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Market size and innovation: Effects of Medicare Part D on pharmaceutical research and development

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ABSTRACT

Recent evidence suggests that Medicare Part D increased prescription drug use among seniors, and increased pharmaceutical firms' revenues from sales. Previous studies also indicate that increases in market size induce pharmaceutical innovation. This paper assesses the impact of the Medicare Part D legislation on pharmaceutical research and development (R&D), using time-series data on the number of drugs entering preclinical and clinical development by therapeutic class and phase. We find that the passage and implementation of Medicare Part D is associated with significant increases in pharmaceutical R&D for therapeutic classes with higher Medicare market share.

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1. Introduction

Understanding the responsiveness of innovation to expected future revenues and market expansions is central to understanding the behavior of private sector innovative firms, and is also critical for evaluating the welfare effects of public policies such as insurance expansions, price controls, and patent protection. Although previous studies have shown that increases in market size are significant drivers of pharmaceutical innovation, magnitudes of the estimates of elasticity of innovation with respect to market size vary widely (Acemoglu and Linn, 2004; Dubois et al., 2011; Lakdawalla and Sood 2012).

This paper builds on the existing literature on the impact of market size on innovation by analyzing the effects of one of the largest expansions of prescription drug insurance on pharmaceutical research and development (R&D). Specifically, we estimate the elasticity of drug R&D efforts—as measured by preclinical testing and clinical trials—following passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and evaluate changes over time in the magnitude of this investment response.

Prior to the MMA's implementation in 2006, with only a few exceptions[1] the Medicare program covered only prescription medicines associated with physician services, i.e., drugs provided in physician offices and hospitals. Medicare Part D significantly expanded drug coverage among older individuals, and as of 2010 approximately 28 million Medicare beneficiaries were enrolled in Part D plans.[2,3] Recent evidence indicates that this expanded insurance coverage increased prescription drug use by seniors (Duggan et al., 2008; Ketcham and Simon, 2008; Lichtenberg and Sun, 2007; Yin et al., 2008).

This increased use of prescription drugs due to expansion of insurance might be expected to yield increases in biopharmaceutical firms' R&D via two mechanisms. First, Scherer (2001) previously showed firms' R&D expenditures are approximately unit elastic with respect to increases in their revenues from sales. Duggan and Scott Morton (2010) showed that overall revenues for pharmaceutical firms increased upon implementation of Part D, despite the price decreases negotiated by private insurers. Thus, R&D might have increased after implementation of Part D simply due to established firms' increased cash flows.

Second, economic theory and prior studies also suggest that firms' investments in R&D should be responsive to changes in the expected profitability of candidate products in their pipelines. Consistent with this notion, Friedman (2009) observed immediate increases after passage of Part D in stock market share prices for firms launching brand-name drugs with high exposure to the Medicare market. These expectations

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[1] Some exceptions to this rule included oral cancer drugs with IV equivalents, oral anti-emetics used within 48 h of chemotherapy, immunosuppressants for recipients of Medicare-covered organ transplants, erythropoietin (EPO) for end-stage renal failure, and drugs administered via covered durable medical equipment, such as albuterol sulfate or ipratropium bromide used with a nebulizer or insulin used with an insulin pump.

[2] See MedPAC (2003) Fact sheet on MedPAC's Report to the Congress: Medicare Payment Policy, accessed online at http://medpac.gov/documents/Mar11_FactSheet.pdf, as of March 22, 2011.

[3] For additional discussion of the details of Part D's implementation, see Duggan et al. (2008).

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of near-term and future revenues also likely contributed to the pharmaceutical industry's switch from opposition towards advocacy for Medicare outpatient prescription drug legislation in 1999:[4]

> Successfully expanding prescription drug coverage for seniors and disabled persons will ensure that breakthroughs in basic scientific knowledge become safe and effective medicines for patients. If we fail, pharmaceutical innovation—especially with respect to medicines designed to treat the illnesses of aging—may suffer, thereby reducing hope for Medicare beneficiaries and their families. Modernizing Medicare is our best hope that today's and tomorrow's beneficiaries will reap the rewards of innovation: longer, happier, healthier, and more fulfilling lives. (Holmer, 1999)

In this paper, we identify the effects of Medicare Part D through variation across drug classes in their pre-Part D Medicare market shares, expecting larger increases in R&D for drug classes with higher pre-Part D Medicare market shares. We control for changes in demographics, as one would expect more R&D for higher-Medicare-share drug classes as the post-war Baby Boom population ages. We also control for changes in public expenditures on biomedical research, due to possible complementarities between public and private biomedical research efforts (Blume-Kohout, 2012).

To further isolate Part D's impact, in additional specifications we investigate heterogeneous effects using variation in drug classes' coverage status, such as whether the drug class was previously covered under Medicare Part B, whether it has "protected" status on plans' formularies, and whether the class is highly used by Medicare-Medicaid dual eligibles. We expect smaller effects for drugs previously covered by Medicare Part B because the MMA legislation decreased physician reimbursement for cancer chemotherapy drugs covered under Part B, and so neither expected utilization nor prices for those drugs should have increased with the MMA (Shea et al., 2008). In contrast, we expect larger Part D effects for protected drug classes, as the Centers for Medicare and Medicaid Services (CMS) require most marketed drugs in certain protected drug classes to be included on Part D plans' formularies, which precludes plans from using threat of exclusion to negotiate prices down. Similarly, we also expect larger Part D effects for drug classes heavily used by Medicare–Medicaid dual eligibles, as pharmaceutical firms are no longer required to offer steep Medicaid discounts for drugs sold to these consumers.

We find that the passage and implementation of Medicare Part D was associated with significant increases in preclinical testing and clinical trials for those drug classes most likely to be affected by Medicare Part D. These effects are robust to controls for expected demographic changes, and changes in public biomedical research funding. As expected, we also typically find smaller effects for drug classes previously covered by Medicare Part B, and larger effects for protected and dual eligible drug classes.

Our paper proceeds as follows. In the next section we describe the various datasets employed, and the construction of our panel dataset. In Sections 3 and 4, we present our empirical strategies, and summarize key results. The final section concludes, with a discussion of the implications and limitations of our analysis.

2. Data and construction of analytic panels

2.1. Data on pharmaceutical R&D pipelines

Time-series data on the number of drugs by therapeutic class and originator firm at each stage of the pharmaceutical R&D pipeline were derived from the Pharmaprojects trend data "snapshot" published each May from 1998 through 2010. Pharmaprojects data are collected from a variety of public sources including press releases, patent filings, conference proceedings, regulatory agencies' reports, and the medical literature, as well as through direct contacts with pharmaceutical companies and researchers. As noted by Adams and Brantner (2006), this collection process may miss some drugs in early stage development. However, commercial databases like Pharmaprojects are generally considered fairly complete for human clinical trials, as existence of a recruiting clinical trial for an already-patented molecule is more difficult to hide than proprietary investigations in a firm laboratory. Potential omissions due to underreporting are also of little concern in this analysis, as we have no reason to expect systematic bias in Pharmaprojects' reporting across therapeutic classes that both (a) coincides with the introduction of Part D and (b) is correlated with Medicare market share. Unless both conditions (a) and (b) are met, underreporting will not bias our estimates.

The duration from entry into human clinical testing (Phase I trials) until market launch can vary widely across individual drugs and broader therapeutic classes, but averages approximately eight years (Abrantes-Metz et al., 2005; Adams and Brantner, 2006; DiMasi, 2001). Phase I trials evaluate safety of the molecule in small numbers of healthy human volunteers, and typically take several months to complete. For successful drugs (i.e., those continuing on to Phase II), duration until start of Phase II is about 20 months. Phase II trials are, in a sense, pilot studies: pharmaceutical firms evaluate efficacy of the drug in a relatively small number of patients (usually just a few hundred), with successful drugs proceeding from Phase II to the most expensive, larger-scale Phase III trials after an average of 2.5 years. Finally, Phase III trials may involve thousands of patients, with average duration of approximately 4 years. As a benchmark, then, if pharmaceutical firms had products 'on the shelf' they could push into clinical testing as investigational new drugs in the months after passage of the legislation, we might expect to see an increase in Phase I trials in 2004, with successful products entering Phase II in 2005–2006, and Phase III in 2008 or later. It is also possible that some molecules directly entered Phase II or Phase III clinical trials soon after passage of Part D. For example, firms could conduct Phase II or Phase III trials to investigate additional indications for drugs already on the market.

With this notional progression in mind, in Fig. 1 we present graphical evidence of structural breaks in the number of drugs entering preclinical testing, and Phase I, Phase II, and Phase III clinical trials. The number of drugs entering preclinical testing was fairly steady or slightly declining until 2003, increased dramatically in 2004 after the passage of Part D, then trended upward from 2005 to its peak in 2009. The number of drugs entering Phase I trials for our panel each year was fairly steady until 2003, increased modestly in 2004 after the passage of Part D, and then remained steady through 2006 when Part D was implemented. In 2007, the number of drugs entering Phase I trials increased markedly, and continued on an upward trajectory through 2010. These aggregate trends certainly suggest that the passage and implementation of Part D was associated with increase in the flow of Phase I trials; however, these trends could also be confounded by changes in other determinants of Phase I R&D that were coincident with the passage and implementation of Part D.

Trends for Phase II and Phase III trials likewise show large increases in R&D only after Part D's implementation. Prior to 2004, Phase II trials were only slightly increasing, and Phase III trials had a slight negative trend. In 2004, both Phase II and Phase III increased only slightly versus prior trends, and remained fairly steady at that level through 2006. Interestingly, while a pulse of drugs entered Phase III trials in 2008, that increase appears to be the peak of the Part D response for Phase III. The apparent leveling off for new Phase III trials after that point could be attributable to capital restriction in the Great Recession, or may simply reflect those 'off the shelf' products progressing through testing.

Two additional features of these data are worth noting. First, the average number of clinical trials in any given year varies significantly across drug classes. Our empirical models include drug class fixed

[4] See Oliver et al. (2004) for historical discussion.

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