PRODUCT MARKET DEFINITION IN PHARMACEUTICAL ANTITRUST CASES: EVALUATING CROSS-PRICE ELASTICITY OF DEMAND

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I. INTRODUCTION

The pharmaceutical industry has, for some time, been a major target of antitrust investigations and litigation.[1] In fact, from 2000 to 2010, twenty-eight of the 229 merger enforcement actions initiated by the Federal Trade Commission (FTC) involved prescription drugs.[2] During the same time period, the FTC also initiated ninety-two nonmerger competition enforcement actions, eleven of which involved prescription drugs.[3] Thus, in the eleven-year span from 2000 to 2010, prescription drugs were the subject of 12% of both merger and nonmerger enforcement actions. The significance of antitrust enforcement in the context of the pharmaceutical industry is further highlighted by the fact that prescription drugs account for approximately 10% of healthcare spending in the United States.[4] Health care spending increased by 4.0% in 2009 to a total of $2.5 trillion—17.6% of U.S. Gross Domestic Product (GDP)—with $250 billion being spent on prescription drugs alone.[5]

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[1] Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L. J. 633, 633 (2003).

[2] *FTC Competition Enforcement Database*, FTC.GOV, http://www.ftc.gov/bc/caselist/inde_sited Oct. 31, 2010).

[3] *Id.*

[4] U.S. Dep't of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., *Nation's Health Dollar, Calendar Year 2009: Where It Went*, CMS.GOV, http://www.cms.gov/NationalHealthExpendData/downloads/PieChartSourcesExpenditures2009.pdf (last visited Apr. 14, 2011).

[5] U.S. Dep't of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., *National Health Expenditures 2009 Highlights*,

Given the significance of prescription drugs to both healthcare quality and cost, and the frequency with which pharmaceutical manufacturers face antitrust scrutiny, appropriate consideration should be given to the characteristics of the pharmaceutical market that may obstruct effective antitrust enforcement. In particular, the first step in analyzing whether a defendant possesses market power is defining the "relevant market"[6]—a step that may be complicated by the peculiar structure of the pharmaceutical market. Determining whether the defendant has market power is important because legality of business conduct often turns on whether that conduct was performed with or without market power.[7] Furthermore, the relevant market consists of both a geographic and a product market.[8] This Note argues that, despite case law to the contrary,[9] the traditional tests to determine the relevant product market for antitrust purposes do not sufficiently address the unique structure of the pharmaceutical market. Specifically, courts do not consider all of the "consumers" that affect

CMS.GOV, http://www.cms.gov/NationalHealthExpendData/downloads/highlights.pdf (last visited Apr. 14, 2011).

[6] *See* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) ("[W]ithout a definition of [the relevant] market, there is no way to measure [a defendant's] ability to lessen or destroy competition."); *see also* Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 268 (2d Cir. 1979) ("[T]he first step in a court's analysis must be a definition of the relevant market." (citing United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391–93 (1956))).

[7] Robert Pitofsky, *New Definitions of Relevant Market and the Assault on Antitrust*, 90 COLUM. L. REV. 1805, 1806–07 (1990).

[8] *See, e.g.*, Brown Shoe Co. v. United States, 370 U.S. 294, 324 (1962) ("The 'area of effective competition' must be determined by reference to a product market (the 'line of commerce') and a geographic market (the 'section of the country').").

[9] *See, e.g.*, SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063 (3d Cir. 1978) (focusing on options available to the "prescribing physician"); United States v. Ciba Geigy Corp., 508 F. Supp. 1118, 1126 (D. N.J. 1976) (same); Fed. Trade Comm'n v. Lundbeck, Inc., Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *20 (D. Minn. Aug. 31, 2010) (holding that physicians are the relevant consumer and cross elasticity of demand is the appropriate test).

pharmaceutical purchasing decisions. As a consequence of the existence of multiple decision-makers, the traditional cross elasticity of demand[10] test for defining product markets is inappropriate in the pharmaceutical context, as relying on it may result in overly narrow product markets. To overcome the difficulties presented by cross elasticity of demand, this Note advocates adopting an approach to pharmaceutical market definition that focuses on non-price elements of competition rather than cross elasticity of demand.

Part II of this Note provides an overview of current market definition practices employed by courts, while Part III discusses the structure of the pharmaceutical market, how this structure presents a problem to traditional market definition techniques, and two possible solutions to the problem. Finally, Part IV discusses the implications of adopting the proposed solutions, and Part V concludes.

II. CURRENT MARKET DEFINITION PRACTICES

As mentioned above, market definition has often been regarded as the starting point for analyzing a monopolization claim brought under Section 2 of the Sherman Act,[11] and for analyzing potentially anticompetitive

[10] Cross elasticity of demand, also called cross-price elasticity of demand, is the "ratio of the percentage change of the quantity of one good demanded with respect to the percentage change in the price of another good," and is calculated as $([\bullet Q_i/Q_i]*100\%)/([\bullet P_j/P_j]*100\%)$, where Q_i and $\bullet Q_i$ are the quantity and change in quantity of Good I demanded, respectively, and P_j and $\bullet P_j$ are the price and change in price of Good J, respectively. This formula simplifies to $(\bullet Q_i/\bullet P_j)*(P_j/Q_i)$. DAVID BESANKO & RONALD R. BRAEUTIGAM, MICROECONOMICS, at 46 (Rhoads et al. eds., 2d ed. 2005).

[11] Sherman Antitrust Act § 2, 15 U.S.C. § 2 (2006) ("Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . . ."); *see also* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, at 177 (1965); Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 268 (2d Cir. 1979) (citing United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391–93 (1956)).

mergers challenged under Section 7 of the Clayton Act.[12] In the merger context the recently revised 2010 Horizontal Merger Guidelines[13] have provided a more flexible approach to competition analysis that allows for reliance on direct evidence of competitive effects as well.[14] Despite the 2010 Guidelines' reduced focus on market definition, defining the antitrust market remains an important aspect of merger enforcement as a result of its familiarity to the court system and its ease of use when compared to direct analysis of anticompetitive effects.[15] Indeed, Robert Pitofsky notes, with

[12] Clayton Act § 7, 15 U.S.C. § 18 (2006) ("No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly . . . .").

[13] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (2010), *available at* http://www.ftc.gov/os/2010/08/100819hmg.pdf.

[14] Deborah L. Feinstein, *The Revised Merger Guidelines: Did the Agencies Heed the Lessons of the Past?* ANTITRUST SOURCE, Oct. 2010, at 1, *available at* http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Oct10_Feinstein10_21f.authcheckdam.pdf ("[T]he 2010 Guidelines establish that . . . [w]here direct evidence of competitive effects is available, the Agencies will rely less on market definition in their analysis.").

[15] Dennis W. Carlton, *Revising the Horizontal Merger Guidelines*, 6 J. COMPETITION L. & ECON. 619, 625–26 (2010) ("While imperfect and necessarily crude, the market definition/market concentration framework has provided a useful starting point for merger analysis and has served practitioners, courts, federal agencies, and state Attorneys General well."); Dennis W. Carlton & Mark Israel, *Will the New Guidelines Clarify or Obscure Antitrust Policy?* ANTITRUST SOURCE, Oct. 2010, at 1, *available at* http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Oct10_Carlton10_21f.authcheckdam.pdf ("Why not skip right to a study of the pricing effects of interest? The answer is that, particularly for users of the Guidelines with relatively little antitrust experience, market definition has one overwhelming advantage. It is easy to use. One does not need a Ph.D. in economics to understand how to use it once it has been established.").

respect to the Sherman Act and Section 7 of the Clayton Act, that "[d]efinition of relevant market is a critical analytical tool . . . because the legality of business conduct almost always depends upon the market power of the participants."[16]

Interestingly, and leading to possible confusion, the standards for market definition under Sections 2 and 7 are not always identical. Market definition standards for Section 2 cases are based largely on case law, whereas the standards for Section 7 cases are based on the Horizontal Merger Guidelines.[17] The difference in standards is particularly striking in light of the fact that courts have struggled to develop independently a market definition test,[18] and the fact that the Supreme Court has declared that there is no reason to differentiate between "line" of commerce in the Clayton Act and "part" of commerce in the Sherman Act.[19] Perhaps adding to the confusion, the Agencies have demonstrated some willingness to apply the Guidelines approach in Section 2 cases and the doctrinal approach in Section 7 cases.[20]

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[16] Pitofsky, *supra* note 7, at 1806–07.

[17] Mark A. Glick, Duncan J. Cameron & David G. Mangum, *Importing the Merger Guidelines Market Test in Section 2 Cases: Potential Benefits and Limitations*, 42 ANTITRUST BULL. 121, 122 (1997) [hereinafter Glick et al.] ("Since its creation, the Guidelines' market definition test has been utilized by several courts in merger cases. A LEXIS search of all federal cases, however, reveals no cases in which the market test in the Guidelines was applied in a monopolization setting.").

[18] *See, e.g.*, Pitofsky, *supra* note 7, at 1807 n.4; Glick et al., *supra* note 17, at 122.

[19] United States v. Grinnell Corp., 384 U.S. 563, 573 (1966). The Sherman and Clayton acts prohibit conduct that tends to create a monopoly in any "part" or "line" of commerce, respectively. The *Grinell* court's admonition that there is no reason to differentiate between these two leads some commentators to believe that the market definition tests under the two acts should be the same. *See, e.g.*, Glick et al., *supra* note 17, at 122.

[20] *See, e.g.*, *In re* Int'l Tel. & Tel. Corp., 104 F.T.C. 280, 409–11 (1984) (using Horizontal Merger Guidelines for market definition in section 2 monopolization case); FTC v. Lundbeck, Inc. Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *19–21 (D. Minn. Aug. 31, 2010)

While this Note has thus far discussed market definition in the context of both monopolization and mergers, the primary focus going forward will be the court-created product market definition test and its application to the pharmaceutical industry. Consequently, the argument presented pertains primarily to monopolization claims brought under the Sherman Act, but to the extent that the Agencies and courts use the court-created market definition test for Section 7 claims, this analysis will be relevant to mergers and acquisitions as well.

A. Doctrinal Approach to Market Definition

As an initial matter, antitrust plaintiffs bear the burden of showing monopoly power in the relevant market.[21] With the exceptions of certain kinds of conduct that are illegal per se, conduct challenged under the Sherman Act is typically analyzed under the "rule of reason," which "requires a detailed examination of a challenged agreement's effect in a well-defined market."[22] Market definition is thus necessary to provide courts with a context within which to conduct a rule of reason analysis.[23] Under certain circumstances however, courts can avoid analyzing conduct that is not per se illegal under the rule of reason by taking a "quick look," which does not require market definition.[24] Quick look does not require market definition because market definition is

(using cross elasticity of demand to define product market in a Section 7 merger challenge).

[21] Morse, *supra* note 1, at 656 n.82.

[22] *Id.* at 652.

[23] Morse, *supra* note 1, at 652 n.70.

[24] *See, e.g.*, Nat'l Collegiate Athletic Ass'n, 468 U.S. at 109 ("As a matter of law, the absence of proof of market power does not justify a naked restriction on price or output. To the contrary, when there is an agreement not to compete in terms of price or output, 'no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement.'" (quoting Nat'l Soc'y of Prof'l Eng'rs, 435 U.S. 679, 692 (1978))); *see also* FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 459 (1986) (holding that no elaborate industry analysis is required to condemn a clearly anticompetitive horizontal restraint).

only required to determine market power, which itself is only a proxy for detrimental effect, [25] and quick look is limited to simple cases where detrimental effect is obvious.[26] To the extent that anticompetitive conduct falls in neither the per se nor the quick look categories, the court must define a market.[27]

The current metric for product market definition has its roots in a footnote in *Times-Picayune Publishing Co. v. United States*,[28] which stated that all products have substitutes, but a relevant market must exclude those products to which only a limited number of buyers will turn in the face of a moderate increase in price of the product in question—that is, products for which cross elasticity of demand is low. This test for market definition was elaborated upon and first employed in *United States v. E. I. du Pont de Nemours & Co.*[29] (a Section 2 case), and rearticulated in *Brown Shoe Co. v. United States*[30] (a pre-Guidelines Section 7 case), which stated that "the outer boundaries of a product market are determined by reasonable interchangeability of use or the cross elasticity of demand between the product itself or substitutes for it."[31] *Brown Shoe* also indicated that well-defined submarkets may exist within the broader market defined by cross

[25] Morse, *supra* note 1, at 653.

[26] In particular, quick look is only appropriate where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question have an anticompetitive effect on customers and markets." Cal. Dental Ass'n v. FTC, 526 U.S. 756, 770 (1999).

[27] Morse, *supra* note 1, at 652–53.

[28] 345 U.S. 594, 612 n.31 (1953) ("For every product, substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small.").

[29] 351 U.S. 377 (1956).

[30] 370 U.S. 294 (1962).

[31] *Id.* at 325.

elasticity of demand,[32] and that these submarkets may be determined by looking at certain "practical indicia" that delineate product markets.[33] While these indicia were likely intended to reflect underlying demand characteristics, they have since proven "impossible to implement," and consequently are rarely used.[34]

At present, when courts are considering a market definition based on this doctrinal approach, they consider whether two products are "reasonably interchangeable" or whether they exhibit some level of cross elasticity of demand.[35] These two tests are essentially different articulations of the same concept of substitutability, as under most circumstances two substitute goods are both reasonably interchangeable and will exhibit a high level of cross elasticity of demand. The primary difference between these two articulations is that the former is qualitative, while the latter is quantitative.

B. Market Definition in the Pharmaceutical Industry

While some cases acknowledge that "the pharmaceutical market is fundamentally different from the market for other products,"[36] the Supreme Court in *du Pont* solidified the universal applicability of cross-price elasticity as a tool for market definition by stating that "[t]he 'market' which one must study to determine when a producer has monopoly power will vary with the part of commerce under consideration. The tests are constant."[37] Accordingly, the Agencies, private plaintiffs, and courts are limited to market

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[32] *Id.* ("[W]ithin this broad market, well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes.").

[33] *Id.*

[34] Pitofsky, *supra* note 7, at 1822.

[35] Brown Shoe Co. v. United States 370 U.S. 294, 325 (1962).

[36] *In re* Cardizem CD Antitrust Litigation, 200 F.R.D. 297, 311 (E.D. Mich. 2001) (order granting class certification); *accord* Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 201 F. Supp. 2d 236, 268 (S.D.N.Y. 2002) (quoting In re *Cardizem CD Antitrust Litigation*).

[37] United States v. E. I. du Pont de Nemours & Co., 351 U.S. 377, 404 (1956).

definitions based either on the Guidelines or on principles of reasonable interchangeability, which includes cross elasticity of demand and the *Brown Shoe* "practical indicia."

While the Agencies and private plaintiffs have relied on cross elasticity of demand in defining markets to some extent,[38] the FTC has come under criticism for its less-than-perfect transparency when explaining its market definition methodology.[39] Since there is a relative scarcity of judicial decisions addressing product market definition in the pharmaceutical industry, consent decrees provide a major source for understanding the FTC's market definition methodology, while still leaving much information to be desired.[40] Though it has been noted that the antitrust bar

[38] *See, e.g.*, Smithkline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063 (3d Cir. 1978); United States v. Ciba Geigy Corp., 508 F. Supp. 1118, 1154–55 (D.N.J. 1976); FTC v. Lundbeck, Inc., Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *19–21 (D. Minn. Aug. 31, 2010).

[39] Jonathan Ian Glenken, *Editor's Note, Symposium on Antitrust Issues in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 577, 580 (2003) ("Given the critical importance of market definition, the FTC's widely varying market definitions in pharmaceutical cases create a substantial challenge for antitrust counselors. The complaints filed in FTC merger challenges typically assert simply that 'the relevant lines of commerce in which to analyze the effects of the merger' are X, Y, and Z, without any justification for why X, Y, and Z are proper antitrust markets."); Morse, *supra* note 1, at 633–34 ("In nonmerger cases, the FTC and private plaintiffs generally allege narrow markets, limited to a single drug and its generic equivalent in some cases and to generic drugs excluding the bioequivalent 'brand-name' drug in other cases. In its merger challenges, on the other hand, the FTC has alleged markets ranging from those based upon a particular chemical compound, to broader markets based upon various drugs' manner of interaction or dosage form, to still broader markets of all drugs used to treat a disease or condition. . . . It is not obvious how all of these cases can meet the Supreme Court's product market test of 'reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.' Unfortunately, most of the government actions contain only barebones market allegations so they provide little guidance.").

[40] Glenken, *supra* note 39, at 580 (noting that the "analysis to aid public comment" required to accompany an FTC consent decree rarely provides significantly more detail regarding market definition practices than FTC complaints).

does not have a perfect understanding of the government's approach to market definition in the pharmaceutical industry,[41] the lack of complete understanding does not mean that what is known cannot be improved. To this end, an overview of the structure of the pharmaceutical industry will provide a deeper understanding of the consequences and faults of using cross elasticity of demand to define product markets in the pharmaceutical industry.

III. ADDRESSING THE ISSUES RAISED BY PHARMACEUTICAL MARKETS

A. The Structure of Pharmaceutical Distribution: Who is the Customer?

The prescription pharmaceutical industry is structurally unique in that multiple individuals or entities are in charge of making decisions that have some effect on product selection.[42] In contrast to typical consumer goods—for which

[41] *Id.* at 580–81 ("Given the critical importance of market definition, the FTC's widely varying market definitions in pharmaceutical cases create a substantial challenge for antitrust counselors. The complaints filed in FTC merger challenges typically assert simply that 'the relevant lines of commerce in which to analyze the effects of the merger' are X, Y, and Z, without any justification for why X, Y, and Z are proper antitrust markets. . . . Even if the merging firms settle rather than putting the Commission to its proof, however, the bar would benefit from an explanation of the FTC's basis for its relevant market definition. For example, the complaint might allege that the parties' documents discount the importance of price or innovation competition from products outside the FTC's alleged market, or that pharmacy benefit managers or other pharmaceutical payers believe that only products within the market as alleged will constrain the price of the merging firms' products.").

[42] W. E. 'Ted' Afield, Note, *The New Drug Buyer: The Changing Definition of the Consumer for Antitrust Enforcement in the Pharmaceutical Industry*, 2001 Colum. Bus. L. Rev. 203, 229 (2001) ("The traditional view of the consumer as physician is certainly no longer adequate for antitrust enforcement in the pharmaceutical industry. Direct-to-consumer advertising and the advent of PBMs have required inclusion of patients and the designers of medical formularies as

the end user typically identifies goods capable of satisfying a need or want, selects among the alternatives, pays for, and uses the good—prescription pharmaceutical products require the input of some combination of the end user, physicians, health plans, and even employers.[43] As a result, courts must be careful in defining markets based on cross elasticity of demand, as it is not immediately clear whose demand is economically most relevant. Additionally, even where it is clear which party plays the predominant role in shaping pharmaceutical demand, a test that focuses on the cross elasticity of demand of only one decision-maker, such as physicians, risks painting an inaccurate or incomplete picture of the true interchangeability of two prescription drugs in the "consumer system."[44] As a consequence of its potential to be misleading, therefore, it is not clear that cross

consumers. Certainly, physicians cannot be ruled out of the equation completely, but the analysis cannot stop with them.").

[43] Telephone Interview with Markus Meier, Assistant Director, Federal Trade Commission, Bureau of Competition, Health Care Division (Oct. 13, 2010).

[44] Cross elasticity of demand is a quantitative metric of the percentage change in quantity demanded of one product in response to a given percentage change in price of another, and as such is only capable of being applied to one decision-maker's demand function at a time. While calculating the cross elasticity of demand of physicians, for example, may have economic meaning in the very narrow sense of providing an estimate of how physicians respond to changes in drug prices, the value of physicians' (or any other party's) cross elasticity of demand for pharmaceutical products is not, and cannot be, indicative of one drug's "bang for its buck," relative to another's (and thus its interchangeability with that drug). This is so because, as a consequence of the pharmaceutical market structure in which physicians and patients choose drugs while insurance companies pay for them, physicians have an incentive to consider a drug's "bang" (value) without respect to its "buck" (price). Since the primary purpose of calculating the cross elasticity of demand between two products is to determine to what extent consumers view the two products as substitutes, accounting for price differentials, calculating cross elasticity is unable to serve its intended purpose in the pharmaceutical market. There is no single entity whose demand function both considers a drug's functional benefits *and* fully accounts for its price, and this single entity is required in order for cross elasticity of demand to be economically meaningful.

elasticity of demand is a sensible metric under these circumstances.

As noted above, some courts have observed that the pharmaceutical market is fundamentally different from the market for other products.[45] However, the cases that have asserted this proposition have done so with reference to the fact that generic drugs are legally identical to brand name drugs (as opposed to generic and brand name watches, for example). Nevertheless, this statement is also true as it pertains to the pharmaceutical market's disaggregated demand. To demonstrate the significance of the disaggregated demand structure of the pharmaceutical market and its potential impact on market definition, each kind of "customer" will be discussed in turn.

1. Patients

While at least one court has considered the role of patients as consumers,[46] the more prevalent view seems to be that the patient's preferences for prescription drugs are irrelevant to the demand for such drugs.[47] While this

[45] *See supra* note 36 and accompanying text.

[46] *See, e.g.*, *In re* Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003) (focusing on options available to the "consumer patient").

[47] *See, e.g.*, United States v. Ciba Geigy Corp., 508 F. Supp. 1118, 1126 (D.N.J. 1976) ("The process of marketing specialty drugs is largely directed at the prescribing physician. While the doctor is not the consumer of the product, the patient-consumer is generally legally incompetent to choose between different medications. The object of a marketing compaign [sic], then, is to convince doctors to prescribe a particular company's drug rather than one of its competitor's."); *In re* Schering-Plough Corp., No. 9297, 2002 WL 1488085, at *62 (F.T.C. June 27, 2002) ("Thus, between the doctor, the pharmacist, and the patient, it is the doctor who exercises most, if not all, control over which potassium supplement product is selected for any given patient. Accordingly, the only logical place from which to determine the relevant product market is from the array of therapeutically substitutable choices available to the doctor."); FTC v. Lundbeck, Inc. Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *15–19, *21 (D. Minn. Aug. 31, 2010) (focusing on testimony by physicians that a change in drug price would not cause significant changes in prescribing behavior).

conclusion may have been sound at some point in the past, it is somewhat suspect in the "information age," since information regarding prescription drugs has become readily available[48] at the same time that patients and drug companies are more able to obtain[49] and provide[50] such information, respectively.[51]

Particularly significant in patients' roles as consumers is the impact of Direct-to-Consumer (DTC) advertising. In 1997, the FDA released draft guidelines allowing the expansion of DTC advertising into broadcast and electronic media,[52] and from a total expenditure of less than $1 billion that year, the pharmaceutical industry increased spending on DTC advertising to a record $4.9 billion in 2007, before cutting back to $4.4 billion in 2008.[53] And while dollars spent on advertising may not alone be indicative of any effect on consumers, studies have shown that increases in DTC advertising were associated with significant increases in prescription drug sales. In fact, two studies independently concluded that for every 10% increase in DTC advertising,

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[48] *See, e.g.*, www.webmd.com; www.drugstore.com.

[49] *World Development Indicators*, WORLDBANK.ORG, http://data.worldbank.org/indicator/IT.NET.USER.P2 (last updated Dec., 2010) (indicating that U.S. internet users as a percentage of population has increased from 9.4% in 1995 to 75.8% in 2008).

[50] Ziad F. Gellad & Kenneth W. Lyles, *Direct-to-Consumer Advertising of Pharmaceuticals*, 120 AM. J. MED. 475, 477 (2007) ("In 2004, the amount spent on direct-to-consumer advertising increased to over $4 billion, another 23% increase from the year prior.").

[51] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, IMPROVING HEALTH CARE: A DOSE OF COMPETITION ch. 5, 28 (2004) (stating that former Speaker of the U.S. House of Representatives Newt Gingrich indicated that "[w]hen consumers have information and knowledge, they will be empowered to make real choices about their care and take responsibility for their choices"), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarept.pdf.

[52] Gellad & Lyles, *supra* note 50, at 476.

[53] Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner, 75 Fed. Reg. 15,376, 15,381 (proposed Mar. 29, 2010) (to be codified at 21 C.F.R. pt. 202).

drug sales increased by an average of 1%.[54] Even presuming that spending on DTC advertising exhibits diminishing marginal returns, the approximately 400% increase in advertising between 1997 and 2007 likely played a significant role in increasing patients' relevance as "consumers."

The effect of DTC advertising on patients or potential patients makes sense. Over 90% of Americans 18 and older claim to have seen a DTC advertisement.[55] Furthermore, a 2002 survey by the FDA showed that 43% of respondents reported seeking more information about a drug in response to seeing an advertisement.[56] The same survey also found that 89% of those who sought more information did so from their doctors. Given that physicians are more likely to prescribe a particular drug when they believe a patient expects to receive that drug,[57] it follows that patients who gain information from DTC advertising or other sources are

[54] Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Arnold M. Epstein & Richard G. Frank, *Demand Effects of Recent Changes in Prescription Drug Promotion*, 6 FRONTIERS HEALTH POL'Y RES. 1, 16 (2003) [hereinafter Rosenthal et al.], *available at* http://www.nber.org/chapters/c9862.pdf; U.S. GEN. ACCOUNTING OFFICE, GAO-03-177, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING HAS LIMITATIONS 15 n.21 (2002), *available at* http://www.gao.gov/new.items/d03177.pdf.

[55] Helen W. Brown, AARP, DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: EXPOSURE AND RESPONSE 11, http://assets.aarp.org/rgcenter/general/prescription-drug-advertising-10.pdf; *see also* Helen W. Brown, AARP, SURVEYS AND STATISTICS: DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS: EXPOSURE AND RESPONSE, http://www.aarp.org/health/drugs-supplements/info-11-2010/prescription-drug-advertising-10.html (last visited Apr. 14, 2011).

[56] Kathryn J. Aikin, John L. Swasy & Amie C. Braman, FOOD AND DRUG ADMIN., PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS – SUMMARY OF FDA SURVEY RESEARCH RESULTS, 2 (2004), http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf.

[57] Gellad & Lyles, *supra* note 50, at 478 ("Physicians are more likely to prescribe a medication when they believe that the patient has an expectation to receive that medication. . . . About half of physicians in [an] FDA survey reported some pressure to prescribe as a result of direct-to-consumer advertising.").

likely to influence the demand for prescription drugs. To the extent that patients influence prescription drug demand, it also follows that courts should view patients as playing a partial role as consumers in the prescription drug context.

It should be acknowledged that a number of facts cut against considering patients as the relevant consumer for prescription drug market-definition purposes. Perhaps most significantly, a patient must have a prescription from a health care practitioner with prescription-writing authority in order to purchase a drug.[58] While patients may have some influence over physicians' choices, the physician is the ultimate gatekeeper. Similarly, the fact that most patients lack the medical training to make informed decisions and the possibility that they may be unaware of the full spectrum of available treatments for a particular ailment weigh against treating patients as the *only* relevant consumer. Despite these limitations on the patient's role as consumer, however, the significance of the patient to the drug selection decision, as indicated by the statistics above, should not be overlooked.

2. Physicians

The prevalent view in the courts is that the physician is the relevant "consumer" for prescription drug purposes.[59] This view makes sense intuitively, as only physicians and a few select others have the power to make the ultimate decision regarding which drug to prescribe.[60] Additionally,

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[58] *Practitioner's Manual: Section V—Valid Prescription Requirements*, U.S. Dep't of Justice, Drug Enforcement Admin. Office of Diversion Control, DEADIVERSION.USDOJ.GOV, http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm (last visited Apr. 14, 2011).

[59] *See supra* note 47.

[60] *Practitioner's Manual: Section V—Valid Prescription Requirements*, *supra* note 58 ("A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice

physicians have historically been the individuals with the knowledge to make informed decisions as to which drugs will be effective at treating a patient's ailment.[61] To the extent that physicians will prescribe drugs only that are necessary to treat their patients, they limit the influence of patients on demand for prescription drugs.

Pharmaceutical manufacturers' high level of spending on marketing to physicians supports the physician-as-customer view. One study found that 95% of prescription drug brands sent "detailers" to visit physicians' offices to promote the brands' products,[62] demonstrating the prevalence of the practice and the extent to which physicians are viewed as the decision-makers. In 2008, the pharmaceutical industry spent $6.5 billion on physician detailing by industry sales representatives, in addition to $387 million on professional journal advertising and a retail value of $14.1 billion in free samples.[63] Approximately $21 billion in promotional activities were thus aimed at physicians in 2008—about 4.8 times the $4.4 billion spent on DTC advertising that year—suggesting that pharmaceutical manufacturers believe that physicians are their primary consumers. Like the typical consumer, furthermore, physicians respond to advertising by pharmaceutical manufacturers: one study has found that detailing "has a significant positive impact" on the number of

2. Registered with DEA or exempted from registration (that is, Public Health Service, Federal Bureau of Prisons, or military practitioners)

3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered provided that additional requirements as set forth in the CFR are met.").

[61] *See* Rosenthal et al., *supra* note 54, at 9.

[62] *Id.* at 2 (citing Scott Neslin, *ROI Analysis of Pharmaceutical Promotion: An Independent Study* (May 22, 2001) (unpublished PowerPoint presentation)).

[63] Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner, 75 Fed. Reg. 15,376, 15,381 (proposed Mar. 29, 2010) (to be codified at 21 C.F.R. pt. 202).

prescriptions written for that drug by physicians, and that this impact increases when free samples are provided to the physician.[64]

The fact that other members of the healthcare community can prescribe some of these products runs counter to the logic that physicians, per se, are the relevant customers for market definition purposes.[65] Thus, focusing exclusively on physicians may result in an inaccurate picture of the way healthcare practitioners as a whole view drug interchangeability. Because of the influence of patients and other entities, this potential problem would remain true even if one were to concede that "the prescriber" is the only entity whose cross elasticity of demand matters for market definition purposes. Furthermore, though perhaps less significant, the fact that prescribing physicians are not typically the end user of the prescribed drug, combined with the fact that physicians do not pay for the drug complicates the traditional view that physicians should be regarded as the only relevant consumer. Lastly, the changing structure of healthcare administration practices may also diminish the role of the physician as the customer. As one group of commentators notes: "physicians may have less discretion over choice of brand name drugs than they once did as a result of direct and indirect constraints placed on their prescribing behavior by managed care."[66]

3. Pharmacy Benefit Managers

Pharmacy Benefit Managers (PBMs) essentially act as middlemen between pharmaceutical manufacturers and health plans, managing the pharmacy benefit of group health plan sponsors such as HMO plans, employer

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[64] *See* Rosenthal et al., *supra* note 54 at 6 (citing Puneet Manchanda, Pradeep Chintagunta & Susan Gertzis, Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis (May 2000) (unpublished manuscript) (on file with Puneet Manchanda)).

[65] *See supra* note 60.

[66] Rosenthal et al., *supra* note 54, at 2. *See infra* section III.A.5, Third Party Payers and Managed Care, for elaboration on the impact of managed care on physician choice.

insurance plans, labor union plans, and plans covering public employees.[67] They also create networks of pharmacies so that enrollees in a health plan can fill prescriptions at multiple locations.[68] PBMs' control over demand for pharmaceuticals arises out of the fact that PBMs handle "claims adjudication"[69] for 95% of patients with prescription drug insurance and also create formularies to determine which drugs will be available to enrollees and at what price.[70]

A formulary is a list of PBM-approved drugs for treating various ailments, and is a PBM's main tool to manage benefits, both in terms of the variety of drugs it makes available to enrollees in a particular plan, and in terms of the prices it is able to offer.[71] Generally, formulary decisions are made by Pharmacy & Therapeutics committees (P&T committees), which evaluate drugs for effectiveness and safety and then classify them for inclusion on or exclusion from the formulary.[72] Since inclusion on a formulary will

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[67] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 51, ch. 7, 11.

[68] FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES i (2005), http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitpt.pdf.

[69] Claims adjudication is the process whereby an enrollee in a health plan who wants to purchase a drug from a pharmacy presents his or her health plan card to the pharmacy, which then transmits that information to the PBM to verify the enrollee's entitlements under the plan, and how much the enrollee owes in copayment. The PBM then records payment by the plan and copayment by the enrollee (if any) and transmits billing information to the health insurers. Health insurers then remit payment to the PBM, which forwards the payment to the dispensing pharmacy.

[70] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 51, ch. 7, 11–12 (2004) ("Through a formulary, the PBM controls the price that health plans and enrollees pay and may influence the use of various drugs and the mix of drugs dispensed." (footnotes omitted)).

[71] *Id.*

[72] *Id.* at ch. 7, 10 ("[A]n independent pharmacy and therapeutics (P&T) committee first evaluates the drugs in the particular class for clinical effectiveness and safety. Each drug is then classified for formulary purposes as 'include on the formulary,' 'exclude from the formulary,' or 'optional.' The next step for drugs classified as 'optional' is that the P&T

improve a drug's sales, pharmaceutical manufacturers compete for presence on formularies by paying PBMs for inclusion or providing volume discounts to incentivize PBMs to dispense their drugs—savings that can be passed on to end users.[73]

PBMs' selection of drugs to include on a formulary shapes demand in the sense that a patient's ability to obtain a particular drug at an insured price turns on whether or not that drug is on the formulary. Once on a formulary, however, PBMs still exert influence over demand for drugs by placing them on different tiers within the formulary.[74] Different tiers reflect different levels of copayment required by the patient, and are essentially monetary incentives to induce patients to adopt cost-containment measures.[75] Consequently, PBMs have influence over the drug selection process both before and after a drug is placed on a formulary—influence that suggests PBMs have some role as a "consumer."

committee ranks them on clinical effectiveness, and then again by cost. The 'optional' drugs also are examined for their market share and likely customer reaction if the PBM were to prefer certain drugs over others. After the rankings are complete, the PBM decides which drugs to include on its national formulary.").

[73] FED. TRADE COMM'N, *supra* note 68, at i ("Because formulary listing will affect a drug's sales, pharmaceutical manufacturers compete to ensure that their products are included on these formularies. They do so by paying PBMs 'formulary payments' to obtain formulary status, and/or 'market-share payments' to encourage PBMs to dispense their drugs. These payments are based on the quantity of drugs dispensed under the plans administered by the PBM.").

[74] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 51, ch. 7, 13 (2004) ("Most group health plan sponsors negotiate a three-tiered co-pay arrangement with the PBM, with the lowest co-pay for generic drugs, the middle tier for brand-name drugs with no generic equivalent, and the highest co-pay for brand-name drugs with a generic equivalent. Some plan sponsors negotiate a fourth tier for drugs not included on the PBM formulary, and so-called lifestyle drugs, e.g., drugs to combat hair loss." (footnotes omitted)).

[75] *Id.*

4. Pharmacists

Pharmacists exert control over the perceived demand of pharmaceutical products primarily by their control over generic substitution and therapeutic interchange.[76] Generic substitution is the pharmacist's ability, without prior authorization from the prescribing physician, to substitute an FDA-approved generic equivalent of a branded drug when the branded version is prescribed.[77] A pharmacist's ability to choose whether or not to engage in generic substitution may, however, in certain situations, be limited by mandatory generic substitution laws that require pharmacists to dispense generic versions of prescribed drugs unless the branded version is specified.[78] Therapeutic interchange, on the other hand, is the pharmacist's ability, with prior authorization from the prescribing physician, to substitute a therapeutically equivalent but molecularly distinct

[76] *Id.* at 12–13.

[77] FED. TRADE COMM'N, *supra* note 68, at 61 ("Generic drugs are bioequivalent to brand drugs, that is, they contain the same active ingredient(s) of the brand drugs and are, among other things, chemically identical in strength, concentration, dosage form, and route of administration. Pharmacists generally can substitute a generic drug for a multi-source brand drug without prior physician authorization when a consumer presents a prescription for the corresponding brand drug." (footnotes omitted)).

[78] William H. Shrank, et. al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 Health Affairs 1383, 1384 (2010) ("U.S. generic substitution laws are determined by individual states and can differ among states in several important ways. Some state boards of pharmacy have adopted mandatory generic substitution laws. These require pharmacists to substitute a generic for a brand-name medication if the prescriber did not specify that the latter drug should be dispensed. More-permissive generic substitution laws enacted in other states give pharmacists more discretion by allowing, but not requiring, pharmacists to substitute generics. In addition, some states require patients to provide consent prior to the substitution of a generic, while other states do not. States that require patient consent provide patients with a greater opportunity to influence the use of medications.").

pharmaceutical product for the particular drug prescribed by the physician.[79]

While therapeutic interchange seems to confer pharmacists with significant decision-making power, suggesting pharmacists play a "customer" role, the fact that therapeutic interchange is relatively rare cuts against such a finding.[80] Generic substitution, on the other hand, grants less significant decision-making power but seems more prevalent, with some studies finding generic substitution rates[81] of approximately 90%.[82] Though the combined effects of therapeutic interchange and generic substitution are still likely to have less impact on drug selection than physician or

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[79] FED. TRADE COMM'N, *supra* note 68, at 81 ("Therapeutic interchange refers to situations in which a pharmacy dispenses a preferred drug rather than the prescribed drug. There are two types of interchanges. The first type involves brand drug-to-brand drug interchanges ("brand-to-brand"). For example, a patient presents a prescription for the cholesterol-lowering drug Crestor, but the pharmacy, after obtaining physician approval, fills the prescription with Lipitor instead. The second type involves brand drug-to-generic drug interchanges in which a generic drug that is therapeutically equivalent, but chemically distinct, from the prescribed brand drug is interchanged ("brand-to-different generic"). For example, with the prescribing physician's approval, generic Prozac is dispensed for a prescription for Zoloft.").

[80] *Id.* at 84 ("In early 2005 after responding to the Special Orders, two large PBMs submitted data on the actual number of interchanges during 2002 and 2003. For these two large PBMs, [therapeutic interchange] affected less than one-half of one percent (0.5%) of prescriptions dispensed at retail and at PBMs' owned mail-order pharmacies.").

[81] DEP'T OF HEALTH AND HUMAN SERVS., OFFICE OF INSPECTOR GEN., GENERIC DRUG UTILIZATION IN STATE MEDICAID PROGRAMS ii (2006) (defining generic substitution rate as "the percentage of all prescriptions for multisource drugs (i.e., drugs that have a generic substitute) that were dispensed as generics").

[82] *See, e.g.*, *id.* at ii ("Across all States, both the median and the average generic substitution rates [for drugs purchased under Medicaid] were 89 percent. Twenty-three States had generic substitution rates at or above 90 percent. This compares favorably with a 90% private sector benchmark."); *see also* Dong-Churl Suh, *Trends of Generic Substitution in Community Pharmacies*, 21 PHARMACY WORLD SCI 260, 260 (1999), *available at* http://www.ncbi.nlm.nih.gov/pubmed/10658234 (finding an increase in generic substitution rate from 47% in 1979 to 96% in 1997).

patient preferences (since physicians and patients are the primary decision-makers), these factors suggest that pharmacists have some effect on drug selection, and thus enter into the "customer" equation.

5. Third Party Payers and Managed Care

Insurance companies play a large role in the pharmaceutical market. In 2009, for example, approximately 85% of Americans used health insurance to pay for healthcare expenditures.[83] More specifically, private health insurers covered 67% of Americans, while government health insurance programs covered another 29%.[84] With respect to prescription drugs, private insurance paid for 43.4% of the nearly $250 billion spent on such drugs in 2009, while Medicare and Medicaid paid for another 21.9% and 8.0% respectively.[85] Patients paid 21.2% of prescription drug expenditures out of pocket in 2009.[86]

The role of insurance in payment for prescription drugs is intimately related to the role of PBMs. According to the FTC, when an insured patient fills a prescription at a pharmacy, the pharmacist transfers the patient's insurance information to the PBM, which adjudicates the claim according to the process described above.[87] The purpose of prescription drug insurance is to pay some or all of a patient's cost of obtaining necessary prescription drugs, such that the amount a patient actually pays varies based on

[83] U.S. Census Bureau, *Health Insurance Highlights: 2009*, CENSUS.GOV, http://www.census.gov/hhes/www/hlthins/data/incpovhlth/2009/highlights.html (last updated Sept. 28, 2010).

[84] *Id.*

[85] U.S. Dept. of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., *National Healthcare Expenditures by Type of Service and Source of Funds, CY 1960-2009*, CMS.GOV, https://www.cms.gov/nationalhealthexpenddata/02_nationalhealthaccountshistorical.asp (last visited Apr. 14, 2011).

[86] *Id.*

[87] *See* FED. TRADE COMM'N, *supra* note 69.

characteristics of the drug.[88] Regardless of the specific amounts paid by the patient and insurance company, however, an insured patient purchasing a drug that is covered by an insurance plan will not pay the full retail price of the drug. While this model is prevalent in the United States today, it is not without its critics. Newt Gingrich, for example, has observed that "a third party payment model is inherently conflict-ridden because you have the person receiving the goods not responsible, the person [providing the] goods confused about who they're responsible to, and the person who is paying the money irritated with both the provider and the patient."[89]

As mentioned above, the concept of managed care may have taken some discretion away from physicians with respect to which drugs they may prescribe, and given it to insurance plans. This is likely due to the more restrictive nature of managed care systems relative to traditional fee-for-service systems. According to the United States National Library of Medicine, "[m]anaged care plans are health insurance plans that contract with health care providers and medical facilities to provide care for members at reduced costs. These providers make up the plan's network. How much of [one's] care the plan will pay for depends on the network's rules."[90] Generally speaking, the concept of

[88] FED. TRADE COMM'N, *supra* note 68, at 8 ("For example, some plans may not require members to make copayments for drugs dispensed by network pharmacies, while others may require varying copayments depending on whether the drug is a generic, a brand, or an off-formulary drug and whether it is purchased at a network retail pharmacy, mail-order pharmacy, or out-of-network pharmacy. Plans also consider other factors, including generic dispensing rates, the range of prescription drug choices available to their members, and the price of dispensing fees, drug ingredient costs, and member copayments. In all, plans seek to match PBM services to best meet their objectives in offering pharmacy benefit insurance coverage.").

[89] *Id.* at 28.

[90] Medline Plus, Nat'l Library of Med., *Definition of Managed Care*, http://www.nlm.nih.gov/medlineplus/managedcare.html (last visited Apr. 14, 2011) (The definition goes on to state: "[r]estrictive plans generally cost you less. More flexible plans cost more. There are three types of managed care plans:

managed care aims to improve care and reduce its costs by emphasizing preventive and primary care, as well as to provide patients and physicians with incentives to choose more cost-effective forms of care.[91] While these incentives may potentially reduce national healthcare expenditure, they can limit physician choice. Consequently, this limits the significance of physicians as the "consumer" of prescription pharmaceuticals while simultaneously enlarging the role of insurers. Limits on physician choice are bolstered by the fact that managed care is the predominant form of healthcare in much of the United States today.[92]

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1. Health Maintenance Organizations (HMO) usually only pay for care within the network. You choose a primary care doctor who coordinates most of your care.
2. Preferred Provider Organizations (PPO) usually pay more if you get care within the network, but they still pay a portion if you go outside.
3. Point of Service (POS) plans let you choose between an HMO or a PPO each time you need care.").

[91] Kaiser Family Found., Kaiser Comm'n on Medicaid and the Uninsured, *Medicaid and Managed Care: Key Data, Trends, and Issues*, (Feb. 2010), http://www.kff.org/medicaid/upload/8046.pdf ("Managed care is an approach to delivering and financing health care that is aimed at both improving the quality of care and saving costs. The fundamental idea is to improve access to care and coordination of care by assuring that enrollees have a 'medical home' with a primary care provider, and to rely more heavily on preventive and primary care. As distinct from the fee-for-service system, in which individual providers are paid for each service they furnish, traditional risk-based managed care systems put networks of providers at financial risk, paying them a fixed monthly 'capitation' rate for each enrollee to provide all or a defined set of Medicaid-covered services. This payment arrangement provides different financial incentives to providers, and ideally, supports an approach to practice that emphasizes early identification and treatment of health problems and coordinated management of patients' conditions. Capitation also gives states more cost predictability and control, and contracts with managed care plans offer states a mechanism, through quality measurement and improvement requirements, for holding plans accountable for the quality of care they provide to Medicaid enrollees.").

[92] Nat'l Conference of State Legislatures, *Managed Care and the States: Overview*, http://www.ncsl.org/Default.aspx?TabId=14470 (last updated Jan. 2011) ("Over the past 15 years, managed care has become the predominant form of health care in most parts of the United States.

6. Hospitals

Hospitals are also purchasers of pharmaceutical products.[93] To this end, hospitals often have their own P&T committees to determine which drugs will be included on the hospital's formulary.[94] As the purpose of the P&T committee and formulary in the hospital context is analogous to their purposes in the PBM context, these entities will not be discussed at length here. To gain a full understanding of the pharmaceutical distribution and consumption process, however, it is important to know that P&T committees and formularies are at work even when a patient does not go directly to a pharmacy to obtain a particular drug. This means that hospitals play a role in determining which drugs a patient ultimately receives as treatment.

B. Problem Presented by this Structure

It should be apparent from the foregoing that many parties have a say in determining which drugs are available to treat a patient's particular ailment, as well as how much the patient actually pays. For example, a patient may not think she needs any medication (and may in fact not) until she sees an advertisement notifying her of a particular health problem and a prescription drug that can treat it.[95]

More than 70 million Americans have been enrolled in HMOs (health maintenance organizations) and almost 90 million have been part of PPOs (preferred provider organizations). Overall enrollment numbers in HMOs peaked in 2001 and are declining substantially in almost every area, but managed care generally remains a dominant type of health care and coverage.").

[93] *See, e.g.*, GOV'T ACCOUNTABILITY OFFICE, MEDICARE HOSPITAL OUTPATIENT DRUG PRICES 4 (2005).

[94] *See, e.g.*, Kent Cnty. Mem'l Hosp. Pharmacy and Therapeutics Comm., *Procedure for Requesting a Drug to be Considered for Formulary Addition*, http://www.kenthospital.org/documents/formulary_request_form.pdf (last visited Apr. 14, 2011).

[95] Restless Legs Syndrome—a disorder characterized by a desire to move one's legs—may be an example of such an ailment. According to Dr. Christopher J. Earley, an associate professor of neurology at Johns Hopkins University, "Restless Legs Syndrome is a great example of a

The patient may then visit her doctor, who will decide whether the patient is indeed sick and in need of medication. If the doctor finds the patient does need to be treated with a prescription drug, the doctor will prescribe the medication she thinks is necessary (taking into consideration all available treatments—both brand name and generic—as well as pressure to prescribe from the expecting patient). However, the patient's health insurance may only cover certain drugs for a given ailment, as it may have entered into an agreement with a PBM that obtained volume discounts by purchasing large quantities of a particular drug to the exclusion of other drugs capable of treating the problem. While a patient may still be able to purchase a particular drug not covered by her insurance, doing so would result in greater patient cost. Alternatively, even if the patient exhibits no preference for any particular drug that can treat her ailment, the pharmacist may provide the patient a generic equivalent of the prescribed drug with no prior authorization, or use a therapeutic equivalent, if authorized by the prescribing physician.

In all of this, it is likely that both the patient who actually consumes the drug and the doctor who prescribes it will remain insensitive to (and perhaps, completely oblivious of) prices and price changes.[96] The patient will be paying

suddenly out-of-the-blue disease." Earley further noted that advertising created an overheated demand for diagnosis among consumers, while drug samples provided a convenient response for busy doctors. JoNel Allecia, *Without TV Ads, Restless Legs May Take a Hike: Generic Drugs Could Lead to Less Hype Over 'Jimmy Legs' Syndrome*, (May 14, 2008, 8:34 AM), http://www.msnbc.msn.com/id/24603237/ns/health-health_care/ (last visited Apr. 14, 2011).

[96] Afield, *supra* note 42, at 217 n.55 ("[P]hysicians as well as patients might not be fully aware of generic alternatives to brand name drugs or of the cost information related to each type of drug. Similarly, both physicians and patients may have less than complete incentives to be concerned about costs, in part because third-party payers cover an increasing portion of the costs of pharmaceuticals." (internal quotations omitted) (citing prepared remarks of Mark D. Whitener, Acting Deputy Director, Bureau of Competition, Federal Trade Commission: FTC Antitrust Enforcement in Pharmaceutical Markets (June 16, 1994) (FTC Today, June 20, 1994))).

only a fraction of the price of the drug, no matter which drug is prescribed, and the doctor will be paying nothing, as she will not be consuming any of the drugs involved in these transactions. Furthermore, even patients and physicians who *are* price sensitive may be unable to express that sensitivity because the patient's insurance forecloses the opportunity to purchase a particular prescription drug,[97] or because copayments are equal for drugs that are not identically priced. This lack of price sensitivity (or its expression) in pharmaceutical purchasing has not gone unnoticed by the FTC,[98] the courts,[99] or commentators.[100] Indeed, the use of formulary tiers and their accompanying copayments are part of an effort to impose price sensitivity on patients by creating price differentials for different drugs.[101] While copayments may be a valuable cost-

[97] *See supra* notes 66–69 and accompanying text.

[98] FED. TRADE COMM'N, *supra* note 68, at 44 ("When a health plan sponsor pays the bulk of a drug's cost, consumers have little incentive to select the most cost effective alternative; indeed, consumers often do not know the full cost of a drug. In addition, physicians, not patients, have the expertise and authority to select the particular drugs their patients take. Physicians may not consider the price of a drug or whether it is covered by a patient's insurance when deciding what to prescribe. This combination of factors results in a low price sensitivity among consumers for prescription drugs." (footnotes omitted)).

[99] *See, e.g.*, SmithKline Corp. v. Eli Lilly & Co., 427 F. Supp. 1089, 1117 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056 (3d Cir. 1978) ("The blunt truth is that most physicians and hospital administrators, in their daily practice, are no closer to the cost-benefit analysis advocated by [the expert] than are little leaguers equal to the performance of the National League All-Star baseball team.").

[100] *See, e.g.*, Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L. J. 633, 662 (2003) ("A key question in defining markets is the extent to which customers shift their purchases in response to changes in price. This analysis is complicated in the case of pharmaceutical markets because—like other health care markets—they are sometimes said to be unresponsive to price because of the complex interactions among providers, patients and payers (who may be the patient, a third-party payer, or a combination of the two where the patient is required to make co-payments).").

[101] Formularies are one way to overcome the fact that consumers with insurance coverage have a low sensitivity to the prices of prescription

containment method, copayments are still only a fraction of drug prices, so patients will likely not be exposed to the full variation in drug prices, and many courts regard the physician (who remains completely unexposed to price variations) as the only relevant consumer.[102]

One problematic outgrowth of patient and physician price insensitivity is that, since these are the two entities most likely to be regarded as a "consumer" for antitrust market definition purposes, cross elasticity of demand between two pharmaceutical products is likely to be low regardless of the functional interchangeability of two products. Under present standards, for example, one court defining a pharmaceutical product market based on cross elasticity of demand found separate markets for two seemingly similar pharmaceutical products because cross elasticity of demand was "very low."[103] This finding was despite testimony from at least four physicians indicating that the drugs were interchangeable.[104] While such a narrow market definition may indeed be appropriate, the use of cross elasticity of demand in this context, with little consideration of the availability of

drugs. *See, e.g.*, CONG. BUDGET OFFICE, HOW THE MEDICAID REBATE ON PRESCRIPTION DRUGS AFFECTS PRICING IN THE PHARMACEUTICAL INDUSTRY 1 (1996) (quoting F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 99 (1993)); *see also* FED. TRADE COMM'N, *supra* note 68, at 44.

[102] *See supra* note 47.

[103] *See, e.g.*, Fed. Trade Comm'n v. Lundbeck, Inc., Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *16–21 (D. Minn. Aug. 31, 2010).

[104] *Id.* at *16–18 (citing testimony from Dr. Jeffrey Gerdes: "[g]iven the shortage of Indocin IV in December 2009, he recognized that he would likely use NeoProfen by the end of 2009 unless Indocin IV became available;" Dr. Mark Mammel: "[h]e would feel comfortable treating the vast majority of his patients with either NeoProfen or Indocin IV;" Dr. Nathaniel Payne, explaining his decision not to use NeoProfen: "[o]ur ultimate decision was we didn't see any real advantages or differences and we had a system that seemed to work well using the indomethacin, and we felt it in everybody's best interest, particularly the babies', to stay with what we were familiar with and know how to manage and administer;" and Dr. Phillip Smith: "[w]ere NeoProfen unavailable he would be comfortable using Indocin IV to treat patent ductus arteriosus.").

functionally similar products, leaves little room for any conclusion other than narrow and separate markets.

Relatedly, the court's reliance on testimony that certain physicians would not change their choice of drug even in the face of a significant price change is less indicative of the fact that the two drugs in question do not exhibit functional interchangeability than it is of the fact that many physicians simply do not care about price.[105] Where evidence suggests that certain consumers do not consider price in making purchasing decisions, that evidence should not, without more, be interpreted as indicating that the products are so vastly different that no amount of money can compensate for the differences between them. Rather, that evidence should be interpreted as indicating what it more plainly indicates: *that price is not being considered.* Under these circumstances, asking physicians and patients about their cross elasticity will understate the true extent of product interchangeability.

It is also important to note that focusing on the cross elasticity of demand of physicians or patients ignores the price sensitivity of hospitals and PBMs—the entities that actually purchase the pharmaceutical products.[106] While physician or patient cross elasticity may indeed be low as a general matter, it may still be the case that P&T committees consider price when creating formularies. Consequently, two or more drugs might actually compete with one another on price despite a showing of low cross elasticity from the patient's or physician's perspective.[107] This price competition

[105] *Id.* at *18–19 (citing testimony from Dr. Jae Kim: "[w]here two drugs are [sic] equally effective, he would not choose the drug that was less safe even if it was priced 20% less than the other drug;" Dr. Ilene Sosenko: "cost does not factor into her decision to use NeoProfen instead of Indocin IV;" and Dr. Mitchell Goldstein: "asked whether a 10% or 20% decrease to NeoProfen's price would cause him to switch from Indocin IV to NeoProfen, Dr. Mitchell responded, 'It is irrelevant.'").

[106] *See supra* Parts III.A.3 and III.A.6.

[107] Indeed, the American Antitrust Institute recognized as much in its Amicus Brief filed in the FTC's appeal of *Lundbeck*. *See* Brief for American Antitrust Institute as Amicus Curiae Supporting Appellants at 20 n.5, FTC v. Lundbeck, Inc., Nos. 10-3548, 10-3549, 2010 WL 3810015,

at the formulary level may be indicative of competition within a single product market even though it cannot be observed by the traditional cross elasticity radar, and as such, should not be overlooked by courts defining pharmaceutical product markets.

Lastly, cross elasticity of demand is incapable of accounting for non-price competition—a central value of the antitrust laws.[108] To the extent that two drugs compete with one another on aspects of quality, as demonstrated by free samples or other promotions, cross elasticity may inaccurately circumscribe the product market. Consumers may in fact be insensitive to the price of two products, but still view them as functional substitutes of varying quality, and thus competitors within the same product market.[109] Product differentiation, moreover, can exist on both positive and negative dimensions: one drug may be more effective than another while also having more severe side effects. Though the possible quality differences among drugs are incalculable, the bottom line is that cross elasticity of demand considers only price-related aspects of competition

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at *16–21 (D. Minn. 2011) *appeal docketed*, Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG) (8th Cir. Jan 3, 2001), *available at* http://www.antitrustinstitute.org/content/amicus-brief-ftc-v-lundbeck-mergers-market-definition [hereinafter AAI Brief] ("The court's findings recognize that hospitals *are* price sensitive, and they (not doctors) make the actual drug purchases, and that Lundbeck sought to influence non-physician members of hospital pharmacy and therapeutics committees to gain access to hospital formularies." (internal citations omitted)).

[108] *Id.* at 8 ("Quality competition and consumer choice are values protected by the antitrust laws, even in the absence of price competitiveness in a given market. The Supreme Court has so held many times."); *see also* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 1, Overview, at 2 (2010) ("Enhanced market power can also be manifested in non-price terms and conditions that adversely affect customers, including reduced product quality, reduced product variety, reduced service, or diminished innovation. Such non-price effects may coexist with price effects, or can arise in their absence.").

[109] *See, e.g.*, *id.* at 4 ("Indeed, it is where price competition lacks vigor that non-price competition is most important."); *see also id.* at 2 ("A lack of price competition between two functionally interchangeable products does not preclude a determination that they are in the same relevant market.").

and that products frequently compete on non-price characteristics via product differentiation. A court defining a pharmaceutical product market, therefore, should not forget Judge Kavanaugh's admonition that "product differentiation does not mean different product markets."[110]

1. Employing Cross Elasticity of Demand: The Relevant Question

Courts employing cross elasticity of demand in defining the relevant market for antitrust purposes, whether or not in the pharmaceutical context, must not do so blindly. Courts must be careful to consider the causal relation between cross elasticity and substitutability. The essence of the inquiry is whether two products are substitutes because they exhibit cross-price elasticity, or alternatively whether they exhibit cross-price elasticity because they are substitutes. This Note argues that the latter is the case—products demonstrating cross-price elasticity are necessarily substitutes, but substitutes do not necessarily exhibit cross-price elasticity. While the last statement—that substitutes do not necessarily exhibit cross-price elasticity—may seem counterintuitive, it may at times be true if market structure decouples payment for, and selection of, a good—as it does in the pharmaceutical market. Under these circumstances, courts must be careful not to rely on "false negatives" in the form of low cross elasticity of demand, when there may in fact be some meaningful amount of functional interchangeability between two or more prescription drugs.

2. The Merits of Calculating Cross Elasticity of Demand

Having asked the causal question posed above, a court calculating cross elasticity of demand must determine whose demand to consider when defining the relevant market. Matt Koehler notes that:

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[110] Fed. Trade Comm'n v. Whole Foods Mkt., Inc., 548 F.3d 1028, 1055 (D.C. Cir. 2008) (Kavanaugh, J., dissenting).

> Properly identifying the customer helps to define a product market because it enables the claimant to show the court the interchangeability factor. The customer is critical because it is the customer that is the flexible element of the "product equation." "Flexible element" is the claimant's ability to show why the product is or is not interchangeable due to the customer's actual or potential purchasing actions.[111]

Exactly who the customer is in pharmaceutical purchasing has proven to be an elusive issue for courts. Some have concluded that the patient is the relevant customer because the patient consumes the product, while other courts argue that the physician is the relevant customer because the physician makes the choice of which drug is purchased.[112] Calculating cross-price elasticity of demand based either on patients' or physicians' responses to price changes may, as mentioned above, produce different results. Each of these results is likely to foreclose finding a broad market due to price insensitivity of both patients and physicians.[113] Furthermore, though at least one court has admitted it must make its pharmaceutical market definition decision on the basis of consumer-physician practices, "whether their practices are rational, irrational, or unnecessarily costly,"[114] doing so without consideration of economic issues related to market structure takes much of the economics out of what is, "in essence, an economic task put to the uses of the law."[115]

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[111] Matt Koehler, Comment, *The Importance of Correctly Identifying the Consumer for an Antitrust Relevant Market Analysis*, 67 UMKC L. REV. 521, 534 (1999).

[112] *See supra* notes 46–47 and accompanying text.

[113] *See supra* notes 96–98 and accompanying text.

[114] SmithKline Corp. v. Eli Lilly & Co., 427 F. Supp. 1089, 1118 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056 (3d Cir. 1978).

[115] United States v. Grinnell Corp., 384 U.S. 563, 587 (1966) (Fortas, J., dissenting). If defining markets based on cross elasticity of demand is an economic task to be put to the uses of the law, it makes little sense to heed mathematical principles of economics (by calculating cross elasticity of demand) while simultaneously ignoring other relevant principles of

The essential problem for market definition based on cross elasticity of demand, then, is how to come to a useful definition of "consumer" whose demand can be studied to define a relevant market for pharmaceutical products. Neither measuring cross elasticity of demand from the patients' perspective nor from the physicians' perspective seems entirely satisfactory, but choosing a different party such as a PBM seems to be even less satisfactory, given that a PBM neither directly chooses, uses, nor pays for prescription drugs. While it is reasonable to argue that either patients or physicians may be suitable "consumers," it may in fact be more appropriate to regard neither of them as *the* consumer, realizing that, as discussed above, a number of entities play a role in selecting and paying for prescription drugs.

The "no single customer" view counsels against using cross elasticity of demand to determine interchangeability of prescription drugs. Relying on cross elasticity of demand to determine product substitutability, and therefore to define a product market, implicitly assumes that the individuals selecting which products to purchase are also the ones paying for it. This is because the traditional view of a market definition based on cross elasticity of demand consists of products to which a consumer would switch in response to a variation in price—switching that would occur, presumably, because a change in price of one product makes either that product or one of its substitutes relatively "less worth it" to the payer.[116] In the case of pharmaceuticals, however, switching is unlikely even if price changes make one drug a worse value than another, because individuals choosing prescription drugs never have to make an analysis of how "worth it" a drug is in the first place.[117] Under these circumstances, the separation of product selection and

economics, such as the fact that market structure may affect the relevance of calculating cross elasticity of demand in the first instance.

[116] *See supra* note 44.

[117] While some physicians may consider a drug's benefit relative to its price when writing a prescription, it is likely that sufficiently large numbers of physicians (perhaps even most) do not. *See supra* note 105.

payment undercuts the assumption of unity of customer, payment, and selection that underlies a market definition based on cross elasticity. Because the unity assumption is essential for substitution to be economically rational in the face of a price change, the fact that the assumption is not true for pharmaceuticals means observed substitution does not correlate with a change in a product's value relative to its price. The failure of customers to respond to changes in a product's value relative to price, and the fact that "value" incorporates elements of a drug's functionality, means that cross elasticity does not reflect functional interchangeability.

Lastly, cross elasticity can be viewed as not entirely appropriate in the pharmaceutical context from a doctrinal perspective. Relying on language from *Times-Picayune*, from which the use of cross elasticity as a tool for market definition arose, it seems that the original purpose of measuring cross elasticity was to limit a product market from spanning an "infinite range," rather than mechanically to define narrow markets.[118]

Relying on cross elasticity of demand to define the relevant market makes yet another related assumption that is not true in the pharmaceutical market: the existence of a single, continuous demand curve for a single product. In a typical market, consumers choose among products and their substitutes, considering the various attributes of each product, including price. In this context, a change in price of one good (Good A) causes a movement along the consumer's demand curve for that product.[119] Simultaneously, the consumer seeing a price change in Good A considers his demand curve for other products (Good B, for example), as

[118] Times-Picayune Publ'g Co. v. United States, 345 U.S. 594, 612 n.31 (1953) ("For every product, substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small.").

[119] *See, e.g.*, DAVID BESANKO & RONALD R. BRAEUTIGAM, MICROECONOMICS Chapter 2.1, Demand, Supply, and Market Equilibrium, at 26 (Rhoads et al. eds., 2d ed. 2005).

well as the fact that he only has a limited income (which may have effectively increased or decreased, depending on whether the price of A decreased or increased, respectively),[120] and responds by allocating purchases in a way that gives him the most benefit or value for the money spent.[121] In the language of economists, the consumer will "maximize utility" by substituting purchases of one good for purchases of another in response to a price change in one of the goods. Under these circumstances, both Good A and Good B each have familiar downward sloping and continuous demand curves, and cross elasticity of demand will be an informative metric of substitutability between A and B.

The pharmaceutical market, however, is structurally unique, and presuming that pharmaceutical products have single, continuous demand curves may be unrealistic. This is because pharmaceutical demand is subject to the input and limitations of many entities, all of which contribute in some form to the selection of, price of, and payment for a particular prescription drug. Given that patients or doctors may not be able to respond to changes in drug price even if they wanted to, and given further that they rarely will want to because of the decoupling of selection and payment in addition to their incomplete pricing information,[122] presuming that pharmaceutical products have demand functions that accurately depict the relation between price and quantity demanded (where quantity demanded reflects some measure of product value) is unrealistic. For these reasons, the usefulness of studying cross elasticity of demand is subverted in this context.[123]

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[120] *Id.* at 98. When the price of Good A changes, the possible purchase options available to a consumer with a limited income also change. For example, in a world with only Goods A and B, an increase in the price of Good A reduces the consumption options available to consumers, in that they can buy the same number of units of Good B, but fewer units of A. Thus, consumers' purchasing power has effectively decreased as a result of the price change. The opposite is true when the price of a good decreases.

[121] *Id.* at 103.

[122] *See supra* notes 96, 105.

[123] It is important to recall that the purpose of studying cross elasticity of demand when defining product markets is to determine

The FTC has expressed a belief that at least some physicians are price sensitive,[124] but there is evidence to the contrary.[125] In light of this evidence, insisting that a judicially created test for market definition premised on price sensitivity is applicable across industries,[126] without consideration of economic differences across those industries, risks putting legal form over economic substance. It is not the case that therapeutically interchangeable prescription pharmaceuticals necessarily demonstrate a significant level of demand cross elasticity from the perspective of the patient or physician. Furthermore, owing to the decoupling of selection and payment, there is not a single continuous demand function from which to measure cross elasticity in a way that meaningfully incorporates functional interchangeability of prescription drugs.

3. Preliminary Defenses

Before addressing potential solutions to the problem posed by relying on cross elasticity of demand to define

"interchangeability of use," United States v. Brown Shoe Co. 370 U.S. 294, 325 (1962), and that cross elasticity of demand is not intrinsically meaningful when its quantitative value does not correlate with functional interchangeability. Because the observable demand functions of physicians and patients consider the utility of a drug without full consideration of the drug's price, a determination of interchangeability based on cross elasticity as calculated from either of these demand functions may find that two drugs are not interchangeable because consumers do not care to switch in the face of a price change, when in fact the drugs do have similar therapeutic qualities, and thus exhibit "interchangeability of use." Therefore, cross elasticity of demand fails to capture the entire picture of substitutability of drugs when price and functionality can be considered separately of one another.

[124] *See In re* Warner-Lambert Co., 87 F.T.C. 812, 877 (1976) ("[W]e cannot assume that all physicians are so fixed in their prescribing habits that a substantial increase in the existing price differential . . . would never cause some shift . . . . [W]e can take notice that some physicians, even if a minority, are conscious of price differences . . . . We see no reason to believe that price would never enter into some physicians' decisions.").

[125] *See supra* notes 103, 105.

[126] *See* United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 404 (1956).

pharmaceutical product markets, it is worth addressing potential arguments that, despite the concerns presented above, there is actually no problem at all.

a. Telescoping Demand

One might argue that, despite multiple "consumers" expressing demand differently, these individual demand functions essentially "telescope" into one. For example, though a patient may see a DTC advertisement that inspires her to express a preference for a particular drug, the actual choice the doctor makes will incorporate the patient's preference. As mentioned earlier, doctors often experience pressure to prescribe when patients come to their offices with demands stimulated by outside information.[127] Nevertheless, doctors are capable of using (and indeed charged with the duty to use) their professional training to make informed decisions as to the necessary treatment. Consequently, the drug a doctor eventually chooses to prescribe is arguably the result of conscious deliberation by the doctor that incorporates information and preferences presented by the patient. According to this line of reasoning, the "multiple demand functions" argument is not viable, at least with respect to an independent patient demand. Similarly, the telescoping demand argument can be used to eliminate pharmacists from the equation, as pharmacists are required to obtain prior authorization from the prescribing physician when substituting a therapeutic equivalent for a prescribed drug.[128]

Admitting that there is some truth to the telescoping demand theory, the use of cross elasticity of demand to define pharmaceutical product markets is still likely to be misleading because the existence of third party payers decouples selection of and payment for drugs. In some cases, uninsured patients may pay for pharmaceuticals directly, but as mentioned above, approximately 85% of Americans use health insurance to pay for healthcare expenditures, so

[127] *See supra* note 57.

[128] *See supra* note 79.

selection and payment remain decoupled for most patients.[129] Owing to the fact that the telescoping demand theory cannot resolve perhaps the most fundamental reason for avoiding cross elasticity as a tool for market definition in decoupled markets, this theory does not fully address the market definition problem described above.

b. So What? Precedent Demands Cross Elasticity

Alternatively, one might argue that relying on cross elasticity of demand to define markets is appropriate because it is the test courts apply, and the Supreme Court has already indicated that although industries may vary, "the tests are constant."[130] This argument is somewhat more difficult to overcome, as it is backed by Supreme Court precedent that has stood for over five decades. Nonetheless, *du Pont* itself focused on interchangeability, noting that "interchangeability is largely gauged by the purchase of competing products for similar uses *considering the price*, characteristics and adaptability *of the competing commodities.*"[131] Thus, it seems that cross elasticity of demand arose as a tool to measure interchangeability considering both product utility and price, and should not be considered doctrinally impenetrable in and of itself when it is incapable of serving its intended purpose.[132]

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[129] *See supra* note 83. While price sensitivity could be measured from the 15% of consumers who pay out of pocket, the administrability concerns of finding these purchasers counsels against doing so.

[130] *Du Pont*, 351 U.S. at 404.

[131] *Id.* at 380–81 (emphasis added).

[132] Indeed, some courts have recognized that a product market can be defined by determining interchangeability without relying on cross elasticity of demand. *See* Nobody in Particular Presents, Inc. v. Clear Channel Commc'ns, Inc., 311 F. Supp. 2d 1048, 1082 (D. Colo. 2004) (noting that "a plaintiff may, through sufficient evidence of other indicia of market definition, define a relevant market without economic study of cross elasticity of demand," and providing extensive analysis of cases defining markets by determining interchangeability without reference to cross elasticity of demand).

One might argue further, however, that in the case of pharmaceuticals, even if two drugs are therapeutically interchangeable in theory, they may not be interchangeable in fact. For example, if PBMs and insurance companies allow patients to obtain only one of the two drugs at the insured price, they thereby create two distinct markets. While this argument has superficial appeal, it fails to consider the reality that therapeutic interchangeability of drugs is a permanent condition, while one's current insurance provider (and its payment policies) is subject to change. In the long and medium runs, a consumer in the hypothetical above who wants a particular non-covered drug could, at least in theory, obtain it by switching insurers or obtaining a new insurance policy. Additionally, given the wide variety of available insurance plans, it is quite likely that some drugs will be interchangeable in fact for certain people, even though the cross elasticity of demand between those drugs is low due to physician and patient price insensitivity.

C. Two Proposed Solutions

1. Increased Reliance on Scientific Testimony

One potential solution to the problem of market definition created by the unique structure of the pharmaceutical industry is to reduce reliance on cross elasticity of demand as a measure of interchangeability, while increasing reliance on scientific testimony from physicians, pharmacists, physiologists, or other qualified scientific experts. Altering the source of expert testimony from economists to healthcare practitioners and scientists would change the basis of the interchangeability determination from perceived consumer demand to therapeutic effect.[133] If, as argued above, cross

[133] The term "perceived consumer demand" is used to indicate the fact that because of the structure of the pharmaceutical market, the actual demand of patients and physicians—that is, their responses to changes in price—as would be demonstrated by their demand functions, cannot be

elasticity of demand was originally employed as a proxy for "reasonable interchangeability of use,"[134] then relying on scientific testimony to determine interchangeability will achieve the goal of determining "interchangeability of use" without the complications created by pharmaceutical market structure.

Shifting the determination of interchangeability from cross elasticity of demand to therapeutic interchangeability would result in a shift from using economists as experts to using scientists or practitioners, but the shift would not significantly increase the use of expert witnesses as a general matter. One potentially significant difference, however, is the fact that the FTC and DOJ have in-house economists, whereas they do not have in-house scientists. To the extent that shifting the source of expertise will result in additional expenditures, this shift may be burdensome for the government as an antitrust plaintiff.[135]

The most significant positive attribute of this proposal is its consistency with existing doctrine. As the Court in *Brown Shoe* put it, "[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use *or* the cross elasticity of demand between the product itself and substitutes for it."[136] Since *Brown Shoe* gives plaintiffs the option of demonstrating interchangeability of use as an alternative to cross elasticity, requiring plaintiffs

observed. This is because price does not fully enter into either the physician's or the patient's consumption decision.

[134] United States v. Brown Shoe Co., 370 U.S. 294, 325 (1962).

[135] It is worth noting that even though the Agencies have internal economists, they frequently rely on experts who are not affiliated with the Agencies, and these experts can be quite expensive. In *Lundbeck*, for example, the FTC hired Jonathan Arnold, Ph.D., who is affiliated with the economic consulting firm Analysis Group. Though Dr. Arnold did not file an official report in *Lundbeck*, his billing rate in 2003 was $450 per hour. *See* Affidavit of Jonathan I. Arnold at 1, *In re* Exide Technologies, 378 B.R. 762 (Bankr. D. Del. 2007) (No. 02-11125), 2003 WL 24196171. Presuming that the Agencies regularly incur expenses from external economic witnesses, expenses incurred from reliance on scientific testimony may result in little if any increase in litigation costs.

[136] *Brown Shoe*, 370 U.S. at 325 (emphasis added).

to demonstrate interchangeability of use instead of cross elasticity of demand may be doctrinally appropriate where cross elasticity is not economically meaningful.[137]

2. Adopt the Merger Guidelines Standard

An alternative solution to using cross elasticity of demand for market definition is to adopt the Horizontal Merger Guidelines approach in all cases. Replacing the court-created market definition test based on cross elasticity of demand with the recently revised Guidelines approach would create uniformity in market definition practices and eliminate the current confusion regarding which method to employ. Additionally, the 2010 Guidelines advocate a more functional approach that allows the agencies to consider the direct competitive effects of a merger without first having to define the market.[138] The 2010 Guidelines' "direct effects" analysis is particularly useful in markets like pharmaceuticals that contain highly differentiated products. Drawing a clear market boundary in such markets is difficult owing to the fact that products "typically are positioned by their manufacturers along a competitive continuum, and compete with one another to varying degrees."[139] And though the Guidelines' approach defines markets based on the hypothetical monopolist test, which relies on consumer price sensitivity,[140] the Guidelines also

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[137] As already noted, some courts have concluded that interchangeability can be determined without reference to cross elasticity of demand. *See supra* note 132.

[138] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 4, Market Definition, at 7 (2010) ("The Agencies' analysis need not start with market definition. Some of the analytical tools used by the Agencies to assess competitive effects do not rely on market definition . . . .").

[139] Eric J. Stock, *New U.S. Merger Guidelines Suggest Increased Focus on Deals in High Tech and Pharmaceutical Sectors*, KLUWER COMPETITION LAW BLOG (Oct. 18, 2010), http://kluwercompetitionlawblog.com/2010/10/18/new-u-s-merger-guidelines-indicate-greater-scrutiny-of-high-tech-and-pharmaceutical-transactions.

[140] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 4.1.1, The Hypothetical Monopolist Test, at 9 (2010) ("The

consider non-price competition in market definition.[141] Because it presumes competition between two products to indicate some level of interchangeability between them, the Guidelines' more comprehensive view of competition helps produce a more accurately defined product market than a test that only considers price.

Related to the effects-based approach to market definition, the new Guidelines also allow the agencies to define markets by taking into account customers who might be subject to price discrimination.[142] For example, if a pharmaceutical manufacturer seeks to acquire a competing product, the agencies may consider whether the two drugs the manufacturer seeks to own are close substitutes for a

hypothetical monopolist test requires that a product market contain enough substitute products so that it could be subject to post-merger exercise of market power significantly exceeding that existing absent the merger. Specifically, the test requires that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products ('hypothetical' monopolist) likely would impose at least a small but significant and non-transitory increase in price ('SSNIP') on at least one product in the market, including at least one product sold by one of the merging firms.").

[141] *Id.* at 2 ("Enhanced market power can also be manifested in non-price terms and conditions that adversely affect customers, including reduced product quality, reduced product variety, reduced service, or diminished innovation. Such non-price effects may coexist with price effects, or can arise in their absence. When the Agencies investigate whether a merger may lead to a substantial lessening of non-price competition, they employ an approach analogous to that used to evaluate price competition."); *see also id.* at 7 ("Market definition focuses solely on demand substitution factors, i.e., on customers' ability and willingness to substitute away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service.").

[142] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 4.1.4, Product Market Definition with Targeted Customers, at 12 (2010) ("If a hypothetical monopolist could profitably target a subset of customers for price increases, the Agencies may identify relevant markets defined around those targeted customers, to whom a hypothetical monopolist would profitably and separately impose at least a SSNIP.").

subset of consumers.[143] If the agencies believe that there is a "realistic prospect of an adverse competitive effect on [that] group of targeted customers,"[144] they may define the market more narrowly than they might in the absence of these "captive" customers.[145]

Note, however, that despite the advantages of an effects-based approach to market definition, the 2010 Guidelines do not get antitrust plaintiffs entirely off the hook. Though the new Guidelines allow the agencies to pursue claims without explaining why the relevant market should exclude certain seemingly competitive products, the agencies must still "explain the competitive significance of these other competing products, and why competition from these products would not be sufficient to counteract any attempt by the merging parties to increase prices post-merger."[146] Furthermore, courts hearing challenges brought under the Guidelines will likely continue to consider market definition a central aspect of the antitrust claim.[147] This will act to temper the influence of a broad adoption of the Guidelines approach. Indeed, commentators agree that requiring market definition under the Guidelines will likely provide discipline to plaintiffs' and courts' competitive analyses and

[143] Stock, *supra* note 139. This factual scenario is analogous to that in *Lundbeck*, where two drug products competed with one another and with a surgical technique capable of treating the same illness. Presuming some but not all customers view the two drugs as close substitutes but view the surgical technique as an entirely separate product, this approach to market definition will protect consumers who are not willing to undergo surgery from a price increase initiated by the owner of the only available pharmaceutical treatments.

[144] HORIZONTAL MERGER GUIDELINES, *supra* note 142, at 12.

[145] This effects-based narrowing of the defined market would be valuable in connection with the approach advocated in this note. Since abandoning cross elasticity of demand as a method of defining pharmaceutical product markets will result in a general broadening of market definitions, the Agencies will still be able to pursue narrow market definitions where appropriate by relying on the Guidelines' effects-based approach.

[146] Stock, *supra* note 139.

[147] *See id.*

will prevent courts from making arbitrary decisions.[148] It is important to note that even though the Guidelines do not specifically rely on "cross elasticity of demand," they require some analysis of substitutability, for which cross elasticity of demand may be evidentiary.[149]

IV. IMPLICATIONS FOR FUTURE CASES

A. Implications of Increased Reliance on Scientific Testimony

The product market will generally be broader when defined based on interchangeability of use as determined by scientific and medical testimony than when defined based on cross elasticity of demand as determined by economic testimony. This is due to the fact that, given the nature of the pharmaceutical distribution structure, cross elasticity of demand, when examined from the perspective of the patient or the physician, is constrained by the decoupling of drug payment and selection at levels that may not reflect the true functional interchangeability of pharmaceutical products. Additionally, cross elasticity is limited further by structural features of the market, such as formularies, which may

[148] *Id.* ("[T]he use of the market definition paradigm has been useful, among other reasons, to provide a discipline for the competitive analysis."); Dennis W. Carlton, *Revising the Horizontal Merger Guidelines*, 6 J. COMPETITION L. & ECON. 619, 626 (2010) ("The discipline of forcing decision-makers to have a reasonable market definition in mind before finding a harmful competitive effect is likely to be valuable in constraining agencies and especially courts from making decisions based on arbitrary criteria."); Carlton & Israel, *supra* note 15, at 2 ("To eliminate market definition would likely lead to arbitrariness and discretionary havoc in courts and at foreign agencies where economics is not as well understood as at U.S. antitrust agencies.").

[149] U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 4.1.3, Implementing the Hypothetical Monopolist Test, at 11 (2010) ("In considering customers' likely responses to higher prices, the Agencies take into account any reasonably available and reliable evidence, including, but not limited to: (1) how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions. . . .").

prevent drug interchange for economic reasons, even if no therapeutic limit to interchangeability exists.[150] Consequently, relaxing the requirement that plaintiffs show sufficiently high cross elasticity of demand will create a "one way ratchet." This will enable plaintiffs to demonstrate "interchangeability of use," without being hindered by a lack of demand cross elasticity. Note, however, that this broadening of product markets caused by reduced reliance on cross elasticity of demand will not result in unreasonably broad markets—medical testimony will indicate if two drugs are not substitutes, and the product market will be appropriately circumscribed.[151]

The final result will be a test for antitrust product market definition that overcomes the unique structural difficulties presented by the pharmaceutical market, with resulting product market definitions that comport with definitions obtained in other industries. This approach will improve antitrust enforcement by providing for a more realistic and customized approach to competitive analysis in the pharmaceutical industry—one that is also consistent with doctrine.

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[150] As already mentioned, formularies may contain one drug to the exclusion of a therapeutically similar drug to achieve volume discounts on the chosen drug, which may not be available if a formulary split total purchase volume among several drugs.

[151] The consequences of broader product markets are complicated. As a general matter, broader markets mean that any given drug is a less significant player in the market, so acquisition of a particular drug may be found to be less detrimental to competition than it would be if the market were narrower. On the other hand, in *Lundbeck*, the court found that acquisition of a product was not anticompetitive because the acquired product was in a different market than Lundbeck's existing product. If the *Lundbeck* court had defined the market broadly enough to include both of the products, then Lundbeck's acquisition would have resulted in Lundbeck owning all of the products in the market, which may have raised anticompetitive concerns. Thus, under certain circumstances, broader markets may mean that a given acquisition will be more, rather than less, anticompetitive. Regardless of the outcome, however, the solutions this Note advocates would allow courts to define markets more accurately, thereby protecting consumers whenever a company attempts to monopolize a market for products that are functionally interchangeable.

B. Implications of Adoption of the Guidelines Approach

Adoption of the Guidelines approach for all antitrust market definition purposes would, at the very least, provide some harmony to a complicated area of the law. More importantly, however, the Guidelines' direct effects analysis may be able to overcome the complications of the pharmaceutical industry. For example, a competitive effects analysis may have been able to save complainant FTC in *Lundbeck*,[152] which found that the FTC had failed to satisfy its burden of showing that Lundbeck had engaged in a competition-lessening acquisition when it acquired both of the FDA-approved pharmaceutical treatments for Patent Ductus Arteriosus[153] and, within two days, increased the price by 1300%. This Note does not argue that *Lundbeck* was wrongly decided, but it does argue that under the cross-elasticity-of-demand-based market definition relied upon by the court, the court had no opportunity to come to any conclusion other than that the two drugs acquired by Lundbeck were in separate product markets and that consequently such acquisition would not "tend to create a monopoly."[154]

Adopting an effects-based approach to market definition—which includes non-price effects—would enable the Agencies and courts to define antitrust product markets in a more realistic manner. The pharmaceutical market is just one market in which market structure interferes with the normal operation of cross elasticity of demand, but there may be others. If effects analysis can overcome market structure problems as a general matter, then adoption of the Guidelines for all market definition purposes may improve antitrust enforcement outside of the pharmaceutical context as well. Furthermore, even though competitive effects

[152] Fed. Trade Comm'n v. Lundbeck, Inc., Nos. 08-6379 (JNE/JJG), 08-6381 (JNE/JJG), 2010 WL 3810015, at *22 (D. Minn. Aug. 31, 2010).

[153] Patent Ductus Arteriosus is a heart condition that primarily affects low-birth-weight, usually premature, babies. *See id.* at *2.

[154] Clayton Act § 7, 15 U.S.C. § 18 (2010).

analysis likely cannot carry the day even under the Guidelines, the test for interchangeability under the Guidelines is broader than a straightforward application of cross elasticity of demand.[155] The flexible and comprehensive approach advocated by the Guidelines might overcome many of the current limitations to effective product market definition in the pharmaceutical industry.

V. CONCLUSION

Antitrust enforcement in the pharmaceutical industry has significant healthcare quality and access consequences for Americans. This is so not only because of pharmaceutical manufacturers' tendency to be the subject of antitrust scrutiny, but also, and perhaps more so, because of the tremendous role pharmaceuticals play in healthcare administration and outcomes. Similarly, product market definition is essential to effective antitrust enforcement, as it provides context for understanding the competitive effects of corporate conduct.[156] As with many judicially created tests, however, the application of cross elasticity of demand to determine product interchangeability and thus the "relevant market" for antitrust purposes may not be universally appropriate. The pharmaceutical industry, owing to its complex structure and to the lack of identity between users, choosers, and payers in the pharmaceutical purchasing process, is one of these cases. In the pharmaceutical market, in contrast to the market for most goods, neither the patient-consumer nor the physician-decision-maker pays the price of the good, and consequently neither the patient nor the physician exhibits much sensitivity to changes in price, despite the fact that therapeutically similar drugs may be available. As a consequence of pharmaceutical market

[155] *See generally* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 4.1.3, Implementing the Hypothetical Monopolist Test (2010).

[156] Pitofsky, *supra* note 7, at 1807 ("Definition of relevant market is a critical analytical tool in antitrust enforcement because the legality of business conduct almost always depends upon the market power of the participants.").

structure, then, cross elasticity of demand fails to serve as an indicator of "reasonable interchangeability of use," and is in fact devoid of much of its original economic significance.[157] The failure of this test to determine interchangeability, in turn, means that courts may fail to detect a product's legitimate competitors and consequent harm to competition when those competitors are prevented from competing. The problem of reliance on cross elasticity is further exacerbated when non-price competition exists, because such competition is not readily detectible by an examination of cross elasticity.

In light of antitrust doctrine's failure to adjust appropriately to the subtleties of the pharmaceutical market, a different approach is required. Two solutions are readily available: the first, which relies on existing doctrine, is to use medical rather than economic testimony to determine "reasonable interchangeability of use;" the second, though not based in doctrine, is to harmonize merger and monopolization market definition practices. Either approach would likely achieve more economically meaningful results, thereby restoring lost power to antitrust enforcement in the pharmaceutical industry. Which, if either, of these alternatives is ultimately adopted is up to the Agencies, courts, and other members of the antitrust bar, but this glitch in the antitrust system is significant enough, in its effects on both dollars and lives, that some reform is necessary.

Barring a change of heart on the part of pharmaceutical executives or the government's enforcement agenda, pharmaceuticals will likely remain a major focus of antitrust law. As a consequence of this continued significance, careful

[157] One could analogize relying on cross elasticity of demand as a metric for reasonable interchangeability of use to simultaneously stepping on the clutch and gas pedals of a car with a manual transmission and concluding that the transmission is incapable of transferring power to the wheels. By pressing the clutch, the driver creates a disconnect between the engine and the wheels, such that stepping on the gas turns the engine but not the wheels. Similarly, calculating cross elasticity of demand can be thought of as turning the engine, but because selection and payment are disconnected, calculating cross elasticity of demand does not produce the end result of determining interchangeability.

attention should be given to market definition methodology to ensure that markets are properly defined, and that doctrine is not blindly applied to novel circumstances without consideration of whether the doctrine remains appropriate. As Justice Fortas noted, using cross elasticity of demand to define markets is "in essence, an economic task put to the uses of the law,"[158] but it would hardly seem appropriate to perform an economic task without considering the economics of the market in which the task is being performed.

[158] United States v. Grinnell Corp., 384 U.S. 563, 587 (1966) (Fortas, J., dissenting).