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C ce i g
H.R. 971
The C i Pha ac Fai e Ac f 2007

Oc be 18, 2007

[4] *See* notes 32 and 33, *infra*, and accompanying text.

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Is the proposed exemption for pharmacies in H.R. 971 one of those rare instances in which the societal benefits from dispensing with antitrust rules and the normal competitive process exceed the costs? In the Federal Trade Commission's view, it is not. The bill would immunize price-fixing and boycotts to enforce fee and other contract demands, conduct that would otherwise amount to blatant antitrust violations. Experience teaches that such conduct can be expected to increase health care costs, both directly through higher fees paid to pharmacies, and less directly by collective obstruction of cost containment strategies of purchasers. These higher costs would fall on consumers, employers – both public and private – who purchase pharmaceuticals and other products on behalf of their employees, and government assistance programs.

In addition, although the stated purpose of H.R. 971 is "[to] ensure and foster continued patient safety and quality of care," the Commission believes that the proposed exemption would not further these goals. Indeed, antitrust immunity not only would grant competing sellers a powerful weapon to obstruct innovative arrangements for the delivery and financing of pharmaceuticals, but also would dull competitive pressures that drive pharmacies to improve quality and efficiency in order to compete more effectively. Moreover, nothing in the bill requires that the collective bargaining it authorizes be directed at improving patient safety or quality, rather than merely increasing pharmacies' revenues from payers.

Health care markets are complex and dynamic, and pharmacy is no exception. The Commission is mindful of the challenges and economic pressures faced by small pharmacies,

concerns about the quality of patient care. But the solution to the concerns raised by pharmacies is not to give them immunity from the antitrust rules that guide our economy. If Congress concludes that the difficulties facing small pharmacies require a legislative solution, then one tailored to the specific problem is called for, not a sweeping antitrust exemption that may bring with it greater harm.

I. FTC Experience with Prescription Drug Competition

Competition in prescription drug markets occurs in the context of a complex web of

[7] *See, e.g.*, *Actavis Group/Abrika Pharmaceuticals, Inc.*, C-4190 (consent order issued May 18, 2007) (http://www.ftc.gov/os/caselist/0710063/index.shtm); *Watson Pharmaceuticals Inc./Andrx Corp.*, C-4172 (consent order issued December 6, 2006) (http://www.ftc.gov/os/caselist/0610139/index.htm); *Schering-Plough Corp.*, 2003 FTC LEXIS

ensuing report on health care competition law and policy issued by the agencies in 2004.[12] In 2005, the Commission reported the findings of an in-depth empirical study of PBM ownership of mail order pharmacies,[13] and the staff is currently conducting a study regarding the competitive effects of branded drug firms' use of "authorized generics."[14]

II. The Proposed Exemption

H.R. 971 would grant "independent pharmacies" broad antitrust immunity to band together and negotiate collectively with health plans.[15] Under the proposed law, groups of independent pharmacies would be treated like a bargaining unit of a labor union operating pursuant to federal labor laws. As we discuss below, this proposed exemption from the antitrust laws, like previous proposed antitrust exemptions, would permit price fixing, coercive boycotts, and other anti-competitive conduct likely to result in significant harm to consumers. Otherwise competing pharmacies could agree on the prices and other terms they would accept from health plans, and collectively refuse to deal with plans that did not accede to their contract demands.

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[12] *See* Federal Trade Commission and Department of Justice, *Improving Health Care: a Dose of Competition*, Chapter 7 (July 2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[13] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005), *available at* http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[14] *See* 71 Fed. Reg. 16,779 (April 4, 2006); 72 Fed. Reg. 25,304 (May 4, 2007).

[15] An independent pharmacy covered by the bill is any pharmacy not owned or operated by a "publicly-traded company."

[16] Section 2 (e), entitled "Limitation on Exemption," states that the bill would not immunize any "agreement or otherwise unlawful conspiracy that excludes, limits the participation or reimbursement of, or otherwise limits the scope of services to be provided by any independent pharmacy . . . with respect to the performance of services that are within their scope

Antitrust law condemns such conduct because it harms competition and consumers – raising prices for health care services and health care insurance coverage, and reducing consumers' choices. Public and private programs that purchase or pay for pharmaceuticals for consumers are likely to have to pay more as a result of the anti-competitive conduct the bill would authorize, and those higher costs, in turn, could increase the costs or lessen the scope or availability of such programs for consumers.

H.R. 971 is modeled on a previous antitrust exemption bill that passed the House in 2000 and covered all health care professionals, including pharmacists. The Commission opposed that bill, as did the Department of Justice, the Antitrust Section of the American Bar Association, health care economists, employers, health plans, consumer groups, and even some health care providers. They did so on the grounds that the exemption would cause substantial harm to consumers, raising prices without any certainty of improved quality, and was not necessary to protect legitimate, pro-competitive cooperative arrangements. While H.R. 971 is limited to a single class of health care providers, it raises the same fundamental issues as the previous exemption bill. Moreover, if enacted, it would invite other health care providers to seek similar antitrust immunity.

Although styled as a labor exemption, the antitrust immunity that H.R. 971 would confer bears no relation to federal labor policy. The labor exemption is limited to the

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of practice as defined or permitted by relevant law or regulation." While it is unclear exactly what this provision is intended to carve out, it does not appear to limit pharmacies' immunity for boycotts of purchasers or payers in order to force price concessions.

employer-employee context; it does not protect combinations of independent business people.[17] H.R. 971, however, would override the distinction Congress drew in the labor laws between employees and independent contractors. Unlike the labor law system, H.R. 971 also lacks the exclusions from protected negotiations for subjects unrelated to the intended purpose of those laws, as well as the oversight of the process by the National Labor Relations Board.

[17] *See, e.g., Columbia River Packers Ass'n v. Hinton*, 315 U.S. 143 (1942); *United States v. Women's Sportswear Mfg. Ass'n*, 336 U.S. 460 (1949); *American Medical Ass'n v. United States*, 317 U.S. 519, 533-36 (1943) (rejecting assertions that the labor exemption to the antitrust laws applied to joint efforts by independent physicians and their professional associations to boycott an HMO in order to force it to cease operating). NLRA Section 2 (3) gives the right to bargain collectively only to "employees." The 1947 Taft-Hartley amendments to the NLRA included a provision expressly stating that the term "employee" does not include "any individual having the status of an independent contractor." 29 U.S.C. § 152 (3).

In sum, H.R. 971 is designed to confer the labor exemption on parties whose situations are vastly different from those eligible for the exemption under long-standing and well-established principles of labor law. Instead, it would merely grant private businesses a broad immunity to present a "united front" when negotiating price and other terms of dealing with health plans, without any efficiency benefits for consumers or any regulatory oversight to safeguard the public interest.

III. The E e i Li e Effec

The proposed exemption can be expected to increase health care costs. There should be little dispute that the collective negotiations authorized by H.R. 971 likely would result in health plans' paying more to pharmacies – indeed that has been the intended and actual effect of such conduct in the cases involving collective negotiation by competing pharmacies that the Commission previously has brought.

The Commission's experience indicates that the conduct that the proposed exemption would allow could impose significant costs on consumers, private and governmental purchasers, and taxpayers, who ultimately foot the bill for government-sponsored health care programs. Past antitrust challenges to collective negotiations by health care professionals show that groups have often sought fee increases of 20 percent or more.[18] For example, in 1998, an association of approximately 125 pharmacies in northern Puerto Rico settled FTC charges that the association

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[18] *See, e.g.*, *Asociacion de Farmacias Region de Arecibo*, 127 F.T.C. 266 (1999) (consent order) (22 percent higher); *Advocate Health Partners, et al.*, C-4184 (consent order issued Feb. 7, 2007) (20-30 percent higher); *Health Care Alliance of Laredo*, C-4158 (consent order issued March 23, 2006) (30 percent higher regarding one payer; 20-90 percent higher for another payer, depending on the particular procedure); *San Juan IPA, Inc.*, 139 F.T.C. 513 (2005) (consent order) (up to 60 percent higher), all available at http://www.ftc.gov/bc/healthcare/antitrust/commissionactions.htm.

including the Baltimore City employees' prescription-drug plan,[23] and a prescription drug

[23] *Baltimore Metropolitan Pharmaceutical Association, Inc. and Maryland Pharmacists Association*, 117 F.T.C. 95 (1994) (consent order).

[24] *Southeast Colorado Pharmacal Association*, 116 F.T.C. 51 (1993) (consent order).

[25] *See Improving Health Care, supra* note 12, at Chapter 7, p. 12.

[26] *See, e.g.*, discussion in Letter from FTC staff to Patrick C. Lynch, Attorney General, and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations (Apr. 8, 2004), at notes 10-12 and accompanying text, *available at* http://www.ftc.gov/os/2004/04/ribills.pdf.

make payments to, all of the pharmacies doing business in a program's service area.[27] Collective bargaining can undercut such competitive efficiencies. To the extent that public payers or the private market demand a certain number and distribution of pharmacies, a health plan or PBM must accede to higher collective fee demands or it will not have a pharmacy network to offer.[28] At the end of the day, unless a health plan can assemble a network of pharmacies willing to contract with the plan, and attractive to consumers and employers, the plan will have nothing to sell in the marketplace.

Increases in unit prices paid to pharmacies are not the only reason that drug costs may increase. The exemption would also permit boycotts by pharmacies to obstruct purchaser cost containment strategies. For example, PBMs typically use formularies to create price competition among drug manufacturers, and many use financial incentives to encourage patients with chronic conditions who require repeated refills of their medications to use lower cost mail order pharmacies. Such cost control programs have been shown to yield significant savings.[29] If some

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[27] *Id.*

[28] The Medicare Part D drug program, for example, requires that a Part D plan sponsor submit a network that includes enough pharmacies to provide potential beneficiaries with "convenient access" to at least one pharmacy. Requirements vary depending on whether beneficiaries are urban, suburban, or rural. In rural areas, at least 70 percent of beneficiaries in a program must be within 15 miles of a network pharmacy. *See* Access to Covered Part D Drugs, 42 C.F.R. § 423.120 (2005), *available at* http://a257.g.akamaitech.net/7/257/2422/09nov20051500/edocket.access.gpo.gov/cfr_2005/octqtr/pdf/42cfr423.120.pdf.

[29] For example, programs to encourage the use of mail-order provision of maintenance drugs alone can offer substantial savings. According to a Maryland report, greater use of mail-order maintenance drugs, as would be enabled by liberalizing Maryland insurance law, would save Maryland consumers 2-6%, and third-party carriers 5-10%, on retail drug purchases *overall*. *See* Md. Health Care Comm. and Md. Ins. Admin., *Mail-Order Purchase of Maintenance Drugs: Impact on Consumers, Payers, and Retail Pharmacies*, 2-3 (Dec. 23, 2005).

This is consistent with the FTC's PBM Study, which found that mail-order pharmacies typically are less expensive than retail pharmacies, even after controlling for prescription size and drug selection. *See supra* note 13 at 25. *See also* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* at 11 (Jan. 2003) ("GAO Report"), *available at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196

be expected to raise the price of the final product.[32] And, as noted above, past enforcement actions provide numerous examples in which health care professionals' collective demands for higher fees resulted in higher costs to government purchasers.

As a major purchaser of prescription drugs, the federal government could bear significant additional costs from conduct the bill would authorize. Although the bill contains an exclusion for certain federal programs from the bill, such as the State Children's Health Insurance Program (SCHIP), and the Federal Employees Health Benefits Program (FEHBP), it expressly includes the Medicare program. Moreover, the Congressional Budget Office evaluation of the 2000 bill to immunize collective bargaining by health care professionals determined that, despite carve-outs of certain federal programs, the legislation would nonetheless significantly increase direct spending for those programs because: (1) private plans administer government benefit programs and often do not separate private and federal programs in their provider contracts; (2) higher private compensation rates would increase the market price for services, which could affect the rates that plans serving federal programs would have to pay in order to secure providers; and

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[32] Health care researchers have found that, while health care costs and health insurance premiums do not necessarily increase at identical rates on a year-to-year basis, over time "the dominant influence on premiums is underlying costs" of health care products and services. Ginsberg & Gabel, "Tracking Health Care Costs: What's New in 1998," 17:5 Health Affairs 141, 145 (Sept./Oct. 1998). In its analysis of the 2000 bill immunizing collective negotiations by health care professionals, the Congressional Budget Office projected that price increases paid by private health plans would increase direct spending by federal programs. *See* Congressional Budget Office Cost Estimate on H.R. 1304, "Quality Health Care Coalition Act of 2000" (May 17, 2000) at 5-6, *available at* http://www.cbo.gov/showdoc.cfm?index=2047&sequence=0.

(3) negotiated relaxation of utilization controls would likely raise community standards for use of certain services, which plans serving federal programs would be pressured to meet.[33]

State and local governments could incur higher costs as well, both in drug benefits for their employees and in public assistance programs. As noted above, such plans have been the victims of coercive boycotts in the past. Absent antitrust enforcement, they are likely to face them again.

Finally, making prescription drug coverage more costly means some individuals may have to do without needed drugs. Fewer employers may offer health plans incorporating prescription drug coverage and some presently covered individuals may have to forgo certain prescription purchases. In those cases, patients would suffer and there could be increased use of hospital emergency rooms, further increasing overall costs for health care and exacerbating pressures on hospital emergency rooms and public assistance programs.

IV. N C e i g Need Ha Bee Sh f he E e i

The fundamental premise of those who seek antitrust immunity for collective negotiations by pharmacies is that health plans, and pharmacy benefits managers in particular, have superior bargaining power when contracting with independent pharmacies. An antitrust exemption, it is said by some, will "level the playing field" by enabling pharmacies to exercise countervailing power. According to proponents, allowing pharmacies to exercise leverage to obtain more favorable contracts will help ensure the survival of small pharmacies, and thereby promote high quality and accessible health care. This type of rationale just as easily could be applied to justify

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[33] *See* Congressional Budget Office Study, *supra* n. 32 at 5-6.

special treatment for a host of situations and participants throughout our economy, both within and outside the health care sector.

To begin with, much joint conduct by health care providers can benefit consumers, create efficiencies, and be pro-competitive, without running afoul of the antitrust laws. For example, joint ventures among pharmacists to provide medication counseling and disease management programs for patients with chronic illnesses such as asthma, diabetes, and heart disease have the potential to improve care and reduce overall costs. Commission staff has issued advisory opinions to groups of pharmacies that planned to develop such programs and jointly negotiate the fees for such services with third-party payers, finding that the antitrust laws presented no barrier to their proposed arrangements.[34] Similarly, independent pharmacies often participate in joint purchasing groups that allow them to lower costs and compete more effectively.[35] However, the proposed exemption would blunt incentives for pharmacies to undertake such lawful,

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[34] Letter to Paul E. Levenson regarding *Northeast Pharmacy Service Corporation* (July 27, 2000) (network of independent pharmacies in Massachusetts and Connecticut offering package of medication-related patient care services to physician groups) (http://www.ftc.gov/bc/adops/neletfi5.htm); Letter to John A. Cronin, Pharm. D., J.D. regarding *Orange Pharmacy Equitable Network* (May 19, 1999) (network of retail pharmacies and pharmacists offering drug product distribution and disease management services) (http://www.ftc.gov/bc/adops/openadop.htm); Letter to Allen Nichol, Pharm. D. regarding *New Jersey Pharmacists Association* (August 12, 1997) (pharmacist network offering health education and monitoring services to diabetes and asthma patients) (http://www.ftc.gov/os/1997/08/newjerad.htm).

[35] For example, the Independent Pharmacy Cooperative (IPC), which describes itself as "the nation's largest group purchasing organization for independent pharmacies," is a member-owned cooperative that has been in operation since 1984. IPC claims to represent 3200 primary and 2500 affiliate pharmacy members, whose annual purchases exceed $8 billion. *See* http://www.ipcrx.com/public/thecooperative.aspx. Another independent pharmacy purchasing cooperative, EPIC Pharmacies, Inc., was formed in 1982, and describes itself as "a not-for-profit buying group of hundreds of independently owned pharmacies across the country." *See* http://www.epicrx.com/about/index.aspx.

[36] Or "oligopsony," when it results from the combination of more than one buyer.

[37] *See* Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./AdvancePCS*, File No. 031 0239 (Feb, 11, 2004).

and has taken enforcement action where it found that the transaction was likely to lead to the exercise of market power in the purchase of physician services.[38]

It appears that the concerns of retail pharmacies center on inequalities in bargaining power, rather than actual buyer market power. But even if there were evidence that health plans or PBMs were able to exercise such power over pharmacies, the Commission believes that the solution is not to authorize private competitors to use countervailing power, especially in ways that are likely to hurt consumers. Antitrust enforcement is designed to attack market power problems when and where they arise, and protecting competition in the health care sector remains a major focus of the Commission.

Proponents of antitrust exemptions in health care sometimes claim that the McCarran-Ferguson Act gives insurance companies leverage in bargaining with health care professionals. This is simply not the case. Although that Act protects certain types of activities by insurers (to the extent that such activity is regulated by state law), it has been clear for nearly thirty years that McCarran-Ferguson provides no antitrust immunity for an insurance company's agreements with providers on what they will be paid.[39] Collusion among insurers regarding the terms of such agreements would not be protected from antitrust challenge.

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[38] *See, e,g., United States v. United Health Group, Inc., and Pacificare Health Systems, Inc.*, 2006 U.S. Dist. Lexis 45938 (D.D.C. 2006), *available at* http://www.usdoj.gov/atr/cases/unitedhealth.htm; *United States v. Aetna, Inc, and The Prudential Insurance Company of America*, 1999 U.S. Dist. Lexis 19691 (D. Tex. 1999), *available at* http://www.usdoj.gov/atr/cases/indx142.htm.

[39] *Group Life and Health Insurance Co. v. Royal Drug Co.*, 440 U.S. 205 (1979); *see also Union Labor Life Ins. Co. v. Pireno*, 458 U.S. 119 (1982).

Moreover, as for concerns about disparities in bargaining power in pharmacies' negotiations with health plans or PBMs, it is important to remember that PBMs may help keep pharmacy benefit programs affordable for consumers. It also bears emphasis that there are a variety of lawful ways – short of price fixing and coercive boycotts – that pharmacies can collectively express their concerns about both price and quality issues relating to managed drug benefit programs. In their joint *Statements of Antitrust Enforcement Policy in Health Care*, the antitrust agencies have expressly recognized the potential competitive benefits of joint action by health care professionals to provide information and views to health plans about such matters.[40] Nor does antitrust law prevent pharmacies from engaging in collective advocacy before legislatures and regulatory bodies, or presenting issues to the media and the public concerning reimbursement policies and procedures of third-party payers.[41]

Lawmakers are understandably concerned that some independent pharmacies may be unable to survive in the current environment, and especially about the prospect that some rural communities might be left without a local pharmacy. But these concerns do not justify a broad antitrust exemption that would apply to diverse businesses in markets throughout the country. "Independent pharmacies" under H.R. 971 include not just rural pharmacies, but urban and

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[40] *See* U.S. Department of Justice and the Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996) at Statements 4 and 5, 4 Trade Reg. Rep. (CCH) ¶ 13,153, *available at* http://www.ftc.gov/reports/hlth3s.pdf.

[41] For example, a 2003 FTC staff advisory opinion explains that the antitrust laws did not prevent physicians in Dayton, Ohio, from collecting and publicizing information about Dayton health care market conditions, including information about insurer payments, to educate the general public about the physicians' concerns about the reimbursement policies and procedures of third-party payers in Dayton. Letter from Jeffrey W. Brennan to Gregory G. Binford, (February 6, 2003), *available at* http://www.ftc.gov/bc/adops/030206dayton.shtm.

suburban ones, and not just single-store entities but multi-store chains, pharmacy franchises, and privately-owned supermarket pharmacies. To the extent that certain local concerns may warrant attention, targeted efforts to address particular issues in the distribution of pharmaceuticals and pharmacy services (perhaps looking to strategies used for medically under-served areas) may be a better way to address problems of access to prescription drugs, while avoiding the concerns that are raised by an antitrust exemption.

V. C c si

Antitrust enforcement in the health care sector has helped ensure that new and potentially more efficient ways of delivering and financing health care services can arise and compete in the market for acceptance by consumers. Although health care markets have changed dramatically over time, and continue to evolve, collective action by health care providers to obstruct new models for providing or paying for care, or to interfere with cost-conscious purchasing, remains a significant threat to consumers. The public is looking to policymakers to address widespread concerns about our health care system: high costs, uneven quality, and a large and increasing number of people who are uninsured. Giving health care providers – whether pharmacies, physicians, or others – a license to engage in price fixing and boycotts in order to extract higher payments from third-party payers would be a costly step backward, not forward, on the path to a better health care system.