

Drug Access Restrictions:



What Are the Medicaid Implications?

**NEW YORK
HEALTH
PRODUCTS
COUNCIL**

Executive Summary
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INTRODUCTION

On March 23, 2005, the New York Health Products Council hosted “Drug Access Restrictions: What is the Social Cost?” presented by Valentine J. Burroughs, MD, MBA at the Legislative Office Building at the Empire State Plaza in Albany, New York. The presentation and Q&A session were part of an ongoing series of health care forums designed to improve the understanding of the importance of pharmaceuticals to New York State’s health care system.

Dr. Burroughs is the Chief Medical Officer of North General Hospital in New York City, the only private hospital located in Harlem, and the premier health care destination in the area, employing new and innovative strategies to address the unique health care needs of the many faces of its community. He serves as the Chair of the Health Policy Committee of the National Medical Association, a national professional and scientific organization of physicians founded in 1895 that promotes the collective interests of physicians and patients of African descent. It is a leading force for parity in medicine, elimination of health disparities and promotion of optimal health.

Dr. Burroughs is a co-author of “Racial And Ethnic Differences In Response To Medicines: Toward Individualized Pharmaceutical Treatment,” published in the *Journal of the National Medical Association*.

Based on his experience as a clinician and practicing physician, Dr. Burroughs’s main hypothesis is that “narrowing patients’ therapeutic options has potentially negative ramifications, especially for minority patients, from a purely genetic standpoint.”

Medicaid Amplifies Health Care Disparities

Health care disparities are defined as “diseases that disproportionately affect a specific population.” In New York state, over 13 million African Americans, Hispanic, Asian and female New Yorkers are at risk of suffering a disproportionately greater incidence of Asthma, HIV, Diabetes, Mental Illness, Chronic Kidney Disease and Heart Disease.

Dr. Burroughs made it clear that a “one size fits all” approach to prescription medicine worsens health care disparities among those with genetic and biological differences will actually increase overall health care costs by far more than the savings realized by restricting access, and that these problems are magnified greatly in the Medicaid population.

Dr. Burroughs pointed out that while it’s easy to focus on trying to save money on prescription drugs, the real health care cost drivers are elsewhere. Prescription drug costs in Medicaid account for less than 10% of the total cost of the program. And just twenty-five percent of the Medicaid population – the aged and disabled — accounts for 70 to 80% of those drug costs.

Despite these facts, states are instituting restricted prescription drug access programs. Even though many of these restricted access

programs attempt to allow for exemption by requiring health care professionals to submit prior authorization and fail first forms – paperwork that explains why a listed drug doesn’t work, why it failed, what other drugs have been tried. The problem with this approach is that it adds red tape, creating another roadblock to equal health care for all. In a national Joint Center for Economic Studies survey, a thousand black elected officials were very concerned that restricted drug lists and prior authorizations would affect minorities disproportionately.

Doctors and other health care providers are already fighting time, and the bureaucracy is adding to their burden. The doctor has to choose among three counter-productive options: to treat the patient from the restricted list, to fill out the forms and make the patient wait for the proper drug, or to give up and stop seeing Medicaid patients at all.

The expedient choice is to treat from the restricted drug list. But the same biological and genetic factors that make specific groups more susceptible to some afflictions also cause differences in their ability to metabolize medicines, alter the effectiveness of medicines, and may trigger unique side effects from medicines in these patients.

Current Research on Restricting Medication Access

- 3 basic points from the research presented in this special issue of the American Journal of Managed Care (AJMC)
- First, the rapid adaptation of PDLs should not proceed without serious research into their consequences for patient outcomes
 - Link to patient discontinuation of therapy
 - Link to increased hospitalizations
 - Link to increased physician visits

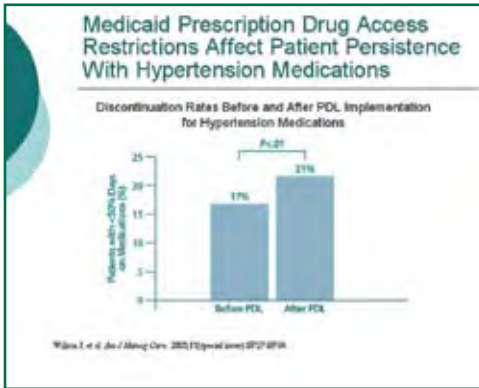
National Survey of 1,000 Black Elected Officials by Joint Center for Political and Economic Studies

- Concerned about potential effects on constituents of Medicaid restrictions on drug access
- Preferred Drug List (PDL's) and prior authorization programs
- 70% believe that such restrictions will make patient health worse
- Current research in the January Special Issue of American Journal of Managed Care supports their concerns

Many drugs affected across different drug classes by genetic variations in drug metabolism enzymes

- Antiarrhythmics, antidepressants
- Beta-blockers, neuroleptics
- Opioids, barbiturates
- Benzodiazepines

As the drugs on the restricted lists change, and they will, the preferred drug for a given condition will change. Since different groups metabolize the same drug differently, the substitutions that result will more than outweigh the savings in drug costs, because patients will experience more problems. That will force them to seek more expensive care – many more visits to doctors and hospitals — to correct those problems caused by the arbitrary restrictions.



Such negative – and costly — results have already been seen in hypertensive patients who were denied a drug that had stabilized their condition, and switched to a drug on a restricted list.

Another unfortunate side effect of restricted drug lists is the likelihood that the decisions will be taken out of the hands of health care professionals and given to the governmental committees decide what drugs can be prescribed.

“...patients with hypertension that were stable, feeling good on their medication, when they were switched ... this led to service substitution – more doctor visits to repair those blood pressures, more hospitalizations and certainly more side effects...”

By changing the focus from the least expensive component of total health care costs to the more expensive components (e.g. long-term care and hospitalization), government and the health care industry together can accomplish two important goals: long-term savings and a real solution to the problem of health care disparities.

The answer is Evidence-Based Medicine, allowing health care professionals to decide the best course of treatment for their patients.

Genuine savings will be realized because the best treatment for each patient will result in a healthier population – regardless of genetic and biological differences – with no need for expensive service substitutions.

- ### Implications of Genetic Polymorphisms
- o Alterations of drugs and pharmacokinetic properties.
 - o Clinically increased or decreased in the intensity and duration of the expected drug effect
 - o Drugs of the same class may be cleared by different metabolic pathways
 - o Pathophysiology and disease may differ among racial groups (e.g., hypertension)

- ### Implications of Genetic Polymorphisms
- o Dosage adjustments may be necessary in using generic drugs as therapeutic substitutions in untested racial and ethnic groups.
 - o Toxic accumulations of substitute generic drugs from slower metabolism.
 - o “Service substitutions” and higher overall health care system costs to supplement ineffective generic drugs.
 - o Demand in either case, for a greater use of health system resources obviating the original purpose of cost containment

CONCLUSION

The “one-size-fits-all” approach to prescribing medicines leaves a significant portion of our population with a level of health care below their neighbors.

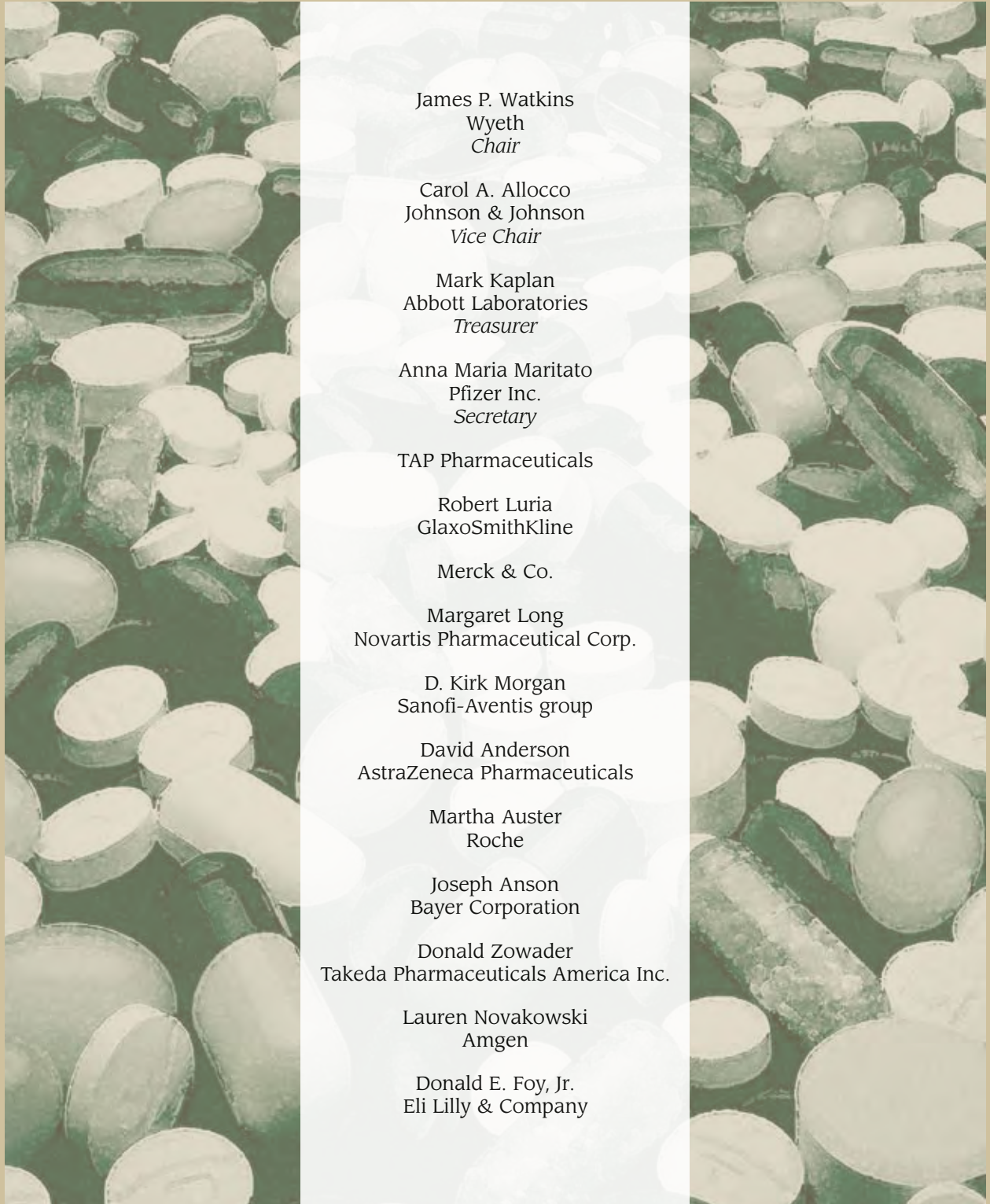
Restrictive formularies and preferred drug lists claim to allow exceptions, but in actual practice, complicated reporting procedures discourage the health care professional from taking time away from treating their patients in order to fill out reports and deal with bureaucracy.

“... it’s our obligation to protect and make sure the poor get and that they continue to get what they’re intended to get ... the proper drug for their condition, and not excluded based on a ... list that’s created by a group of consultants not including health care providers... who know something about what their real needs are.”

The ill effects of these access restrictions will fall disproportionately on the minority community. And that leaves us with a strong likelihood that we’ll have a great setback in any advances we’ve had toward resolving health care disparities by 2010, the year the U.S. Surgeon General has targeted.

Health care disparities will be exacerbated if we continue to limit access to pharmaceuticals. The consequences will be measured not just in added cost, but also in lower quality of life and unfortunately death. Greater choices in treating our diverse population are critical and the key to improving the health care for our minority populations.

The opinions expressed are of the presenters, and do not necessarily reflect the opinions of any institutions with which they are affiliated with, or of the sponsor.



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