HARVARD Kennedy School
JOHN F. KENNEDY SCHOOL OF GOVERNMENT

Pricing and Reimbursement in U.S. Pharmaceutical Markets

Faculty Research Working Paper Series

Ernst R. Berndt

MIT Sloan School of Management and NBER

Joseph P. Newhouse

Harvard School of Public Health, Harvard Kennedy School, and NBER

September 2010
RWP10-039

NBER WORKING PAPER SERIES

PRICING AND REIMBURSEMENT IN U.S. PHARMACEUTICAL MARKETS

Ernst R. Berndt
Joseph P. Newhouse

Working Paper 16297
http://www.nber.org/papers/w16297

NATIONAL BUREAU OF ECONOMIC RESEARCH
1050 Massachusetts Avenue
Cambridge, MA 02138
August 2010

Revised version to appear in Patricia M. Danzon and Sean Nicholson, eds., The Economics of the Biopharmaceutical Industry. The authors have benefited from discussions with Richard G. Frank and E. Mick Kolassa, but are solely responsible for the views expressed herein. This research was not sponsored. The views expressed herein are those of the authors and do not necessarily reflect the views of the National Bureau of Economic Research.

Pricing and Reimbursement in U.S. Pharmaceutical Markets
Ernst R. Berndt and Joseph P. Newhouse
NBER Working Paper No. 16297
August 2010
JEL No. D4,I11,I18,L11,L65

ABSTRACT

In this survey chapter on pricing and reimbursement in U.S. pharmaceutical markets, we first provide background information on important federal legislation, institutional details regarding distribution channel logistics, definitions of alternative price measures, related historical developments, and reasons why price discrimination is highly prevalent among branded pharmaceuticals. We then present a theoretical framework for the pricing of branded pharmaceuticals, without and then in the presence of prescription drug insurance, noting factors affecting the relative impacts of drug insurance on prices and on utilization. With this as background, we summarize major long-term trends in copayments and coinsurance rates for retail and mail order purchases, average percentage discounts off Average Whole Price paid by third party payers to pharmacy benefit managers as well as average dispensing fees, and generic penetration rates. We conclude with a summary of the evidence regarding the impact of the 2006 implementation of the Medicare Part D benefits on pharmaceutical prices and utilization, and comment on very recent developments concerning the entry of large retailers such as Wal-Mart into domains traditionally dominated by large retail chains and the "commoditization" of generic drugs.

Ernst R. Berndt
MIT Sloan School of Management
100 Main Street, E62-518
Cambridge, MA 02142
and NBER
eberndt@mit.edu

Joseph P. Newhouse
Division of Health Policy Research and Education
Harvard University
180 Longwood Avenue
Boston, MA 02115-5899
and NBER
newhouse@hcp.med.harvard.edu

I. Introduction

The pricing and reimbursement of prescription drugs in the United States is important for at least two reasons. First, from the perspective of US consumers, prescription drugs constitute 12 percent of total U.S. health care spending (2008) or roughly two percent of GDP.[1] Thirty-seven percent of this amount was tax financed, with the associated deadweight loss to finance that spending.[2] An additional 42 percent was financed through insurance, the bulk of which flowed through employer provided and subsidized insurance. The employer subsidies for this insurance cause distortions in the labor market with associated inefficiencies.[3] Thus, the financing of pharmaceuticals in the U.S. is associated with various types of deadweight losses. Second, from the perspective of all consumers, the U.S. constitutes about 40 percent of the world pharmaceutical market. As a result, its pricing and regulatory policies materially influence world demand and hence the incentives of pharmaceutical firms to innovate.[4]

In this survey chapter on pricing and reimbursement in U.S. pharmaceutical markets, we first provide background information on important federal legislation, institutional details regarding distribution channel logistics, definitions of alternative price measures, related historical developments, and reasons why price discrimination is highly prevalent among branded pharmaceuticals. We then present a theoretical framework for pricing of branded pharmaceuticals without and then in the presence of prescription drug insurance, noting factors affecting the relative impacts of insurance on prices and on utilization. With this as background, we summarize major long-term trends in copayments and coinsurance for retail and mail order purchases, average percentage discounts off Average Wholesale Price paid by third party payers to pharmacy benefit managers as well as average dispensing fees, and generic penetration rates, We conclude with a summary of the evidence regarding the impact of the 2006 implementation of the Medicare Part D benefits on pharmaceutical prices and utilization, and comment on very recent developments concerning the entry of large retailers such as Wal-Mart into domains traditionally dominated by large retail chains and the "commoditization" of generic drugs.

II. Background: Legislation, Institutions and Historical Developments

We begin with a brief background section that focuses on important U.S. legislative developments. This lays the groundwork for our later discussion of the marketing and pricing of generic and brand prescription drugs in the U.S. For the most part the U.S. generic drug industry approximates competitive conditions with price approaching marginal costs. As a result, we employ traditional microeconomic tools to describe the structure and pricing of that industry. We defer discussion of brand pricing in the presence of market power to later in this chapter. Next we outline the structure and distribution logistics of U.S. markets for pharmaceuticals, distinguishing roles and prices faced by providers from those of payers. Then, since any researcher focusing on the pricing of branded and generic drugs in the U.S. cannot avoid encountering the critical functions played by the misnamed Average Wholesale Price ("AWP", aka "Ain't What's Paid"), we digress to provide background on the origins, history and evolution of the very important and sometimes misunderstood central role played by AWP in various segments of the U.S. pharmaceutical industry. We conclude this section with a discussion highlighting the demand and cost conditions facing biopharmaceutical manufacturers that make third degree price discrimination an attractive and widespread practice.

A. Important Legislative Developments Affecting Drug Pricing

The pricing of branded and generic drugs has long been a focus of controversy. Although Congressional attention to pharmaceutical pricing dates back further, a good place to begin is with the Congressional hearings conducted by Senator Estes Kefauver's Anti-Trust and Monopoly subcommittee between 1959 and 1962. These hearings dealt not only with the thalidomide tragedy in which many children were born with birth defects as a result of their mothers taking thalidomide for morning sickness during pregnancy, but also with allegations of pharmaceutical companies engaging in various questionable practices to realize excess profits. One writer describes the hearings as follows:

> "Witnesses told of conflicts of interest for the AMA (whose Journal, for example, received millions of dollars in drug advertising and was, therefore, reluctant to challenge claims made by drug company ads)…The drug companies themselves were shown to be engaged in frenzied advertising campaigns designed to sell trade name versions of drugs that could otherwise be prescribed under generic names at a fraction of the cost; this competition, in turn, had led to the marketing

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.