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How Generic Drugs, Patents, and Price Controls Affect Markets

Two recent studies focus on government policies that affect the development and pricing of new drugs, and the effect of such policies on marketing practices both in the United States and abroad.

In Starving (or Fattening) the Golden Goose?: Generic Entry and the Incentives for Early -Stage Pharmaceutical Innovation (NBER Working Paper No. 20532), Lee Branstetter, Chirantan Chatterjee, and Matthew J. Higgins analyze the impact

that the increasing popularity of generic drugs over the past decade has had on the rate and nature of early-stage pharmaceutical innovation. Their research indicates that while the overall level of innovation has increased, a 10 percent increase in generic penetration in a given market is associated with a 7.9 percent decline in the number of early-stage innovations, and a 4.6 percent decline in the number of "first-

in-class" pharmaceutical innovations in that market.

The researchers construct a unique dataset to analyze the early stages of drug development within narrowly defined therapeutic areas. They also use data on

branded and generic drug sales across all therapeutic categories in the U.S. market, obtained at the firm-product-year level. generics on early-stage innovations. In contrast, in markets with higher levels of cross-molecular substitution, such as anti-infec-

Generics reduce early-stage innovation in their market segments; patents encourage diffusion, while price regulation discourages it.

They find that the effects of generic entry appear to vary with the extent of cross-molecular substitution, or the rate at which drugs within a particular therapeutic class can be substituted. For example,

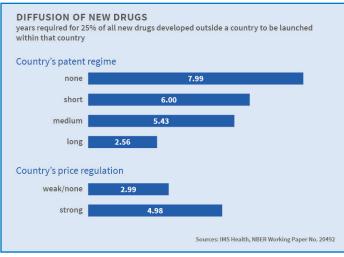
tives, they find substantial negative effects of generic entry on innovation.

The authors also document a change in the nature of innovation. In markets with significant generic entry, they

> find companies responding by shifting from chemicalbased products towards biologic-based products (that is, products based on extremely large, complex molecules such as proteins). They argue this move is a rational response given the lack of an entry pathway for generic equivalents to biologics-based drugs over their sample period.

> The researchers suggest that in order to determine

whether the shift in pharmaceutical R&D associated with generic entry raises consumer welfare, it is necessary to create a "map" that locates the various therapeutic categories in technology space. By defining the proximity of various therapies to each



in markets with limited substitution, such as neurological and psychiatric disorders, doctors may be reluctant to move away from a good "match" between a patient and a drug. In these markets, the researchers find no statistically significant effect of

other, such data could facilitate the comparison of research success probabilities in domains where drug development effort is declining and ones in which it is increasing. The authors add that the welfare questions have worldwide implications, since the rise of generics in the U.S. market is reshaping global drug development.

Looking at drug development from a different angle, in **Patents and the Global Diffusion of New Drugs** (NBER Working Paper No. 20492), **Iain M. Cockburn, Jean O. Lanjouw,** and **Mark Schankerman** note that governments use patents to encourage development of new drugs and price regulation to ensure afford-

ability. The tension between these objectives is perhaps most starkly seen outside the U.S., where large numbers of patients may be unable to afford patent-protected medications. At the very least, there may be a considerable lag between, say, the FDA's approval of a new drug for the American market and its introduction abroad. New drugs often become available in global markets a decade or more after they are launched commercially in the U.S., Europe, or Japan. Indeed, many new drugs ultimately reach only a few wealthy countries.

The authors use data on the launches of 642 new compounds in 76 countries during 1983–2002 to demonstrate that,

all else being equal, longer and more extensive patent protection accelerated diffusion of new drugs abroad, while price regulation strongly delayed it. Health care policies, institutions, and economic and demographic factors that make markets more profitable also speed diffusion.

The authors' findings raise the broader point, not limited to pharmaceuticals, that patent rights can strongly impact the diffusion of innovations as well as the rate at which innovations are made. The policies that promote faster launch—more rigorous patent rights and the absence of price regulation— are also those that raise prices.

— Matt Nesvisky

Borrowers Forgo Billions through Failure to Refinance Mortgages

Buying and financing a house is one of the most important financial decisions a household makes. It can have substantial long-term consequences for household wealth accumulation. In the United States, where housing equity makes up almost two thirds of the median household's total wealth, public policies have been crafted to encourage home ownership and to help households finance and refinance home mortgages.

The impact of these policies hinges on the decisions that households make.

Households that fail to refinance when interest rates decline can lose out on tens of thousands of dollars in savings. For example, a household with a 30-year, fixed-rate mortgage of \$200,000 at an interest rate of 6.5 percent that refinances when rates fall to 4.5 percent will save over \$80,000 in interest payments over the

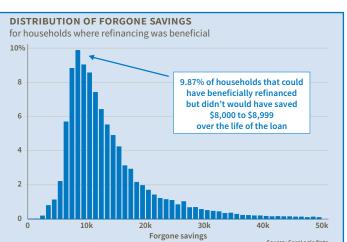
life of the loan, even after accounting for typical refinancing costs. With long-term mortgage rates at roughly 3.35 percent, this same household would save roughly \$130,000 over the life of the loan by

and they approximate the magnitude of forgone interest savings. The analysis uti-

As of December 2010, approximately 20 percent of households with mortgages could have refinanced profitably but did not do so.

refinancing. But in spite of these potential savings, many households do not refinance when interest rates decline.

In **Failure to Refinance** (NBER Working Paper No. 20401), **Benjamin J.**



Keys, Devin G. Pope, and Jaren C. Pope provide empirical evidence that many households in the U.S. fail to refinance, lizes a nationally representative sample of approximately one million single-family residential mortgages that were active in December 2010. These data include information about the origination character-

istics of each loan, the current balance, second liens, payment history, and interest rate being paid. Given these data, the authors calculate how many households would save money over the life of the loan if they were to refinance their mortgages at the prevailing interest rate while adjusting for tax implications and probability of the household moving.

A key challenge in determining whether house-

holds are failing to refinance is knowing whether a household had the option to refinance—especially given the tightening

banking standards over this time period. The authors take advantage of the rich data environment to make reasonable assumptions about the ability of individuals to refinance based on various factors (e.g. loan-to-value ratios) and provide evidence of robustness to the assumptions made.

The authors find that, in December of 2010, approximately 20 percent of households that appeared unconstrained to refinance and were in a position in which refinancing would have been beneficial had failed to do so. The median household would have saved \$160 per month over the remaining life of the loan, and the total present discounted value of the forgone savings was approximately \$11,500. The authors estimate that the total forgone savings of U.S. households was approximately \$5.4 billion.

In 2009, the Federal Housing Finance Agency (FHFA) and the Department of the Treasury announced a refinancing program entitled "Home Affordable Refinance Program" (HARP). This program enabled homeowners who were current on their federally guaranteed mortgage and met other conditions of the loan to refinance to a lower interest rate even if they had little or no equity in their homes. When HARP was announced, FHFA and the Treasury estimated that four to five million borrowers whose mortgages were backed by Fannie Mae and Freddie Mac could take advantage of it. By September 2011, however, fewer than a million mortgagors had refinanced under HARP. Although modifications to the program have resulted in more households taking up refinance

offers, the overall take-up rate remains low.

These results raise questions about why borrowers do not take advantage of refinancing opportunities that would substantially lower their interest payments. The authors suggest that there may be information barriers regarding potential benefits and costs of refinancing, and that expanding and developing partnerships with certified housing counseling agencies to offer more-targeted and in-depth workshops and counseling surrounding the refinancing decision could alleviate barriers for people in need of financial education.

The authors also suggest that psychological factors, such as procrastination, mistrust, and the inability to understand complex decisions, may be barriers to refinancing.

—Les Picker

The Link between High Employment and Labor Market Fluidity

U.S. labor markets lost much of their fluidity well before the onset of the Great Recession, according to Labor Market Fluidity and Economic Performance (NBER Working Paper No. 20479). The economy's ability to move jobs quickly from shrinking firms to young, growing enterprises slowed after 1990. Job reallocation rates fell by more than a quarter. After 2000, the volume of hiring and firing—known as the worker reallocation rate—also dropped. The decline was

broad-based, affecting multiple industries, states, and demographic groups. The groups that suffered the most were the less-educated and the young, particularly young men.

"The loss of labor market fluidity suggests the U.S. economy became less dynamic and responsive in recent decades," authors **Steven J. Davis** and **John Haltiwanger** conclude. "Direct evidence confirms that U.S. employers became less responsive to shocks in recent decades, not that employer-level shocks became less variable."

Many factors contributed to the

and government policies.

About a quarter of the decline in job reallocation can be explained by the

Declining rates of creative destruction and factor reallocation raise concerns about future productivity growth and youth employment.

decline in job and worker reallocation rates, among them a shift to older companies, an aging workforce, changing business models and supply chains, the effects of the information revolution on hiring,

ANNUAL JOB REALLOCATION RATES
1979-2010
45%
40
Retail trade
35
25
20
1979 1983 1987 1991 1995 1999 2003 2007

decline in the formation of young firms in the U.S. From the early 1980s and until about 2000, retail and services accounted for most of the decline in job reallocation. This occurred even though jobs shifted

away from manufacturing and toward retail, where job creation is normally more dynamic and worker turnover more pronounced. One reason for the slowdown in turnover was the growing importance of big box chains in the retail sector. The authors note that other studies find that jobs are more durable in larger retail firms, and their workers are more productive than workers at the smaller stores these retailers replaced.

Fewer layoffs and more employment stability are generally considered positive trends and natural outgrowths of an aging workforce. The flip side of this equation, however, is that slower job and worker reallocation mean slower creation of new jobs, putting the jobless, including young people, at a heightened risk of long-term unemployment. These developments also slow job advancement and career changes, which are associated with boosts in wages.

This is of particular significance since 2000, when the concentration of declines in job reallocation rates and the employment share of young firms shifted from the retail sector to high-tech industries.

"These developments raise concerns

about productivity growth, which has close links to creative destruction and factor reallocation in prominent theories of innovation and growth and in many empirical studies," the authors write.

Government regulation also played a role in slowing job and worker reallocation rates. In 1950, under five percent of workers required a government license to hold their job; by 2008, the percentage had risen to 29 percent. Add in government certification and the share rises to 38 percent. Wrongful discharge laws make it harder to fire employees. Federal and state laws protect classes of workers based on race, religion, gender, and other attributes. Minimum-wage laws and

the heightened importance of employerprovided health insurance also make job changes less frequent.

The authors study the effects of the decline in job and worker reallocation rates on employment rates by gender, education, and age, using state-level data. They find that states with especially large declines in labor market fluidity also experienced the largest declines in employment rates, with young and less-educated persons the most adversely affected.

"...if our assessment is correct," the authors conclude, "the United States is unlikely to return to sustained high employment rates without restoring labor market fluidity."

—Laurent Belsie

The Value of Brownfield Remediation

Revitalizing contaminated land is a costly process and for sites known as brownfields, where health hazards are low, it is unclear that the health benefits of remediation outweigh the costs. However, even though these sites may not be especially toxic, their oftentimes poor aesthetic quality, combined with their need for special treatment in order to be redeveloped, causes the surrounding area to be an undesirable place to live or

work. Thus benefits of revitalization also include economic development that results from making brownfields productive and attractive so that the surrounding area becomes more desirable.

In **The Value of Brownfield Remediation** (NBER Working Paper No. 20296), **Kevin Haninger, Lala Ma,** and **Christopher Timmins** use quasi-experimental approaches to estimate the benefits of brownfield

cleanup through its effect on nearby property values. Using a high-resolution, high-

frequency housing dataset combined with Environmental Protection Agency (EPA) data, they provide the first nationwide resident preferences for brownfield remediation before cleanup differ substantially from that of new residents moving in after

In the vast majority of the 51 cleanup sites in the United States, total economic benefits exceed cleanup costs by an order of magnitude.

analysis of the EPA Brownfields Program.

Recovering welfare estimates for brownfield cleanup from property-value changes over time may prove challenging cleanup, the capitalization of changes in environmental quality into housing prices over time does not measure the willingness to pay of either group. Instead, the

authors propose a difference-in-differences nearest-neighbor matching procedure that does not require any comparisons over time. In particular, they compare price differences of houses that are "treated" with cleanup with those that are not, based on a property's location in adjacent neighborhoods around sites that were cleaned, to the same differences in prices of houses near sites that were not cleaned. Each house near cleaned sites is

matched to its most-similar counterpart near untreated sites based on site, house,

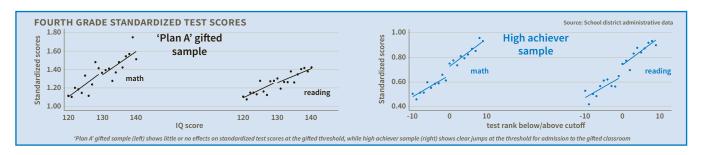


if there is substantial neighborhood turnover following remediation. In this case, if and neighborhood characteristics.

The results suggest that the cleanups conducted under the Brownfields Program yield a large, statistically significant positive effect, but that effect is highly localized. The rise in housing values that can be attributed to brownfield remediation ranges from 5 to 15 percent, depending on the criteria specified by the researchers. These numbers can be interpreted as a measure of willingness to pay for remediation. Using their

more conservative results, the authors conclude that, in the vast majority of the 51 cleanup sites in the United States, the total economic benefits exceed the cleanup costs by an order of magnitude.

— Claire Brunel



Who Benefits from Education for the Gifted?

In Does Gifted Education Work? For Which Students? (NBER Working Paper No. 20453), David Card and Laura Giuliano report that full-time classes set up for gifted students don't raise the achievement of gifted students, but have large positive effects on non-gifted high achievers in those classes—especially on the reading and math scores of low-income high achievers. The authors conclude that establishing "a separate classroom in every school for the top-performing students could significantly boost the performance of [these] students in even the poorest neighborhoods," without harming other students or increasing school budgets.

Using detailed administrative data from one of the largest school districts in the United States, the authors tracked the progress of three distinct groups of students who were eligible for placement in classes for the gifted from 2004 through 2011. District policy required each elementary school to set up a separate gifted class for all students in the fourth or fifth grade who met one of two criteria. So-called "Plan A" gifted students scored at least 130 points on an IQ test. The policy also allows a lower threshold (116 points) for the "Plan B" gifted students

-i.e., English-language learners and participants in the free and reduced-price lunch program. Finally, since many schools have relatively few gifted students in a grade, were more like those of the high achievers and were low relative to their scores on tests of cognitive ability. They note that it is possible that the program had a negligible

Full-time classes for the gifted don't raise scores of high-IQ gifted students but have positive effects on other high achievers.

the remaining seats are offered to nongifted students who scored the highest on the previous year's state-wide achievement tests (known as "high achievers"). Classes for the gifted are the same size as other classes in the district, and students follow the same curriculum and write the same standardized achievement test each spring.

The positive and relatively large effects on the math and reading achievement of the non-gifted high achievers was concentrated among free and reduced-price lunch students and black and Hispanic students. There was also a small positive effect on the writing scores of Plan B gifted students—especially boys and students at schools with high fractions of students who were eligible for free and reduced-price lunches.

The authors note that Plan B gifted students tended to be "underachievers" because their scores on standardized tests impact on the test scores of Plan A gifted students because it is difficult to raise the scores of students who are already performing in the top percentiles. This argument is less compelling for Plan B students whose scores, like those of the high achievers, had ample room for improvement.

Based on interviews with teachers, the authors speculate that many Plan B students may have lacked non-cognitive traits, such as attention-to-task and a willingness to meet social expectations. Such traits may have helped high achievers perform well on standardized tests of routine knowledge despite their lower IQ scores. Differences in these traits may explain why high achievers benefitted more from gifted classes than the Plan B students, and may also explain why Plan B students reported lower satisfaction with the gifted classroom environment than either the Plan A students or the high achievers.

CEOs Often Time News Releases to Boost Value of Stock Grants

he timely release of news, from corporate quarterly reports to information about mergers or other significant corporate events, can have major impacts on companies' share prices. Chief executives are well aware of this. As Alex Edmans, Luis Goncalves-Pinto, Yanbo Wang, and Moqi Xu show in Strategic News Releases in Equity Vesting Months (NBER Working Paper No. 20476), CEOs often strategically time the issuance of favorable news releases for the months when their previously agreed upon equity grants are scheduled to vest. This raises the value of their equity positions at the time when they could first liquidate their holdings.

For years, public companies have been required by regulators to release certain types of information, such as corporate financials or plans for annual shareholder meetings, on a timely basis as part of the effort to create a level playing field for all investors. Previous studies have shown that both non-discretionary (mandatory) and discretionary (voluntary) news releases by companies can increase liquidity, firm value, and share prices, and they have also explored the roles of CEOs in publicly distributing company information.

In this study, the authors sought to determine whether CEOs' partici-

pation in the release of discretionary information could be linked to months when their equity grants, often negotiated years in advance, were scheduled to and that this return was statistically significant. Over 31 days, the return was smaller, suggesting that discretionary news releases may have only temporary

Managers strategically time the disclosure of discretionary corporate news to coincide with the scheduled vesting of their equity grants.

vest. To determine the vesting months for CEOs, the authors relied on data from Equilar between 2006 and 2011 and on hand-collected data from proxy statements and other SEC filings from 1994 to 2005. They found that CEOs were more likely to sell shares during their vesting months, although many CEOs did not sell shares at all.

The authors then sampled 160,000 corporate news releases, using a database that allowed them to differentiate between non-discretionary and discretionary releases. They used Thomson Reuters News Analytics to determine whether subsequent media coverage was favorable or non-favorable to the company, and found that, on average, discretionary news releases were associated with positive media coverage.

The authors conclude that disclosure of one discretionary news item in a vesting month generated an average 16-day abnormal return of 28 basis points,

price effects. The authors found 5 percent more discretionary news releases in CEO vesting months than in prior months.

By linking the timing of discretionary news releases with their data on the exercise of stock options, the authors found that the median interval between a disclosure in a vesting month and the first equity sale by a CEO who sold was five days; the median interval until sale for the CEOs who sold the entire vesting amount was seven days.

"This paper shows that managers strategically time the disclosure of discretionary corporate news to coincide with the scheduled vesting of their equity grants," the authors conclude. The news is associated with favorable media coverage and "leads to temporary increases in the stock price and trading volume, consistent with an attention[-getting] story. CEOs exploit these temporary effects."

— Jay Fitzgerald

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