Exploring the Timing of Reviews and Approvals of New Drugs

Government approval of drugs surges before major holidays, at month-end, and especially at the end of the year, according to research by Lauren Cohen, Umit Gurun, and Danielle Li. In *Internal Deadlines, Drug Approvals, and Safety Problems* (NBER Working Paper 28071), they find that drugs approved during such surges are associated with more hospitalizations, life-threatening incidents, and deaths than those approved at other times. The researchers estimate that rushed reviews lead to between 1,400 and 9,000 lives lost per year.

The researchers study 3,312 unique drug applications in the US that were approved between January 1980 and September 2016, and 4,871 drugs approved by the EU or one of its member nations between January 1980 and July 2014.

Twenty-one percent of the drugs approved in a typical year in the US, EU, Japan, China, and South Korea are approved in December. Approvals in that month are double those in any other month. In the US, the December approvals represent about 15 percent of the annual total.

The idea that informal production targets cause spikes in output is not new. Such patterns have been documented in retail sales, patent office approvals, judicial decisions, and spending by federal agencies.

The researchers attribute these approval patterns to a "desk clearing objective" on the part of reviewers preparing for time out of the office. They point out that while there are no formal deadlines for drug reviews, reviewers typically are evaluated, in part, on the share of applications that get a timely review. Different nations have different definitions of timeliness: within 300 days for a regular review and 180 days for a priority review in the US; 210 and 150 days, respectively, in the EU; and 360 and 270 in Japan. If those deadlines were the driving factor in approval decisions, then the surges of approvals would happen at these anniversaries of the start of the review process, not in December or before major holidays. These deadlines would also fail to explain the observed surges associated with country-specific holidays, such as Thanksgiving in the US and the Lunar New Year in Asia.

The researchers rule out the possibility

About 20 percent of drug approvals come in pre-holiday surges in December. They are associated with more adverse outcomes than drugs approved at other times.


*Source: Researchers' calculations using data from the Food and Drug Administration*
that the reviewers save their most difficult approvals for last, and push through the easy ones first. Such behavior could explain the higher rate of adverse outcomes for December approvals. The higher rates of adverse events for December approvals persist even after controlling for the drug’s target disease and whether it was marked for priority review status. There is no evidence that drugs approved in December are more complicated or difficult to review. The researchers also look for, but do not find, evidence that firms time their submissions so that the timely review target will fall in December, when they might get a less rigorous review.

Why do reviewers appear to tilt toward approval, rather than rejection, around these self-imposed deadlines? The researchers suggest that regulators are judged in part based on the number of drugs approved, which are immediately visible, while an approved drug’s adverse effects are only evident in the future. This may create a pro-approval bias.

—Laurent Belisle

Stock Market Trading Rules and Corporate Share Repurchases

Stock repurchases by US corporations have trended higher in recent decades, particularly in comparison to corporate dividend payouts. One explanation is that the capital gains that buybacks generate for investors are generally taxed less heavily than dividend payments. However, the tax rate difference between dividends and capital gains in the last two decades has been smaller than in earlier years, making it difficult to explain rising repurchases with a tax-based explanation alone.

In Price Ceiling, Market Structure, and Payout Policies (NBER Working Paper 28054), Mao Ye, Miles Zheng, and Xiongshi Li posit that equity market regulations governing the share-trading process have also been an important determinant of share repurchase activity. They point out that the resulting price ceilings, combined with market structure frictions, discourage stock buybacks.

In 1982, the Securities and Exchange Commission (SEC) imposed price ceilings on share repurchases in order to prevent firms from inflating their share prices by outbidding other traders. This regulation, Rule 10b-18, specified that firms should buy their shares at prices that do not exceed the highest independent bids or last transaction prices. As firms cannot repurchase shares on open markets by offering higher prices than other traders, market structure emerges as a first-order effect because it determines execution priority among traders who quote the same price. Decades ago, dealers enjoyed the privilege of trading before issuers at the same price. The dealer priority at price ceilings provides one explanation for why share repurchases were low.

A series of market reforms beginning in the mid-1990s reduced the trading-related frictions of repurchasing shares. These reforms included the Manning Rule (1994) and the Order Handling Rules (1997), which increased the repurchasing firm’s priority in executing trades and reduced the market maker’s competitive advantage, and the Common Cents Stock Pricing Act (1997), which reduced the minimum unit of share price movements — the tick size — from 12.5 cents to 6.25 cents in 1997 and from 6.25 cents to 1 cent in 2001. A more continuous price grid relaxes the price ceiling and reduces the level of competition at the same price. In 2003, the New York Stock Exchange installed automated quotes, which allowed issuers and their brokers to monitor markets in real time using computer algorithms, effectively leveling the playing field for issuers and market makers.

The researchers find an increase in share repurchase activity after each of these regulatory or institutional reforms.

They also study the effect of the 2016 Tick Size Pilot Program. In contrast to the regulatory reforms of the last three decades that lowered the cost of firms entering the stock market to repurchase shares, this SEC program raised the tick size for 1,200 randomly selected stocks from 1 to 5 cents, while preserving the tick size at 1 cent for a similar-sized control group. During this two-year experiment, share repurchases fell by 21 percent for firms facing higher tick sizes, while dividend payouts were unchanged. This effect was concentrated among firms with bid-ask spreads of less than 5 cents before the start of the pilot.

In another related experiment, the pilot restricted the execution of off-exchange trades, so-called “dark pool” trades—which give certain large investors the ability to trade large positions without impacting market prices — by requiring dark pools to improve the National Best Bid and Offer by more than 2.5 cents when they execute trades. This restriction unintentionally banned share repur-
Effects of College Merit Scholarships on Low-Income Students

The goal of most financial aid programs is to increase educational attainment for prospective students who might not otherwise be able to enroll in college or to complete a degree. In Marginal Effects of Merit Aid for Low-Income Students (NBER Working Paper 27834), Joshua Angrist, David Autor, and Amanda Pallais measure the impact of a Nebraska program that provides students from low-income families with full scholarships to public colleges and universities. Unusually for research of this sort, the study relies on a randomized controlled trial.

Each year, the Omaha-based Susan Thompson Buffett Foundation (STBF) provides scholarships to thousands of economically disadvantaged students who are judged to be capable of college-level work. To assess the program’s impact, the foundation partnered with the researchers to randomize aid awards to 3,700 high school seniors between 2012 and 2016, and to track their subsequent educational attainment. Each award covered tuition and books for up to five years at any Nebraska public four-year institution, and for up to three years at any Nebraska two-year college. With funding provided by STBF, the researchers tracked the progress of those who received aid awards, and of those who did not, through the educational system.

The study found that award recipients enrolled in four-year degree programs at higher rates and were less likely to drop out than those in the randomly selected control group. Among those who said they were targeting four-year degree programs, awards increased bachelor’s degree completion by 8.4 percent, relative to the mean of 63 percent for the control group that did not receive aid. Conversely, awards made to applicants who planned to seek a two-year degree did not increase their likelihood of earning that degree.

Across the board, awardees from groups that are on average less well-prepared for college-level work, including those with relatively low ACT scores and GPAs, enjoyed the largest scholarship-induced boosts in degree completion. Conversely, academically well-prepared students from somewhat higher-income families saw little increase in degree completion, though they finished college with substantially less debt. Students who aspired to attend the University of Nebraska at Omaha — which serves a mostly low-income, disproportionately non-White popu-
Residential Property Markets and Exposure to Rising Sea Level

Forty-two percent of the US population resides in shoreline counties. Whether and how property and mortgage markets incorporate information on the risk of climate-related sea level rise is therefore an issue of broad significance.

In *Neglected No More: Housing Markets, Mortgage Lending, and Sea Level Rise* (NBER Working Paper 27930), Benjamin J. Keys and Philip Mulder study the relationship between exposure to sea level rise and changes in housing and mortgage markets over the 2001–20 period. They focus on the coastal Florida market, where the Union of Concerned Scientists projects that more than one million properties are at risk of chronic inundation due to sea level rise by 2100. Their analysis emphasizes tract-level variation in flood risk, and includes data from over 1,380,000 home sales and 2,650,000 loan applications, as well as extensive data on flood insurance premiums and take-up rates.

The researchers examine whether the post-2013 volume and price trends diverge more from their 2001–12 trends in markets with more exposure to prospective sea level rise than in observationally similar areas with less exposure. Three different approaches to selecting “control” areas — synthetic control, nearest neighbor, and generalized propensity score-matching — produce similar results. More-exposed markets experienced declines in housing transaction volumes, but comparatively little change in prices, after 2013 relative to observationally similar less-exposed markets. By 2018, the most-exposed census tracts in Florida had transaction volumes 16 to 20 percent below their 2001–12 annual averages relative to trends in a matched sample of markets with low exposure to sea level rise. These estimates indicate that approximately 16,500 fewer home transactions took place from 2013–18 among the 187 census tracts most exposed to sea level rise relative to counterfactual trends.

The researchers do not find a strong relationship between home price changes and risk of sea level rise from 2013–16, but they detect some evidence of price decline in more-exposed tracts after 2016. By 2020, prices in these markets were 5 to 10 percent below trend. They find little evidence that changes in lender standards with respect to sea level rise risk are behind the changes they observe in at-risk housing markets. There are only small relative changes in loan denial, securitization, and refinancing volumes between markets facing different sea level rise risk, and they estimate similar declines in both cash and mortgage home purchase volumes in the most sea level rise-exposed tracts. They also conclude that these responses are not due to pricing practices of the National Flood Insurance Program, which tends to underprice insurance for at-risk coastal properties and therefore encourages housing investment in the tracts most exposed to prospective sea-level rise.

The researchers find that exposed housing markets are experiencing demand-driven declines in transaction volume and home prices over a period coinciding with increasing climate risk salience. They note that transaction volumes began to diverge in 2013, a year in which a confluence of events — including Hurricane Sandy, the release of two critical climate assessment reports, and Pew Research data showing Americans becoming more worried (and polarized) about climate issues — focused public attention on climate risk. Given these changing beliefs around sea level rise, they say, their findings are best characterized by housing market bubble dynamics, where prospective sellers of homes with sea level rise risk remain optimistic about their home’s value even as prospective buyers grow more pessimistic. Thus, sellers set prices higher than most prospective buyers are willing to pay, causing transaction volumes to decline before prices. Supporting the role of beliefs in driving these demand dynamics, the researchers find that the at-risk tracts with the biggest declines are in counties where more residents report being worried about climate change.

— Lauri Scherer
How and Why Black Riders Were Driven from American Racetracks

In Jim Crow in the Saddle: The Expulsion of African American Jockeys from American Racing (NBER Working Paper 28167), Michael Leeds and Hugh Rockoff document the expulsion of African American jockeys from the Triple Crown races as a striking example of the surge in racism in the 1890s. The researchers suggest that horse racing provides a particularly helpful case study for untangling Jim Crow’s effects because it was popular both in the North and the South, was integrated for years after the Civil War, and offers quantitative data that reflect underlying attitudes. Using a new dataset that includes information on all entrants in all races, they find some evidence of prejudice by horse owners and the betting public, but conclude that the final push for expulsion came from White jockeys who were determined to “draw the color line.”

In the years following the Civil War, as in the pre-war era, most jockeys on Southern tracks were African American. At the first Kentucky Derby, in 1875, 13 of 15 jockeys were African American. Between 1890 and 1899, Black jockeys won six Derbies, one Preakness Stakes, and three Belmont Stakes. But in the early 1900s Black jockeys disappeared. Jimmy Winkfield was the last African American to win a Triple Crown race, in 1902. He was one of the last African Americans to ride in a Triple Crown race for almost a century.

The researchers test for the presence of discrimination against Black jockeys in two ways. First, they study the relationship between the rise of Jim Crow and the decline in the number of mounts going to Black riders. Second, they examine whether a particular class of jockeys outperform the odds, which reflect the bets that race spectators have placed. This test could detect spectator discrimination against Black jockeys.

The researchers do not find any evidence of racial prejudice by the betting public for races run on Northern Triple Crown tracks, but they find some evidence of such prejudice at the Kentucky Derby. Horses ridden by Black jockeys were more likely to finish in the money (first, second, or third) than predicted by the odds. This suggests that bettor preferences at the Derby may have contributed to the expulsion of African American jockeys.

The key push to exclude Black jockeys came when White jockeys began violently attacking their African American counterparts by boxing them out during races, running them into the rail, and hitting them with riding crops. These attacks prevented Black jockeys from finishing in the money, and endangered fragile and valuable racehorses. Soon after the attacks began, African American jockeys found they could not get rides. Anxiety over job insecurity appears to have played an important role in White jockeys’ actions: there were only a limited number of riding slots. White jockeys would have benefitted in any circumstances from the exclusion of Black jockeys, but in the late 1890s the US was in a depression, and unease about finding rides was especially high. Combined with a growing anti-gambling crusade that reduced attendance at racetracks and eliminated some tracks entirely, jockeys found demand for their services contracting.

 Owners tacitly participated in the expulsion of African American jockeys. For some, it could have been a matter of prejudice, but for others, it was likely a business decision. Why employ a Black jockey if White jockeys would use violence to prevent him from finishing in the money, and risk damaging a valuable horse in the process?

The researchers conclude that African American jockeys were victims of discrimination at multiple levels. The findings add to the evidence that anxiety about jobs was an important contributing factor to the racism that produced Jim Crow.

— Lauri Scherer
Employment Effects of Demolishing Distressed Public Housing

Between 1996 and 2003, the Department of Housing and Urban Development (HUD) awarded nearly $400 million in grants to localities for the demolition of more than 57,000 public housing units. Through this HOPE VI program, HUD sought to improve families’ living conditions by demolishing severely distressed subsidized public housing and relocating those who lived in it.

In The Children of HOPE VI Demolitions: National Evidence on Labor Market Outcomes (NBER Working Paper 28157), John C. Haltiwanger, Mark J. Kutzbach, Giordano E. Palloni, Henry O. Pollakowski, Matthew Staiger, and Daniel H. Weinberg consider the HOPE VI program’s effects on young adults who were exposed to the program as children.

Using records from HUD and the Census Bureau, the researchers generated a dataset of 18,500 children from 160 demolished housing projects and examined their labor market status at age 26. From the same records, the researchers generated a control group of children from 570 public housing projects that were not demolished.

Children exposed to a HOPE VI demolition earned substantially more — about 14 percent, or $622 — at age 26 than non-exposed children. The probability of working all four quarters of the year was 1.6 percent greater for those affected. On average, children from large housing projects — those of more than 2,500 units — experienced more benefits. Earnings at age 26 for those from large projects were 19.5 percent greater than for those in the control group, compared with just 4.5 percent for those in smaller projects. The age at which a child moved was not a factor. Also, moving had no effect on job market outcomes for the parents; earnings for heads of household remained unchanged after relocation.

Children who lived in neighborhoods that were denser, poorer, and farther from jobs prior to the demolition benefited most from the program. But the gains are difficult to attribute to improvements in either the children’s home or neighborhood environment. The families did not move to higher quality neighborhoods, as measured by school quality or the poverty rate. The new neighborhoods were significantly better, though, in terms of the ratio of jobs to people, average commute time, and a “job proximity index” constructed by HUD.

The demolitions transformed the neighborhoods in which the HOPE VI projects were originally located. Public housing projects, particularly large projects, often provide housing to large numbers of people in geographically concentrated areas. This results in many job-seekers competing for nearby work. Demolitions reduced population density and raised the job-to-people ratio by 22 percent. Even HOPE VI children who remained near their original housing project experienced an improvement in job proximity. Once again, the findings are driven by large projects. The researchers found no evidence that HOPE VI demolitions improved geographic proximity to jobs for former residents of small housing projects, and some evidence that they reduced it.

– Brett M. Rhyne