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On

“Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets”

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Framing

Why are US healthcare costs rising so fast?\(^1\) One reason is a lack of competition. The narrative that healthcare costs are high because we use markets, rather than government, to provide healthcare is not correct in my view. Rather, healthcare costs are high because we do **not** have competitive markets for these services. Private providers that are not subject to competitive forces create the worst of both worlds. Because the sector is so regulated there are many ways for private healthcare providers to successfully lobby for regulations and practices that shield themselves from competition. For the last decade or so, Congress has been explicitly enabling this lack of competition by designing, or failing to correct, the methods by which the public sector procures drugs and controls access to markets so as to benefit providers. The good news, therefore, is that high prices in many areas of pharmaceutical and medical care are eminently fixable and there is a great deal of evidence about what policies will bring down prices. The bad news is that the providers whose prices will come down - should they have to vigorously compete for business - will lobby against any changes in the law, and have historically been very successful at doing that.

Some of the behaviors detailed below are violations of existing antitrust law. However, antitrust enforcement has become weak in the US for a variety of reasons and, in addition, it is a slow and expensive way to deal with many healthcare markets that regularly experience new product entry. Even if the leadership of the antitrust agencies found increasing competition in healthcare markets to be a priority, they likely do not have the resources to address all the known competition problems, much less new problems driven by changing regulations and new technologies or products.

Congress could significantly lower healthcare costs and restrain cost increases with some relatively simple statutes that create more competition in this sector. Congress could also instruct - and fund - the FTC to pursue particular enforcement projects in this sector that Congress finds critical to restraining healthcare costs. Significant increases in the budgets of the antitrust

enforcement agencies are absolutely necessary if Congress wishes to have more competition in any market, including in healthcare markets. Those funds would be leveraged, and therefore more effective, if combined with some statutory changes recommended below.

The sources of market power in many healthcare markets come from both intellectual property and the nature of government programs. My colleague and co-author, Professor Craig Garthwaite, has provided the background reasons for market power in his statement. I will not repeat that material here, but rather move on to particular solutions.

Specific Topics

1. Behavior that could be a violation of antitrust laws

When brands try to use FDA regulations concerning provision of samples or protection of consumers from dangerous drugs as a means to improperly exclude generic entrants, they may be violating antitrust laws. The CREATES Act requires brands to sell generic and biosimilar firms samples under reasonable terms and prevents abuse of a REMS restricted distribution system. This new legislation will help keep brands from hampering and delaying the entry of generics and biosimilars after the brand’s patent has expired. It should be enacted promptly. The abuse of citizens’ petitions should also be addressed by Congress.

The Supreme Court’s Actavis decision is helpful in preventing pay-for-delay schemes and therefore promoting new generic and biosimilar entry that lowers prices. However, firms continue to enter into these agreements and the FTC continues to expend resources investigating and litigating against this abusive behavior. Congress could end this wasteful situation by passing more specific laws against pay for delay in both small molecule and biologic markets. This would save enforcement resources in the drug markets, and also control a practice that is spreading to the biologics markets. Enforcement is weaker in biologics because competition among biosimilars and the reference biologic product are slightly different than the well-studied small molecule drug case, and therefore there is uncertainty about how courts will rule on these

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cases. In the United States, biologics grew from just 13% of biopharmaceutical spending in 2006 to 27% in 2016, and growth continues, so timely entry of biosimilar (clinically equivalent) products at patent expiration is critical to limiting biopharmaceutical expenditures.4

Another industry tactic that insulates a reference biologic or branded small molecule product with a large and durable market share from price competition is a loyalty rebate. A loyalty rebate gives a customer a large ex post rebate on its drug purchases, but only if the customer has stayed loyal to the brand (either exclusively or with a high share such as 90%), meaning the buyer has not purchased any significant share from the generic or biosimilar entrant. A loyalty rebate successfully excludes the newest entrants when the brand has an entrenched share of the market (known as non-contestable share). Non-contestable share is the segment of the market that the generic or entrant cannot serve (perhaps it is a version they do not make, an indication they are not approved for, or the segment of chronic patients that are taking the brand and are stable and happy on it). The generic or biosimilar entrant cannot compete for all the business of the buyer because of this non-contestable share, so it competes for only part – but at a lower price. The new entrant comes in with a lower price for the contestable share, but critically, it cannot compete for 100% of the needs of the buyer. This is where the loyalty rebate has a harmful effect on competition. A brand with large and durable market share will create a rebate in exchange for the buyer making purchases (or adopting formularies) that exclude entirely a new entrant or reduce the share of the new entrant.

Buyers (plans or PBMs) that must purchase the brand to serve their non-contestable share (e.g. the patients stabilized on the brand) realize they will be buying those branded units on unfavorable terms -- unless they agree to the loyalty rebate. The buyer faces a choice between staying loyal (buying 100% from the brand and receiving the rebate on all those purchases) or buying the contestable share from the entrant at a low price and the balance of their needs from the brand at a high price (forfeiting the rebate). An anticompetitive loyalty rebate scheme causes buyers to avoid purchasing from the new entrant for no reason related to the entrant’s quality or price, but because of the brand’s ability to withhold a rebate on the share of purchases the new entrant cannot supply. The entrant therefore earns less share than it would under competition on

the merits. Loyalty rebates can be designed so that even if the new entrant charges zero for its product, the buyer still pays more in total by forgoing the rebates on the noncontestable share. Such rebates generate a larger share for the brand than it would have secured through competition on the merits, dose by dose.\textsuperscript{5}

There are now two biosimilar infliximab molecules that compete with the brand, Remicade. Those biosimilars offer prices 30\% below the branded price and yet, combined, have a 7\% market share.\textsuperscript{6} Why is it that demand does not shift to an almost identical product with a lower price? On the public side it is likely due to Medicare reimbursement (explained below) and on the commercial side it is likely due to anticompetitive loyalty rebate contracts. By way of contrast, the US Veterans Administration has a financial incentive to procure drugs at the lowest possible price and controls physician prescribing. The US VA has been able to negotiate more than an 80\% lower price for a biosimilar as compared to the reference product.\textsuperscript{7} Data from Europe demonstrate similar levels of savings. Given the ease of enabling competition in this sector, these are savings that Congress is choosing to forgo on behalf of US taxpayers and patients.

A second way that reference biologics exclude biosimilar entrants is by continually updating their FDA application file. A biologic medication may have its BLA approved by the FDA and therefore be selling on the market while its manufacturer continues to make changes to its file. Those changes then become part of the reference product. Thus a biosimilar, instead of attempting to imitate a product that is fixed at the moment of launch, is chasing a moving target. The reference product can choose to make changes at any time that make imitation more difficult or costly. In particular, the reference biologic can patent the changes it makes and in that way create a thicket of dozens of patents that take decades to expire. The migration of the reference product in this way is a huge barrier to entry for competing products. Biologics already have 12 years of market exclusivity (granted to them because they claimed to the government that their patents would be weak and so the market exclusivity would be a necessary substitute). Instead we see products on the market with 30 or more years of patent protection. There are 17

\textsuperscript{7} A\textsuperscript{B Bernstein report 18 January 2019
biosimilar products approved by the FDA that cannot launch because of patent issues. For example, the biosimilar competitors of Humira, a product that sells over 13 billion per year in the US, have settled with Abbvie that they will launch in 2023 in the US. In Europe, these biosimilars are already on the market and Abbvie has offered discounts of 80% in order to retain its market share. These are cost savings the United States is foregoing with its suboptimal regulation.

The solution is straightforward. A new regulation stipulates that at the time of launch the file constituting the reference product’s BLA is fixed; and this product is the one the biosimilar must match. Any additional improvement the reference product maker would like to make can become an improved, different, product as is normally done in small molecule drugs. Any intellectual property needed to make the reference product would be notified to the FDA at the time of the original BLA; any subsequent products could have subsequent intellectual property attached to them. This would prevent the migration of the reference product and its role as a barrier to entry.

2. Pharmaceutical procurement is a problem

Medicare Part B is a growing area of expenditure – due to biologics and oncology drugs – and yet Medicare procures these drugs in a way that avoids almost all competitive forces. Physicians typically purchase the drugs and are reimbursed by Part B for whatever they choose to give the patient. Because physicians are paid a markup over the average cost of purchasing the

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10 “61% of Part B drugs approved by the FDA in 2006-2013 were biologics, and two-thirds of all biologics approved by FDA during this time were paid for by Part B.” (p10) “Expenditures for the 75 new Part B drugs for which we identified claims in 2013 were concentrated among a small number of drugs. The 20 highest expenditure drugs accounted for 92 percent of 2013 expenditures on new Part B drugs and 26 percent of total Part B drug expenditures. Biologics accounted for 13 of the top 20 highest expenditure new Part B drugs and 82 percent of expenditures for these 20 drugs (see table 2).” Page 14 of Medicare Part B, Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries, Report to the Ranking Member, Committee on the Budget, House of Representatives (Government Accountability Office, October 2015), [https://www.gao.gov/assets/680/673304.pdf](https://www.gao.gov/assets/680/673304.pdf), at 10, 14.
drug, they have no incentive to consider equally effective, but lower-priced product. Indeed, because the physician earns a percentage margin on the medication, a physician has a financial incentive to use a higher priced branded product. Demand from Medicare patients does not decline appreciably with high prices (many enrollees are insured for their 20% copay, so their costs are zero), so a manufacturer wants to set a high list price when it anticipates high Medicare sales. That high list price must then be paid by commercial customers. And the manufacturer faces a strong incentive not to give discounts in order to sustain its high price to Medicare. So the Part B procurement policy is actively harmful to privately insured patients.

The situation is particularly bad when a reference biologic experiences entry and competition from a much cheaper, but clinically identical, biosimilar. Under current Medicare rules each manufacturer of a biologic gets its own reimbursement price from Medicare. Each product is labeled with a different “J-code” and associated price. A physician that continues buying a $1,000 reference product rather than switching to the $600 biosimilar need not worry about payment because he or she gets reimbursed the full $1000 for using the brand. The entry of a cheaper version of the same product has no impact on Medicare’s payment for the brand. In particular, the way Medicare pays the doctor means she has zero incentive to use a lower priced product in a case when there is choice. The solution here is to adopt one reimbursement amount (one “J-code”) for Medicare to pay for any of either the reference biologic or its competing biosimilars. These are all the same molecule that deliver the same therapeutic benefit and should therefore be competition with one another, but current regulations insulate them from this price competition. This is a massive waste of Medicare funds. If there were one price across the group, a physician would be reimbursed that fixed amount for administering any one of those products, and would therefore care about seeking out a manufacturer charging a low price. This in turn would cause manufacturers to compete by lowering prices.

Secondly, Congress should authorize Medicare to use “least costly alternative” models of payment for Medicare Part B drugs where several equivalent competing therapies (possibly still

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under patent protection) are grouped and one payment amount is set for the group. This causes expensive drugs that are not superior in efficacy to lose sales – or lower their price. OIG has studied this way of procuring drugs and found it delivers large cost savings.¹³

Part D purchases drugs using the technique of a formulary run by a private insurer. This allows for much stronger negotiation of prices for some drugs. However, the protected classes in Part D most effectively ‘protect’ manufacturers from competition. Requiring Part D plans to have a robust formulary that offers covered options for every patient is critical, but that regulation can be paired with a relaxation of rigid protected class rules. In addition, the Part D catastrophic region appears to create incentives that cause higher list prices and consumer costs, and needs to be reformed as suggested by Craig Garthwaite.

3. **High consumer out-of-pocket costs are a problem**

High out-of-pocket costs for drugs are inconsistent with one purpose of insurance, which is to smooth financial shocks over time by paying a regular premium to cover infrequent healthcare expenditures. If a person has pharmaceutical insurance we ideally want it to reduce her out-of-pocket costs below the market price for the drug, not make them more than the market price for the drug. For example, if the list price of a drug is $600 while a plan has negotiated a price of $300, a consumer with a $1000 deductible will pay the full $600 list price. Her plan will receive a $300 rebate from the manufacturer, but will have paid out nothing for the claim. In this situation, not only is the patient paying more than the competitive price for the medication, but the employer or plan has made a profit on the claim. This practice generates a transfer from the sick to the healthy, which is the opposite of the purpose of insurance. The solution is a regulation that requires insurers to design their insurance so that patients’ out of pocket payments in the deductible are equal or less than the final net price of the medication incurred by the insurer (or perhaps less than some kind of average of that final net price).

The recent HHS rule would effectively require any patient out-of-pocket payment that depends on the list price of the drug be calculated based on the net price after rebates. This rule will do at least two helpful things: lower patient out-of-pocket prices and reduce the ability to

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exclude with a loyalty rebate contract. However, the rule is likely to weaken price competition between branded products, and this may be why pharmaceutical manufacturers are in favor of the rule change. The way in which the rule change would soften price competition works as follows (as far as I understand the rule at present). First, a patient payment that is a function of the negotiated price has the potential to reveal negotiated prices, which is likely to reduce discounts (as described in Craig Garthwaite’s testimony). However, a plan could design out-of-pocket payments to be fixed amounts (e.g. $25) rather than percentages of a medication’s price. More importantly, the rule may prevent performance-based contracts. A PBM that commits to move 50% share from drug A to drug B in a calendar year in exchange for a low price may not succeed. The maker of drug B might not want to offer a very low price because it worries that the PBM will not deliver its end of the deal. That manufacturer may want to offer one price in case the PBM does not move 50% share, and a lower price if it does – a performance-based contract. But consumers could not be charged that lower price before either side knows if it is in fact the true net price. If such contracts are ruled out by the change in the safe harbor definition, then price competition will become less vigorous. Prices will rise in equilibrium when PBMs cannot condition low prices on achieving certain shares. Higher prices will raise manufacturer profits, which may be the analysis manufacturers have carried out, and the reason they support the rule. The rule should be structured so that the safe harbor still applies if the patient’s out-of-pocket costs are fixed, if the patient’s out-of-pocket costs are a function of a price that is below the final net price the plan pays, or if they are a function of a well-defined average price the plan expects to pay. In this way performance-based contracts and confidential price discounts will both be permitted and will bring down prices.

The HHS proposed rule would also encourage intermediaries in the supply chain to be paid in some way that is not as a percentage of the list price. A wholesaler that is transporting drugs could be paid a dollar amount per box, for example, and would then no longer have an incentive to support higher list prices.

Recent evidence demonstrates another method by which drug manufacturers avoid competition; they use various techniques to make side payments to patients in order to undo the incentives created by the PBM and thereby shift consumption toward more expensive branded drugs. These side payments can take the form of coupons, in-kind benefits provided under the guise of marketing, or charitable assistance programs. For example, a brand gives a patient a
coupon for $80 that reduces the patient’s co-pay from $90 down to $10. Suppose that in the consumer’s plan the generic equivalent has a copay of $10. Now the patient is happy to choose the brand (which has a much higher list price, e.g. $250) because both options cost her $10. Meanwhile healthcare costs have risen because the plan is paying for a $250 brand instead of a $15 generic. In addition, the plan loses bargaining leverage with manufacturers and must acquiesce to higher prices. Why? Because when the coupons or financial aid undo the financial incentives put in place by the plan, it has lost one of its main tools to move patients to the cheaper drug. Without being able to “shift share” in response to price, the plan doesn’t have bargaining power. With less plan bargaining power, pharmaceutical prices rise. It is important to note that these coupons are banned in the Medicare and Medicaid programs because they are a violation of the anti-kickback statues and raise costs to the government. However, they are permitted in commercial insurance where we have no reason to believe the effects are any different. Indeed, the research finding that coupons lead to higher drug costs and less generic competition studied the time when Massachusetts banned these coupons. 14

Such practices are particularly extensive and problematic in populations with high per-patient expenditure, such as hemophilia, that are often treated with biologics. Insurance companies cannot typically see exactly what source of funds is used for a co-payment and therefore cannot monitor these kickbacks. In addition, by driving the effective price borne by patients to zero, manufacturers can encourage over-consumption of their drug, increasing costs for insurers and driving up premiums. 15

The solution to this problem is to implement two policies simultaneously: first, a ban on any kind of manufacturer payment to patients whether coupons, financial aid, wrap-around services, etc., paired with a limit on out of pocket expenditure per prescription (or 30 day supply) at some reasonable level such as $200. The limit on out of pocket expenditure protects the patient who has purchased insurance; the ban on coupons and financial aid to patients empowers the PBM to create formularies that can shift share and drive down prices while preventing

manufacturers from “buying” sales they cannot achieve on the merits. A plan will be able to shift share by adjusting the out of pocket payment between zero and $200 and thus be well positioned to bargain for lower prices from manufacturers.

A solution to tackle the problem of high out-of-pocket consumer costs that also promotes competition, such as the proposal above, is more desirable than one that reduces competition, such as the HHS rule. The HHS rule, by reducing competition between drugs, will lead to higher equilibrium prices.

4. **PBM’s dual role**

PBMs can play a good role in today’s pharmaceutical markets, and also, potentially, a bad one. The good role of the PBM is to create price competition among branded and generic treatments. In pharmaceutical and device markets, final consumers are generally both uninformed and insured, so on their own they cannot respond to a price discount by moving their purchases, nor are they able to ask for one as individuals. The institutional innovation that creates competition in pharmaceuticals is the PBM. The PBM is informed about available substitute treatments, is sensitive to price, and controls a large group of final consumers. Of course, the PBM has far less bargaining power in markets where there is insufficient competition, for example, a monopoly market structure or a government requirement to buy a particular product. In a market with competitive alternatives the PBM has the ability to negotiate for lower prices in exchange for market share. Those lower prices take the form of a rebate from the manufacturer back to the PBM (because the patient has purchased the drug at a pharmacy that typically serves many different PBMs.) The PBM’s role of seeking out discounts from manufacturers is critical because it is one of the few agents in our commercial pharmaceutical marketplace that creates price competition.

It is also key that these rebates stay confidential. Suppose a small staff-model HMO says it will be able to move 99% of patients to a substitute drug and, with that threat of walking away, obtains a huge rebate on the drug. If that discount were to become public, other buyers who cannot move as much share would nonetheless demand the same discount, and those bargaining costs would likely stop the manufacturer from offering it to the small HMO in the first place. We
have seen this dynamic before in the Medicaid MFN rules. One reason pharmaceutical manufacturers like restrictions on rebates, such as those in the proposed HHS rule, is that such restrictions suppress price competition and less price competition increase manufacturer profits.

The side of PBMs that needs policy attention is their increasing consolidation and market power; however, this is fixable and may already be weakening. The FTC has allowed many PBM mergers over the last 20 years while there may not have been enough competition among PBMs to protect end consumers, particularly given PBMs’ use of MFNs, limited information disclosures, and other practices detailed in the Garthwaite testimony. Under these conditions, some PBMs may have stopped being good agents for final consumers without losing business. This a phenomenon Craig Garthwaite and I wrote about 18 months ago. If the rebate process is opaque, the PBM may find that a good way to raise prices is to keep more of the rebate dollars. This in turn leads to an incentive for the PBM to encourage the manufacturer to raise the list price of the drug (e.g., by $100), increase the rebate (e.g., by $80 so that the manufacturer gains an extra $20), thereby allowing the PBM to pass only some of the increased rebate to the customer (e.g. $50 so that the PBM’s profits rise by $30). This tactic leads to rising list prices, rising net prices, and rising rebates, the last of which benefits the PBM. There are a number of possible solutions. Congress could require a PBM to have a fiduciary duty to its clients. Alternatively, PBM contracts could require all payments from the manufacturer, whether labeled as rebates, administrative fees, consulting fees, marketing fees, or any other title, flow directly to the end client (the employer). Indeed, there could be a safe harbor for payments from the manufacturer to the end client, rather than to the PBM. If the employer and PBM so choose, they can specify in a contract how to share them with the PBM. A third point is that competition in the health insurance market may improve the agency of PBMs. Due to recent mergers between PBMs and health insurers, all the large PBMs in the US are now vertically integrated. This integration may be due to both parties’ interest in internalizing the externalities between pharmaceutical consumption and medical care. Between the mergers and significant public exposure, the agency problems outlined above may be on the wane already.

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5. Many past mergers were anticompetitive

Unlike many other sectors, healthcare providers often have geographically spaced facilities that limit the extent to which company activities can be combined and made more efficient in the event of a merger. This integration is often referred to as “scrambling the eggs” because such it is difficult to undo after a merger. Because there is no time limit on Clayton Act violations, Congress could instruct the FTC to open a unit to revisit healthcare mergers that have harmed competition. A substantial literature concludes that there have been many anticompetitive hospital mergers over the last 30 years.¹⁸

A second area of focus for consummated anticompetitive mergers are transactions that fall below the Hart-Scott-Rodino Antitrust Improvements Act (“HSR”) threshold. Professors Thomas Wollmann (University of Chicago) and Paul Eliason (Brigham Young) have work in the area of dialysis clinics that shows the harm from mergers.¹⁹ Wollmann’s dialysis paper shows that when a transaction falls below the HSR threshold, the FTC essentially requires no divestitures. This is true regardless of the geographic overlap of the clinics; in particular it is true when a similar case reported under HSR would be required to divest in order to merge.²⁰ The paper shows that the bulk of the increase in concentration in the dialysis industry comes from these small, unreported mergers. Revisiting those past transactions and requiring appropriate divestitures of dialysis clinics could increase competition.

Lowering the HSR threshold for merger review going forward would also allow for more vigorous enforcement. Indeed, if an automated process were adopted, a very low threshold could also be cost-effective. For example, Congress could instruct the FTC to design a form “EZ-merge” for mergers between $2 and $20m, with a standard HSR process for anything larger.


Businesses could choose their type (e.g., auto tire retailer, primary care physicians, or funeral home) from a drop-down menu and enter the zipcodes of their customers. An algorithm could determine if, for example, two small orthopedic groups serve the same geographic area, or two dialysis clinics are in the same town. Flagged mergers could be passed on to FTC staff for further review. We know that simply notifying a merger to federal authorities creates a deterrent effect; therefore, the simple adoption of Form EZ-merge might cause dialysis clinics and other local businesses in the same town to stop proposing anticompetitive mergers.

6. Nonprofits

US competition laws should apply to nonprofits just as they do for for-profit companies. In health care, many hospitals and insurers are nonprofits, but their nonprofit status exempts them from the Federal Trade Commission Act and its prohibition on unfair methods of competition and unfair and deceptive acts or practices. (The FTC has jurisdiction over nonprofits for Section 7 violations.) Congress should eliminate this exemption.