Health and Mental Hygiene, 2006.
3. New York City Department of City Planning: Population Division. The newest New Yorkers 2000: immigrant New York in the new millennium. (Pub. no. [NYC DCP] 04-09.) New York City: Department of City Planning, Oct 2004.
4. Handler JF, Hasenfeld Y. The State of Poverty. In: Blame Welfare, Ignore Poverty and Inequality. Cambridge: Cambridge University Press, 2006.
5. Schneiderman N. Psychosocial, behavioral, and biological aspects of chronic diseases. Current Directions in Psychological Science. 2004 Dec;13(6):247–51.
6. Elstad JI. The psychosocial perspective on social inequalities in health. Sociology of Health & Illness. 1998;20(5):598-618.
7. Masi C. Community and Health. In: Gehlert G, Browne TA, eds. Handbook of Health Social Work. Hoboken, New Jersey: John Wiley & Sons, Inc, 2006.
8. Olson EC, Van Wye G, Kerker B, et al. Take Care Lower East Side. NYC Community Health Profiles, Second Edition; 2006;27(42):1-16.
9. McGinnis JM, Williams-Russo P, Knickman JR. The case for more active policy attention to health promotion. Health Affairs. 2002 March/April;21(2):78-93.
10. Jenkins CN, Le T, McPhee SJ, Stewart S, et al. Health care access and preventative care among Vietnamese immigrants: do traditional beliefs and practices pose barriers? Soc Sci Med. 1996 Oct;43(7):1049-56.
11. Ahmed MH, Lemkau JP, Nealeigh N, et al. Barriers to healthcare access in a non-elderly urban poor American population. Health and Social Care in the Community. 2001 Oct 15;9(6):445–53.
12. Ma GX, Shive SE, Fang CY, et al. Knowledge, attitudes, and behaviors of hepatitis B screening and vaccination and liver cancer risks among Vietnamese Americans. J Health Care Poor Underserved. 2007 Feb;18(1):62-73.
13. Pollack H, Wan K, Ramos R, et al. Screening for chronic hepatitis B among Asian/Pacific islander populations—New York City, 2005. Morbidity and Mortality Weekly Report. 2006 May 12;55(18):505-10.
14. Chen TM, Huang FY, Chang C, et al. Using the PHQ-9 for depression screening and treatment monitoring for Chinese Americans in primary care. Psychiatr Serv. 2006 Jul;57(7):976-81.
15. Lin DH, Au L, Lee W, et al. Evaluating the Use of School-based Asthma and Allergy Screening Questionnaires in Lower Manhattan Public Primary Schools. Presented at: American College of Allergy, Asthma and Immunology Annual Scientific Meeting, Philadelphia (PA), Nov 9-15 2006.
16. Lee E. Asian American families: an overview. In: McGoldrick M, Giordano J, Pearce JK, eds. Ethnicity and Family Therapy. New York: The Guilford Press, 1996.
17. Lee E. Chinese Families. In: McGoldrick M, Giordano J, Pearce JK, eds. Ethnicity and Family Therapy. New York: The Guilford Press, 1996.
18. Rolland JS, Werner-Lin A. Families, health, and illness. In: Gehlert G, Browne TA, eds. Handbook of Health Social Work. Hoboken: John Wiley & Sons, Inc., 2006.
19. Block P. Alternative, complementary, and integrative medicine in a conventional setting. In: Gehlert G, Browne, TA, eds. Handbook of Health Social Work. Hoboken: John Wiley & Sons, Inc., 2006.
20. Griffith DM, Moy E, Reischl TM, et al. National data for monitoring and evaluating racial and ethnic health inequities: where do we go from here? Health Educ Behav. 2006 Aug;33(4):470-87.
21. Davies HT, Washington AE, Bindman AB. Health care report cards: implications for vulnerable patient groups and the organizations providing them care. J Health Polit Policy Law. 2002 Jun;27(3):379-99.
22. Chin JJ, Kang E, Kim JH, et al. Serving Asians and Pacific Islanders with HIV/AIDS: challenges and lessons learned. J Health Care Poor Underserved. 2006 Nov;17(4):910-27.
23. Gehlert S. Communication in healthcare. In: Gehlert G, Browne TA, eds. Handbook of Health Social Work. Hoboken: John Wiley & Sons, Inc., 2006.
24. Institute of Medicine. IOM report: Improving Medical Education—Enhancing the behavioral and social science content of medical school curricula. Acad Emerg Med. 2006 Feb; 13(2):230-1. Epub 2006 Jan 25.
25. Committee on Psychosocial Aspects of Child and Family Health. American Academy of Pediatrics. The new morbidity revisited: a renewed commitment to the psychosocial aspects of pediatric care. Pediatrics. 2001 Nov;108(5):1227-30.
26. Garg A, Butz AM, Dworkin P, et al. Pediatric residents' attitudes and behaviors regarding family psychosocial screening at well-child care visits. Presented at: Pediatric Academic Societies' Annual Meeting, Toronto (Canada), May 2007.
27. Gunasekera H, Buckmaster A. Training in general pediatrics: Is it time for change? J Paediatr Child Health. 2004 Sept-Oct;40(9-10):510-6.
28. Garg A, Butz AM, Dworkin, P, et al. Low-Income Parents' Attitudes and Willingness to Seek Assistance for Social Needs from Their Child's Medical Home. Presented at: Pediatric Academic Societies' Annual Meeting, Toronto (Canada), May 2007.
29. Nelson KR, Bui H, Samet JH. Screening in special populations: a "case study" of recent Vietnamese immigrants. Am J Med. 1997 May;102(5):435-40.

# Opposing Viewpoints

In this new section, *TuftScope* presents two contrasting commentaries on a controversial issue: pharmaceutical patent laws. Article I, Section 8, Clause 8 of the U.S. Constitution states, "The Congress Shall Have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries...." The practical result of this stipulation is that creators of drugs have exclusive rights to produce and sell their products for 20 years. This effective monopoly, in theory, serves as an incentive to create new drugs. It also allows drug companies to recuperate the considerable costs associated with developing and testing a new drug or therapy. The problem, however, is that drugs are sold at a higher cost during this 20-year period than they would be as generics. This higher price puts new, life-saving medications out of the reach of many who cannot afford them. The two articles below describe further the two main "Opposing Viewpoints" on this vital issue.

## CURRENT PATENT LAWS MUST REMAIN UNCHANGED IN ORDER TO INCENTIVIZE INNOVATION

*Adam Snider, Michael DeCarlo, Dave Gennert, Corrina Hansen*

Nobody would argue that withholding life-saving drugs from deserving, underdeveloped nations is a good thing. The opposition to the current patent structure contends that patents slow the development of vital medications, and impede access to these drugs for poorer, developing nations. They claim, the right to health is more important than intellectual property rights, especially in the case of an emergency, such as the AIDS epidemic. While this is a reasonable argument, it is irrelevant, as the current system of international patent law protects the property rights of inventors and researchers while creating conditions where there are incentives to develop new drugs; drugs which are ultimately available to developing nations.[1] The twenty-year patents currently allotted by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement create incentives for pharmaceutical companies to develop new drugs by granting them temporary monopolies in the form of patents on new compounds (drugs). This allows the pharmaceutical corporation to recoup the large costs associated with the R&D of a new medications.[2] After a set time, patents expire, production rights are given to other companies while more efficient production becomes possible; drugs become dramatically cheaper, making them accessible to developing nations.[1] In certain cases, TRIPS mandates that production rights be extended before the patent expires. In a state of *national emergency* or *extreme urgency* the patent may be suspended. While TRIPS may be ambiguous in defining these terms, it also stipulates that developing nations may engage in parallel importation: commonly known as the grey market.[1] The current patent system, as contracted by the TRIPS agreement is the most socially just outcome, it creates strong incentives for drugs to efficiently and quickly be created, which then reach developing nations through trickle-down effect and government action.

The development of pharmaceutical drugs is an arduous process. The purpose of the patent system is to create incentive for investors, researchers, corporations, and entrepreneurs to devote their personal capital towards the development of new treatments.[1] Pharmaceutical corporations must be able to financially offset a lengthy development process including pre-clinical testing in animals, submitting a New Drug Application to the FDA, waiting for the application to be granted, three phases of clinical testing on humans, resubmission to the FDA, and continued testing and quality assurance measures. All-in-all the process takes an industry average of 500-800 million dollars, and about 10 years.[1] Because patents are typically submitted before this process begins, the pharmaceutical company is left with only 10 years to profit from a 20 year patent. Furthermore, in the United States, only a third of developed drugs prove to be profitable.[1] With these tremendous costs, and risks associated with gaining FDA approval and probability of profitability; the need for strong incentives is clear. While reducing the length of patents on medications would lead to a brief period of more equitable distribution, it would also lead to a dearth of new drugs in the long-term.[3] Incentives for future medical advancement must be maintained so that there are always new drugs to distribute to all nations, rich and poor.

Regardless of initial market price, chemical

formulas (drugs) tend to exhibit tremendous depreciation as production becomes for efficient, patents expire and more effective versions of existing drugs are developed. Temporary high price for patented drugs can be justified by the long-term benefits to society, including those for the least advantaged members.[1] While developing nations may not be able to initially afford new technology, the technology becomes more affordable over time. As an example, in 1941 there were only 200 doses of penicillin, by 1964 there were thousands of doses available, and the price of each dose fell from the modern equivalent of $7730 to $351.[1] Further, as a guard against opportunistic profiting from natural disasters, the TRIPS agreement allows the World Trade Organization (WTO) to suspend patent law in the case of emergency.[2]

With patents in place, pharmaceuticals still have incentive to provide life-saving drugs to developing nations at a loss. Being able to profit from a monopoly on a new drug in developed nations affords the company an opportunity to lose money in other markets, particularly developing nations. Positive P.R. from providing this service alone is usually worth the associated cost to these corporations. Bristol-Myers Squibb Co. announced they would sell ddI and d4T (new AIDS drugs) to all African nations at a loss to combat the current HIV/AIDS epidemic.[4] Continuing this trend, Merck & Co. have began to sell Crixivan and Stocrin to developing nations at well below their market price.[4] A reduction in patent length would mean these corporations would not be able to afford these charitable acts.

The current patent system, as stipulated by the TRIPS agreement is an optimal solution to the complex problem of balancing equitable drug distribution, the protection of intellectual property rights, and the creation of incentives for companies and inventors to develop new drugs. Pharmaceutical patents reimburse firms for undertaking the tremendous risk and cost association with the R&D of a new drug. These incentives create a large and competitive market to develop and produce effective drugs as quickly and efficiently as possible. Initial high cost for these drugs can ethically be offset by the long-term positive externalities associated from the drugs being available to all members of society. Drugs quickly depreciate, and become available to even the poorest of developing nations. Finally, the brief period of monopoly power allows pharmaceutical companies the opportunity to engage in charity as they profit from more wealthier markets. This market-based system of incentives balances efficiency and equity to create the best possible social outcome.

**References**

1. Resnik, David B. Fair Drug Prices and the Patent System. Springer Netherlands. 03 Jan. 2005. SpringerLink. 9 Nov. 2008.
2. Condon, Bradly J., and Tapen Sinha. Global Diseases, Global Patents and Developing Countries in WTO Law. Springer Berlin Heidelberg. 22 July 2008. Springerlink. 10 Nov. 2008.
3. Amado, Rivka, and Nevin M. Gewertz. Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads Between Health and Policy. 3 Jan. 2005. SpringerLink. 8 Nov. 2008.
4. James, John S. "Merck, Bristol-Myers Squibb Announce Major Price Reductions for Poorest Countries: Major Access Progress but Questions Remain." The Body: The Complete HIV/AIDS Resource. 28 Feb. 2001. 9 Nov. 2008 <http://http://www.thebody.com/content/art31992.html>.

# THE FLAWS OF THE CURRENT PATENT SYSTEM MUST BE ADDRESSED TO EXPAND ACCESS TO NEW MEDICATIONS

*Emily Clark, Amanda Jichlinski, Ben Scoblionko, Quentin Lott, Samantha Turner, Avigya Shrestha*

As pharmaceutical companies will attest, there is a reason that the United States strongly enforces patent laws. Inventing a new drug suitable for distribution to the general public requires considerable amounts of research and testing before any profit can be realized by the company. Firms argue that for this reason, they require the guarantee of a twenty-year monopoly over their product in order to even recover their initial investment. Yet the current system has several key flaws, and it is imperative that these shortcomings be addressed if the benefit from a drug therapy is to be maximized domestically, as well as internationally.

The present system for awarding patents to drug companies involves proving the superiority of the new drug through comparison with similar drugs. As a result, drug companies allocate much of their research funding towards the formulation of new drugs that are only slightly altered from the previous version. The FDA estimates that only one third of pharmaceutical patents are awarded to "qualitatively new" drugs.[1] The current system, therefore, provides an incentive not to develop innovative new drugs, but to modify existing formulas, thus slowing the overall progress of medicine.

An even more urgent problem resulting from current patent laws is that they both directly and indirectly prevent certain groups of people from receiving treatment for for life-threatening diseases. Patent laws prevent drugs from reaching populations in underdeveloped countries by allowing firms

in first world countries to export drugs at exorbitantly high prices, without the tempering effect of competition. The most commonly cited example of this is in the case of HIV/AIDS, where an estimated 77% of individuals in sub-Saharan Africa lack affordable access to drugs.[2] Treatments available for HIV/AIDS are relatively new, therefore most have at least ten years left on their patents. Affording medications is a huge burden for underdeveloped countries and two thirds of healthcare budgets in these countries goes towards the purchase of patented drugs.[3]

Furthermore, patent laws have the indirect effect of reducing the incentive for drug companies to research cures for diseases that are not prevalent in urbanized countries. Since a few U.S. and Western European firms disproportionately represent the pharmaceutical industry as a whole, most of the drugs that are invented are invented to treat "global diseases" such as heart disease, cancer, and diabetes. Even though these diseases also affect developing countries, the treatments produced by pharmaceutical companies are targeted towards wealthy nations and thus hard to implement without a high degree of financial, structural and technological resources. In contrast, because parasitic and infectious diseases such as malaria and tuberculosis are primarily a concern for less developed countries, there is much less interest in researching drugs for them.

When considering alternatives to the current system, it is important to refute the idea that private firms are by nature better suited than publicly funded projects in inventing new drug therapies. A few prominent examples, such as the invention of penicillin, the polio vaccine, AZT (an HIV/AIDS medication), and Taxol (a cancer drug), demonstrate the capability of the public sector in creating groundbreaking drugs.[1] Private foundations, universities, and organizations such as the NIH and CDC already have some involvement in the research phase of drug production, but private companies tend to take over during the refinement, manufacture, and approval phases.

One alternative to the current system suggests issuing conditional tax credits to pharmaceutical companies.[4] The idea behind this solution emphasizes that government should support innovation that benefits society as a whole, just as it supports other public goods such as national parks and education. With this policy prescription, tax credits would be issued to firms in proportion to how socially beneficial their new drugs were, providing a much clearer and more direct incentive for firms to produce cutting-edge solutions. Reciprocally, the companies would agree to price their drugs at "marginal cost," based on (but not necessarily equaling) the price of producing and distributing the medication. This market model stands in direct opposition to the current system of pricing.

Another proposed solution targets the global rather than domestic consequences of patent laws.[5] Assuming that the market for global diseases resides primarily in developed nations, and that the only market for infectious and parasitic diseases is in developing countries, this solution separates the two classes of medications. The proposal works around the issue of how pharmaceutical companies in the U.S. obtain foreign patents. If a firm gets a patent in the U.S., it can apply for a "foreign patent filing" allowing it to apply for patents in other countries, each patent being restricted to and enforced within certain political boundaries. If a U.S. firm has a patent in another country and a company within that country tries to sell the same drug, the U.S. company normally sues for patent infringement. The proposal states that in this when applying for the foreign patent filing, the U.S. drug company must also agree *not* to sue, with the penalty being forfeiting its patent in the U.S. In this situation, the American company would be forced to either withdraw from the specific foreign market, or lower its prices to compete with the "copycat" drug, hence reducing drug prices in poorer countries while allowing the firm to reap the same profits domestically. In contrast, if the drug were for a disease endemic to developing countries, the company would be willing to give up its U.S. patent in exchange for retaining patent rights in the foreign market. This policy would encourage the innovation of drugs for parasitic and infectious diseases while also keeping prices in underdeveloped countries reasonable.

Whether or not the best solution has been outlined thus far, it is clear that the current system promotes inequities and burdens the current medical system, and must be reformed.

**References**

1. Baker, D. (2001) Patent Medicine. Journal of Public Health Policy. 22: 275-279

2. Cohen-Kohler, J.C., Forman, L. and Lipkus, N. (2008) Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights and the imposition of TRIPS-plus standards. *Health Economics, Policy and Law*. **3:** 229-256

3. Watal, J. (2000). *Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?* Science, Technology and Innovation Discussion Paper No. 8, Center for International Development, Harvard University, Cambridge, MA, USA.

4. Lybecker, K. and Freeman, R. (2007) Funding Pharmaceutical Innovation through Direct Tax Credits. *Health Economics, Policy and Law*. **2:** 267-284

5. Lanjouw, J. (2001) "A Patent Policy Proposal for Global Diseases". Mimeo. Yale University.
At http://pantheon.yale.edu/~lanjovw.

## Featured article

# PATENTS VERSUS PEOPLE: THE BATTLE OVER GENERIC ANTIRETROVIRAL DRUGS IN INDIA

*Rachel Rizal**

*HIV presents one of the greatest global health problems of the late 20th and early 21st centuries. No cure or vaccine for HIV exists, though antiretroviral drugs (ARVs) can be provided for infected individuals. ARVs inhibit the replication of the virus within infected cells, slowing the deterioration of the immune system and the spread of the virus. The development of new ARVs, however, requires years of research and clinical trials by major pharmaceutical corporations. As a result, the drugs are often priced at unaffordable rates for individuals in developing countries. A complex ethical debate exists over the right of developing countries to provide generic ARVs in order to produce low-cost treatments and the rights of pharmaceutical corporations to hold a patent to cover research and development costs. This paper will focus on the debate about generic ARV production by local pharmaceutical industries in India and implications and challenges with regards to other developing countries.*

**Introduction**

Every day, more than 11,000 people become infected with human immunodeficiency virus (HIV) while about 8,000 infected individuals die worldwide.[1] At the end of 2007, there were an estimated 33 million people living with HIV.[1] The developing world, particularly sub-Saharan Africa, suffers the greatest disease burden from HIV. While there is currently no cure or vaccine for HIV, antiretroviral drugs (ARVs) can be given to infected individuals. ARVs inhibit the replication of the virus in their bodies. As a result, an individual's immune system deterioration can be delayed, lengthening his life expectancy. ARVs also reduce the overall rates of HIV transmission.[2]

Through a long process of research and clinical trials, large multinational pharmaceutical companies create new ARVs. Unfortunately, many people in developing countries have limited access to ARVs; they do not have the financial resources to buy costly drugs from multinational pharmaceutical companies. Once a drug is created, other pharmaceutical companies can produce and sell cheaper generic versions of the drug. However, multinational pharmaceutical companies contend that generic drugs steal revenues that cover their research and development costs. Thus, an ethical debate arises about whether pharmaceutical companies in developing countries should be able to provide generic ARVs, despite patent laws, in order to provide low-cost treatments. This paper will specifically focus on the debate about generic ARV production by local pharmaceutical industries in India. The ethical debate has been socially constructed by historical events and reflects that society has drawn attention away from the individuals who benefit from ARVs. The power of the pharmaceutical industry and its influence over patent agreements have shifted the focus of ARVs, from its life-saving potential to money, power, and discovery.

*** Author Contact Information:**
Princeton University. Woodrow Wilson School. Class of 2009. Address correspondence to rachel.rizal@gmail.com.

**Two Sides of the Debate in India**

On one side of the debate are multinational pharmaceutical companies that discover new drugs and express concerns about protecting their business interests. According to the Pharmaceutical Research and Manufacturers of America, estimates show that "it takes approximately 10-15 years and costs roughly $800 million to introduce a new medicine to the market."[3] One way large pharmaceutical companies protect their huge investments is through patents. When a drug is invented, companies may receive patents from individual countries. Patents are local monopolies for a given period of time that grant the inventor exclusivity in producing or selling the drugs. Although patents allow pharmaceutical companies to charge high prices for ARVs, companies contend that patents are essential to their business model. Multinational pharmaceutical companies do not support the manufacturing of generic ARVs in developing countries. The production of generic drugs will hurt the companies' ability to reclaim both the large expenses incurred during research and development, and their ability to reinvest in other research projects.[3]

The other side of the argument consists of individuals, non-government organizations (NGOs), and certain national governments that support the manufacturing of cheap generic ARVs for India to benefit those suffering from HIV. India is considered the "pharmacy of the developing world," selling essential medicines to developing countries at affordable prices.[4] Generic ARVs from India improve the possibility for people from extremely resource-limited settings to purchase the drugs. For example, Nwagwu from Africa recalled how she had to pay $500 per month for brand-name ARVs. But, she claims, "the arrival of generic drugs from Indian companies

changed all that. I now spend just $25 on generic drugs."[5] By purchasing generic ARVs from India, the costs of treating an HIV-infected individual dropped to $140 from $12,000 a year.[6]

**Trade Negotiations**

Multinational pharmaceutical companies, mostly headquartered in developed countries, felt threatened by competitors in developing countries like India and lobbied their governments to negotiate a series of trade agreements to push for stronger intellectual property protections. The pharmaceutical industry, along with other trademark-based industries, felt like victims of piracy and "wanted to gain increased protection for their products."[7] As a result, the United States and other developed countries spear-headed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. In 1995, the developing nations that signed the TRIPS Agreement decided to grant patent protection for pharmaceutical inventions, which prevents competing companies from producing generic drugs for 20 years.[3] India had to change its patent laws by 2005. In return, developed countries increased exports of agricultural and textile products to developing countries.[7]

After the TRIPS Agreement, new ARVs remained expensive because of their patent protections; there was growing concern among developing countries that TRIPS would restrict their access to necessary drugs.[8] In another round of trade negotiations in 2001, the Doha declaration was signed. The declaration clarified that the TRIPS agreement "contains flexibilities that allow countries to enable both the import and production of generic versions of antiretroviral drugs under patent to protect public health."[9] The declaration stated that countries could grant compulsory licenses to address a national health emergency. Compulsory licenses "enable a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder."[8] The Doha Declaration theoretically gives countries more freedom to produce generics. However, when Thailand authorized the use of a compulsory license to produce a generic ARV, it faced significant threats of trade sanctions from developed countries. The outcomes of the TRIPS Agreement and Doha declaration reflect that the debate about medicines is embedded in trade negotiations and patent laws, instead of health outcomes.

In 2005, India passed the Patent Amendment Bill to remain in accordance with TRIPS.[10] The new patent law replaced the existing legislation, which had allowed local pharmaceutical companies to produce generic ARVs if they used a different manufacturing process. Local Indian pharmaceutical companies could only produce generic ARVs if the patent holder granted it a voluntary license to the company. The Patent Amendment Bill severely hurt the drug industry that had thrived in India since 1970 because it limited the manufacturing of generic drugs. After the Patent Amendment Bill, generic supply to developing countries became limited and access to drugs subsequently worsened for individuals in dire need.

**Social Reflections**

The current patent system rewards innovative scientific discovery, and values the intellectual property issues surrounding it, often more highly than any adverse social implications. The importance of supporting new scientific discoveries is reflected in the 2008 International AIDS Conference. The first sentence in the "About the Conference" section states, "AIDS 2008 will provide many opportunities for the presentation of important new scientific research."[11] Pharmaceutical companies believe that patents are necessary in order to give them financial security when developing new drugs. They support the idea that "innovation must get its reward."[15] However, as countries support incentives for new scientific discovery, they establish a trade-off between innovation versus treating infected individuals in the present. The same patents that give pharmaceutical companies incentives to produce new drugs also prevent affordable ARVs from reaching the market. Thus, many HIV-infected individuals do not get access to the latest and most effective ARVs. The patent system creates an environment where access to medicines and innovation are mutually exclusive, rather than complementary. The system allows pharmaceutical companies to make their values of making profit, protecting innovation, and gaining power a priority. As a result, the rest of society is influenced to consider the pharmaceuticals' values with humanitarian concerns.

Due to the emphasis on innovation, countries that support intellectual property rights and grant pharmaceutical companies patent protection are rewarded with a better reputation. One pharmaceutical executive noted that any country "that aspires to have a genuine global footprint will necessarily have to focus on driving true innovation with greater emphasis on creating intellectual property and a global presence in key markets."[12] India has been praised for adhering to the TRIPS Agreement. When India passed the Patent Amendment Bill in 2005, newspapers around the world portrayed India as a country poised to be "an economic powerhouse"[13] and "on the road to becoming a world leader in drug research."[14] India took advantage of the opportunity to bask as a potential leader in the pharmaceutical industry. One Indian pharmaceutical company's president noted, "We have very good intellectual capacity, good chemistry, and mathematical skills which is the

foundation for the pharmaceutical business."[13] India's actions reflect that countries care about power and prestige alongside the protection of the health of HIV-infected individuals around the world.

Multinational pharmaceutical companies are concerned about maintaining control over ARVs. For example, Thailand wanted to use its right to issue a compulsory license for a generic version of the ARV drug, Efavirenz. The Thai Ministry of Public Health stated their interest in producing local generic versions of Efavirenz and wanted to issue a compulsory license "to protect public health, especially for universal access to essential medicines."[15] Merck, the company that has a patent for Efavirenz, objected to Thailand's desire to create universal access for ARVs in its country. Instead, Merck offered to sell Efavirenz at a lower price.[19] Thailand listened to the advice of the World Trade Organization and negotiated with Merck for lower Efavirenz prices. The deal reflects that pharmaceutical companies and the World Trade Organization have influence over developing countries' decisions to grant its compulsory licenses. Furthermore, the patent system and voluntary licenses have created a hierarchy in the pharmaceutical industry. This hierarchy allows large pharmaceutical companies, like Merck, to maintain control of the distribution and sales of ARVs during the patent period.

Indian pharmaceutical companies are aware of the current hierarchy within the pharmaceutical industry and are interested in gaining more power. Scholars have pointed out that after the Patent Amendment Bill, "Indian firms start with a handicap, even before they start the game, in that they do not have the deep pockets necessary to create international blockbuster [drugs]."[16] However, Indian pharmaceutical industry representatives want to attract Indian scientists and researchers back from abroad. Ajit Dang, director-general of the Organization of Pharmaceutical Producers of India, hopes that the Bill will create a "'reverse brain drain' from the West back to India."[14] Again, the concern over power and having the resources to create future drugs draws attention away from providing low-cost ARVs to patients.

Other than power, pharmaceutical companies show that they are most concerned about making profits. For example, Cipla, and Indian-based company and the world's largest manufacturer of ARVs, has the corporate slogan, "None shall be denied." However, Cipla charges two-and-a-half times as much for its antiretroviral drugs in India as it does in Africa. Cipla's reasoning behind this decision is that it has to cover its manufacturing costs. Many people in India cannot afford Cipla's prices and are thus denied access to lifesaving ARVs.[17] Thus, companies' economic concerns interfere with their interest of producing ARVs that are affordable and accessible.

Pharmaceutical companies' interests in costs and revenues cause concern in the rest of the world with ARV financing rather than the health outcomes of HIV-infected individuals. NGOs' and governments' primary concern are the costs and affordability of ARVs before they determine to whom and how to administer treatment. For instance, the international humanitarian NGO Doctors Without Borders has to wait for affordable therapies before it treats people in over 30 countries. Doctors Without Borders claims that the biggest difficulty getting the best available drugs.[18] It negotiates with companies like Cipla to purchase antiretroviral drugs in bulk for the cheapest price possible. Currently, the NGO is faced with the question "do you want to treat more patients on a more affordable combination, or do you want fewer patients on a better combination?"[18] Although Doctors Without Borders is devoted to providing universal access to essential medicines, it has to focus its attention on costs before it can treat patients. The current patent system requires NGOs and governments to compromise its humanitarian desires of helping HIV-infected individuals. At times, they have to persuade and negotiate with pharmaceutical companies in order to treat more people. But, the question remains, should the value of human life be negotiable? And, if so, what is the cost of saving people's lives?

**Alternative Questions**

Currently, the debate about generic ARVs has focused on the manufacturing of the drugs. Pharmaceutical companies have dominated the debate and have successfully pushed for patents that deny low-cost, generic ARVs from being manufactured. However, there are other bioethical questions which can re-center the debate concerning ARVs to focus on individuals. If people shift their questions toward individuals, they can begin to uncover the stakes of centering the current bioethical debate on patent laws and motivate them to make changes.

First, should pharmaceutical companies be given the power to decide prices for patients? Court battles reveal that different pharmaceutical companies fight for the right to sell drugs; therefore, they determine what prices drugs are sold for. In one court battle, California-based Gilead Sciences filed a lawsuit in India regarding its antiretroviral drug, Tenofovir, against the Indian pharmaceutical company, Cipla. Cipla produced the generic version of Tenofovir, Tenvir. Tenofovir costs patients $5,718 a year while Tenvir costs $700.19 Gilead Sciences voiced its concerns about making its ARV drug available to poor people, "We will use this patent responsibly, and will not block access to our medication in India or in other resource-limited countries where the HIV

epidemic has hit the hardest."[19] However, its actions clearly do not reflect its claim. Tenofovir is too costly for patients in India and other developing countries, denying them access. As the debate over producing cheap ARVs is fought in court between pharmaceutical companies, the people who actually benefit from the treatments are not heard.

Second, is access to life-saving drugs, such as ARVs, a human right? Currently, the high prices of patented ARVs make them appear as a luxury good as opposed to a necessary product. This attitude is reflected by the director of the International Federation of Pharmaceutical Manufacturers, "for people with no income or little income, price is a barrier you know, which might be a Jaguar SJE."[20] Even in developed countries, ARVs are expensively priced. The ARV Viread costs $5,718 per patient per year, which makes it difficult for low-income HIV-infected patients to afford the drug.[19] The current patent system does allow for scientific innovation, but at the expense of poor people's lives.

Third, who should be responsible for distributing ARVs to individuals? Presently there is no international standard to answer this question. The responsibility has fallen in the hands of individuals, governments, and NGOs. Individuals have to pay a monthly or annual expense for ARVs. Some governments provide ARVs to its population. For instance, in Nigeria, the government subsidizes ARVs so that individuals pay $7 a month.[21] Still other patients receive ARVs from NGOs. Doctors Without Borders provides ARVs to 30,000 people living with HIV / AIDS around the world. By focusing and solving the problem on whom and how ARVs should be delivered, individuals may be more likely to receive ARV.

**Conclusion**

The current set of international trade agreements and patent laws does not provide everyone suffering from HIV access to essential ARVs. Instead, the current patent system maintains the dominance of large pharmaceutical companies and gives them the power to decide at what price and to whom they want to sell ARVs. So-called "miracle drugs" that society has encouraged do not reach the hands of everyone who needs them. Developing countries that suffer the greatest disease burden have the least access to expensive drugs. Furthermore, the current patent system allows pharmaceutical companies to decide what type of drugs to produce. Currently, "90% of all medical research involves diseases that cause 10% of the global health burden."[22] If society agrees that everyone should benefit from medical research, including ARVs, then there has to be a fundamental shift in current laws and attitudes. Individuals have to re-think how they can provide incentives so that researchers and companies will produce medicines that will have a greater and broader impact on people's health. Universal access to essential medicines does not necessarily hinder innovation. Rather, future generations of policymakers and leaders face the challenge of creating an environment where both innovation *and* universal access to essential medicines can co-exist.

**References**

1. The United Nations Program on HIV / AIDS. Global Summary of the Aids Epidemic. 2006. 11 May 2008. <http://www.unaids.ru/en/HIV_data/>.
2. Fink, Carsten. "How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries." Diss. U of Heidelberg, 1997.
3. Kanna, Balavenkatesh. "Access to Highly Active Anti-Retroviral Therapy (HAART) for HIV Infection in India." The Internet Journal of Law, Healthcare and Ethics 4((2007).
4. Basu, Dipak. "Patent Laws Developing Countries Suffer Most." The Statesman 31 Dec. 2004.
5. "Global Support for India's Generic HIV Drugs." The Times of India. 22 Jan. 2005.
6. "AIDS drugs in India." International Herald Tribune 19 Jan. 2005.
7. Barton, John. "TRIPS and the Global Pharmaceutical Market." Health Affairs 23.3 (2004): 146-154.
8. World Health Organization. The Doha Declaration on the TRIPS Agreement and Public Health. 2008. 7 May 2008 <http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html>.
9. World Health Organization. Progress on global access to HIV antiretroviral therapy: a report on "3 by 5" and beyond. 2006. 9 May 2008 <http://www.who.int/hiv/fullreport_en_highres.pdf>.
10. Devraj, Ranjit. "Health: Global Poor to Suffer if Denied Indian Generics." Inter Press Service. 22 Feb. 2005.
11. AIDS 2008. Conference Overview. 5 May 2008 <http://www.aids2008.org/mainpage.aspx?pageId=3>.
12. "India to Curb Export of Cheap Copycat Generic Drugs in Line with WTO Rules." AFX Asia. 26 Dec. 2004.
13. Acharya, Keya. "Activists Fight Novartis' Bid to Hog Cancer Drug" Inter Press Service 30 Jan. 2007.
14. Deshmukh, Jay. "New Patent Law Will Make India Research Base for Drug Majors" AFX Asia 23 Mar. 2005.
15. Steinbrook, Robert. "Thailand and the Compulsory Licensing of Efavirenz." The New England Journal of Medicine. 356.6 (2007): 544-546.
16. "India to Curb Export of Cheap Copycat Generic Drugs in Line with WTO Rules." AFX Asia. 26 Dec. 2004.
17. Banta, David. "Worldwide Interest in Global Access to Drugs." The Journal of the American Medical Association. 235.22 (2001): 2844-2846.
18. Medecins Sans Frontieres. Campaign for Access to Essential Medicines. 2008. 12 May 2008. <http://www.accessmed-msf.org/main/medical-innovation/igwg-page/igwg-booklet-is-aids-a-neglected-disease/>.
19. Gentleman, Amelia and Hari Kumar. "AIDS Groups in India Sue to Halt Patent for U.S. Drug." The New York Times. 21 May 2006, late ed., sec. 4.
20. Ford, Nathan. "Public Health and Company Wealth." British Medical Journal 326(2003): 1296.
21. "Global Support for India's Generic HIV Drugs." The Times of India. 22 Jan. 2005.
22. CG Victora, K Hanson, J Bryce and JP Vaughan, Achieving universal coverage with health interventions, Lancet 364 (2004), pp. 1541–1548.

## Featured article

# PAY FOR PERFORMANCE: PERSUADING PROVIDERS USING LESSONS FROM HOME AND ABROAD

*Margaret O'Connor**

*Pay for performance (P4P) programs aim to align providers' payment incentives with quality of care. It is no surprise that many providers have reservations about the design and goals of P4P programs which may impact their income. Provider opposition to P4P is rooted in three major areas of concern: the impact of P4P programs on their pocketbooks, professionalism, and patients. Policy makers at all levels who want to include P4P programs in their efforts to raise quality and lower costs must anticipate and respond to provider opposition along these lines. This paper will examine three case studies and analyze how P4P initiatives in California, state Medicaid programs and the United Kingdom have been designed to accommodate these concerns. It will conclude with a discussion of whether and how current efforts to introduce P4P to Medicare are applying these lessons.*

**Introduction**

One of the loudest critiques of the American healthcare system is its extremely high cost. The 2001 Institute of Medicine report, Crossing the Quality Chasm, cast doubt on whether the standard of care received under this system was in fact worth such high costs. The idea of "pay for performance" (P4P) was introduced as a potential remedy for these dual system ills.

P4P programs aim to align providers' payment incentives with quality of care. In other payment models, providers can maximize their income by adjusting the amount of care delivered (for example, by providing additional care under fee-for-service payments). P4P programs are designed to link part of provider payments to certain evidence-based quality measures, creating an environment where providers can maximize income by delivering the highest standard of care to their patients.

While theoretically supportive of financial incentives for quality[1], many providers have reservations about the design, goals, and potential for negative outcomes from P4P programs. Policy makers at the national, state, health plan, and employer level who want to include P4P programs in their efforts to raise quality and lower costs must anticipate and respond to provider opposition. This paper will outline three major areas of concern from the provider perspective, introduce three case studies of P4P programs, analyze features of the California, Medicaid, and United Kingdom programs that were designed to accommodate these concerns. Finally, this paper will conclude with a discussion of whether and how current efforts to introduce P4P to Medicare is applying these lessons.

**Providers' Concerns: Pocketbook, Professionalism, and Patients**

It is no surprise that many providers have reservations about P4P programs. When discussing costs and incentives in a healthcare system, one must keep in mind that for providers, "cost" is income, and attempts to manipulate "incentive" may imply interference and control. A 2006 article in the Journal of Healthcare Management highlighted some of the conflicting interests between providers and payers regarding P4P programs:

*Issue 1:* Payers pay for the cost of care for a group of patients. Providers think of payment in terms of price paid for their effort.

*Issue 2:* Payers see the care delivery system as a whole and seek to hold "the enterprise" accountable for value and performance. Providers can only influence what is in their direct control.

*Issue 3:* Payers assume money incentives can solve the problem of practice pattern variations. Providers choose practice patterns for many nonfinancial reasons.[2]

This is a succinct summary of provider concerns about their incomes and clinical autonomy. Yet P4P raises provider concern in a third area, that of the diffuse effects of P4P policies on their patients. Consequently, to better understand the provider perspective, it is helpful to distinguish among the three areas in which providers fear the negative impact of P4P programs: their pocketbooks, their professionalism, and their patients.

**Pocketbook.** Perhaps providers' most obvious concern about P4P programs is the effect that any payment restructuring will have on their personal income. Criticisms of both the incentive (its size, structure, and application) and the performance measures that are assessed are the two main sources of this concern. Providers may fear that P4P is simply the latest in a stream of cost-control measures aimed at ultimately reducing their payments. P4P incentives may vary in size, structure (bonuses, penalties, differential reimbursement), and application (whether they are paid based on attainment of a certain level, improvement, or by comparison with other providers). Conse-

*** Author Contact Information:**
Tufts University, Class of 2010. Adress correspondence to Margaret.O_Connor@tufts.edu.

quently, providers may have different opinions about a variety of incentive designs. Providers are also concerned whether proposed changes will adequately compensate them for the additional time, personnel, and information technology investments that may be required for them to report on the measures.

Structure and selection of the measures to be assessed is also likely to affect providers unevenly. A 2007 survey of internists found that although 73% agreed that "If the measures are accurate, physicians should be given financial incentives for quality," only 30% agreed that "at present, measures of quality are generally accurate."[1] The same survey found that 88% of physicians believed that current measures were not accurately adjusted for the medical status of patients, while 85% believed they were not adequately adjusted for socioeconomic status. Measures that do not adequately adjust for the characteristics of patient populations may mean that some providers perform less well on certain measures due to factors outside their control.

Provider concerns about the impact of P4P on their pocketbooks is reflected in the American Medical Association (AMA)'s statement of principles and guidelines for P4P programs. This statement gives the endorsement of the medical profession only to those programs that provides fair and equitable incentives (through the provision of new, additional funds), are subject to the best-available risk adjustment, reimburse providers for administrative costs associated with the measures, and distribute rewards for achievement and improvement on targets (not through rankings).[3]

**Professionalism.** Providers are also concerned that measuring and paying according to performance may impinge upon professional autonomy. Many common performance measures (such as those outlined in the Healthcare Effectiveness Data and Information Set, known as HEDIS measures) are process-based, meaning they relate to the sequential process of diagnosis and care delivery. Although scientific evidence may indicate certain best-practices for dealing with most or average patients, such practices may not be appropriate for all patients. Doctors are likely to resist any "incentive structure" that appears to dictate care for their individual patients.

Similarly, while certain measures (such as HEDIS measures) are widely accepted, in other cases there remains much debate in the medical community about what constitutes best-practice. The "evidence" upon which performance measures are based may be disputed. Providers may resist linking their pay to performance measures that they do not believe accurately represent the highest standard of care that they can deliver to their patients. Not all variations in care can be linked to variations in quality, and according to the AMA, good P4P programs will ensure quality while permitting variations.[3] Regionally and internationally, these variations can be linked to such factors as difference in training and genuine divergence of professional opinion. Perceived attacks on medical professionalism may ignite resistance to P4P programs.

> The physician culture is an expert one and places a high value on autonomy. In such cultures, financial rewards or penalties can be viewed as a threat to pursuing quality. Imposing a pay-for-performance penalty on a practice pattern rooted in a training experience can be compared to fining someone for believing in God; doing so is not likely to change belief but is likely to elicit anger.[2]

**Patients.** In their role as patient advocates, providers also concern themselves with the impact P4P may ultimately have on their patients. Providers are concerned with potential negative outcomes of P4P incentives at the clinical and systemic levels.

Because P4P programs are likely to be implemented only for areas of care where there is a consensus on quality measures, there is a potential to skew care towards those "incentivized" areas. Rosenthal and colleagues find it "inevitable" that "the dimensions of care that will receive the most attention will be those that are most easily measured, and not necessarily those that are most valued."[2] This statement reflects the view of 61% of physicians who agree "measuring quality will divert physicians attention from important types of care for which quality is not measured."[1] Others fear that this problem of misplaced attention may manifest itself during the clinical encounter, as doctors adhere to a checklist of measures rather than communicating with their patients.[5]

Provider response to payment incentives could ultimately impact patient access. Because P4P programs are not implemented universally, providers may choose to leave P4P programs if incentives are insufficient or the costs of implementation are too high. This could restrict access and provider choice among patients covered by plans with P4P programs. Alternatively, providers participating in P4P programs that are inadequately adjusted for "may lead physicians to avoid high-risk patients"; 82% of providers harbor this fear.[1] The AMA's principles reflect these concerns about the affect of P4P as well and stipulate that good programs will support the patient/physician relationship and must not limit access or cause patient de-selection.[3]

A perceived threat to their pocketbooks, professionalism, or patients in any health policy proposal is likely to stimulate objections among providers. The particular concerns raised by P4P have been described above. Any policy maker intent upon implementing P4P programs can anticipate similar opposition in these three areas, and should craft their proposals to respond to these concerns.

**Case Studies: California, Medicaid, and the United**

**Kingdom**

P4P programs have been attempted in a wide variety of contexts. In California, state Medicaid Programs, and the United Kingdom, P4P programs are widely used and accepted. Each used a unique combination of innovations and strategies to accommodate provider concerns that has contributed to their continuation and acceptance by the provider community. Future advocates of P4P can draw lessons from their examples on ways to design programs with widespread support.

These cases were selected because of the availability and accessibility of development, structure, and implementation data. Each program has a broad jurisdiction and plans to move forward. The breadth of these programs implies that consensus from a diverse set of providers was needed, which should enhance the applicability of lessons gained from these experiences to a variety of contexts. The selection of these cases is not exhaustive (other examples include the Leapfrog Group, Bridges to Excellence, and Australia's program), nor to imply that important lessons cannot be gained from unsuccessful P4P experiments. Because a variety of data sources are used to illustrate the highlights of each program, direct dimensional comparisons may not always be possible. In acknowledgement of these weaknesses, the sketches below still provide a comprehensive picture of each program and many opportunities to learn.

**California: The Integrated Healthcare Association.** Backlash against the managed care initiatives of the 1990s led many private California health plans to turn to P4P as a way to promote quality and control costs. These programs faced many obstacles, including minimal funding for incentives and an insufficient sample size to lend credibility to the results of their quality-improving thrust. Providers were frustrated by competing sets of metrics and found themselves in an arena of "dueling report cards" and one-up-manship.[6]

At this time the health policy context of California featured visible interest groups such integrated provider associations clearly voicing the provider position, The Pacific Business Group on Health representing purchasers, and the California Association of Health Plans. Formed in 1996, the Integrated Healthcare Association (IHA) was a forum representing the voices of all of these stakeholders. Seven major health plans were IHA members, accounting for 60% of California's market share.[7] In 2001, California's providers asked the IHA to help devise a state-wide P4P program that would be universally acceptable. Before designing a specific model, the IHA agreed on a set of guiding principles: voluntary participation in the program, publicly reported scorecards on a common set of measures, significant incentives for participation offered by health plans, and a collaborative model of decision making.[6]

The IHA's Pay for Performance Program first collected data in 2003 and distributed payments in 2004. Although each plan distributed payments variably and in different amounts, all plans used a common set of measures. These measures spanned three categories, with opportunities for payment in each: clinical, patient experience, and technology. A technical team was set the task of developing the measures, and included staff from the National Committee for Quality Assurance (NCQA) and sponsor of HEDIS measures. Clinical measures emphasized preventative care and process measures. The weighting of measures for the initial payments were 50% for clinical, 40% for patient experience, and 10% for technology, but had been changed in 2006 to a 50/30/20 formula. For 2005, the average performance-based compensation accounted for 1.5% of total physician group compensation. Six of the seven participating plans based these payments on rankings. "New money" was introduced to the system to fund this program; plans raised funds by increasing premiums, achieving greater administrative efficiencies, offsetting increases to capitation payments, and reallocating funds from other incentives. IHA's five year plan calls for increasing the share of P4P compensation to 10%. Although the initial goal of the program was not to reduce existing payments to any provider, the proposed increases will require "alternative approaches."

**Medicaid: The Collective Experience of State Programs.** Twenty-eight state Medicaid programs currently operate at least one P4P program, and many of these programs have been in existence for five years or more. As of April 2007, existing plans to initiate further programs would have led 43 states to do so by 2011. A large majority (70%) of these programs function in managed care or primary care case management environments.[8]

In contrast to California's private P4P initiatives, Medicaid is a publicly financed program whose beneficiary is a traditionally marginalized group, the poor. Interestingly, a Commonwealth Fund survey of state Medicaid directors found that this set of policy makers was concerned with the long-term impact of P4P programs upon their beneficiaries. For example, improving quality was more important to these programs than controlling costs. Controlling costs was ranked lowest, by only 14% of respondents as a "very important" attribute of a good P4P program. Features that garnered more support were that measures be nationally recognized (35%), that they provided opportunities for continuous quality improvement and not just a one-time target (62%), and that they be scientifically sound (78%).[8] These priorities coincide with potential provider concerns.

This convergence of interest was widely acknowledged: "In the context of Medicaid's traditionally lower payment rates

and smaller provider networks, maintaining good relations with all providers is important to ensure adequate capacity in plans' networks."[9] This statement by experts accords with the views of 69% of Medicaid directors who said that penalizing providers would be a detriment to a successful P4P program. However, only 19% worried that reducing the numbers of providers would be an actual consequence of a P4P program.[8] A possible interpretation of these findings is that Medicaid directors are conscious of this potential adverse effect, but are confident in their ability to design programs that provide sufficient counterbalance.

The content of P4P programs vary. HEDIS and structural measures of quality predominate Medicaid P4P programs, used in 69% and 60% of programs, respectively. The utilization of these measures is likely due to their scientific basis and the feasibility of collection. On the contrary, patient experience measures were used by only 37% of programs. Bonuses are the most common form of incentive for existing programs (69%), followed by penalties (34%) and differential reimbursement (31%). Reflecting programs' negative experience incurring penalties on providers, only 7% of new programs propose to structure rewards in this manner. Of existing Medicaid P4P programs, 85% distribute incentives based on attainment, 33% based on improvement, and 21% based on peer comparisons (rankings). Plans for new programs indicate some shift in this pattern, reducing the share of programs who use peer comparisons to 9% and increasing the use of both attainment and improvement to 91% and 55%, respectively (note that some programs compensate using a mix of approaches). The increasing move towards health information technology has led some programs to introduce a "pay for participation" component to their programs. A final trend in Medicaid P4P programs is a move to join with other payers, employers, consumers and providers in state-wide or regional P4P and quality improvement initiatives.

**The United Kingdom: Quality Outcomes Framework.** Since the birth of the National Health Service (NHS) in 1948, the payment of British general practitioners (GPs) has been determined by periodic contract negations between the British Medical Association (BMA) and the central government, with major revisions made only in 1966 and 1990. The traditional General Medical Services Contract combined capitation (40%), salary (30%), fee-for-service (15%) and information technology (15%) components.[10] In 1990s, incentives were incorporated to fee-for-service payments to encourage vaccination and PAP screening. In 2004, a new contract introduced P4P programs on a large scale. According to Martin Roland, a British health policy expert who advised negotiations of the 2004 contract, both the academic and political context facilitated the reform. In contrast to the 1980s, when the idea that variations in medical practice existed or had a negative impact on quality was largely rejected, in the 1990s "it became increasingly possible both to define high quality care and to provide methods that could be used to measure some aspects of quality."[11] Newsmedia attention to the UK's draconian health spending and scandalizing stories about substandard levels of care created the political will for reinvesting in the NHS. The concept of P4P arrived in the right place at the right time:

> To tie a substantial proportion of physicians' income to the quality of care they provided would produce winners and losers. However, the British Medical Association was unlikely to negotiate a change in remuneration that would result in the loss of income for large numbers of its members. Therefore, the scale of the change that came about was possible only because in 2000 the government of the United Kingdom decided to provide a substantial increase in health care funding.[11]

After eighteen months of negotiations, the new GP contract rolled out in April 2004 and was approved by 79.4% of physicians. The P4P program, called the Quality and Outcomes Framework (QOF) made 18% of GP income susceptible to quality measures. Providers could earn up to 1,050 points in 146 indicators in seven areas. A technical team developed measures with the intention that they be kept at the minimum number necessary to accurately assess care, and that they be based on information that was routinely collected. It was also the intent that the points available reflect the workload required. Thus, providers can receive points for complying with process measures for a certain threshold of patients, addition points patient compliance, and still more points based on "intermediate" patient outcomes. The QOF also introduced "exception reporting." GPs may exclude patients from eligibility for compliance with certain measures based on such factors as preconditions, concurrent drug treatments, or noncompliance. Regional health system oversight boards called Primary Care Trusts are responsible for regulating GPs to avoid "gaming" the system through excessive use of exception reporting.

Initial experience with the QOF has raised both anticipated and unanticipated and unanticipated issues in the UK. In the first year under the QOF, the NHS paid out $1.8 billion in "new money," equivalent to a 20% increase in the NHS family practice budget. GPs exceeded NHS' estimates for compliance with new measures, causing them to pay $700 million more than anticipated, causing architects of the QOF to conclude that, "in retrospect, the government paid out more than it needed to, to achieve the levels of quality."[12] This miscalculation was either the result of wrong assumptions about the baseline of care already being delivered by British GPs, or wrong assumptions about how hard they would work to meet the measures. There is also growing concern that P4P might result in the fragmentation of GP, with different GPs in a practice narrowing their focus to provide high-quality care to certain aspects of care under the

QOF. If significant, this trend could have a potentially negative impact on the coordination of care within a practice, particularly for patients with co-morbidities.

**Discussion: Persuading Providers**

Experiences from California, Medicaid and the United Kingdom constitute an abundant source of lessons to be learned about P4P programs. Each case made different and innovative attempts to achieve consensus with providers and assuage concerns about threats to pocketbooks, professionalism, and patients.

Provider support for P4P in both California and the UK was contingent upon the introduction of "new money" to the system. Avoiding the creation of explicit "losers" was a lesson learned by Medicaid as well, where the use of penalties and negative incentives for providers is rapidly diminishing. Both California and Medicaid tried to provide some relief to providers for the costs of participation in P4P. For example, HEDIS-based measures predominate in both cases, reducing the load of additional data collection. The IHA program's low thresholds in the technology category rewards technology investment and aimed to encourage reinvestment in quality.[6] With similar goals, several Medicaid programs have instituted "pay for participation" components. These program features were included in efforts to convince providers that their pocketbooks would not be threatened by P4P programs, and that they in fact stood much to gain financially.

P4P policies included other components to assure providers that P4P programs would not impinge upon their professional ethos. The use of HEDIS measures by California and state Medicaid programs precluded opposition that less accepted or scientific measures might have roused. Additionally, like the UK, California's IHA created a technical team to allow for provider input to determination of measures that was distinct from the team determining the incentive structure. This division of labor may have helped minimize any perceived or actual bias to favor certain providers. In the QOF, an aggregate score allows providers to maintain their autonomy by prioritizing focus areas and also receive rewards. Exception reporting also allows providers to make diagnostic and treatment decisions on a case-by-case basis without penalty.

P4P initiatives must also address provider's anxieties about their impact on patients. Exception reporting in the UK effectively enabled providers to perform their own risk adjustment on patients, reducing the incentive to turn away patients that might negatively affect their quality scores. In the California and Medicaid programs, patient surveys provide some consolation to providers that any negative effect on clinical experience will be monitored. The fear that P4P would drive a significant number of providers out of program networks was precluded in California by the fact that the IHA plans accounted for 60% of the private insurance market. Trying to exit these networks could have had deleterious effects on providers' supply of patients, particularly in areas where IHA plans dominated. The directors of state Medicaid programs made explicit attempts to ensure that their P4P programs did not negatively impact beneficiaries' access to care. Medicaid programs are consequently moving away from features unpopular with providers, such as penalties and payments based on ranking.

These programs thus incorporate characteristics expressly tailored to addressing the three levels of provider reservations about P4P programs. They offer a diverse menu of options from which the authors of future P4P programs can learn.

**Conclusions: The Unfolding Case of Medicare**

In recent years, P4P has been proposed in the discourse surrounding Medicare reform. In an open letter published in Health Affairs in 2003, quality crusader Donald Berwick and colleagues first called for Medicare to lead the movement towards P4P:

> At issue is not the dedication of health professionals but the lack of systems- including information systems- that reduce error and reinforce best practices…We have concluded that such systemic changes will not come forth quickly enough unless strong financial incentives are offered to get the attention of managers and governing boards. As the biggest purchaser in the system, the Medicare program should take the lead in this regard.[13]

Five years later, P4P programs in the private sector and state Medicaid programs have taken off, while Medicare initiatives move tortoise-paced through Washington.

In 2006, the Medicare Payment Advisory Committee (MedPAC) unveiled design principles, measure criteria, and an implementation strategy for a P4P program for Medicare. The proposal was designed to be budget-neutral, affecting only 1-2% of payments, and "shifting the incentives for payment, not the level."[14] It would reward providers both for attaing a certain level of care, as well as for improvement. Collection of measures was not to be unduly burdensome, and the measures themselves were to be evidence-based, focused on aspects of care in need of improvement and that providers could affect, and subject to "appropriate" risk adjustment. MedPAC's two-step implementation process included an initial 2-3 year period in which quality would be measured, existing NCQA practices enhanced, and activities associated with information technology use rewarded. The second stage would establish and implement a set of clinically appropriate measures. The philosophy behind the MedPAC proposal was simple: "Although incentives for quality might not reduce costs, MedPAC believed that Medicare should, at a minimum, get the best value possible for the dollars it was spending."[14]

MedPAC's proposal was accompanied by a provision

in HR 6111, the 2006 Tax Relief and Healthcare Act that called for an additional fee increase of 1.5% for care provided by physicians who reported on a set of measures.[15] This compromise was hammered out in the context of threatened 4.4% reimbursement cuts under the current Medicare payment system. Part of this compromise included the agreement of the AMA to assist in the development of quality measures.[16]

Opposition to P4P in Medicare remains fierce because of the program's size and prohibition against interfering in the practice of medicine. These factors cut to the quick of providers' pocketbook, professional and patient concerns. On the one hand, like the California case Medicare's large market share is unlikely to make it desirable for many providers to stop seeing Medicare patients because of the burdens of P4P program. But providers are also concerned about an inequitable distribution of P4P outcomes. According to William Jessee, president and CEO of the Medical Group Management Association, "The reason some hospitals and practices don't perform well is that the lack the resources to improve. So if you transfer resources from poorer performers, you end up exacerbating the problem rather than solving it."[17] A Medicare P4P plan is also likely to raise provider hackles over the specter of "government-run medicine." By eliciting the help of the AMA in developing measures, and emphasizing the role of already-established measures, the MedPAC proponents of P4P are clearly trying to accommodate concerns of professional autonomy. The sticking point remains the effect of P4P on provider pocketbooks. By touting their proposal as "budget neutral," and introducing a "pay for participation" plan, MedPAC is attempting to convince providers that P4P is not simply a euphemism for pay-cuts. Yet the daily rhetoric about Medicare's cost "crisis" makes these overtures seem thin. In California and the UK, where large market shares were at stake, the success of P4P proposals depended on the introduction of new money.

This July physicians rallied in Washington against a proposed 10.6% Medicare payment reduction.[18] SB 2785, the Save Medicare Act of 2008, gives policy-makers an 18-month window to find a solution to Medicare's flawed payment system. For those who want to see P4P a part of this reform, discussion of provider pocketbook, professionalism, and patients as three areas of concern must form the basis of consensus. Policy-makers should think critically about the lessons learned from California, Medicaid, and UK P4P programs, and use these lessons in creating a Medicare program that will garner support from a wide variety of stakeholders.

**References**


1. Casalino, Lawrence P, et al. "General Internists' Views on Pay-for-Performance and Public Reporting of Quality Scores: A National Survey". Health Affairs. 26 (2007): 492-499. p. 494
2. Safavi, Kaveh. "Pay for Performance: Finding Common Ground". Journal of Healthcare Management. 51.1 (2006): 9-12. Expanded Academic ASAP. Accessed 23 July 2008 http://find.galegroup.com.ezproxy.library.tufts.edu/itx/start.do?prodId=EAIM. p. 9
3. American Medical Association. "Pay-for-Performance Principles and Guidelines". Accessed 3 Aug 2008. http://www.ama-assn.org/apps/pf_new/pf_online.
4. Rosenthal, Meredith B., Rushika Fernandopulle, HyunSook Ryu Song, et al. "Paying for Quality: Providers' Incentives for Quality Improvement". Health Affairs. 23, no. 2 (2004): 127-141. Accessed 5 Aug 2008. http://content.healthaffairs.org.ezproxy.library.tufts.edu/cgi/reprint/23/2/127. p. 139
5. Galvin, Robert. "Pay for Performance: Too Much of a Good Thing? A Conversation with Martin Roland." Health Affairs. 25 (2006): w412-w419. Accessed 23 July 2008. http://content.healthaffairs.org.ezproxy.library.tufts.edu/cgi/reprint/25/5/w412. p. w416
6. McDermott, Steve and Tom Williams, eds. Advancing Quality Through Collaboration: The California Pay for Performance Program. Integrated Healthcare Association, February 2006. Accessed 5 Aug 2008. http://www.iha.org/wp020606.pdf p. 3
7. Rosenthal, Meredith B., Rushika Fernandopulle, HyunSook Ryu Song, et al. p. 133
8. Kuhmerker, Kathryn and Thomas Hartman. "Pay-for-Performance in State Medicaid Programs: A Survey of State Medicaid Directors and Programs". The Commonwealth Fund. April 2007. Accessed 5 Aug 2008. http://www.commonwealthfund.org/publications/publications_show.htm?doc_id=472891.
9. Felt-Lisk, Suzanne, Gilbert Gimm and Stephanie Peterson. "Making Pay-for-Performance Work in Medicaid". Health Affairs. 26 (2007): w516-w527. Accessed 5 Aug 2008. http://content.healthaffairs.org.ezproxy.library.tufts.edu/cgi/reprint/26/4/w516. p. w517
10. Smith, Peter C annd Nick York. "Quality Incentives: The Case of UK General Practitioners". Health Affairs. 23 (2004): 112-118. p. 113
11. Roland, Martin. "Linking Physicians' Pay to the Quality of Care: A Major Experiment in the United Kingdom". The New England Journal of Medicine. 351 (2004): 1448-1454. PubMed. 23 July 2008. http://content.nejm.org.ezproxy.library.tufts.edu/cgi/reprint/351/14/1448.pdf. p. 1448
12. Galvin, Robert. "Pay for Performance: Too Much of a Good Thing? A Conversation with Martin Roland." Health Affairs. 25 (2006): w412-w419. Accessed 23 July 2008. http://content.healthaffairs.org.ezproxy.library.tufts.edu/cgi/reprint/25/5/w412. p. w417
13. Berwick, Donald M, et al. "Paying for Performance: Medicare Should Lead". Health Affairs. 22, no. 6 (2003): 8-10. Accessed 5 Aug 2008. http://content.healthaffairs.org.ezproxy.library.tufts.edu/cgi/reprint/22/6/8. p. 8
14. Milgate, Karen and Sharon Bee Cheng. "Pay-for-performance: The MedPAC Perspective". Health Affairs. 25 (2006): 413-419. Accessed 3 Aug 2008. http://content.healthaffairs.org.ezproxy.library.tufts.edu/cgi/reprint/25/2/413. p. 415
15. Wilensky, Gail R. "Pay for Performance and Physicians: An Open Question." Healthcare Financial Management. 61.2 (2007): 40-41. Academic OneFile. Accessed 23 July 2008. http://find.galegroup.com.ezproxy.library.tufts.edu/itx/start.do?prodId=AONE. p. 40
16. Terry, Ken. "Score One for CMS." Medical Economics. 16 June 2006: 44-46. Accessed 3 Aug 2008. http://find.galegroup.com.ezproxy.library.tufts.edu/itx/start.do?prodId=AONE.
17. Terry, Ken. "Tackling Pay for Performance: Professional Associations are Moving to Help Ensure its Fair to All Physicians." Medical Economics. 6 May 2005: 16. Academic OneFile. Accessed 23 July 2008. http://find.galegroup.com.ezproxy.library.tufts.edu/itx/start.do?prodId=AONE.
18. "Physicians Participate in Capitol Hill Rally to Support Medicare Payment Reform." American Family Physician. 77 (2008): 1209. Expanded Academic. Accessed 3 Aug 2008. http://find.galegroup.com.ezproxy.library.tufts.edu/itx/start.do?prodId=EAIM

# Health, Ethics, and Policy News

### Genetic Information Nondiscrimination Act

On May 21, 2008, President Bush signed into Law the Genetic Information Nondiscrimination Act which will ensure that individuals genetic histories cannot by used against them in gaining insurance or employment. Insurance companies may not request that individuals receive genetic tests, access personal genetic information, or use genetic data in premium and enrollment decisions. Similar standards were set for employers, including stiff fines for collecting genetic data illegally. Concerns, however, have arisen that the law "is emblematic of this country's piecemeal and inconsistent approach to health care policy," as noted by Korobkin and Rajkumar in the *New England Journal of Medicine* (Volume 359, 335-337). The authors argue that the law will not cover an individual with a family history of colon cancer whose recent colonoscopy reveals pre-malignant polyps. As a result an insurance company may still legally raise the costs for this individual, though the individual may bear as of yet unknown colon cancer markers. The critique of the law may be found at http://content.nejm.org/cgi/content/full/359/4/335.

### Post-Election Medicaid Regulations

The Bush Administration recently announced that it will enforce a new regulation, initially proposed in 2007, limiting the provision of outpatient hospital services to individuals on Medicaid. The rule is scheduled to take effect on December 8, 2008. The administration argues that payments for some services have become excessive and the regulation notice states that the rule "represents a new initiative to preserve the fiscal integrity of the Medicaid program." Various hospitals and officials have argued that these reductions will cut back on services like dental and vision care, diagnostic and laboratory services, and medical transportation. Charges for outpatient services for Medicaid, which provides healthcare coverage for over 50 million individuals with low incomes, are typically higher in hospital settings. The administration has already posted several new regulations regarding Medicaid, all of which would have cut services. However, Congress has posted moratoriums on the remaining rules, though it did not do so in this case. A comprehensive overview of the regulations can be found through the Kaiser Family Foundation website at http://www.kff.org/medicaid/upload/7739.pdf.

### Genome of Individual with Cancer

Researchers at the University of Washington in St. Louis have recently sequenced the genome of a woman who died at age 50 from acute myeloid leukemia. The effort marks the first time that large scale genetic sequencing has been used to sequence cancerous cells and compare them against normal cellular DNA. Ten mutations were observed within the cancerous cells, eight of which had been previously unobserved by conventional small scale genome studies. The mutations observed accounted for factors such as the cancerous cell's ability to grow abnormally and resist chemotherapy. Current practical applications of the research are limited, but scientists expect the findings to contribute towards the development of new treatments and the ability to tailor therapy plans for patient specific cancers. The complete paper "DNA sequencing of a cytogenetically normal acute myeloid leukaemia genome," can be found in the November 6, 2008 issue of *Nature* (Volume 456, 66-72).

### National Children's Health Study

In 2000, Congress passed the Children's Health Act which was designed to provide funding and support for a "national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development (Section 1004)." Now researchers have finally begun to assemble the 100,000 pregnant women whose children they will follow for the next 21 years. Researchers hope that the project, which is slated to cost nearly $2.7 billion, will discover some of the factors contributing to the current rise in autism, premature births, obesity, asthma, diabetes, mental health disorders, and many other health related issues. Subjects in the study will be drawn from 105 study locations and selected from a mixture of ethnic, racial, economic, religious, geographic, and social groupings. The health study was designed by over 2,400 researchers and will be administrated primarily through major health institutions and universities, totaling forty regional centers. Preliminary results from the study are expected to be available as early as 2011. Additional information regarding the study and its goals is available at http://www.nationalchildrensstudy.gov.

### Physician Assisted Suicide

On November 4, 2008 voters in Washington State passed Initiative 1000 by a margin of 59 to 41 percent, approving the prescription of medication by physicians to terminally ill patients to accelerate the patient's death. In order to request this service patients must be deemed mentally competent, be residents of the state, and have a predicted life expectancy of less than six months, as deemed independently by two physicians. The patient must also submit the request orally and in written form. The patient is required to administer the medications him- or herself and they are required to be informed about alternatives to the procedure. For more information about physician assisted death see Dr. Timothy E. Quill's paper on the topic in the *Hastings Report* 38, no. 5 (2008) at http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=2232.

### Doctors Prescribe Placebos

A survey of 1200 randomly chosen internists and rheumatologists, of whom 679 responded, found that approximately half prescribed placebo treatments. Vitamins and analgesics were the two most commonly prescribed forms of placebos. Those physicians who did prescribe placebos often described them as either potentially useful or did not inform the patient what the medication would actually do. The study is in the *BMJ* 2008; 337:a1938 and is available at http://www.bmj.com/cgi/content/full/337/oct23_2/a1938.

### Cardiac Transplantation for Infants

Cardiac transplant surgeons at the Denver Children's Hospital decided to remove the hearts of infants 75 seconds after the hearts stopped beating. No heart has been recorded as spontaneously restarting after more than 60 seconds. The physicians decided to allow 75 seconds for two of the infant donors, after allowing 18 minutes of cardiac-death pre-transplantation for three other infant donors. Current organ donor rules indicate that the donor must be declared either brain-dead or suffer from cardiac-death. The procedure remains ethically and medically controversial at the time. For more information, see the study, published in the *New England Journal of Medicine* (Volume 359:709-714) at http://content.nejm.org/cgi/ content/full/359/7/709.

This section was compiled and researched by Michael Shusterman (Associate Editor). News briefs and highlights are selected for relevant, interesting, and potentially controversial health, ethics, and policy topics.

### Research Highlights: Healthcare Policy

During this election cycle healthcare once again returned as a pivotal issue. The election of Senator Barrack Obama has led many to believe that fundamental change in the American healthcare system will follow in the next four years. Yet, the current economic crisis and the details of the Obama proposal make many wonder whether reform will be possible. In this special section TuftScope highlights current views on the healthcare system, the Obama/Biden plan, and critiques of the proposal.

#### Overview

- "Myths and Misconceptions about U.S. Health Insurance"

*Health Affairs*. Web Exclusive, October 21, 2008 http://content.healthaffairs.org/cgi/content/abstract/hlthaff.27.6.w533

- "The Politics of Paying For Health Reform: Zombies, Payroll Taxes, and the Holy Grail"

*Health Affairs*. Web Exclusive, October 21, 2008 http://content.healthaffairs.org/cgi/content/abstract/hlthaff.27.6.w544

- "Voters and Health Reform in the 2008 Presidential Election"

*The New England Journal of Medicine*. Volume 359:2050-2061. http://content.nejm.org/cgi/reprint/359/19/2050.pdf

#### Obama Plan

- "Affordable Health Care for All Americans"

*JAMA*. 2008; 300(16):1927-1928 http://jama.ama-assn.org/cgi /reprint/300/16/1927

#### Critiques

- "Symptomatic Relief, but No Cure — The Obama Health Care Reform"

*The New England Journal of Medicine*. Volume 359:1648-1650. http://content.nejm.org/cgi/content/full/359/16/1648

- "The Obama Plan: More Regulation, Unsustainable Spending"

*Health Affairs*. Web Exclusive, September 16, 2008 http://content.healthaffairs.org/cgi/reprint/hlthaff.27.6.w462v2

TUFTSCOPE
Mayer Campus Center
Mailbox #146
Tufts University
Medford, Massachusetts 02155
ISSN: 1534-7397
Website: http://ase.tufts.edu/tuftscope
Email: TuftScope@gmail.com