

## RX AND HEALTH CARE REFORM

*Ann Woloson, Executive Director, and Jean Grigsby, Communications Director*

ONE OF THE BIGGEST QUESTIONS ABOUT the past several decades of US domestic policy has finally been answered: Yes, the Patient Protection and Affordable Care Act will help correct what has become a fundamentally unjust US health care system. By providing coverage to an estimated 32 million uninsured people, this new law marks the beginning of a far more equitable system in which almost all of us will have access to comprehensive health care coverage. We won't be denied coverage because of pre-existing conditions, nor will it be canceled because of illness. These policy changes usher in a new era of health care that helps pave the way to expanding access to prescription drugs, which we hope will be the safest, most effective, and most affordable medications.

One notable aspect of the new law is the inclusion of the Physician Payment Sunshine provisions to require drug and device companies to disclose gifts and payments they make to physicians and teaching hospitals. In response to the revelation that physicians receive millions of undisclosed dollars for speaking and advisory roles for drug companies—even as they conduct research on drugs made by those companies—the Sunshine provisions will help protect prescribing from the excessive influence of the pharmaceutical industry. At the same time, they empower consumers by making the disclosures available to the public on a searchable website thereby exposing possible conflicts of interest to the light of day.

Another feature of the new law, which is of particular significance to those on Medicare, is the first step



Prescription drug policy is a great place to start in terms of improving health care quality—especially safety and effectiveness—while containing costs.

toward closing the infamous gap in Part D coverage, known as the “donut hole.” This year, seniors who enter the prescription drug coverage gap will get \$250 to help pay for their medications. Going forward, drug-company discounts on brand-name drugs and federal subsidies and discounts for all drugs will gradually reduce the gap, eliminating it by 2020. By that time, seniors, who now pay 100 percent of their drug

costs once they hit the gap, will pay 25 percent. And, as has already been the law, once seniors spend a certain amount on medications, they will get “catastrophic” coverage and pay only 5 percent of the cost of their medications.

The new law also provides a 23 percent Medicaid discount (rebate) on new drugs, which may appear to be good news. However, it's unclear how effective the rebates will be in providing relief since the rebates are based on the price set for the drug by the manufacturers and are usually offered only for the newer, more expensive drugs, which often are no more effective or safer than others on the market. As states and the federal government are pushed to put newer, more expensive drugs on their formularies and preferred drug lists, rebates are held out like carrots in an effort to persuade the inclusion of certain drugs. How the increased rebates for certain drugs affect the ability of consumers to access the most effective and safest prescription drugs they need should be carefully monitored, as

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## ENGAGING CONSUMERS IN EVIDENCE-BASED PRESCRIBING

WE ALL ARE EXPOSED TO PRESCRIPTION DRUG ADS EVERY DAY, on television, on the radio, on the Internet, or in the magazines. They are ubiquitous. On television alone there are, on average, 80 drug ads every hour, every day according to Nielsen Company data. Pharmaceutical industry spending on direct-to-consumer drug marketing totals approximately \$4 billion each year.

Drug companies defend aggressive direct-to-consumer advertising, saying that drug ads play a necessary role in patient education, yet they heavily rely on traditional advertising techniques such as emotional appeals and “branding” rather than on the scientific facts. These pervasive drug industry marketing tactics push up costs by steering patients to the newest, most expensive, and widely advertised drugs, even when those drugs might not be the best choices for them in terms of safety, efficacy, and cost.

PPC fully supports consumer engagement in prescription drug decision-making and is taking action to help connect consumers in Maine with the best available, objective, sci-

**Credible, independent information can help patients become part of the movement toward evidence-based prescribing which can improve health care quality while controlling costs.**

entific sources of information on prescription drugs to guide their choices and empower them to have thoughtful conversations with their prescribers.

Replacing the marketing hype with credible, independent information can help patients become part of the movement toward evidence-based prescribing

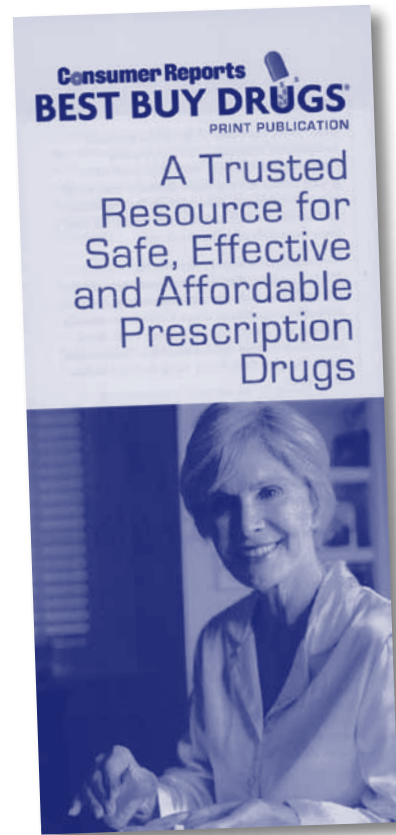
which can improve health care quality while controlling costs. The ultimate goal is to help consumers ensure they are getting the right drug at the right time for the right price.

PPC’s work to engage Maine consumers in evidence-based prescribing is supported by the Maine Health Access Foundation. The second year of this two-year grant builds on PPC’s previous work to promote evidence-based prescribing by reaching out to clinicians, including supporting the launch of Maine’s Independent Clinical Information Service (MICIS).

By addressing both prescribers and consumers in Maine, PPC is helping to shape how drugs are prescribed, moving the culture away from a top-down, commercially influenced approach and toward a norm of fully informed, shared decision-making.

PPC will develop channels for reaching Maine consumers, including working with large employers that are already actively attempting to engage employees in improving their health. There will also be a special focus on reaching out to pharmacies within the state, a natural ally in this important effort.

PPC will also tap into emerging online social networks of engaged consumers in Maine, to ensure that our message



*Collaborating with Consumer Reports Health Best Buy Drugs™ in order to provide consumers with unbiased information about prescription drugs is just one aspect of PPC’s evolving consumer engagement efforts. To learn more about the drugs available to treat specific illnesses and diseases, the differences among them, and how they stack up against each other, go to [www.policychoices.org](http://www.policychoices.org) and follow the link to Consumer Reports Health Best Buy Drugs™ in the lower left-hand corner of the home page.*

### MAINE’S INDEPENDENT CLINICAL INFORMATION SERVICE (MICIS)

MICIS has recently expanded its offerings to include a new educational module on the latest evidence concerning anti-platelet therapies. The module covers the risks, benefits, and indications for a range of anti-platelet therapies and answers common questions, such as when is Plavix preferred over aspirin and when is it not. Practitioners interested in receiving an educational visit by a trained clinician in the convenience of their own office may contact Kellie Miller at the Maine Medical Association at 207-622-3374, ext. 229 or [kmiller@mainemed.com](mailto:kmiller@mainemed.com). An Adult Type 2 Diabetes module is also available.



utilizes all of the existing channels for reaching consumers. For example, PPC is supporting the efforts of Quality Counts, the Maine Health Management Coalition, and the Maine Quality Forum as they work collaboratively on a Robert Wood Johnson Foundation initiative known as Aligning Forces for Quality. Specifically, PPC has joined Align-

PPC will offer educational resources for consumers detailing where to go for unbiased information about prescription drugs, as well as questions to ask their doctor to ensure they are getting the safest, most effective, and most affordable drug choice.

ing Forces for Quality's Consumer Engagement Leadership Team which has recently launched the HealthyME pages on Facebook and Twitter that give consumers information about staying healthy and managing ongoing health conditions. The pages also provide opportunities to connect with other consumers and providers on the discussion boards.

*Facebook:* <http://www.facebook.com/pages/HealthyME/487810665006?ref=ts>,  
*Twitter:* <http://twitter.com/HealthyME2>

Finally, PPC will offer educational resources for consumers detailing where to go for unbiased information about prescription drugs, as well as questions to ask their doctor to ensure they are getting the safest, most effective, and most affordable drug choice. These resources will build upon and serve as a complement to the work of the Agency for Healthcare Research and Quality and *Consumer Reports Health Best Buy Drugs™*.

## PPC NEWS AND ANNOUNCEMENTS

### PPC Cited in AARP Rx Watchdog Report on Academic Detailing

PPC was cited in an AARP report that focuses on academic detailing programs that improve access to effective and affordable prescription drugs. The *AARP Rx Watchdog Report* highlights trends in the prescription drug marketplace and how those trends impact consumers. PPC was cited in the issue, *Academic Detailing in Practice: A Tale of Four States*, which gives an overview of academic detailing, also known as prescriber education, the practice of sending trained clinicians to



prescribers' offices to provide them with independent, objective, scientific information about prescription drugs. PPC promotes academic detailing as a countermeasure to the aggressive marketing tactics used by the pharmaceutical industry and as a strategy for improving access

to safe, effective, and affordable prescription drugs.

PPC's best practices and education materials are cited in the report, which also includes an interview with Jerry Avorn, the Harvard professor of medicine who first envisioned academic detailing; information about prescription drug advocacy at the federal and state levels; and reports on academic detailing in a number of states, including Maine, where PPC has been directly involved.

In 2008, PPC convened an Academic Detailing Planning Summit involving Maine, New Hampshire, Vermont, and other states. Those involved collaborated

on the development of *A Template for Establishing and Administering Prescriber Support and Education Programs*, which offers guidance to those looking to build prescriber education programs. Since then, PPC has promoted academic detailing and provided technical assistance to those interested in developing academic detailing programs.

The *AARP Rx Watchdog Report: Academic Detailing in Practice: A Tale of Four States* is available on the PPC Web site, which also features an "Academic Detailing Toolkit," including the aforementioned prescriber education template.

## WHAT'S TRADE GOT TO DO WITH IT? MEDICAID, PREFERRED DRUG LISTS, AND US TRADE POLICY

Sharon Treat, Legal Project Director

IN THE MIDST OF THIS RECESSION, STATES FROM ARIZONA TO Minnesota to Virginia have announced dramatic cuts to health care and prescription drug coverage. The federal government has responded with recovery funds, enhancing federal payments for Medicaid and waiving payments related to the Medicare Part D “clawback.”

Yet at the same time, the Office of the United States Trade Representative (USTR) is articulating a policy direction that could endanger the future viability of Medicaid prescription drug coverage by limiting the use of preferred drug lists to negotiate rebates. State policy makers need to get educated about trade policy and make their voices heard. If they don't, these trade initiatives could directly and negatively affect the capacity of states to provide medicines to their residents and cripple states' ability to expand access to health care in the future.

In early March, the USTR held a hearing to receive comments on its annual report on intellectual property, which identifies countries that lack adequate patent protection or “deny fair and equitable market access to United States persons that rely upon intellectual property protection.” For the first time, states were represented and provided testimony at a trade policy hearing. The Forum on Democracy and Trade, a nonpartisan public policy organization whose mission is to support public officials engaged in global trade debates, and the states of Vermont and Maine provided testimony.

American University law professor Sean Fiis-Flynn, representing the Forum, explained the states' interest: “Patents on medicines can create a particularly strong form of monopoly leading to extraordinarily high prices. This is because medicines can be basic life necessities that few will do without and because many purchasers are insulated from actual costs by insurance.”

Fiis-Flynn noted that state governments “use a wide variety of regulatory tools and policies to restrain excessive pricing by medicine suppliers.” He added that “these are often the same tools used by foreign governments that the USTR describes as ‘unreasonable’ in the ‘Special 301’ Report<sup>\*</sup> and has sought to restrict or eliminate in recent trade agreements.”

Nowhere is the use of these tools more widespread than in the states' implementation of Medicaid, the joint state/federal program that provides a comprehensive health insurance safety net to 60 million poor and disabled Americans. Medicaid costs topped \$350 billion in 2008; it is the single largest state government expenditure after education.

A key component of Medicaid is the use of preferred drug

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lists (PDLs). The idea is simple—the best drugs should be preferred, and costs should be in line with effectiveness, not market power. More than 40 states use PDLs for Medicaid and other programs, including state-funded prescription drug benefits for the elderly that “wrap around” Medicare Part D and discount drug programs for the non-elderly who do not qualify for Medicaid but who lack insurance with pharmaceutical coverage.

PDLs really work. Iowa saved \$100 million between 2005 and 2009 through its PDL—last year saving 34.7% of its total drug budget. Oregon reports saving 40% per prescription in 2009 due to greater generic uptake resulting from its use of a PDL. According to the January 2003 annual report of the Office of Vermont Health Access, spending on acid reducers, anti-inflammatory drugs, and opiate analgesics dropped from \$15.8 million to \$12 million within eight months of introducing the Medicaid PDL. In Maine, negotiating supplemental rebates and purchasing drugs through a multistate initiative results in an average drug price that is 50 percent of the average wholesale price.

Alarming, the USTR's 2009 “Special 301” Report raised

\* The “Special 301” Report is an annual review of the global state of intellectual property rights protection and enforcement, conducted by the USTR.

concerns about “price controls and regulatory and other barriers [that] can discourage the development of new drugs” and singled out Japan, Canada, France, Germany, New Zealand, Taiwan, and Poland for administering “unreasonable . . . reference pricing or other potentially unfair reimbursement policies.” These are the very same countries that many states have looked to in adopting their own policies and programs to rein in drug prices.

Without access to these tools, states would simply be unable to provide comprehensive access to medicines in their Medicaid and other health insurance programs. Pharmaceutical costs can account for 10 to 25% of the cost of these programs, even with the rebates and pricing tools currently available, and states are already struggling to continue the programs they fund right now.

The Obama Administration has embraced health reform in partnership with the states, with a nod to the best evidence-based practices the states have pioneered. Preferred drug lists are a best practice that illustrates the approach the Administration is seeking to replicate in its national health reform initiative. Indeed, the President’s

budget for 2008 specifically noted that Medicaid allows states “to use [such] private sector management techniques to leverage greater discounts through negotiations with drug manufacturers.”

Yet the USTR’s efforts to promote new international standards limiting domestic medicine pricing regulations will significantly increase the cost of public health programs and limit the use of evidence-based tools here in the US—and harm efforts to extend health insurance to all Americans.

The idea is simple—the best drugs should be preferred, and costs should be in line with effectiveness, not market power.

Trade policy may appear esoteric and complicated. Few states are truly engaged in understanding how trade agreements are developed and how these agreements affect state policy. What state policymakers don’t know could hurt them—they need to learn about trade policy and get involved so that international agreements do not undermine medical care and access in the US.

## BOARD PROFILES



### MICHAEL BRENNAN

Advocate, social worker, and legislative leader Michael Brennan has more than 30 years of experience in education, government relations, housing, human services, and public policy. He currently works as a policy associate for the Muskie School of Public Service at the

University of Southern Maine, where he directs projects related to child welfare, juvenile justice, mental health, public policy, and substance abuse. He is a licensed clinical social worker and has served on numerous committees, boards, and task forces. He has also been an adjunct faculty member at the University of New England.

In 1992, Brennan was elected to the Maine House of Representatives, where he served four terms before being term limited in 2000. While a representative, he chaired the Education Committee and the Joint Select Committee on Substance Abuse. From 2002 to 2006, he served in the Maine State Senate, where he chaired both the Health and Human Services Committee and the Joint Select Committee on Health Care Reform. During his final term, he was selected to be the Senate Majority Leader.

Brennan earned his bachelor’s degree in Education from Florida State University, his master’s degree in Public Policy from the Muskie School, and his master’s degree in Social Work from the University of New England. In addition, he completed the Senior Executive Program in State and Local Government at the John F. Kennedy School of Government at Harvard University.



### JOHN BRAUTIGAM

John Brautigam has had a rich and varied career in both the private and public sectors. Currently serving as Director of the Energy Programs Division of the Maine Public Utilities Commission, he administers state energy efficiency programs and manages Recovery Act

funding in the energy sector.

Brautigam has served in private practice, with the US Securities and Exchange Commission, as an Assistant Attorney General for the State of Maine, and as the executive director of a nonprofit, the Maine Citizen Leadership Fund.

While at the Attorney General’s office, Brautigam managed a number of prescription drug related matters and was co-counsel in the legal defense of Maine Rx, a program to lower prescription drug prices for the uninsured. He helped successfully defend the program against challenges from the pharmaceutical industry, finally winning the legal battle in the US Supreme Court.

In addition, Brautigam served in the Maine Legislature from 2004 to 2008, including two years as Chairman of the Insurance and Financial Services Committee. He was a candidate for Attorney General for the State of Maine in 2008.

Brautigam is a 1991 graduate of Stanford University Law School, where he edited the Stanford Law Review. He earned his bachelor’s degree from Wesleyan University and his master’s degree from Trinity College.

## KIDS AND PSYCHOTROPIC DRUGS: ENSURING ACCESS WHILE SAFEGUARDING KIDS

WITH CONTINUED SUPPORT FROM THE ENDOWMENT FOR HEALTH, PPC carries on its work to research and explore best practices related to the use of certain antipsychotic drugs in children.

Given the FDA's recent approval of a few of these drugs for use in children, PPC's work could not be more timely. Prescribing of antipsychotic medications to children in the US has increased dramatically. In less than a decade, the use of potent psychotropic medication (mostly prescribed "off-label") in children and adolescents grew by five-fold, raising policy challenges for patients, clinicians, and payers. In fact, some children as young as just one year old are being prescribed these medications at increasing rates. Behaviors once considered "normal"—a baby not sleeping through the night or a toddler going through the "terrible twos"—are being diagnosed as sleep-resistant or oppositional-defiant with mood swings.

Youth in foster care covered by Medicaid insurance receive psychotropic medication at a rate greater than three times more than other Medicaid-insured youth, even though such treatment lacks substantive evidence as to its effectiveness and safety. Medicaid expenditures for atypical antipsychotics grew 21% between 2000 and 2007.

The growth in prescribing rates previously described occurred prior to new FDA approval of three atypical antipsychotic drugs associated with serious health risks, including significant weight gain and high blood sugar (diabetes) and cardiovascular disorders. Seroquel, Geodon, and Zyprexa were approved last year for use in the treatment of schizophrenia and bipolar mania or mixed episodes associated with bipolar disorder.

The prescribing of these powerful drugs to kids needs to be of concern to policy makers and caregivers. A preliminary

study of several states supported by the Agency for Health Research and Quality found widespread use of the drugs in certain children, including foster care children, even though evidence justifying such use was limited. There is wide variation in the use of these drugs across clinics and geographical areas, and concerns have been raised about the adequacy of initial assessment(s) leading to the prescribing of the drugs, as well as ongoing monitoring and follow-up. While the final report has not been released, initial presentations of information gained from the study suggest that too many kids are being prescribed these drugs.

With the approval of some of these drugs (in spite of weak recommendations from the FDA advisory panel), state health programs and private insurers will now be under tremendous pressure by the drug industry to provide instant coverage for the drugs. Certainly children with severe mental health diagnoses who may benefit from the drugs should have access. The question is, who actually needs the drugs and who actually benefits from taking them?

Negative health risks should be weighed as part of the decision about whether or not to prescribe the drugs, and careful thought and diligence in monitoring children who use the drugs should be considered. Caregivers should also be informed of negative health consequences, some of which will

last a lifetime, as well as the evidence (or lack thereof) as to the effectiveness of using these medications. State drug utilization review (DUR) committees that decide which drugs are covered and which require prior authorization are being barraged by drug manufacturers in an effort to get their drugs on approved list(s) for public health programs. At the same time, drug reps are headed to physician's offices to promote use of these drugs for kids.

Fortunately, many states are taking steps to ensure access while safeguarding kids. Those steps and other policy options to best help and protect children will be described in the next issue of the newsletter.

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should the cost implications as higher priced drugs are used because of the rebates offered.

Of course, the biggest question about the new law is whether the legislation to mend the broken system will break the bank or save the day. The Congressional Budget Office (CBO) estimates that the new law will reduce the federal budget deficit by \$143 billion through 2019 and will yield even greater savings in the decades to come. Additionally, there are opportunities to put more cost controls in place.

Prescription drug policy is a great place to start in terms of improving health care quality—especially safety and effectiveness—while containing costs. One opportunity missed in the new law is giving the federal government the authority to negotiate prescription drug prices for the newly insured and the elderly under Medicare Part D. Currently, the private sector reaps billions in revenues by negotiating prices and steering plans (and beneficiaries) toward certain drugs under Part D. Meanwhile, the government obtains lower prices for veterans and Medicaid patients and could achieve huge savings as the nation's largest drug purchaser for our elderly. There is the potential for great savings through prescription drug price negotiations that could be used to help slow Medicare's growth and pay for expanded health care coverage. Efforts to

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strengthen the new law ought to include price negotiations.

In terms of improving health care quality while containing costs, the importance of comparative effectiveness research and evidence-based medicine cannot be underestimated. Emphasis must continue to be placed on providing doctors and consumers with the best information available regarding treatment options, that is, the science showing what works best, is safest, and is most effective. Data from comparative effectiveness research does and will continue to help doctors choose the most effective treatments based on scientific evidence rather than drug industry influence. Likewise, academic detailing programs, also known as prescriber education, in which trained clinicians provide prescribers with unbiased information regarding certain therapeutic areas and drug classes, have proven effective in countering industry influence, improving health care quality, and reducing costs. More often than not, the most effective treatments yield savings in terms of patient health and safety as well as prescription drug costs.

While the inclusion of the Sunshine provisions is a step in the right direction, reporting will not begin until 2012, and not made publicly available until 2013. Furthermore, failure to report will be fined, but such fines are not to exceed \$1,000,000 annually. In an industry with annual sales in the hundreds of billions of dollars (in the US alone) paying the fines, instead of disclosing gift and payment information, may end up being the better business strategy for drug companies that already flaunt regulations by aggressively marketing their products for unapproved (off-label) uses and have a history of putting profits before patients.

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## PPC SHOWCASES EVIDENCE-BASED PRESCRIBING

IN RECOGNITION OF ITS EXEMPLARY WORK TO PROMOTE EVIDENCE-based prescribing in Maine, PPC was invited to participate in an event marking the 10<sup>th</sup> anniversary of the Maine Health Access Foundation (MeHAF). PPC joined other MeHAF grantees at the Maine State House Hall of Flags to recognize MeHAF's founding and its efforts to improve access to health care in Maine.

PPC received MeHAF funding to enhance its work to improve access to affordable prescription drugs. As part of its Cost Containment Strategy Grant Initiative to Preserve and Expand Health Care Access, MeHAF awarded funds to support PPC's efforts to promote evidenced-based prescribing to help Maine providers and consumers learn which drugs work best, are safest, and, more often than not, cost less. Evidence-based prescribing is based on the use of the best available, objective scientific evidence in a given therapeutic area.



*PPC Communications Director Jean Grigsby shares unbiased information about prescription drugs with a consumer as part of an event at the Maine State House Hall of Flags.*

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Prescription Policy Choices

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