

Cancer and Diabetes Innovations, Opportunities and Challenges

Presented on March 5, 2008

A forum discussing the current and future biopharmaceutical innovations in cancer and diabetes; the latest approaches to chronic care, disease management and drug therapy and the immediate help available to New Yorkers who do not possess prescription drug coverage.



ALBANY LAW SCHOOL
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Community Health Care Association of New York State
Defining New Directions

INTRODUCTION

On March 5, 2008, The New York Health Products Council hosted a forum, “Cancer and Diabetes Innovations, Opportunities and Challenges” in the Presidents Room of Albany’s Fort Orange Club.

In sponsoring the forum, the Council was joined by the American Cancer Society (ACS), The Community Health Care Association of New York State (CHCANYS), The Business Council of New York State, Inc., The New York Biotechnology Association (NYBA), The Medical Society of the State of New York (MSSNY), PhRMA, Rensselaer Polytechnic Institute’s Center for Biotechnology and Interdisciplinary Studies, Albany Law School’s Science & Technology Law Center, and the Center for Economic Growth, and Bioconnex.

The forum’s discussion centered on current and future biopharmaceutical innovations in cancer and diabetes, the latest approaches to chronic care, disease management, drug therapy and the immediate help available to New Yorkers who do not possess prescription drug coverage.

Sharing the duties of moderator were Peter Slocum, Vice President Advocacy, American Cancer Society, Eastern Division and Patricia Clancy, MPH, Vice President, Public Health and Education, The Medical Society of the State of New York.

Biopharmaceutical Innovations in Oncology and Diabetes - The Vital Role of The R&D Pipeline was presented by Jean Beebe, PhD, Executive Director, Development Team Leader, Inflammation, Pfizer Global Research and Development, Groton/New London Labs.

Loretta Molinari, R.N., Deputy Director, Putnam County Health Department joined with moderator Peter Slocum for a presentation of *Pain Management, Palliative Care, Initiatives of ACS, NYS Cancer Consortium and, an update on the State Cancer Plan.*

Margaret A. Brennan, MPH, Chief Operating Officer of the Community Health Care Association of New York State (CHCANYS) and Kate Breslin, Director of Policy at CHCANYS, discussed *The Role of Federally Qualified Health Centers (FQHC’s) in Improving Primary Care and Chronic Disease Management and the Success of Patient Screening Initiatives.*

Nathan Tinker, PhD, Executive Director, New York Biotechnology Association, Inc., emphasized *The Importance of the Biopharmaceutical Industry and its Innovation Gateway to the Empire State’s Economy.*

The forum concluded with a presentation from Scott Armstrong, President of Armstrong Communications/Alliance Development, Partnership for Prescription Assistance, entitled *Help is Here: the immediate help available to New Yorkers who do not possess Rx Drug Coverage.*

Cancer and Diabetes Innovations, Opportunities and Challenges: presented by Dr. Jean Beebe

Biopharmaceutical companies have dedicated many years of scientific research attempting to uncover the mysteries of two of the world's most prevalent, and growing diseases -- cancer and diabetes. While much is understood about their causes, complexities, and symptoms, solutions come slowly, and at great cost.

The need for solutions is clear. In America alone, projections are that 1.2 million people will be diagnosed with cancer, causing half a million deaths per year. On average, that's a fatality rate of one person per minute.



As for Type 2 diabetes, there is a 59% increase projected for North America -- and a startling 91% increase in Asia, Europe, and Africa. Ninety-seven percent of all insulin users and 80% of non-insulin users will develop retinopathy which will result in blindness. And, a majority of all diabetics will develop nerve pain.

Now that the human genome has been mapped, there is even greater promise in pharmacology for the treatment of these all too common, deadly afflictions. But discovering and developing solutions is a long and arduous road to travel. The starting point is an idea, based on what is already understood.

In oncology, the idea can begin with the goal of inhibiting the growth of the cancer cell - Finding and interrupting a signaling pathway in the tumor that will stop the cancer cell from growing.



It's not as simple as it may sound. The process can take up to 12-15 years, and success is rare. It starts by assembling a team of scientists -- chemists, biologists, clinicians -- who figure out what pathways to interrupt to discover a new drug. They look through a company library of millions of existing compounds to find compounds that have the desired activity. Chemists synthesize and optimize these compounds for the desired activity in the lab.

If there's success in laboratory tests, then the scientists progress to animal studies, and it's at this early stage that discussions begin with the FDA about benefits and risks to potential patients. Safety studies are devised and implemented. If positive data results, the next step is to produce the medicine in appropriate form for administration in clinical trials. Next, clinical testing requires enough of the compound -- as tablets, capsules or IV injection -- to ensure that patients in the study have sufficient medicine to last through the clinical trial.

There are three stages of clinical development, a key difference being the numbers of people exposed to the new medicine. In phase one, the emphasis is on safety, and to minimize risk, the drug is tested in forty or so healthy volunteers. In phase two, safety is still a major concern, and now efficacy is measured with a focus as to whether there is an early indication that the drug has a clinical benefit for a patient with the targeted disease.

If the results are positive, phase three clinical trials can include between 3,000 and 10,000 patients. This is a global trial, which attempts to confirm the drug's efficacy and safety in different geographies, among different ethnicities.

Success there leads to registration with the FDA so the compound can be available to physicians and patients. The odds are long -- a hundred to one.

We Will...

- **Prosecute 100 different discovery ideas;**
 - **Generate over 100,000,000 data points;**
 - **Bring over 20 candidates into development;**
 - **Spend \$500 MM - \$1 Billion over 8-12 years**
- to find a single drug.**

For every 100 discovery ideas, only one of these will ultimately become a drug. This will cost between a half a billion to a billion dollars over a period of 12-15 years. The most challenging and costly part of the business is when drugs fail in the large patient studies, which is the reason that so much is being invested in to trying to find the winners early in the discovery process. It benefits everyone - shareholders included -- when the patients being exposed to the drug are the ones most likely to respond.

Before electronic filing, the amount of paper that was generated for FDA approval for just one drug would fill a tractor-trailer. While electronic filings are saving paper, the amount of documentation is actually growing every year.

In Type 2 diabetes - the most prevalent type of the disease - patients have insulin resistance and/or produce insufficient amounts of insulin. Preferred treatment areas focus on risk factors that lead up to the disease and its complications. Thirty years ago, what science knew about insulin was simply that it binds its receptor and delivers a desired effect.

The sequencing of the human genome has opened up a world of possibilities for new drug discoveries, such as intervening at different points in the process, providing the same effect but without the damage that insulin causes.

There are a variety of approaches being explored to modulate the storage and metabolism of glucose. It will take many more years of testing and clinical trials before these products are approved by the FDA.

In the future treatment of cancer, the key is targeted therapies, to avoid the toxic side effects of standard chemotherapy. Normal cells have a built-in time limit -- divide many times, then die. Cancer cells ignore this "trigger."

A targeted drug would help the immune system recognize tumor cells, so that it could destroy it without the need for any other medicines. Another solution would be to block cancer-signaling pathways without blocking healthy cell growth.

MOLECULAR PROFILING

Molecular profiling - a key to future therapy - means that when cancer is diagnosed, the particular pathways that a specific cancer needs to grow would be identified, and there would be a drug to intervene in precisely those pathways. This kind of targeted chemotherapy is more effective and less toxic.

Therapeutic retarding of the disease is already working in very selective patient populations. The long term vision is to view cancer as a chronic manageable disease that's treated with highly effective agents that oncologists will have at their disposal -- a number of drugs that are designed to treat or inhibit different signaling pathways. If and when that stage is reached, cancer will be treated earlier.

INDUSTRY R&D ANNUAL OUTLAY

The investment in all this science: one biopharmaceutical company alone has an R&D budget between 7 and 8 billion dollars -- roughly one third of the entire National Institutes of Health academic research budget. The company's cancer research accounts for 10 to 15% of that budget.

Pain and Palliative Care: presented by Peter Slocum and Loretta Molinari, R.N.

Pain and palliative care is an important consideration in treating both diabetes and cancer. The American Cancer Society's concern reaches from the laboratory to the bedside. The Society's support for cancer patients and their families involves funding and advocacy for research, demanding access to care, prevention, diagnosis and treatment, and paying special attention to the quality of life issues faced by patients and their families.

Data shows that 50 to 70% of all cancer patients, and 40% of those with advanced cancer, experience uncontrolled pain. While there are many medications available to address the problem, not all of them work for everyone, and finding the right solution is often difficult.

But are we really trying? Only recently have major hospitals established pain and palliative care programs. The problem is balancing society's legitimate concerns with drug dependence and abuse with a patient's equally compelling concern for pain relief and appropriate treatment.

Improved education for patients, families, nurses, and physicians about the possibilities and science of pain management is important. To that end, a bill passed by the New York State legislature will establish new education programs and grants for medical schools, and will authorize the creation of palliative care resource centers. The issue is one of the focal points of the NYS Cancer Consortium. And, there is federal legislation to fund more pain palliative care research at the National Institutes of Health.

HUDSON VALLEY PAIN IMPROVEMENT PARTNERSHIP

New York State is leading in many important ways. One is community-based efforts to spread the word to lay and medical people about the opportunities for improved pain management. A good example of this grassroots approach is the Hudson Valley Pain Improvement Partnership.

Develop comprehensive, interdisciplinary pain management programs in health care organizations across the Hudson Valley.

PAIN FOLLOWS THE PATIENT

The guiding principle, Pain Follows the Patient, makes the point that it's management of pain across the continuum of care that's so necessary -- not just in the acute care hospital setting, but in all health care provider settings that the patient may be accessing, such as home care agencies, nursing homes, and rehabilitation facilities. Once the patient is returned to his/her own home, care must be taken to assure that the patient and family can continue effective pain management practices independently at home. The goal is to improve how pain is managed by providers, which includes improving knowledge and attitudes about pain and pain management, fostering development and implementation of pain action plans, and developing comprehensive interdisciplinary pain management programs in health care organizations.

To be effective, the knowledge and practice of pain management should be woven through all levels of a health care institution -- not just nurses, but therapists, and nurses' aides. Most importantly, administrators must lead the way and establish a culture whereby effective pain management is the expectation. As was stated at the presentation, uncontrolled pain is an organizational issue.

It's important to know the basics of effective pain management:

- How to correctly assess pain;
- How to correctly classify pain; knowing that there is a difference between cancer pain and diabetic pain, for example;
- Once assessed and classified, how to effectively treat the pain.

This knowledge has led to new pain assessment and monitoring tools, pain action plans, and revamped management policies and procedures that help clinicians understand the principles of effective pain management including knowledge of pain assessment skills and treatment options.

Barriers to pain management:

- **Patient and family barriers that include fear of addiction and compliance issues;**
- **Health professional barriers that include lack of knowledge and lack of clinical skills;**
- **Health care system barriers that include lack of access to health care and a low priority given to pain control;**
- **Regulatory barriers;**
- **Economic barriers.**

These barriers can be overcome with education, commitment, and dedication.

**Pain management is everyone's responsibility.
Organizational commitment to pain management
is needed.**

What's true in the Hudson Valley holds true throughout New York State: a guiding principle for caregivers is effective pain management -- compassion in action.

The Role of Federally Qualified Health Centers in Improving Primary Care and Chronic Disease Management and the Success of Patient Screening Initiatives: presented by Margaret Brennan and Kate Breslin

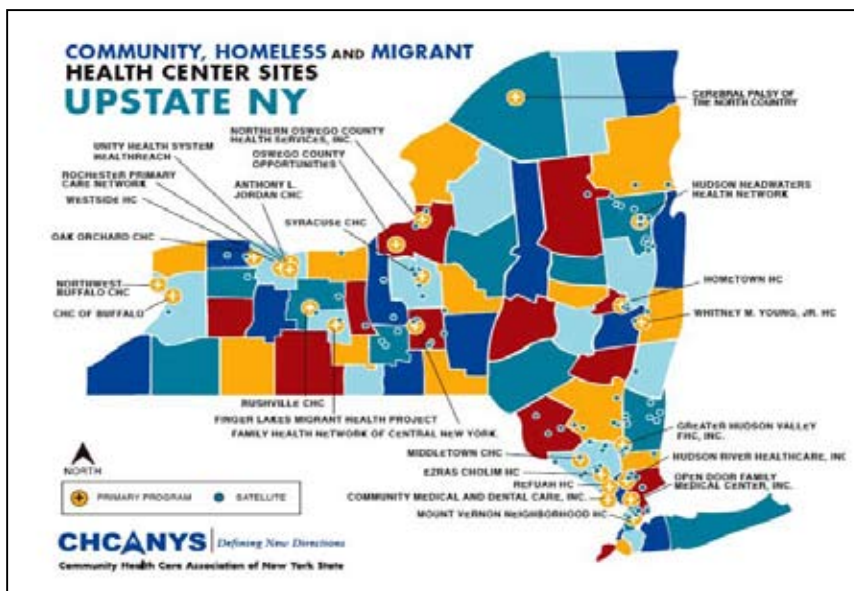
For over 37 years, that’s been an important objective of federally qualified health centers (FQHC) in the state, under their umbrella organization, the Community Health Care Association of New York State (CHCANYS).

FQHC’s have long been an important part of improving primary care and chronic disease management. CHCANYS works to ensure access to high quality community based health care services for all New Yorkers, particularly those in under-served communities.

Federally Qualified Health Centers

- **Local, non-profit, community-run health care providers;**
- **Provide high quality, affordable primary care and preventive services – dental, pharmaceutical, mental health, substance abuse, etc.;**
- **Improve access to care for millions of Americans regardless of their insurance status or ability to pay;**
- **Cost effective, reducing costly emergency, hospital and specialty care, and saving the health care system between \$9.9 to \$17.6 billion a year nationally.**

FQHC’s are local, non-profit community-run health care providers with a mandated 51% or more of their board of directors comprised by consumers of record. These centers improve access to care for millions of Americans, regardless of insurance status or ability to pay, so that anyone walking in the door is served. These centers, which reduce emergency hospital and specialty care are cost effective, as they save the health care system between 9.9 and 17.6 billion dollars a year.



In New York State, the centers see a higher percentage of Medicaid patients than the national average, which results in Medicaid revenues accounting for more than half of the revenues.

Currently there are 56 centers at over 400 sites, serving over 1.1 million New Yorkers, almost 14,000 migrant seasonal farm workers and close to 80,000 homeless patients. Comprehensive services are provided at most of them, including blood pressure monitoring, cholesterol screenings, and even preventive dental services.

CHCANYS staff and patient board members meet with legislators to work to ensure that all New Yorkers have access to high quality community based services.

CHCANYS priorities are focused around ensuring:

- **Health insurance coverage for all New Yorkers;**
- **Access to a high quality health care delivery system for all New Yorkers;**
- **Investment in community-based primary care;**
- **A strong primary care workforce;**
- **Investment in health information technology for primary care providers;**
- **Capital for primary care in under-served communities;**
- **Integration of behavioral health care with primary care;**
- **Access and coverage for high quality oral health care.**

In addition, CHCANYS works to insure health insurance coverage for all and ensure investment in community based primary care. It urges policy makers to invest in reform that strengthens the state's health care infrastructure -- by ensuring a strong primary care workforce, investment in health information technology for primary care providers, investment for primary care in under-served communities, integrating behavioral health with primary care and ensuring access and coverage for quality oral health care.

**The Importance of Biotechnology -- for the region, the state, and patients:
presented by Nathan Tinker, PhD**

Besides contributing to the health of local, regional and state economies, the bioscience industry -- known to insiders as the "Innovation Gateway" -- contributes mightily to the health of patients.

Public perception: private biopharmaceutical companies are responsible for discovering 27% of today's prescription drugs.

Reality: about 90% of the drugs that enter the market place actually begin in private industry, and are developed through private industry pathways.

This "Innovation Highway" starts with research and discovery, technology transfer and business development, develops new medical devices, tests drugs, and provides related services. From an economic and work force development standpoint, it creates new jobs, better health care and quality of life for the patients at the end of that process.

All along this pathway, private industry is opening up economic opportunities, becoming more and more important to New York State as it grows steadily as a center of focus.

Access to Prescription Drug Coverage – Help is Here for New Yorkers who do not possess Prescription Drug Coverage: presented by Scott Armstrong

Prescription assistance for patients has been available for 50 years. Developing, producing and marketing the products of biopharmaceutical industry is an expensive process. The objective is to get the prescription medicine to the patient who needs it.

Prescription Coverage Options for New Yorkers					
Program Name	Eligibility	Description/Benefits	Fee for Participation	Drug Source	How to Contact/Apply
PUBLIC PROGRAMS					
Elderly Pharmaceutical Assistance Coverage (EPAC)	67 years or older, age 67+ who are uninsured or underinsured with gross yearly income of \$15,000 (single) or \$20,000 (joint) or less.	State-sponsored prescription plan. May be used to supplement existing health insurance. Covers most prescription medications.	No Plan fee of \$8 - \$200 based on income plus co-payment of \$3 - \$20 depending on Rx. Indentified Plan. Deductible of \$200 - \$275 based on income plus co-payment of \$3 - \$20. Deductible waived after deductible is met.	Direct pay pharmacy in New York State.	1-888-221-2942 or www.health.ny.gov/epac
Child Health Plus (CHP) (A or B)	Child under age 19. 67 days resident and must not have other equivalent health insurance coverage. Also for pregnant women.	Full Rx coverage and medical services.	Free, or monthly premium of \$9 - \$15 per child depending on family size and income. No co-payment or cost of visit.	Participating pharmacies only.	1-888-478-4342 or www.health.ny.gov/chp
Family Health Plus (FHP)	Lower income adults, age 19-64, who do not currently have coverage or qualify for other public programs such as Medicaid. Eligible income levels change annually and are based on family size.	Full Rx coverage and medical services provided through a local managed care provider.	Yes.	Plans based on managed care program enrollment choices.	Personal literature mailed or www.health.ny.gov/fhp
Medicare Prescription Drug Plans (Now Medicaid Plan 11 for B)	Over age 65 or permanently disabled.	None by Rx and plan.	Monthly premium (avg \$22/month) plus co-pay depending on Rx and plan.	Participating pharmacies.	1-800-469-6248 or 1-888-433-4227
MediGap (Medicare supplemental insurance)	Over age 65 or permanently disabled.	Covers services that are not part of Medicare health plan. 11 MediGap plans provide Rx coverage \$5 (and \$) with savings up to 20% off the cost of prescriptions.	Monthly premium varies by plan and amount of medication. Annual deductibles and yearly co-pay vary by plan.	Direct pay pharmacy in New York State.	Contact the Health Insurance Information, Counseling and Assistance Program at 1-888-731-4331 or www.hicgap.ny.gov
Medicaid	One may be covered by Medicaid if you have high medical bills, receive Supplemental Security Income (SSI) or you meet certain income, resource, age, or disability requirements.	100% Rx coverage and medical services.	Free (some co-payments and premiums may apply depending on income and resources).	Participating pharmacies only.	Contact your local Department of Social Services or the Medicaid Help line at 315-494-9527 / 800-342-3831

The challenge has always been getting the message to those patients. That's why the New York Health Products Council has produced and distributed the Prescription Options Coverage Chart, and why PhRMA created PPA – the Partnership for Prescription Assistance.

PPA works as a “clearing house” of all the programs provided by its members. It began in 2005 out of the recognition that the point of all efforts to develop and promote drugs that can prevent disease and death, is that those drugs get to patients who need them, regardless of their ability to pay.

Trained specialists help patients through the application process. The call center can accommodate approximately 150 languages. 1-888-4PPA-NOW



PPA provides a single point of access for the 500 programs and 2,500 different drugs that are available, in every major disease category, through a toll-free number and website. The patient's privacy is guaranteed, and in most programs, income reporting is on the honor system. In ten minutes, PPA can help put a patient in touch with the right programs.

“I had over \$600 in prescriptions a month and could not afford the medicine I needed to control my diabetes. I contacted a PPA operator and in less than ten minutes I was able to reduce my cost to just \$85 per month. I now rest easy knowing I can get the prescriptions I need to live.” Edito Vasquez, Buffalo, NY

Proof of this was evident right from the start. When the program was being introduced in New York State, Edito Vasquez, a man with advanced type two diabetes, happened in to a health center where PPA representatives were in the middle of a press conference. He didn't have the ability to pay for over \$600 a month for his medications, and he was spending 3 to 4 days a week searching for samples.

The staff called the PPA hotline with Mr. Vasquez's information, and in 10 minutes and 40 seconds, Edito had his 6 medications, at a monthly saving of over \$500, and appeared, gratefully, at the press conference.

- **Largest private-sector effort to help uninsured pay for prescription medicines;**
- **More than 4.5 million patients matched with programs to date;**
- **Helped patients who did not know help was available. 90% of those contacting the PPA have never before enrolled in a patient assistance program, despite the fact that they may have qualified;**
- **Patients are satisfied – More than 70% of patients surveyed are satisfied with the services offered through the PPA.**

Since Edito's experience, 4.5 million prescriptions have been filled, including 150,000 for New Yorkers.

Summation

This forum made clear that intercommunication among biopharmaceutical companies' scientists and researchers, community leaders, state and regional public and private health care givers, administrators and consumer advocates is vital to helping to create an understanding of a vast wealth of specialized knowledge.

The information shared -- cancer and diabetes solutions that are in the biopharmaceutical pipeline, the needs of patients and the concerns of their families, the efforts of advocacy organizations, the cooperation of government leaders and the availability of relief to under- and uninsured New Yorkers -- can result in a continued advancement of the objective of all of the health care stakeholders: the ultimate conquest of two of society's greatest ills cancer and diabetes.



The New York Health Products Council is a non-profit educational organization of the research oriented biopharmaceutical companies doing business in New York State. The Council's major objective is both to improve the understanding of the important role of biopharmaceuticals and the biopharmaceutical innovation and discoveries to the advancement of patient centered health care; and to demonstrate the value of the considerable contributions of our member companies to the economic and technological vitality of the Empire State.

- Abbott Laboratories • Amgen • Astellas Pharma US., Inc. • Daiichi Sankyo, Inc.
 • Eli Lilly & Company • GlaxoSmithKline • Johnson & Johnson • Novartis Pharmaceutical Corp.
 • Pfizer Inc. • sanofi-aventis Group • Takeda Pharmaceuticals