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RISKY BUSINESS: SHOULD THE FDA PAY ATTENTION TO DRUG PRICES?

Prices provide information that the agency needs to consider.

✦ BY DAVID A. HYMAN AND WILLIAM E. KOVACIC

The dream is always the same. Congress should enact sweeping laws that turn everything over to technocratic regulators, giving them *carte blanche* to do whatever serves the public interest. These disinterested experts will apply the delegated authority wisely and effectively, delivering truth, justice, and prosperity—and will do so without the rent-seeking, log-rolling, and earmarks that are associated with the political branches (i.e., Congress and the president).

Of course, that's often not the way things turn out. Market failure is real, but so is government failure. Regulators are not always neutral, and many of them are not actually technocratic experts. Stated differently, expertise informs their judgments, but so does politics (both in the sense of partisanship and of organizational machinations). They can pick sides and use their sweeping regulatory authority to make life miserable for those who are on the other side.

Regulators can also screw up. Sometimes they don't have the requisite information to understand (let alone fix) the problem. Sometimes their tools are the wrong ones for the job (i.e., "if the only tool you have is a hammer..."). Regulators can also be too risk-averse, or not risk-averse enough. They can have tunnel vision, or they can seek to use their power to leverage outcomes that lie far outside the scope of their properly delegated authority. They

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can be too cozy with the industries they regulate, or not cozy enough. And so on.

To be sure, some agencies are less prone to this laundry list of problems than others. Consider the U.S. Food and Drug Administration. To its credit, the FDA has done a fairly good job of avoiding problems, but it is not perfect.

The FDA's biggest challenge is that it is in the business of making tradeoffs between innovation and safety. Advocates for each of these (laudable) goals are quick to condemn decisions that seem to favor the other goal. In the words of recently departed FDA commissioner Margaret Hamburg:

The balancing of risks and benefits is fundamental to FDA's regulatory role. And it is always a challenge. We joke that FDA is viewed as having only two approval speeds: too fast and too slow. We are perceived as too quick to approve a drug or device when a significant safety issue is identified in the post-market context once the product is in widespread use. On the other hand, we were too slow in approving when a drug that has undergone a lengthy development and review is finally approved and provides a real therapeutic benefit to patients. The task for FDA's scientist is to strike the right regulatory balance.

More concretely, those who prioritize innovation criticize the FDA for being too risk-averse in approving drugs because the agency (rightly) anticipates being pilloried for "false positives" (i.e., approving drugs it should not), but knows it will receive much less criticism for false negatives (i.e., delaying or denying approval of drugs that it should have). These critics, who tend



Martin Shkreli, former CEO of Turing Pharmaceuticals, confers with his attorney before the start of a 2016 House committee hearing.

to come from the right side of the political spectrum, believe the result of this risk aversion is delayed and/or denied approvals, resulting in tens of thousands of invisible (but no less real) deaths. Conversely, those who prioritize safety believe that the FDA has been too willing to approve ineffective and risky drugs, in part because of congressional pressure to lower the standards for drug approval, compounded by the corrupting influence of user fees. (See “How Have User Fees Affected the FDA?” Spring 2002.) These critics, who tend to come from the left side of the political spectrum, believe the result is tens of thousands of visible deaths and considerable disability. Both sides point to specific examples supporting their respective positions and are quick to discount the concerns raised by the opposing side.

These battles have been going on for decades, with both sides arguing about where, at any given point in time, the FDA falls on the drug approval “Goldilocks” spectrum (i.e., is the agency acting too fast, too slow, or just right?). These issues seem likely to remain policy perennials, if the recent debates over the 21st Century Cures Act and “Right to Try” laws are any indication. (See “Is State ‘Right to Try’ Legislation Misguided Policy?” Fall 2014.)

Notwithstanding these disputes, if you asked a random mem-

ber of the general public or of Congress to identify the single most important issue in the drug policy space, our bet is that “cost” would be by far the most popular response. There is no shortage of examples that help explain that response, whether it is Martin Shkreli (Daraprim), Mylan (the Epi-pen), or the spiral of increases in the sticker price for a wide array of brand-name drugs. (See “Legislating Drug Price Transparency,” Summer 2017.)

So where is the FDA when it comes to drug costs? When asked, FDA personnel are quick to explain that drug pricing is not their responsibility. As Zachary Brennan of the health care industry group Regulatory Affairs Professionals Society wrote in a November 2015 essay, “FDA doesn’t dip its toe into the pricing bog while deciding whether to approve or reject a new drug, and it also doesn’t negotiate with pharmaceutical companies over how to price drugs.” This response captures the agency’s longstanding position. Its organization, culture, and behavior reflect its self-understanding that it is the safety and efficacy czar. No drug gets onto the market without FDA permission, but once the drug is approved, the agency

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has no interest in the price point at which it changes hands. Periodic attempts to get the agency to respond to drug pricing “problems” have been deflected, deflated, or simply ignored.

As we detail below, the FDA’s decades-long honeymoon on this issue is almost certainly over. We anticipate the agency will come under increasing pressure to address drug pricing. When that happens, the question will no longer be whether it should pay attention to drug prices, but how and when the FDA should do so.

WHY THE FDA SHOULD PAY ATTENTION TO DRUG PRICES

Prices communicate information. Why wouldn’t an agency charged with regulating a market pay attention to pricing information about the goods being sold in that market—particularly when the agency controls access to the market? Of course, the FDA does not regulate prices directly, but that does not mean the agency should simply ignore prices, even if it would prefer to focus on the technocratic “thumbs up” or “thumbs down” drug approval decision.

Knowledgeable observers know that the agency’s statutory mandate focuses on safety and efficacy, not prices. But there are two distinct reasons why the FDA should pay at least some attention to drug prices. First, at least for generics, drug pricing can communicate information about the FDA’s performance. Generic drug entry is an immensely powerful tool with which to lower drug prices. But if generics are not being approved in a timely fashion, drug prices may remain at elevated levels, even though the underlying drug is long since off-patent.

Bureaucracies can easily become complacent about backlogs because they experience them only as an ever-growing pile of paperwork accumulating in the agency’s inbox. After all, it’s only paperwork. The pile was there yesterday and will be there tomorrow. Maybe drug companies have to wait longer for their drug approvals than they would like, but there are $n + 1$ holes in the dike that the FDA is guarding, and only n plugs with which to fill them. As long as every drug company is treated the same, no company has a valid complaint.

But if the FDA starts paying attention to drug pricing, the human cost of the agency’s approval backlog suddenly becomes immediate and concrete. Agency leaders are forced to recognize the significant harms that result when the FDA has a backlog of generic drug approval requests. Indeed, drug prices provide an immediate feedback loop on the real-world consequences of the agency failing to clear its backlog. The FDA can also use pricing information to identify and prioritize applications that should get bumped to the front of the queue for processing. And it can use the pricing information to lobby Congress for more personnel: “We need more money to process generic drug applications. The level and trends in drug pricing show that we aren’t blowing smoke.”

Pricing information also helps cast light on the consequences of other aspects of the FDA’s operations. Consider the Unapproved Drugs Initiative (UDI), launched in 2006. The UDI was an attempt to deal with various drugs that were being sold without FDA approval because they had been on the market before the 1938 Food and Drug Act requiring safety evidence or the 1962 amendments requiring safety and effectiveness evidence. Consistent with the UDI, the FDA warned companies that specific drugs were unapproved and invited them to test them. Firms that tested their drugs received a period of market exclusivity.

From the FDA’s perspective, the UDI was a straightforward strategy to push unapproved drugs off the market, using a carrot (market exclusivity for firms that tested their drugs) and a stick (enforcement actions against firms that failed to test their drugs). Best of all, the costs of market exclusivity were externalized to consumers, rather than treated as an on-budget expense for the agency. Predictably enough, multiple companies conducted

Why wouldn’t an agency charged with regulating a market pay attention to pricing information about the goods being sold in that market—especially when the agency controls access to that market?

some quick and dirty testing, and then used the resulting market exclusivity to jack up prices. The most aggressive/creative companies also sought to achieve orphan drug status for their products, further increasing the period of market exclusivity.

The pricing consequences of the UDI were clear. To pick one example, the price of colchicine, used to treat gout, went from 10¢ a tablet to \$5. Unsurprisingly, these increases in cost affected utilization. One study found “a reduction in colchicine initiation and an increase in patient spending ... [but no] association with improvements in avoidance of potentially dangerous co-prescriptions.”

Of course, the pricing consequences of the UDI were not limited to colchicine. The price of 17-OHP, used to prevent premature births, went from \$15 per injection to \$1,440. The price of extended-release guaifenesin, used in cough syrup, went up by 700%. Other examples are not hard to find.

If the policy focus is solely on reducing the number of unapproved drugs on the market, the UDI would have to be scored an unmixed success. But if the focus includes information on drug pricing and access to care, the case looks quite different. Indeed, if the FDA had thought about drug prices, it is far from clear that it should have gone forward with the UDI. At a minimum, greater consideration should have been given to the likely pricing conse-

quences of granting an extended period of market exclusivity for cheap drugs that had been on the market for decades.

The FDA's response to criticisms of the UDI also reveals its mindset. In an October 2010 letter published in the *New England Journal of Medicine* in response to an article about the colchicine debacle, FDA officials Janet Woodcock and Sarah Okada wrote:

Because URL Pharma was the first to submit clinical trial data and be granted approval for oral colchicine, federal law required that the company be given marketing exclusivity for the indication of acute gout for 3 years and for the indication of familial Mediterranean fever for 7 years. Congress wrote these laws to encourage innovation, although such regulations sometimes have a broader sweep. The FDA is required to implement the laws as written and has no authority to regulate drug prices. Manufacturers could seek approval for colchicine for chronic gout; no marketing exclusivity exists for this indication.

The FDA is focused on ensuring that all drugs are held to the same safety, efficacy, and quality standards. The FDA noted 117 non-overdose deaths (some recent) that were associated with oral colchicine (with 51% involving an interaction between colchicine and clarithromycin). Clinical trials of Colcrys showed that lower doses were as effective as higher doses and produced fewer side effects. As a result of the FDA's review and approval of Colcrys, this information must now be included in the drug's label.

Stated more concisely: "It's not us; it's the law. And don't bother us about pricing, because that's not our problem either."

But Congress and the general public were entirely unpersuaded by these arguments. For colchicine, there was universal outrage about the price increases. For 17-OHP, the outcry in Congress and the news media was so loud that the FDA backed down and allowed compounding pharmacies to continue to manufacture the product. These reactions point to the second reason for the FDA to pay attention to drug prices: because people expect it to. When a public agency visibly fails to do what Congress and the general public expect it to do, bad things happen to agency leadership—and sometimes to the agency itself.

For both of these reasons, we believe the time is ripe for the FDA to start paying attention to drug prices. If the agency doesn't address this issue on its own, it may well find the issue rammed down its throat.

GAMING THE FDA APPROVAL PROCESS: CITIZEN PETITIONS AND REMS

So far, we have focused on the pricing consequences of the UDI and the FDA's failure to approve generic drugs in a timely manner. But other aspects of the FDA's operations create the opportunity for similar adverse effects on pricing. Consider citizen petitions. In theory, citizen petitions provide a way for external constituencies to trigger FDA scrutiny of drugs that the agency would otherwise overlook or assign a lower priority. But citizen

petitions can also be used to deter generic entry, as Mylan did with the Epi-pen and ViroPharma did with Vancomycin.

The FDA's Risk Evaluation and Mitigation Strategy (REMS) authority raises many of the same concerns as citizen petitions. The authority enables the FDA to require drug manufacturers to formulate and carry out strategies intended to mitigate risks associated with unrestricted use of specific drugs. But REMS can also be used to delay generic entry. In 2014, fully 40% of newly approved drugs had a REMS. One study estimated that delays in generic entry attributable to REMS cause Americans to pay an extra \$5.4 billion per year for drugs. If that estimate is correct, branded drug companies are likely to view REMS as a briar patch they want to be thrown into, rather than a real constraint on their ability to market their products.

As these examples indicate, the pricing problems associated with FDA action/inaction are not limited to UDIs and the agency's failure to approve generic drugs on a timely basis. As our discussion of citizen petitions and REMS indicates, multiple aspects of the agency's operations can have unintended adverse consequences on drug pricing. Unless the agency is paying attention to the issue, it will find it more difficult to detect such (mis)conduct and track changes in the tactics that are being employed to game the FDA approval process. Even if the agency partners with the Federal Trade Commission to address anticompetitive behavior, it still needs to regularly scrutinize its own operations to ensure they are not being turned to anticompetitive ends.

RISKS OF UNLEASHING THE PRICING GENIE WITHIN THE FDA

The FDA has long thought of itself as the safety and efficacy agency. What are the likely consequences and risks of allowing or encouraging the FDA to pay attention to drug prices? The most obvious risk is that the agency will decide it is in the price-setting business or come under sufficient pressure that it starts doing so. This is likely to prove a particular problem for branded drugs, where high prices are primarily attributable to the mechanisms by which we pay for prescription drugs, rather than to anything the FDA is or isn't doing.

Of course, paying attention to prices will require the FDA to hire personnel with the appropriate skill-set: economists and lawyers. Organizational issues (e.g., should those responsible for the pricing portfolio be integrated into the drug approval teams, or set up in their own bureau? Who gets the last word?) will need to be resolved. There are likely to be intra- and inter-agency conflicts that will need to be mediated. How well or poorly these complexities are handled will make a big difference in whether having the FDA pay attention to drug prices works out well or poorly.

INTRUDER ALERT!

The most common objection to our proposal is based on statutory text. If the FDA is the safety and efficacy agency, doesn't it violate the statutory mandate for it to pay attention to drug pricing? And

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doesn't the absence of statutory provisions relating to drug pricing from the 21st Century Cures Act indicate that Congress has no interest in allowing the FDA to pay attention to drug pricing?

We think both of these objections are overstated. For those who believe in a "living Constitution" and free-wheeling policy-oriented theories of statutory interpretation, the absence of explicit congressional authorization is a barely discernable speed bump on the way to the desired objective.

For textualists and originalists, the absence of explicit statutory authorization implies the FDA may not consider drug pricing in deciding whether to approve or disapprove a drug. Any doubt

and the public that the agency can't fix everything that is dysfunctional about drug pricing. For example, to the extent pricing problems are attributable to the way we have chosen to pay for pharmaceuticals, the FDA can do little or nothing to remedy that issue.

FDA Commissioner Scott Gottlieb has announced his intention to move forward on the first two of our proposals as part of a new "Drug Competition Action Plan." The plan will simultaneously encourage innovation in drug development while "accelerating the availability to the public of lower cost alternatives to innovator drugs." The FDA even held a hearing in mid-July 2017 to solicit input on ways to fix the FDA's policies and procedures. So, we're already halfway home.

What about the UDI? As we have already suggested, viewed from an FDA-centric perspective, the UDI was a sensible and cost-effective way to get manufacturers to conduct the necessary tests for safety and efficacy, making it possible for the FDA to focus its efforts on getting the remaining unapproved drugs off the market. But from

a broader perspective, the UDI was a foolish bureaucratic response to what was, from all appearances, a non-problem. The FDA did not bear the cost of conducting the necessary tests and it paid no attention to the pricing consequences of the market exclusivity it was handing out. But that did not make those costs any less real for the consumers who had to pay them. So what should the FDA have done? Sometimes leaving well enough alone is the optimal solution, particularly when the alternative is to make things worse.

The information conveyed by drug prices will motivate the FDA to change course or reallocate its priorities. Even if the agency elects not to make changes, at least it will know the consequences of its actions and inactions.

on that issue is removed by the failure of Congress to include specific language on the subject in the 21st Century Cures Act after it was urged to do so by various commentators.

But even if we adopt the strictest possible construction of the agency's statutory authority, it does not follow that the agency may not consider drug pricing in setting the agenda for the drug approval/review process, let alone in evaluating the effect of handing out market exclusivity. Other drug companies might complain about queue-jumping, but there is no property right in a company's place in the queue. Besides, the knowledge that the FDA might opt for queue-jumping if prices for generics rise discourages incumbent drug companies from doing just that.

WHAT IS TO BE DONE?

It is one thing to say that the FDA should pay attention to drug prices and entirely another to have a theory about what constitutes a pricing problem, let alone what the agency should do if it finds one. In this short essay we cannot address these problems in any detail. In a longer version of this article that is forthcoming in the *New York University Journal of Law & Liberty*, we offer four simple but workable policy proposals:

- The FDA and FTC should work together more closely.
- The FDA should tighten its policies and procedures—starting with those relating to REMS—to make it harder to game them to serve anti-competitive ends.
- The FDA should send a clear signal to pharmaceutical companies that anti-competitive behavior will not be tolerated.
- Finally, the FDA should also send a clear signal to Congress

CONCLUSION

In our view, the FDA should pay attention to drug prices when the information imbedded in them is about the real-world consequences of the agency's actions and inactions. In some instances, the information conveyed by drug prices in this space will motivate the FDA to change course or reallocate its priorities. Even if the agency elects not to make changes, at least it will know the consequences of its actions and inactions.

What about pricing information that reflects larger market dynamics, such as supply disruptions, monopoly power, and differences in prices across countries? In our view, the FDA should pay attention to pricing information that signals supply disruptions, inform the FTC and Justice Department about pricing that appears to be attributable to monopoly or oligopoly, and ignore disparities in pricing across countries. Of course, reasonable people will disagree on where exactly each of those lines should be drawn and what the FDA should do once it starts paying attention to pricing.

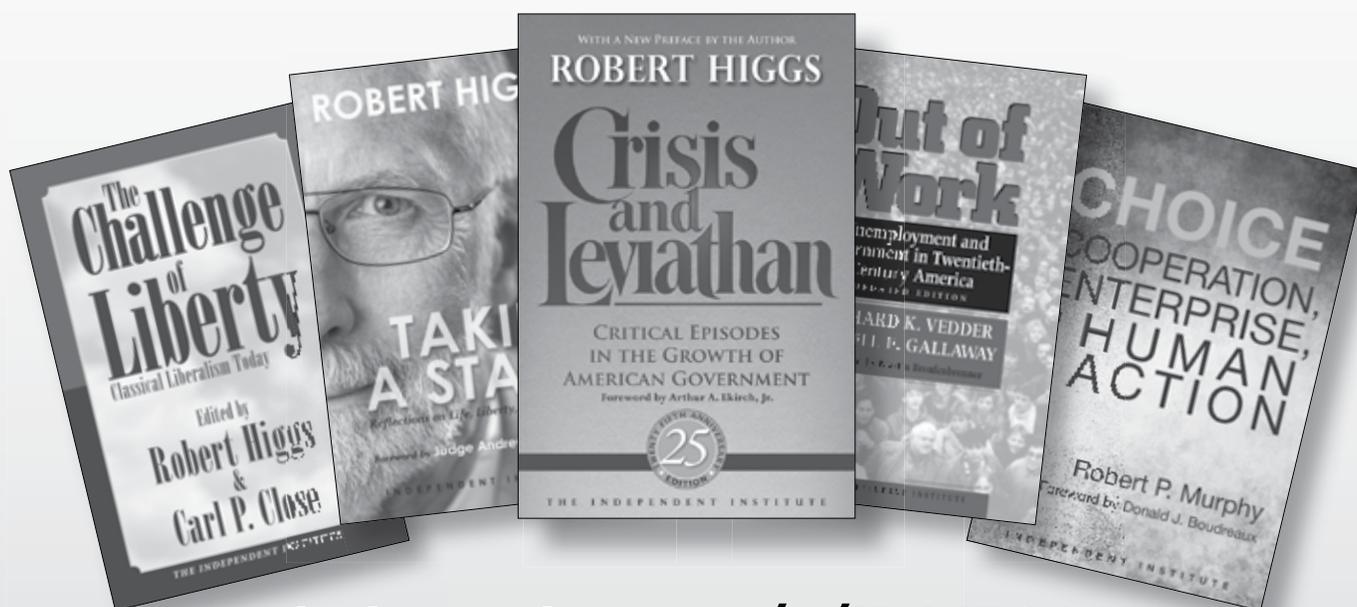
Finally, regardless of where the lines are drawn, everyone involved should understand that the FDA is not the "fix everything that's wrong with the drug market" agency. That way lies chaos. R

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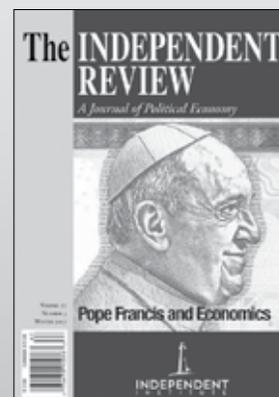
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