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Is There an Efficient Antitrust Approach to Health Care?

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# Table of Contents

I. **How Antitrust Law Works** ........................................................................................................... 1

II. **Chicago School and Antitrust Goals** ......................................................................................... 4

   A. American and European Approach to Evaluating Public Health ............................................. 6

   B. Enforcement: US v. European Model ....................................................................................... 9

III. **Antitrust Scholarship Specific to Pharmaceuticals and Particularly Reverse Payments** ("Exit Payments") .......................................................... 10

   A. Health Care and Antitrust ....................................................................................................... 10

   B. Reverse Payments .................................................................................................................. 13

IV. **International Antitrust Law and Vertical Restraints** ................................................................. 14

   A. Vertical Restraints .................................................................................................................... 15

   B. Free-Riding Across Antitrust Regimes .................................................................................... 16

   C. Single-Payer Structure for Health Care .................................................................................. 17

V. **Enforcement Mechanisms Across Jurisdictions** ................................................................. 18

VI. **Civil Law v. Code-based Antitrust** ....................................................................................... 20

VII. **Market Power** ....................................................................................................................... 21

VIII. **Health Care Law: Between Public and Private Law** ................................................... 23

   A. A New Approach to Health Care Trust .................................................................................. 24

   B. Policy Prescriptions ............................................................................................................... 25
IS THERE AN EFFICIENT ANTITRUST APPROACH TO HEALTH CARE?

I. HOW ANTITRUST LAW WORKS

Antitrust law exists to increase consumers’ access to the products they want to buy. The theory goes that, left alone, corporations would inevitably collude and do whatever they can to increase market share so companies can charge any price they want for the goods they sell.

Of course, there is a “sweet spot” for Antitrust law, as for every area of law and economics. Just as in tax policy the Laffer Curve suggests that the highest revenue earned from taxes is not when the cost of taxes is highest, but rather at some point in the middle of the price curve. For all of economics the principle is the same: When opportunity cost is very high, people seek alternatives. Income taxes that approach punitive on the high end will discourage people from working an extra hour or two, or will at least discourage them from admitting those hours to the IRS.

Similarly, Antitrust law must grow and change to suit an increasingly globalized economy. Once upon a time, a small number of American companies might have cooperated to keep prices high. Now high American prices are practically a cordial invitation for firms abroad to undercut those prices. In fact, when a firm has not stepped up to do it cheaper (whatever “it” is) the assumption is no longer that there is an antitrust problem, but that the going rate is simply the real cost of doing business.

In this brave new world of global corporatism, the face of the victim of anticompetitive behavior has changed. Courts still issue injunctions to order firms acting in bad faith to cut it out.
Yet even the inquiry has shifted in the past decade. Gone is the paternalistic judiciary willing to stop companies from acting in a way somehow “per se illegal on its face.” In its stead the new antitrust model asks nuanced questions about how the trust behavior actually affects consumers.

For an analysis that only relatively recently began probing the question of market power, the complex balance between anti- and pro-competitive behavior now standard to the Rule of Reason is a sophisticated tool indeed.

II. CHICAGO SCHOOL AND ANTITRUST GOALS

American antitrust law has hovered around a Chicago School formulation since its return to that model in the 1970’s. This template applies a minimalist approach to antitrust. Rather than attempt to control or prescribe business behavior, the Chicago School model relies on a few foundational principles to police the baseline for competitive behavior, keeping markets as free and efficient as possible. Seventh Circuit Judge Richard Posner vocalized this baseline view when he observed that “by 1969 . . . an orthodox Chicago School position . . . had crystallized:

Only explicit price fixing and very large horizontal mergers (mergers to monopoly) were worthy of serious concern.”

1 Richard A. Posner, The Chicago School of Antitrust, 127 U.PA. L. REV. 925, 933 (1979). Frank Easterbrook's position that “[Courts] should adopt some simple presumptions that structure antitrust inquiry . . . . For a number of reasons, errors on the side of excusing questionable practices are preferable. First, because most forms of cooperation are beneficial, excusing a particular practice about which we are ill-informed is unlikely to be harmful . . . . Second, the economic system corrects monopoly more readily than it corrects judicial errors . . . . Third, in many cases the costs of monopoly wrongly permitted are small, while the costs of competition wrongly condemned are large.” Frank Easterbrook, The Limits of Antitrust, 63 Tex. L. Rev. 1, 14-14 (1984); and Robert Bork's contention that horizontal mergers be permitted up to 60 or 70% of the market (or, alternatively, “up to market shares that would allow for other mergers of similar size in the industry and still leave three significant companies.”) Robert H. Bork, The Antitrust Paradox 221-22 (1978).
What makes the Chicago School special with regard to its approach to antitrust is its singular attention to two mutually-reinforcing goals: (1) efficiency; and (2) consumer access. Efficiency as a Chicagoan goal means only economic efficiency. Indeed, from this perspective, everything can be reduced to a question of economics. Thus the Chicago School applies a microeconomic price theory to determine whether the second goal—consumer access, defined as maximizing net consumer and producer surplus—is achieved.\(^2\)

This premise is simple in application. To protect a truly free market from undue pressures, antitrust authorities must intervene only when pressures become so great as to interfere with the very operations of the market. On a broad day-to-day basis markets tend to self-correct. Even when businesses enter or exit the market, traumatic though that may be for an individual business owner, that is merely the course of anticipated dealing for the greater market model at large.

Finally, because the market permits such broad freedom with regard to participants’ interactions against the market backdrop, free market adherents remain deeply suspicious of courts that attempt to direct business behavior. Courts cannot possibly understand the intricacies of this business, the logic goes, because this judge is not privy to the business cycle, nor does she hold the same type of personal stake in business practices the way the business owner himself does.

\(^2\) See Herbert Hovenkamp, Post-Chicago Antitrust: A Review and Critique, 2001 Colum. Bus. L. Rev. 257, 269-70 ("Building on an imposing foundation of neoclassical economics, Chicago School antitrust writers developed well-reasoned arguments that in the long run markets tend to correct their own imperfections, that the history of aggressive judicial intervention has produced many indefensible results and that tribunals would be well advised to study practices much more thoroughly before deciding that intervention is appropriate."); see also Michael S. Jacobs, An Essay on the Normative Foundations of Antitrust Economics, 74 N.C. L. Rev. 219, 260 (1995) ("Chicagoans believe that, left alone, markets will almost always function competitively, that market imperfections are transitory ...").
Through this formulation of antitrust operation, health care comes into stark focus against the regulatory background bolstered (but not wholly akin to!) antitrust law. Professor Havighurst, health care and antitrust scholar, notes that antitrust has only limited application in the field of health care:

[T]he antitrust initiative has clearly failed to create a true, consumer-driven market for health services in the United States. The reason is quite simple: While effective antitrust enforcement is a necessary condition for a market-oriented policy, it is far from being a sufficient one. Indeed, if a market-oriented health policy seems unworkable in health care today, it may only be because, for whatever reason, our system as a whole . . . has not embraced it fully and given it a chance to work as other markets do.\(^3\)

Considering the backdrop for the health care market, it seems impossible to compare the freedom in this market unfavorably to any other. Even those markets where a parallel “originator” spends time and resources developing a copyrightable market entrant with limited lifespan cannot compare to health care. Musicians, for example, must renew copyright protections on their songs, and there is no income during the “research and development” period for musical albums. The difference, of course, is that musicians need not lay out as great a cost as the expensive, liability-ridden drug companies must spend at the outset to make pharmaceutical development possible at all.

A. AMERICAN AND EUROPEAN APPROACH TO EVALUATING PUBLIC HEALTH

While American antitrust turns on the neoclassical assumptions characteristic of Chicago School economics, the health care industry has long and decisively split from that model.

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Economists refer to the health care industry’s departure as a “market failure,” yet such “failure” is so endemic as simply to constitute a different formulation.4

The argument that health care represents a market failure in antitrust terms is best summarized by the idea that:

Health markets fail to satisfy the substantial list of requirements that must be met to be classified as perfectly competitive: Large numbers of consumers and firms, free entry and exist, marketability of all goods and services including risk, symmetric information with zero search costs, and no increasing returns, externalities, or collusion. While health markets satisfy none of these requirements fully, they fail the requirements of symmetric information, zero search costs, and the marketability of all products most dramatically.5

Looking abroad, the most interesting antitrust discussions come in the context of pharmaceutical pricing. Profit in the pharmaceutical world is impossibly delicate and subject to all the knives and arrows of research, development, and liability. Drug profit protections are fleeting, and subject in turn to aggressive generics ready to move in at the expiration of a drug’s patent-conferrd monopoly, or, in less regulated economies, even in the midst of that temporary monopoly.

4 Were the health care industry attempting to follow an efficiency-based formula, its current position would be an utter failure. The goals of health care—at least health care as articulated in modern American and European politics—merely teeter on efficiency, while delving much deeper into coverage. An efficient health care model would admit that many individuals simply “choose” to self-insure, under the belief that they cannot afford health care. This choice captures the very essence of efficiency, yet “health care reform” rejects the possibility of efficient rejection entirely and explicitly, preferring instead to attempt a highly inefficient health care mandate with the goal of ensuring that every individual finds himself covered. For a broad discussion of economics in health care reform, see Robert Evans, Reconsidering the Role of Competition in Health Care Markets, 25 J. Health Pol., Pol’y & Law 889 (2000).
5 See David Dranove & Mark A. Satterthwaite, The Industrial Organization of Health Care Markets, in 1B Handbook of Health Economics 1093, 1134 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000) (“adopt[ing] the perspective that the institutional peculiarities of health care can often be best understood as attempts to solve the principal-agent problem that the consumer faces with respect to his health care”).
Single payer systems threaten the precious balance drug companies have achieved between profit and perish. When the Spanish government set a price cap on pharmaceuticals, the drug company GlaxoSmithKline immediately attempted to recuperate imminent lost profits by striking deals with other buyers. Pharmaceutical distributors cannot subsist without profits. Nor can drug companies bring new drugs to market without earning a profit on their existing products.

Despite GSK’s pleading that the company cannot continue to exist, and particularly cannot continue to bring new drugs to market, without the ability to profit somewhere along their distribution chain, the European Court of Justice refused to grant an exemption to the rigid restriction against restraints on parallel imports. In the course of its opinion, the ECJ recognized that consumers will be better off if drugs are permitted to make their way down the production line into distribution. Importantly, GSK was not arguing for an exemption based on the possibility of profitability alone. Instead, the case reflected the pharmaceutical company’s attempt to secure profits for a drug already on the market, simply so that the company could properly recuperate its Research and Development costs for that drug as well as for other drugs in production.

At first blush this consumer-discarding conception of antitrust law seems like a dramatic departure from the Chicago School entrenched in American caselaw. Yet the imminent single-payer system for American health care proposes to install precisely the same type of slippery slope endemic to vertical restraints like top-down single-buyer anticompetitive nationalized health care.

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7 *Id.*
8 *Id.*
B. ENFORCEMENT: US v. EUROPEAN MODEL

The American model of antitrust enforcement is largely unique in the world in that the American model relies primarily on private enforcement, while most other antitrust systems rest entirely on public enforcement. The US Supreme Court has stated again and again that the goals of antitrust enforcement are two: Compensation and Enforcement.9

Compensation means compensation for victims of monopolistic behavior. Specifically, the Court urges lower courts in private suits to compensate people injured by wrongdoers. The primary distinction between publicly-enforced antitrust regimes (the European model) and private enforcement in America is that parties that bring private cases against ostensibly-illegal trusts enjoy the possibility of compensation for their trouble.10

In 2008 the European Commission published a statement calling for increased private antitrust policing in Europe.11 Because, according to the White Paper, “full compensation is . . . the first and foremost guiding principle” of private antitrust litigation, the Paper suggested that “[m]ore effective compensation mechanisms mean that the costs of antitrust infringements would be borne by the infringers, and not by the victims and law-abiding businesses.”12 Private

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9 See, e.g., Am. Soc’y of Mech. Eng’rs, Inc. v. Hydrolevel Corp., 456 U.S. 556, 572 n. 10 (1982) (“Congress created the treble-damages remedy . . . precisely for the purpose of encouraging private challenges to antitrust violations. These private suits provide a significant supplement to the limited resources available to the Department of Justice for enforcing the antitrust laws and deterring violations.” (citing Reiter v. Sonotone Corp., 442 U.S. 330, 344 (1979)).

10 The Sherman Act confers treble-damages for precisely this purpose: trust victims would never risk offending larger competitors if there were no promised benefit for their troubles. Robert H. Lande, Wealth Transfers as the Original and Primary Concern of Antitrust: The Efficiency Interpretation Challenged, 50 Hastings L.J. 871, 911-35 (1999).


12 Id.
European businesses have proven reluctant to bring many private suits against alleged harmful trusts, but with the emergence of arguments like this for private antitrust litigation (and, perhaps, with some comparison to the more-successful largely-private American model), Europeans are reversing that trend.\(^\text{13}\)

III. ANTITRUST SCHOLARSHIP SPECIFIC TO PHARMACEUTICALS AND PARTICULARLY REVERSE PAYMENTS (“EXIT PAYMENTS”)

In July 2009 the European Commission released a report into the European Union’s pharmaceutical sector. This report outlined problems in drug patent litigation, threats to industry competition e.g. multiple patents on the same prescription, and problems with advertisement and control rights for generic medication. While the EU outlined all of these as problems to be addressed, in part, through antitrust/competition law, American courts have refused to assign antitrust liability in these pharmaceutical settlements.

A. HEALTH CARE AND ANTITRUST

Antitrust as a general discipline attempts to balance questions of fairness and efficiency, keeping in mind that accessibility to the market is the issue that spells success or failure for a business or industry. When it comes to pharmaceuticals, questions of fairness and accessibility come up against an even tougher governor: Feasibility.

In the US, the Food and Drug Administration (“FDA”) regulates pharmaceuticals. Companies that deal with pharmaceutical development must remain intimately aware of what the

\(^\text{13}\) Unfortunately because private antitrust litigation so poorly compensates injured victims, antitrust cases remain largely a question for public enforcement.
FDA expects and what it will permit. Most new pharmaceuticals permitted to enter the market receive FDA approval only after companies spend more than a decade developing the drug and studying its effects.\(^\text{14}\)

“Originator” drug developers – those pharmaceutical companies that actually finance the R&D – generally relies on the monopoly patent immediately following such R&D period. Yet even with this patent-conferred protection, recoupment is not always possible. According to the Congressional Budget Office, the cost of bringing a new drug to market approaches $200 million, while less than one-third of the drugs that make it to market actually earn that much in discounted returns.\(^\text{15}\) Adding to these bleak projections is the risk that the potential drug will not survive the approval process at all. Because only a small minority of drugs gains ultimate approval, monopoly pricing must reflect both the fleeting benefit of patent-conferred market power and it must cover the expense of a firm’s unsuccessful trials as well as those drugs that do gain approval but are simply not profitable. PhRMA estimates that for every 5,000 to 10,000 compounds tested by drug manufacturers, only five reach clinical trials, and the FDA will ultimately approve just one.\(^\text{16}\)

When the originator’s patent-conferred monopoly expires, generic pharmaceutical companies close in on the market for that drug. Yet the market for generics is not without pitfalls

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\(^\text{15}\) CBO Report, supra note 5, at xiv-xv (July 1998) (“For most drugs, the returns from marketing do not exceed the average capitalized costs of development. As a result, for a company’s average returns to exceed is average development costs, the company must discover and market a highly profitable drug from time to time.”).

\(^\text{16}\) Pharmaceutical Research and Manufacturers of America, Pharmaceutical Industry Profile 209, 36 (2009), available at [http://www.phrma.org/files/attachments/PhRMA%202009%20Profile%20FINAL.pdf](http://www.phrma.org/files/attachments/PhRMA%202009%20Profile%20FINAL.pdf).
of its own. Generic distributors lack the benefit of any patent at all. When a generics distributor enters the market, it does so alongside multiple rivals peddling the same newly-available formula, absent any procedural method for protecting its market share. Further, the market restricts prices to an average of about half the price demanded by originators’ patented formulas. Thus generic drug companies simply cannot afford to run the kinds of tests afforded by branded competitors and still expect to recoup their costs.

Competition in the drug market is far from simple in the United States, but in this country legislation and market controls exist to encourage innovation and competition in pharmaceuticals. For example, the Hatch-Waxman Act levied a series of provisions to extend incentives to both originator companies and generics distributors.

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18 From the thalidomide scare in the late 1950’s until the mid-80’s, the FDA required nonoriginator drug distributors to subject generic pharmaceuticals to further clinical testing. See Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 Food and Drug L.J. 187, 187 (1999). In the mid-80’s, legislators and the FDA separately addressed generics’ plight in the pharmaceutical market. Congress cited scholarship suggesting that it was unethical to continue testing a pharmaceutical after the originator drug earned approval, because the additional clinical trials subjected some patients to placebos instead of a tried and true effective treatment. See H.R. Rep. No. 98-857, at 16 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2649.

19 The Hatch-Waxman Act is an industry-specific comprehensive methodology designed to internalize regulatory interference and streamline the application process for approval for branded and generic drugs alike. For branded drugs, Hatch-Waxman streamlined the application process, so fewer clinical trials are required and certain federal protections insulate the originator drug and formula to a degree even during the trial stage. For generics, Hatch-Waxman discarded entirely the preexisting requirement of further clinical trials. Instead, post-Waxman generics need provide only an abbreviated statement of the generic’s ingredients. In return, the first generic to establish dominance upon expiration of the originator drug’s patent receives a valuable 180-day monopoly period. Perhaps most interesting from an Antitrust perspective is the permission Hatch-Waxman extends to generic manufacturers with regards to the use of patented products. Developers of generic drugs are permitted to experiment with originators’ drugs for the purpose of developing marketable generics; they are excepted from infringement liability even during the originators’ monopoly period.
B. REVERSE PAYMENTS

It is through these questions of competition that antitrust enters the health care picture. So-called “reverse payments” have become the typical settlement method in the Hatch-Waxman era. Reverse payments are:

Payments pursuant to the settlement of a patent suit such as those required under the settlement agreement are referred to as reverse payments because, by contrast, typically, in patent infringement cases the payment flows from the alleged infringer to the patent holder. Here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so.\(^2\)

In other words, reverse payments are payments made by the patent holder to potential or actual patent infringers in consideration of the infringers’ compliance to cease and desist. Reverse payments incur a great deal of legal criticism because they are often used as a contract to further enjoin patent infringers from future competitive conduct, thus keeping the market artificially small against consumers’ interest.\(^2\) Reverse payment settlements are typically associated with drug patent challenges mounted by generic drug companies under the Hatch-Waxman Act, despite the efforts of the Federal Trade Commission to characterize these settlements broadly as antitrust violations.

Yet courts and the Government alike have resisted the FTC’s condemnation of reverse payments. The Supreme Court acknowledged that reverse payments may be a means of sharing monopoly rents, but rejected the broad challenge to reverse payments as a legal tool in 2007.\(^2\)

\(^2\) In Re: Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)
\(^2\) Joblove v. Barr Labs., Inc., 551 U.S. 1144 (2007) (No. 06-830) (explicitly noting that reverse payments may offend antitrust principles, but finding that the specific facts of that case made the precise legal balance so “unlikely to recur” that the Court would not examine the merits of reverse payment.
Applying a more efficiency-friendly view, the Department of Justice urges courts to analyze reverse payments according to the Rule of Reason. While the Department of Justice does not categorically approve of pay-for-delay settlements, DOJ considers the possibility of reverse payment settlement merely one consideration under a thorough Rule of Reason analysis. Under this latter construction, antitrust liability can attach even in some circumstances without a patent.

IV. INTERNATIONAL ANTITRUST LAW AND VERTICAL RESTRAINTS

In the United States, Antitrust law is constructed primarily to increase competition and to increase consumers’ access to goods and services in the market. This consumer-based “Chicago School” formulation is largely unique to the United States, however. In much of the world, however, antitrust authorities take a much more permissive view of vertical restraints.

Antitrust in the United States exists primarily to keep competition and cooperation efficient. These goals color nearly all behavior among firms and across industries. Because horizontal restraints—restraints that limit consumers’ actual access to a product, market-wide—discourage competitors in a market from focusing first on what the consumer wants, these restraints are banned from companies’ repertoires. Antitrust authorities closely monitor

23 Opposing certiorari in Joblove v. Barr Labs., the DOJ rejected the narrow question of whether reverse payments have merit as a settlement schema, and instead looked at the question of settlement only against the broader balance in place under antitrust law.
24 In its brief opposing certiorari, supra, DOJ argued that the Second Circuit had been wrong in applying the less-stringent “objectively baseless” standard for filtering out needless litigation under the Noerr-Pennington doctrine. Id. at 13-14.
companies’ behavior to ensure that cooperation does not border on collusion, and to keep competition consumer-oriented.

A. VERTICAL RESTRAINTS

Vertical restraints are another animal entirely. Vertical restraints are mechanisms by which companies may place restrictions on distributors or manufacturers—“competitors” in the same chain of consumer access that the company in question finds itself. American antitrust law recognizes that vertical restraint even demands a less rigorous procedural approach than that commanded by horizontal restraints or other antitrust variations the courts have found consistently non deserving of *per se* antitrust culpability over the years.

American courts have consistently found that some degree of vertical restraint can be beneficial for competition. For courts outside of the United States, where consumer access is not the main driver for what defines “competition,” vertical restraints encounter much greater resistance from antitrust authorities. In Europe, for example, antitrust authorities are primarily concerned with market integration, and therefore structure competition law to encourage the flow of goods across borders.26 Under this formula, European courts are much more concerned with encouraging businesses *to do business*, and cautious about discouraging trade at the margins, and therefore employ a less accepting view of vertical restraints, lest marginal restrictions discourage integration.

Asian antitrust authorities similarly reject America’s accepting view of vertical restraints. While Asian authorities do not place their primary concern on integration as do European

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26 *Id.*
lawmakers, Asian authorities do find themselves much more concerned with ensuring firms’ fair
treatment on the merits than do American authorities.27

In America, the goals of antitrust are clearly defined. These goals come with strong
economic incentives that are in turn enforced throughout policy and law. Just as Antitrust law
assigns liability to behaviors that unduly inhibit trade and good faith in the marketplace, so does
contract law rely on standards of fair dealing and good faith in practice to “fill in the gaps” and
designate baseline expectations. Blame in tort law—especially in product liability—also parallels
these established goals of encouraging trade and furthering well-defined responsibility for what
behaviors a company can actually control within a free market.

B. FREE RIDING ACROSS ANTITRUST REGIMES

Much of what differs across varying legal treatments of restraint is how a regime views
free riding. In the United States, a strong free market tradition permits authorities to conclude
that companies will clamp down on free riding if it begins to impinge on business practices.
Where free riding continues to exist then, business and antitrust authorities alike must conclude
that it is efficient, that is, it is not so bothersome as to be worthwhile even to the affected
business to counteract that behavior.

In Europe, competition authorities view standards of restraint differently. In any market
economy, price can be conceived as a proxy for production and innovation. Consumers will
always pay only up to the amount that reflects their demand, while businesses will always charge
as much as they can while maximizing revenue. The formula for reflecting supply and demand is

27 Id.
direct, but the ways in which authorities and businesses understand price *composition* is quite nuanced.

C. SINGLE-PAYER STRUCTURE FOR HEALTH CARE

Antitrust theory has always been an attempt to stop monopolistic behavior, which is considered bad for competition, bad for the market, and bad for consumers. Yet in these tough economic times, as more industry is tinged with public money, the notion of competition has fundamentally changed. Corn, for example, is an industry that belongs to private farmers. Yet for every dollar an American corn farmer earns, some sixty-two cents comes from the government.²⁸ Not only are notions of “government” and “industry” intimately intertwined, but our conception of “competition” now includes many caveats. It is impossible, for example, even to ask whether the consumer’s meaningful choice is preserved, with so pockmarked a notion of who acts as a consumer in any given case.

As the United States approaches its new model of public health care, the question of *who consumes* becomes vitally important when it comes to distribution of pharmaceuticals. In established economies, individuals have a great deal of control over their pharmaceutical-consuming lives. Yet governments in these established economies exert control over the market in the form of food and drug oversight. Market power should be considered not in terms of share in a given drug, but rather shares in all of the methods people employ in the pursuit of health. Thus governments that permit sales from a drug company peddling one specific formula, while blocking (even blocking in the name of time or uncertainty) an untold number of competitors eager to rise up.

While many of the protections for pharmaceutical companies come through abbreviated trial periods and streamlined application procedures, many protections are procedural. Both the Federal Trade Commission and the Department of Justice have come down hard against alleged anticompetitive practices in the drug world. As Congress has pushed health care reform in the past year, the FTC has taken a strong stance against any legislation that takes a permissive view of this “pay-for-delay” phenomenon, calling generic distributors’ behavior anticompetitive collusion if it keeps medicine off drugstore shelves, or keeps prices artificially high.29

Competition for pharmaceutical market share is both globalized and uniquely stilted. Drug development takes years – even decades – to perfect. The long and risky development stage, exposure to liability, and short patent life create an environment where only large companies with significant market share have any hope of success.

V. ENFORCEMENT MECHANISMS ACROSS JURISDICTIONS

Even more fundamental to the ways in which antitrust law interacts with health care and pharmaceutical access is the question of how antitrust orders behavior at all. In Europe, for example, it was not until the very end of the twentieth century that authorities conceived of antitrust law as a method for ordering corporate behavior. In Consten and Grundig v. Commission, the European Court of Justice discussed questions of vertical restraints and free

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riding against the backdrop of complex quota systems in place throughout Europe designed to regulate the flow of trade and order business and corporate behavior.\textsuperscript{30}

Throughout the middle part of the twentieth century, and during the 1960’s in which the ECR considered the \textit{Consten and Grundig} case, Europe was divided by a complex series of trade agreements, regulations, and quotas. Though not all antitrust law from that time period refers to this backdrop of methods for ordering business behavior, these laws were so controlling as to direct the primary venues through which the state interacted with the market. Similarly, the American antitrust return to Chicago School economics rode on the back of the regulatory era.

This shift in American antitrust conscience from hypersensitive protectionist antitrust authorities to a more efficiency-oriented permissive approach incorporates the idea that regulation will take care of consumer safety, and the policy regime need only ensure consumer access. In Europe (and, as we will see on the following pages, in Asia), business faced trade regulations that were so numerous and so restrictive in nature as to be inefficient.\textsuperscript{31} Thus European antitrust law stepped in to provide an overriding coherence across varying legal regimes as directive as they were divergent.

\textsuperscript{30} \textit{Id.} at 201.

\textsuperscript{31} America’s shift from designating vertical restraints presumptively anticompetitive to permitting vertical restraints on the basis of promoting access and competition from the standpoint of the consumer turns around the \textit{Schwinn} and \textit{GTE Sylvania} cases in the 1970’s. Earlier, in 1967, the Supreme Court found a vertical restraint between bicycle manufacturer and distributor presumptively illegal. \textit{United States v. Arnold, Schwinn & Co.}, 388 U.S. 365 (1967) (overruled in 1977). There, despite the fact that the manufacturer was merely attempting to organize sales among distributors so as to maximize efficiency, and even though the motivation for such vertical restraint was largely Schwinn’s (at the time) seemingly imminent bankruptcy, the Court found for the distributors’ rights over the manufacturer’s to organize their sales and salesmanship as they saw fit. Ten years later, the Court considered the interaction between interbrand and intrabrand competition and saw fit to overrule \textit{Schwinn}. According to the later decision, when non-price restraints imposed by a manufacturer on its own distributors can improve the efficiency of the manufacturer and improve competition among brands, then this stimulation of interbrand competition can outweigh harm from the decrease in intrabrand competition. \textit{Continental T.V., Inc. v. GTE Sylvania Inc.}, 433 U.S. 36 (1977).
Unlike horizontal restraints, offensive to every legal regime that considered them, the danger posed by vertical restraint rests almost entirely on the possibility of slippery slope. An organization permitted to set the standard for proper price runs the risk of becoming like a trade organization, with the danger that it will contribute in the long run to possible collusion.32

VI. CIVIL LAW v. CODE-BASED ANTITRUST

Perhaps the most marked difference between the American approach to law generally as compared to the European approach is that Europe has a civil law tradition, while America adheres more to common law principles. Antitrust in the United States certainly rests on legislature—like the Sherman Act—but litigation and hearings remain nimble and responsive to changing facts or circumstances.

Code-based European law cannot apply such sensitive views of facts and circumstances. European courts can choose not to hear a case, or to decline to enforce some code. The civil law tradition grants a much more rigid view of incentives and behavior. In some ways this unchanging antitrust methodology may be beneficial—legal consistency reduces risk and tends to enhance the business environment. The switch from protectionist antitrust enforcement to couching all antitrust analyses in Chicago School economics must have been a curveball to businesses and industries who ordered their behavior around legal prescriptions at the time, and must have been shocked when changing laws meant that they had to change their business plans accordingly!

32 See, e.g., In the Matter Between Nationwide Poles and Sasol (Oil) Pty Ltd, Competition Tribunal, South Africa, case 72/CR/Dec03 (reversed by Court of Appeal) (despite scholarship that suggests that there is no danger inherent to a given anticompetitive practice, here price discrimination, the potential for abuse justifies proscription in the antitrust context where the potential for slippery slope is so dire that regulatory law cannot protect against it as efficiently as competition law can). This case reflects the idea that even if producers are not directly colluding, they will still find ways to cooperate to the detriment of consumers and the market alike.
More often than not, though, code-based antitrust enforcement has less to do with upholding a consistent view of the law and more to do with fact-sensitive enforcement. Recall for example the circumstantial background to cases like Consten and Grundig. The court’s decision to strike the vertical restraint in that case had virtually nothing to do with consumer access, the very professed soul of antitrust law. Instead, the Consten and Grundig judge focused solely on intrabrand competition.

As in the American Schwinn case, when the pressures of interbrand competition are disregarded, intrabrand anticompetitive behavior can appear quite damning. Thus, in an era where hefty trade tariffs meant very few imports coming into Europe, when tight restrictions on all economic activity choked competitiveness nearly to a standstill, the Consten and Grundig judge permitted that case to turn not on the goals of competition or the free market, but rather on the protectionist design of the times.33

VII. MARKET POWER

In ruling against GlaxoSmithKline, the European Court stated that the request for an exemption from the restriction against parallel imports was an attempt to abuse market power. The argument against the exemption here is that it would constitute a vertical restraint if big companies get protections that are not available to small companies. This went directly against the European direction trending towards American-style antitrust enforcement, some twenty

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33 Consten and Grundig v. Commission, Cases 56, 58/64, [1966] ECR 299, ECJ.
years after the United States relaxed its formerly stringent antitrust laws in the name of “competitiveness.”

When it comes to patents and intellectual property, the very monopolies relevant to pharmaceutical market share, both the administrators and the courts have adopted the view that an intellectual property owner has no relevant market power (in the way of antitrust) if close substitutes exist for either the product or the process. This shift towards deep Chicago School economics thinking reflects a deep change in political power for patent-holding industries. Permitting greater trust-like behavior on the parts of big companies that also hold patent results in a reduction of the number of suppliers of certain kinds of technology, reduced competition, and higher technology costs.

All of these changes reflect a shift taking place in a country that can afford marginally higher technology costs. The effect this has on developing nations is not so clear. Assad Omer points out that:

Developing countries are confronted with the following dilemma: on the one side, in order to attract more investment and technology they have to press to open up their markets, and on the other side, the reduction of regulatory barriers gives rise to the emergence of anti-competitive behaviour of firms.

Perhaps more ominously, Drahos and Braithwaite argue that:

The globalization of intellectual property rights will rob much knowledge of its public good qualities. When knowledge becomes a private good to be traded in markets the demands of many, paradoxically, go unmet. Patent-based R&D is not responsive to demand, but to ability to pay. . . . Much of what happens in the

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agriculture and health sectors of developed and developing countries will end up depending on the bidding or charity of biogopolists as they make strategic commercial decisions on how to use their intellectual property rights.\textsuperscript{37}

Just as all law should be analyzed against the backdrop of economic and regulatory circumstances, the effect technology firms have on public health abroad must be analyzed in the context of IMF loans, governments’ actual efforts to meet public health needs, and the overwhelming effect of tropical diseases on burgeoning population, absent effective government or private aid.

VIII. HEALTH CARE LAW: BETWEEN PUBLIC AND PRIVATE LAW

All of these pressures have changed the way health care operates in the context of globalization. This “global shift” towards concentrated market power has led to the “marked ascendance of private (for profit) sector actors in health policy in recent decades.”\textsuperscript{38} Not only have private actors risen to replace roles traditionally reserved to public actors in the health care market, but private-public partnerships have also taken the place of public policy.\textsuperscript{39}

With the rise of corporate political power in the realm of health care policy, global public-private partnerships have raised concerns such as the question of representative legitimacy and the struggle for cooperative voices. “Health GPPP’s are those collaborative

\textsuperscript{38} Kent Buse et al., Globalisation and health policy: trends and opportunities, in Health Policy in a Globalising World 261 (Kelley Lee et al. eds., 2002).
\textsuperscript{39} Id. See also See Drahos & Braithwaite, supra note 27, at 12 (noting that only a small number of US companies have exerted influence over certain international health care partnerships, but they have done so using their trade power to force developing economies to cooperate).
relationships which transcend national boundaries and bring together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organization so as to achieve as shared health-creating goal on the basis of a mutually agreed and explicitly defined division of labor.”

These GPPP’s exist in part to address global health problems where the traditional antitrust fallbacks—competition, enhanced performance, shared market power—have made little difference. GPPP’s have been established to address the HIV/AIDS pandemic, for example, and these quasi-governmental partnerships have counseled in favor of “long-term donation programs instituted by pharmaceutical companies . . . .” In other words, these global public-private partnerships plead with increasingly powerful corporations to discourage compulsory drug licensing in the interest of facilitating access to medicines.

A. A NEW APPROACH TO HEALTH CARE TRUST

Consider all of the foregoing in formulating the best approach to how antitrust law should articulate with health care. First, because the European Commission has issued extensive documentation urging members of the European business community to follow the American approach to antitrust litigation, we can assume that the US approach yields the “best” outcome, and this is the approach an ideal new model should emulate. Second, because the goal of the American approach—to improve conditions from the standpoint of accessibility for consumers—is the only model universally applicable regardless of regulation or trade restrictions, this goal should be preserved.

40 Buse at 41.
41 Buse et al, at 54.
42 For example, “the Bristol-Myers Squib’s partnership with the Joint United Nations Programme on HIV/AIDS (“UNAIDS”) and a variety of actors in southern Africa, ‘Bridging the Gap,’ has been cited as the way forward in lieu of compulsory licensing,” Id. at 55.
A model approach to health care law need not incorporate the Chicago School approach whole cloth, but those twin goals of (1) efficiency; and (2) consumer access best capture the proposed goal of having health care at all. Consider the flaws of the *GlaxoSmithKline* case: Because the European Court refused to permit GSK to recoup costs of Research and Development where possible, the Court jeopardized all consumers hoping to benefit from such research and development.

Perhaps GSK’s attempt to corner profits in their own market is a powerful reach into a dominant market, but at least the drug company’s market power accomplishes something for those who need the pharmaceuticals. Spain’s prohibition threatens the entire production of GSK’s line of pharmaceuticals, which benefits only the conceptual competitiveness of non-GSK drug manufacturers, at the expense of all consumers and the developer drug company itself.

B. POLICY PRESCRIPTIONS

Many scholars approach the question of what, normatively, *should* be done in the way of increasing access to much-needed drugs in the developing world from the perspective of international law. Health care scholar Patrick Wojahn, for example, suggests that the right to health is guaranteed under numerous conventions and should therefore be recognized in global health care law and incorporated in turn into international antitrust.43

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Notoriously weak, international law lacks sufficient enforcement mechanisms and is hardly swarthy enough to broach the “elimination of all discrimination,” much less the thorny world of business and corporate drug peddling. Proponents of global pharmaceutical holdings argue that there can be no drugs at all if the mechanisms in place to protect profit and development are pushed aside in favor of equal access. Conversely, NGO’s representing public health and consumer interests argue that efforts towards public health are meaningless if they do not undermine patent protections when the health of an entire class of users is at stake.44

Antitrust concerns have always ceded ground in favor of true competition or pursuit of the free market. When it comes to ensuring that impoverished parts of the world retain access to pharmaceuticals, the problem is not patents but poverty. Drugs are expensive to develop. To protect the process and development of future cures, protective interests should advocate not for open markets against patent protection, but rather for property protection for pharmaceuticals. Strong property rights—including patent protection and intellectual property enforcement—incentivize innovation.45

Developing county governments and NGO’s argue that patent protection serves as a barrier to access to essential medicines. The property protection granted though patent-conferred monopoly requires a series of public health exceptions to keep the market for medicine fair. Public health, these NGO’s argue, should trump the interests of patent privilege, and antitrust is


the vehicle through which legal enforcement can reach drug distributors to effect a meaningful change.⁴⁶

From an American Chicago School perspective, these arguments are simply not strong. The cornerstone of American antitrust law is the idea of “expanding the pie” rather than merely treating resources as a zero-sum instrument. Efficiency and consumer access are the goal because increasing these in turn increases corporate profits, which ultimately enhance access for everyone, including secondary markets plagued by poverty. American antitrust law is not identical to international antitrust, but principles hold true across sovereign boundaries, and the fact that so much international antitrust policy has incorporated American principles suggests that the Chicago School is onto something.

Thus developing nations’ accusations of “grey market arbitrage” are unfounded and detrimental to global well-being over time. By keeping patent protections strong and permitting incentives for private firms to donate drugs abroad, more pharmaceuticals will reach impoverished developing economies, and firms will retain the capacity to create even more beneficial drugs in the future.

Brazil has emerged as a leader in the global effort to address the global health emergency. By threatening compulsory licensing to negotiate steep drug discounts, Brazil has managed to provide universal access to HIV/AIDS drugs.⁴⁷ Jose Viana, a Brazilian trade delegate, is quoted as saying: “[t]he Brazilian government has consistently supported the idea that public health

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should not be subordinate to abuses of economic power.” Indeed, Brazil's duress has created a market for Brazilian-manufactured generics, which has increased competition in South America.49

The question is not, however, whether antitrust regimes can impose difficult standards and manage to disseminate the pressures onto other companies that can afford to keep producing. An effective antitrust regime begins its analysis by first establishing the goals of a given system, and then outlining how best to further those goals.

When it comes to health care, antitrust has little business attempting to dissuade drug developers from establishing price points that reflect supply and demand as well as the high cost of developing drugs at all. Indeed, as with the GlaxoSmithKline litigation in Spain and the seminal Schwinn case in the United States, the only way that drug distributors can keep producing is by enforcing a vertically integrated regime to keep costs manageable and the production lines running.

Should global governance effectively install antitrust as a tool to break apart this delicate competitive structure, not only will drug access decrease across the board, but prices will skyrocket to reflect the consumer surplus suddenly unavailable to pharmaceutical developers that desperately need to recoup Research and Development costs or risk going under. In the same way that traditionally-public Europeans have begun to encourage private lawsuits to enforce antitrust law, so should the international community begin to demand actual individualized harm

49 See generally Frederick Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 J. Int'l Econ. L. 469 (2002) (describing the effects of the Doha Declaration, which in effect promised developing economies that their efforts to protect their drug development against larger global pharmaceutical companies would be protected through American and European Union political maneuvering established under the treaty).
in order to gain standing to request a change in distribution strategy. When viewed in this light, the role of antitrust in health care policy will likely veer sharply toward the Chicago School already dominant in other antitrust disciplines, because it is the Chicago School that best reflects free market principles against the twin goals of consumer access and market efficiency.