Testimony of:

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Generic Drug Utilization in Medicare Part D

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I. Introduction

Good Morning Chairman Smith, Ranking Member Kohl and Members of the Committee. My name is William Shrank. I am an Internal Medicine physician at the Brigham & Women's Hospital in Boston where I am an Instructor in the Division of Pharmacoepidemiology and Pharmacoeconomics and at the Harvard Medical School. I spend most of my time researching how to improve efficiency and effectiveness of drug coverage policies. It is an honor to have the opportunity to share my thoughts with you today about the costs of prescription drug care in the United States, the role that generic drugs can play in reducing those costs, and policy implications for Medicare Part D.

II. Background

Tensions exist regarding appropriate spending for prescription drugs. On the one hand, we spend a staggering amount, over $200 billion annually, on prescription drugs in the U.S.[1] Growth in spending for drugs has outpaced spending growth in all other sectors of the healthcare system in the last decade,[2] and is predicted to continue to do so.[3] The federal government's exposure to those costs has increased with passage of the Medicare Modernization Act which allows seniors to voluntarily enroll in federally-funded, private prescription drug coverage plans.[4] Even the most conservative estimates suggest that the federal Government will spend over $40 billion annually for this benefit.[5] Efforts to stem the rising costs of prescription drugs are needed.

On the other hand, the quality of care in the United States is disappointingly poor,[6] and highly effective, evidence-based medication therapy is often underused.[7] Patients with chronic disease frequently do not receive or do not take necessary

medications.[8] Patients, even those with drug coverage, frequently do not fill or refill their medications due to excessive out-of-pocket costs. [9,10] Policy-makers often struggle to reconcile the need to increase medication use for patients with chronic disease without adding to the unsustainable rise in prescription drug costs.

III. Potential Role of Generics in Reducing Overall Prescription Drug Costs

Numerous studies document the potential cost-savings that could be realized by greater use of generic medications. According to one study based on a nationally representative sample, switching prescriptions from branded medications to molecularly-identical generics could lead to an 11% reduction in overall drugs costs.[11] Another study of treatment for hypertension found that prescribing in accordance with established national guidelines (JNC-VII) can lead to greater generic drug use and substantial prescription drug cost savings (approximately 25% of total drug costs for hypertension medications) while providing higher quality, evidence-based care.[12] The potential cost-savings in the United States associated with switching generic medications for molecularly identical branded drugs typically is estimated at over $20 billion annually in this country.[13]

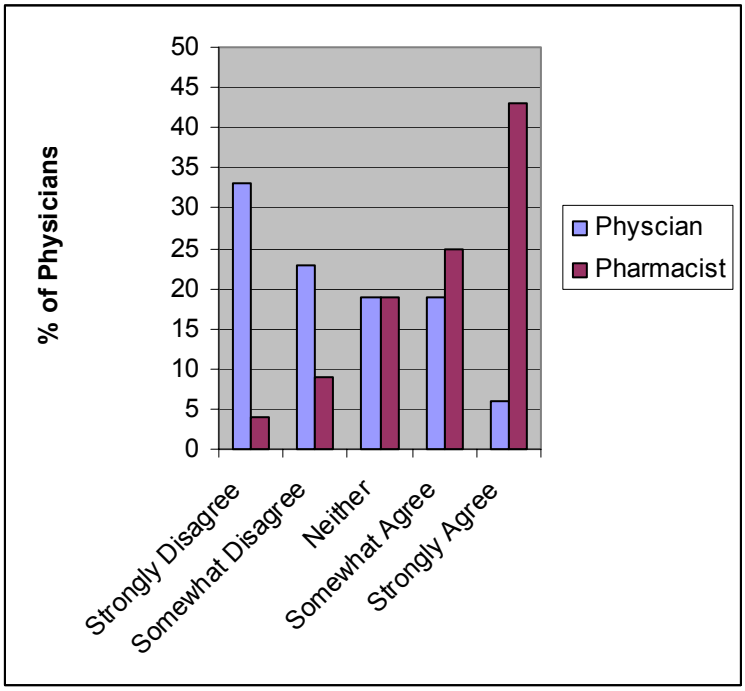
IV. Current Challenges for Doctors and Patients in our Market-Based System

Many policy makers have touted a market-based approach as the solution to inefficiency in health care. They predict that an "ownership society," in which educated consumers will be sensitive to medical care costs and communicate their preferences to their physicians, will lead to greater efficiency and cost management.[14] As a result, approximately three quarters of Americans with prescription drug coverage were enrolled

in pharmacy benefit designs with at least three tiers of copayments by 2004.[15] These plans require patients to pay lowest copayments for generic drugs, middle copayments for preferred branded mediations and highest copayments for non-preferred branded drugs. These plans utilize financial incentives to steer patients towards drugs they consider more cost-effective. The Medicare Modernization Act (MMA) has endorsed the creation of market-based prescription drug coverage for seniors,[16] and most seniors in Part D are enrolled in tiered plans.

Through both my clinical experience and my academic research, I have found that the critical assumptions of an efficient market are not met when it comes to prescription drugs. First of all, physicians face challenges when prescribing due to the substantial variability between formularies offered by different insurers in the community.[17] They also encounter challenges in identifying preferred formulary options for seniors enrolled in hundreds of different Medicare Part D plans, each with a unique formulary and set of benefits.[18] As a result, physicians frequently lack knowledge about patients' out-of-pocket costs. I performed a survey of California physician leaders and found that physicians are frequently unaware of patients' formularies and out-of-pocket costs and, furthermore, they do not feel responsible for managing patients' out-of-pocket costs.[19] Rather, physicians believe it is the responsibility of the pharmacist to be aware of patients' formularies and to help steer patients towards generic or less expensive medications.[19] (Figure 1.) In a statewide survey of California physicians, I confirmed these findings and found that physicians who prescribe electronically and who practice in large organizations were most likely to be aware of patients' out-of-pocket costs.[20]

Figure 1. Physicians' Responses When Asked if They Agree that it is the Physician's or the Pharmacist's Responsibility to Identify "Preferred" Formulary Medications (N = 129)

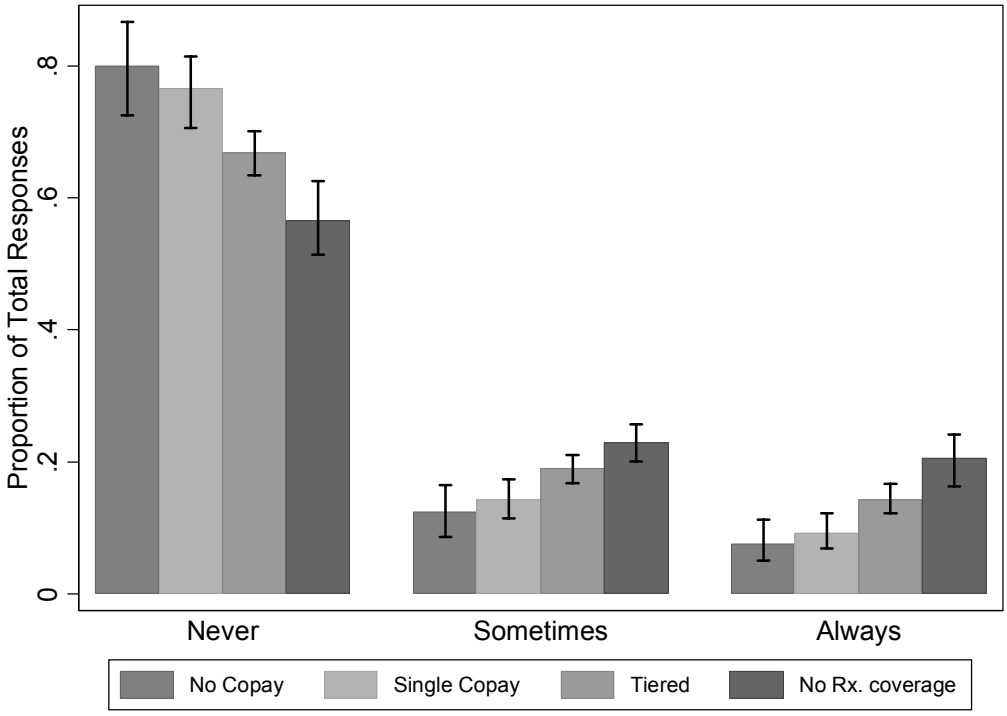


Adapted from Shrank WH, et al. American Journal of Managed Care, 2005.

In a follow-up study, I examined whether patients are aware of their cost requirements at the clinical encounter with their physicians and whether the use of market forces influences rates that patients communicate with their physicians about costs.[21] I performed a telephone survey of patients in California to assess their knowledge of out-of-pocket costs at the time of prescribing, the frequency that patients communicate with their doctors about medication costs, and the association between enrollment in tiered pharmacy benefit plans and the likelihood that patients and physicians communicate about costs. In a paper published in the *Journal of General Internal Medicine*, I found that patients are frequently unaware of the out-of-pocket costs of their medications when prescriptions are written, and they rarely talk to their physicians about costs. In addition, enrollment in a tiered or incentive-based formulary was associated with only a small increase in the likelihood that physicians and patients communicate about costs of

prescription drugs; the majority of patients reported that they never talk to their doctors about medication costs regardless of their pharmacy benefit design.[21] (Figure 2.)

Figure 2. Rates at which Patients Report they Discuss Out-of-Pocket Costs with their Physicians- By Pharmaceutical Benefit System



Adapted from Shrank WH, et al. Journal of General Internal Medicine, 2006.

In sum, in our current system, doctors and patients are unaware of patients' costs and do not communicate about these costs. Doctors rely on pharmacists or patients to intervene beyond the clinical encounter, when discussions about costs and benefits are less likely. However, it is the physician that must change the prescription to a less expensive medication. We have adopted a convoluted and inefficient system in which none of the parties involved have the both the necessary information and authorization to make a reasoned and cost-effective decision before the prescription is filled.

V. Generic Drug Use Can Improve Patient Adherence to Chronic Medications

Considering the challenges patients and physicians face when trying to identify medications that require lower out-of-pocket costs, I next studied how prescription choice influenced whether or not patients took their medication as prescribed. Specifically, I sought to understand whether patients were more or less likely to adhere to lower cost generic medications than branded medications. I collaborated with a large health plan to evaluate medication utilization in over 7,000 patients enrolled in three-tier benefit plans who were prescribed a chronic medication. I studied the relationship between receiving a generic medication, a preferred branded medication or a non-preferred branded medication from a patients' formulary and the odds that the patient adequately adhered to therapy. Adequate adherence was defined as filling 80% or more of prescriptions in the year subsequent to initiation of an important chronic medication.[9]

I found that when patients were prescribed generics, they were more adherent to chronic medications. When patients received generics they filled, on average, 12.6% more prescriptions in the subsequent year as compared to patients who were prescribed third tier, non-preferred branded medications. Patients prescribed preferred branded drugs filled 8.8% more prescriptions than those who received non-preferred branded drugs. Patients who received generics had 62% greater odds of adequate adherence than those who received non-preferred branded medications.[9] (Appendix 1.)

These findings suggest that greater generic drug use can increase adherence to important chronic medications, and can offer assistance in addressing the problem of underuse of appropriate medications in the United States.

VI. Value of Generic Drugs for Patients and the Health Care System

Greater generic drug use can address both aspects of the key tension we face when creating policies to reduce prescription drug costs and improve the quality of care that patients receive. By substituting less expensive generics for branded medications, we could reduce spending on prescription by tens of billions of dollars a year in this country. Additionally, by helping patients to receive generic medications that require lower out-of-pocket cost requirements, we could see increased rates that patients adhere to important chronic medications, which could avert hospitalizations and other adverse health outcomes.

VII. Limitations of Generic Drug Use

It is important to note that not all branded drugs have a generic alternative and that generic drugs are not appropriate for all patients. Some patients are better served by newer branded drugs, and for many patients who are treated effectively with branded drugs for which no generic exists, it may be unwise to try to switch to generic medications. For example, in patients stably treated for mental health disorders on newer anti-depressant or anti-psychotic medications, a switch to an older generic alternative may be clinically unwise. No policy to increase generic drug use should place any patients at risk of receiving worse quality of care. Thus, policies to increase generic drug use must be flexible enough to allow the use of branded drugs when deemed appropriate by the prescribing physician.

VIII. Interventions to Increase Generic Drug Use

Financial Barriers to Branded Medications: Insurers, pharmacy benefit managers, and state and national governments have implemented interventions using financial barriers to increase generic drug use. Insurers have overwhelmingly adopted tiered pharmacy benefit designs which use out-of-pocket cost incentives to steer patients towards generic medications. Tiered benefit designs have been shown to increase generic drug utilization in several settings.[10,22,23] In Canada, an intervention known as reference-pricing has been implemented. In such a benefit design, patients who are prescribed medications that cost more than a government selected reference drug (one drug for each drug class) are personally responsible for paying the difference in cost. Reference pricing has also been shown to increase generic medication utilization.[24]

Administrative Barriers to Branded Medications: Administrative barriers, such as prior authorization requirements, have also been implemented to stimulate greater generic drug utilization. In general, these requirements mandate that physicians who choose to prescribe an expensive medication must justify the decision prior to the patient's receipt of the medication. Studies indicate that prior authorization requirements can decrease prescribing of expensive branded medications. A nationwide evaluation of the effects of prior authorization requirements for COX-II non-steroidal anti-inflammatory medications was performed for patients enrolled in Medicaid. The study demonstrated that implementing a prior authorization program led to a 15% decrease in branded COX-II prescribing.[25]

Throughout the United States, mandatory generic substitution has also been widely adopted to substitute generic alternatives for the molecular entity at the point of

the pharmacy. This policy allows pharmacists to switch branded prescriptions to molecularly-identical generic prescriptions as long as the prescriber does not specifically indicate that the brand is to be filled. Mandatory generic substitution has been shown to reduce overall prescription drug costs as well as patient out-of-pocket costs.[26,27]

Educational Interventions: Jerry Avorn MD, the chief of my Division, and colleagues have developed an educational intervention known as ***academic detailing***. This intervention may be familiar to Senator Santorum; we have implemented an academic detailing program titled the Independent Drug Information Service (iDiS) for Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) enrollees.[28]

Academic detailing is a method by which university-based outreach educators ("detailers") conduct educational sessions with physicians in the physicians' offices to deliver focused, evidence-based, non-commercial clinical messages about appropriate drug choices. The enhancements in the quality of prescribing due to academic detailing are well documented,[29,30] with opportunities for great cost savings (benefit-to-cost ratio of approximately 2).[31] In general, the key components of academic detailing include: (1) conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns, (2) focusing programs on specific categories of physicians as well as on their opinion leaders, (3) defining clear educational and behavioral objectives, (4) establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues, (5) stimulating active physician participation in educational interactions, (6) using concise graphic educational materials, (7) highlighting and repeating the essential messages, and (8) providing positive reinforcement of improved

practices in follow-up visits.[32] Studies consistently demonstrate that academic detailing is an efficacious means to improve appropriate prescribing in a variety of drug categories and in various settings, often through the proper prescribing of generic alternatives.[27,28]

In 2005, our division teamed up with the state of Pennsylvania to create the iDiS program to educate the state's doctors about improving the cost-effectiveness and quality of prescribing in the state. While we are in the process of measuring the effects of this intervention on the quality and costs of prescription drug care, early surveys of physicians suggest that they overwhelmingly appreciate the educational experience and they have requested that the program continues.

In addition, a number of resources have recently become available to educate patients about the costs and benefits of medication options for their conditions. Consumer Reports Best Buy Drugs is one such resource. While studies to evaluate the effects of these resources on prescription drug choices are currently unavailable, the makers of these resources should be commended for their efforts to stimulate demand for lower-cost, highly effective medications. The limitations of patient education must also be recognized. Educators rely on activated and engaged patients to participate in the decision-making process, but many patients may not have the desire or ability to participate. Nonetheless, arming patients with better information about the costs and benefits of medications will be critical in creating an environment in which patients are activated consumers who play an educated, meaningful role in their health care decision-making.

IX. Recommendations to the Committee

A) IMPROVE PRESCRIBING SYSTEMS:

We need better prescribing systems to provide doctors and patients with information about drug costs and formularies. Currently, most doctors write their prescriptions by hand, and efforts to gather knowledge about a patient's formulary requires the physician to take the time to look up that information in a handbook, on software available for handheld computers, or on insurer's web sites. Better systems to provide doctors with real-time information about patients' costs would enhance the likelihood that doctors would consider and discuss medication costs when prescribing.

Broader use of electronic prescribing could greatly assist in providing this information. E-prescribing could provide doctors with real-time information about costs and decision-support to help steer doctors towards equally effective generic medications when they are available. Greater generic prescribing and cost-effective prescribing could be some of the many beneficial effects of electronic prescribing.

b) SIMPLIFY COVERAGE: Missed Opportunity in Part D

Simplifying coverage could help streamline prescribing decisions. In Part D alone, doctors and patients are overwhelmed by the complexity of the multiple formularies they must navigate. Outside of Medicare, doctors manage patients from, on average, over a dozen different insurers, each with it's own set of pharmacy benefits and unique formulary. This complexity has led doctors to abdicate the role of financial agent for their patients, and hope that patients or pharmacists can help

identify less expensive options, leading patients to take unnecessarily expensive medications.

Now that the government is the biggest purchaser of drugs in this country, the government should take steps to simplify prescribing decisions in Medicare by reducing the number of formularies from which doctors must prescribe. Additionally, the government could identify certain first-line medications that are highly cost-effective and require that they are offered at the lowest tier copayments or no copayments at all in all Part D plans. Such policies could simplify the prescribing process for physicians and could help to insure that patients will be directed to clinically effective and cost-effective medications. Such policies could increase the likelihood that initial prescriptions for chronic conditions are filled with generic drugs – the best opportunity to influence prescribing decisions and stimulate long-term generic drug use.

c) EDUCATE DOCTORS AND PATIENTS ABOUT PRESCRIBING: Academic Detailing

Third, we need to educate doctors and patients more about generic drugs and drug costs. Branded manufacturers are winning the education war, spending tens of billions of dollars annually in the U.S. to provide free samples to physicians, to detail physicians in their offices, and to educate patients through direct-to-consumer advertising. Consumer Reports Best Buy Drugs should be commended for providing better information to patients – offering them an objective resource to learn more

about the costs and benefits of their medications. But many patients are incapable of accessing this information or effectively participating in these decisions.

Development of broader academic detailing programs to educate physicians, as have been done in many other countries such as Canada and Australia, could substantially improve the quality and cost-effectiveness of prescribing in the U.S. Medicare's massive investment in providing prescription drugs to seniors should inspire the federal government to play a more active role in improving the quality and cost-effectiveness of care and strive to get the most benefit from their investment. If Medicare were to invest just 1 tenth of a percent of their $40 billion annual budget on Part D to create academic detailing programs to educate doctors, they could save resources for the government, reduce health care costs in general, and help patients receive more affordable medications. Such an investment could also help to foster a culture of cost and efficacy awareness about medications.

X. Conclusion

Thank you for this opportunity to appear before you today to testify on my findings and recommendations. By creating better systems and policies I believe we can design coverage that helps Americans receive the right drug for their diagnosis at a fair price.

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