

subsidies
providing
targeting
cost higher covered

LEVEL 2 - 1 OF 2 STORIES

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USA TODAY

September 30, 1999, Thursday, FINAL EDITION

SECTION: MONEY; Pg. 1B

LENGTH: 409 words

HEADLINE: **FTC targets deal to keep generic off shelf Drugmakers may face antitrust action for \$100M pact**

BYLINE: Jayne O'Donnell

BODY:

Federal antitrust enforcers plan to recommend an antitrust lawsuit against brand-name drugmaker Hoechst Marion Roussel and a generic firm because of a multimillion-dollar deal that may have kept a cheaper version of a popular heart drug off the market.

The **Federal Trade Commission's** expected lawsuit would target an agreement under which Andrx was to get \$ 100 million a year from Hoechst not to sell a generic version of Cardizem CD.

A generic drug can be sold before a brand-name drug's 20-year patent expires only if the generic firm can prove that the patent is invalid or that its drug doesn't violate the terms.

If a generic firm tries to sell a drug before a patent expires, the brand-name firm usually files a patent-infringement lawsuit. Such lawsuits are often settled with the brand-name firm allowing the generic firm to go to market if it agrees to pay royalties. However, after six months, any other company can sell the drug.

But if the brand-name company can keep the first generic out of the market until the patent expires, it locks all others out, too. Thus, the benefit of paying the generic firm to keep its drug off the market.

Hoechst had filed a patent-infringement lawsuit against Andrx, then agreed to the payment while the lawsuit dragged through court. Eventually, Hoechst dropped the lawsuit when Andrx reformulated its drug, which sells for \$ 5 to \$ 10 less a month than Cardizem CD.

Antitrust experts expected the **FTC** to close the investigation when Hoechst dropped its case. But lawyers involved in the probe say that the **FTC** wants to alert firms those deals violate antitrust law.

"You have potential or actual competitors buying each other off," says George Cary, a former top **FTC** litigator who represents Biovail,

File
Generic
Andrx



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USA TODAY, September 30, 1999

a generic firm suing Hoechst over the deal. "It's always profitable to share monopoly profits."

Spokesman Charles Rouse says Hoechst expected the investigation would be closed when it dropped its case. "There are other competitors in that arena now," he says. "We certainly don't believe there is any wrongdoing involved." Hoechst recently refused to sign an **FTC** consent decree admitting to antitrust violations.

] → ?

Andrx did not return a call seeking comment.

The **FTC's** Bureau of Competition is expected to recommend suing Hoechst and Andrx within weeks. The four **FTC** commissioners will have to approve the lawsuit before it is filed.

LANGUAGE: ENGLISH

LOAD-DATE: September 30, 1999



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LEVEL 2 - 2 OF 2 STORIES

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USA TODAY

September 30, 1999, Thursday, FINAL EDITION

SECTION: MONEY; Pg. 3B

LENGTH: 438 words

HEADLINE: **FTC** looks at deals by drugmakers **Patent**-related pacts may thwart cheaper generics

BYLINE: Jayne O'Donnell

BODY:

Federal antitrust enforcers are investigating at least four deals they think may be stealing some of the promise of cheap, widely available generic **drugs**.

- 4 deals

Along with Hoechst's agreement with generic drugmaker Andrx (story, 1B), the **Federal Trade Commission** is investigating two other patent-related deals between brand-name and generic drugmakers that involve popular medications, including the antidepressant Prozac.

The Justice Department also has been investigating a settlement involving a leading breast cancer **drug**, tamoxifen.

Government officials are concerned that some brand-name companies are paying off generic companies after suing them for **patent** infringement. "It's like getting run over by a car, suing the guy that hit you and then paying him and saying you settled the lawsuit," says antitrust lawyer George Cary of Cleary Gottlieb Steen & Hamilton in Washington.

Viren Mehta, a pharmaceutical industry analyst and adviser, says some of the deals are questionable: "There should be certain limits to a business' right to do everything legally possible to protect its franchise."

But others say the government is going too far in challenging settlements.

Former **FTC** lawyer Marc Schildkraut says it is asking too much to suggest drugmakers can't settle under these circumstances. Companies, he says, can't be expected to pay for lengthy trials to "vindicate the rights of all citizens."

Under investigation:

* Zeneca Pharmaceuticals' deal with Barr Laboratories involving the generic equivalent of the breast cancer **drug** tamoxifen. Zeneca



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settled a 1993 **patent**-infringement lawsuit against Barr by paying Barr \$ 21 million and giving it a nonexclusive deal to distribute a generic form of tamoxifen manufactured by Zeneca. Barr now makes about \$ 30 million a year from the deal. The Justice Department is not expected to bring a case, but the probe remains open.

* Abbott Laboratories' deals with generic firms Ivax and Geneva Pharmaceuticals involving the blood pressure medication Hytrin.

To settle **patent** litigation, Abbott agreed to pay \$ 24 million a year to Ivax and an undisclosed sum to Geneva until the first generic went to market.

* Eli Lilly's agreement with Sepracor involving an antidepressant similar to Lilly's Prozac.

Eli Lilly gave Sepracor a \$ 20 million contract and up to \$ 70 million in cash to develop a purified form of Prozac patented by Sepracor.

Critics say the deal lets Eli Lilly extend its **patent**, which runs out in 2004, for 15 years. But Eli Lilly says R-flooxetine is different chemically.

GRAPHIC: PHOTO, B/W, USA TODAY; Under the microscope: An Eli Lilly-Sepracor deal involving the antidepressant Prozac is being investigated.

LANGUAGE: ENGLISH

LOAD-DATE: September 30, 1999



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**OFFICE OF CONGRESSIONAL AFFAIRS**

Bureau of the Census
U. S. Department of Commerce
Washington, D C 20233

Telecopier Cover Sheet

DATE: 10.25.99

FROM: Robin Bachman

Telecopier
301-457-3679

Telephone
301-457-2123

TO: Sarah Bianchi

456.5557

No. of pages attached:

4

California.....	2,779	166	30.0	1.53
Colorado.....	156	34	15.6	3.13
Connecticut.....	130	32	15.8	3.58
Delaware.....	52	10	24.5	3.91
District of Columbia..	53	8	52.6	5.65
Florida.....	901	83	28.1	2.21
Georgia.....	655	85	32.0	3.45
Hawaii.....	59	13	18.8	3.70
Idaho.....	113	16	28.8	3.37
Illinois.....	649	72	18.4	1.85
Indiana.....	227	50	15.0	3.05
Iowa.....	156	30	21.4	3.61
Kansas.....	132	26	18.7	3.35
Kentucky.....	245	42	26.0	3.88
Louisiana.....	397	55	34.7	3.88
Maine.....	66	14	21.2	3.98
Maryland.....	127	37	10.8	3.01
Massachusetts.....	295	44	20.0	2.65
Michigan.....	617	67	21.4	2.09
Minnesota.....	235	46	16.9	2.99
Mississippi.....	223	34	29.1	3.72
Missouri.....	295	57	21.4	3.65
Montana.....	72	11	27.2	3.46
Nebraska.....	100	18	20.0	3.27
Nevada.....	101	19	19.0	3.18
New Hampshire.....	77	15	22.5	3.95
New Jersey.....	357	48	17.7	2.17
New Mexico.....	179	24	31.8	3.51
New York.....	1,416	99	29.6	1.76
North Carolina.....	470	59	25.9	2.82
North Dakota.....	49	8	27.0	3.72
Ohio.....	628	71	21.4	2.17
Oklahoma.....	189	33	23.4	3.60
Oregon.....	242	41	27.8	3.98
Pennsylvania.....	627	69	21.4	2.10
Rhode Island.....	55	12	23.7	4.32
South Carolina.....	214	42	21.5	3.70

Table 25. Poverty Status by State and Ten Large Metropolitan Areas in 1998
(Numbers in thousands)

4

	Below 125 Percent of Poverty			
	Number below 125%		Percent below 125%	
	Value	Standard Error	Value	Standard Error
South Dakota.....	30	6	15.9	3.10
Tennessee.....	324	59	22.3	3.58
Texas.....	1,593	123	28.1	1.86
Utah.....	121	20	18.1	2.75
Vermont.....	25	6	16.9	3.70
Virginia.....	205	49	12.4	2.79
Washington.....	233	52	15.5	3.20
West Virginia.....	119	19	34.1	4.49
Wisconsin.....	212	46	16.6	3.26
Wyoming.....	27	5	21.0	3.51

AREA

New York-Northern				
New Jersey-Long				
Island CMSA.....	1,398	95	26.5	1.56
Central Cities.....	987	80	42.2	2.62
Los Angeles-				
Anaheim-Riverside				
CMSA.....	1,374	94	30.2	1.74
Central Cities.....	648	65	41.0	3.17
Chicago-Gary-Lake				
County CMSA.....	453	59	19.0	2.24
Central Cities.....	285	47	32.3	4.39
San Francisco-				

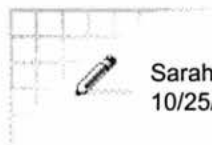
Oakland-San Jose				
CMSA.....	172	41	10.1	2.29
Central Cities.....	77	28	33.7	9.83
Philadelphia-				
Wilmington-Trenton				
CMSA.....	241	43	15.4	2.50
Central Cities.....	138	32	21.7	4.48
Detroit-Ann				
Arbor CMSA.....	379	53	23.7	2.89
Central Cities.....	268	44	53.9	6.06
Boston-Lawrence-				
Salem CMSA.....	259	41	18.4	2.62
Central Cities.....	170	33	39.5	5.99
Houston-Galveston-				
Brazoria CMSA.....	404	62	23.8	3.18
Central Cities.....	270	50	53.3	6.82
Dallas-Fort Worth				
CMSA.....	332	56	21.2	3.18
Central Cities.....	233	47	33.2	5.46
Washington DC-MD-				
VA MSA.....	297	57	21.7	3.68
Central Cities.....	213	48	34.4	6.30

Source: U.S. Census Bureau

Contact: (hhes-info@census.gov) Housing and Household Economic Statistics Information Staff

Last revised: October 13, 1999

URL: http://ferret.bls.census.gov/macro/031999/pov/new25_003.htm



Sarah A. Bianchi
10/25/99 05:39:53 PM

Record Type: Non-Record

To: Sarah A. Bianchi/OVP@OVP

cc:

Subject: generic

Press accounts recommending action in the conduct anti-trust violation -- paralell private cases in anti-trust law suits -- attorney

There is nothing -- was in USA Today WSJ -- sometime in the last month

Private class actions anti-trust cases similar conduct -- that Hatch Waxman -- companies can get patents -- if a generic entrant come to the market before law allows the name brand on patent -infringements - can still conduct infringement - nogenerated come on into the law settlement litigation needs to be settlement -- challenge to the patent -- while is that generic the name brand settlement claims quirk in the law Hatch Waxman -- anti-trust - typically legal public policy anti-trust laws in the law violation courts - potentially pretext valid anti-competitive the name brand is generics to get enter into the settlements. -- generic --

say that you would change the law does allow for any other generic during the times - bought off. Suing another generic competitive -- They can't brand name A and brand name B --

Private cases -- sure of the

Democratic Stark and Waxman -- did have to the interest. At the end of the Congress revisit Hatch-Waxman -- one hearing 1984 --

call more your staff -- 326 2172

sb

Tuesday, November 9, 1999

Health News Daily

2

prescription drug benefit to the Medicare program would cost an additional \$10 bil. per year. ♦♦

Gore Would Seek To Prevent Patent Extensions As Riders To Larger Bills

Presidential candidate Al Gore says he would work to enact legislation to increase generic drug competition and prevent brand-name manufacturers from gaining "unwarranted" patent extensions.

Vice President Gore appeared at a Washington, D.C. independent pharmacy Nov. 8 to discuss steps he would take to lower drug costs, re-establishing the issue as a primary focus of the Gore 2000 campaign.

If elected president, Gore said, he will work with Congress to ensure that proposals to extend prescription drug patents must pass as stand-alone legislation, not as riders attached to larger, unrelated legislative vehicles.

"Today, many patent extensions are attached to larger pieces of legislation in the middle of the night through special interest," Gore campaign literature states. The candidate "believes that patent extensions should be granted only after full consideration by Congress as stand alone legislation."

Gore's statements preceded Senate Judiciary Committee debate scheduled for Nov. 9 on Sen. Robert Toricelli's (D-N.J.) "Drug Patent Term Restoration Review Procedures Act."

The committee agreed to mark up the bill after the New Jersey Democrat attempted to attach the legislation to an unrelated piece of legislation considered by the committee Nov. 4. The Toricelli bill would extend the patent life of Schering-Plough's **Claritin** antihistamine and other "pipeline" drugs.

At the Nov. 8 event, Gore emphasized his role as a co-sponsor of the Waxman/Hatch "Drug Price Competition and Patent Term Restoration Act of 1984" as proof of his commitment to faster approval for generic drugs.

The VP also said that as president, he would work to enact legislation that would require all proposed patent extensions to undergo independent analysis of the cost implications to

Medicaid and veterans' health programs. "Before granting such exceptions, Congress should assess the real costs to the American taxpayer," a campaign statement says.

Gore suggested that he would enforce laws preventing collusion between brand and generic drug makers, and would direct the Federal Trade Commission to review those laws "to determine if they have sufficient authority and information to prevent colluding that stops quality generic drugs from entering the market."

Use of FDA citizen petitions as a method to delay generic entry was also discouraged by Gore, who cited an HHS Inspector General report showing the agency has a backlog of petitions slowing down the generic approval process. ♦♦

About 75% Of Health Insurance Executives Say Internet Will Alter Customer Relations

Only 6% of health insurance executives believe that their company and their industry make strategic use of the Internet and other information technology systems, according to Russell Ricci, MD, IBM Global Health Care Industry group manager.

Speaking at the Health Insurance Association of America annual forum in New Orleans, Ricci said that most respondents agreed that IT is currently used in a "supportive" rather than strategic capacity, such as reducing administrative costs.

Ricci noted that the poll showed large gaps between the industry's current IT practices and its future expectations; 80% of executives surveyed acknowledged that the Internet will have a significant impact on their business in the next three to five years.

The poll of industry executives on the future of e-commerce in health care was sponsored by HIAA, IBM, Harvard University and the Gartner Group. Ricci said a written survey was followed up by telephone interviews with executives.

About 75% of respondents believe that the Internet will "fundamentally alter their relationship with their members" in three to five years. However, Ricci noted, 45% of industry execs said that they would not allow members

Visit to Center Pharmacy

Center Pharmacy

12:45 p.m. – 1:15 p.m., Monday, November 8, 1999

Briefing prepared by Sarah Bianchi and Dan Taylor.

EVENT

You are visiting the Center Pharmacy, a local family owned and operated pharmacy, to hear firsthand about the prescription drug needs of seniors and others.

Role and Contribution: This is an opportunity to talk about the steps **You** would take as President to help assure that Americans have access to lower-priced, generic drugs and underscore the need for Medicare coverage of prescription drugs. The four steps **You** would take to ensure access to generic drugs are:

1. enacting legislation that requires all proposed patent extensions to include an independent analysis of the cost implications for consumers and for taxpayers due to increased costs to Medicaid and veterans programs;
2. working with Congress to assure patent extensions be considered as free-standing bills;
3. enforcing and review laws that prevent collusion; and
4. enacting legislation to discourage brand-name firms from using the citizen petition process as a means to maintain their competitive advantage.

This event is **POLITICAL**.

Your conversation with pharmacists and others and remarks are **OPEN PRESS**.

LOGISTICS

- Upon arrival, **You** are greeted by Dr. Harold Kramm, owner and proprietor of Center Pharmacy.
- **You** walk down an aisle with Dr. Kramm to a group of pharmacy staff, a senior, and a seniors' organization representative. *Note: Information about the senior and seniors' organization will be provided.*
- **You** talk about affordability of prescription drugs with the group of five people.

- Without introduction, you make remarks to the press, who will be observing. *Note: Because of the room's small size, you will not use a microphone for this event.*
- **You** thank participants and depart.

PROGRAM NOTES

Policy background.

Today, you will:

Outline New Steps to Help Assure Generic Drugs Are Available to Consumers. You announced four principles to ensure that Americans have the benefits of lower priced generic drugs. As President, **You** will oppose all unwarranted patent extensions. He would:

1. **Enact legislation that requires all proposed patent extensions to include an independent analysis of the cost implications for consumers and for taxpayers due to increased costs to Medicaid and veterans programs.** Today, when unfair patent extensions are granted, consumers pay the difference in higher drug prices. Before granting such exceptions, Congress should assess the real costs to the American taxpayer.
2. **Work with Congress to assure patent extensions be considered as free-standing bills.** Today, many patent extensions are attached to larger pieces of legislation in the middle of the night through special interests. **You** believes that patent extension should be granted only after full consideration by Congress as stand alone legislation.
3. **Enforce and review laws that prevent collusion.** In cases where collusion results in artificially high prices for drugs, Al Gore will seek to these types of back door deal making. Brand-name companies should not be able to collude with potential generic competitors to prevent generic competition after their patent expires. As President, Al Gore would direct the Federal Trade Commission to do a comprehensive review of current laws to determine if they have sufficient authority and information to prevent colluding that stop quality generic drugs from entering the market.
4. **Enact legislation to discourage brand-name firms from using the citizen petition process as a means to maintain their competitive advantage.** The Inspector General Report states the FDA has a backlog of hundreds of petitions, many of which are instigated by lawyers for brand-name drug companies. To prevent brand-name companies from abusing administrative processes to delay the introduction of high quality generic drugs, Al Gore

would propose legislation to ensure that the petition process does not delay the approval of a generic application unless the petitioner can establish clear scientific evidence that its proposed changes are necessary to ensure patient safety.

Underscore the Need for Medicare Coverage of Prescription Drugs. About 85 percent of Medicare beneficiaries fill at least one prescription a year for such conditions as osteoporosis, hypertension, myocardial infarction (heart attacks), diabetes, and depression. However, two-third of Medicare beneficiaries have unstable or inadequate prescription drug coverage. Many have no coverage at all and those in managed care plans are seeing less benefits at higher out of pocket costs. Al Gore believes that we must have a prescription drug benefit for Medicare beneficiaries to help older Americans and people with disabilities pay for their medications. Gore supports a new prescription drug benefit that is available to all beneficiaries up to \$5,000 per year in spending. The proposal also eliminates cost-sharing for the drug benefit for beneficiaries below 150 percent of poverty.

Criticize Pharmaceutical Ads on Flo citing a Real "Flo" with Real Concerns. For the past few months the pharmaceutical industry has been running a blitz of ads with a leading character "Flo" a fictitious woman who is concerned about the new proposals on prescription drugs in Washington means the government might take over her drugs. Flo's motto is: "I don't want big government in my medicine cabinet." The industry fears that that the Administration's plan could lead to price controls and that it could cause millions of seniors who currently purchase a drug benefit to lose them. Al Gore has met a real "Flo" with real concerns -- Florence Seitz from New Hampshire is an 88 year old woman who cuts her prescription drugs in half because she cannot afford them. As President Al Gore would listen to the real Flo of New Hampshire not one made up by special interests and fight for Medicare coverage of prescription drugs.

Background

- **You Have Made Increased Access, Affordability, and a Faster Approval Process for Generic Drugs as Priority Throughout His Career.** You were at the forefront of the battle for the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). This landmark law has made it easier and less costly for manufacturers to enter the market for generic drugs. The pharmaceutical market has become more competitive since the early 1980s, in part, because of the dramatic growth of the generic drug industry.
- **Generic Drugs Save Consumers Billions of Dollars.** According to the Congressional Budget Office, by substituting generic for brand-name drugs, purchasers saved at least \$8 billion to \$10 billion each year (at retail prices). CBO also estimates that quality generic drugs are between 25 percent and 50 percent lower than brand-name drugs. You understand the importance of patent protections to develop innovation and new treatments and medications. You also worked for FDA reform and through reinvention efforts he has helped bring drugs to the market faster while maintaining quality. You

believe that we should assure, when appropriate, consumers have access to quality generic drugs.

- **More Progress Needs To Be Made to Assure Affordable Prescription Drugs Are Available.** Despite the progress that has been made, too often generics are unnecessarily kept out of the market place leaving consumers with higher prescription drug bills. The current system is often gamed by the brand-name companies to ensure higher profits. They use their influence to pass legislation in the dark of night, lobby states to ensure they don't cover generics in their Medicaid programs, and tie up administrative review processes such as citizen petitions for months and even years. These delaying strategies cost consumers billions of dollars. A University of Minnesota study released just this year shows that current patent extension legislation for an extremely limited number of drugs being considered by Congress would itself cost consumers over \$11 billion between 2002 and 2012. According to a 1998 HHS Inspector General Report, "citizens' petitions ... and lawsuits are simply ploys to delay the marketing of safe and generic drugs that can save our citizens substantial money and health care costs."

Event Details:

- **Center Pharmacy.** Dr. Harold Kramm and his wife, Judy, have run Center Pharmacy in Northwest Washington for thirty-five years. The Kramms' son, Andy, also helps the pharmacy, which has about eight staff members, with public affairs and other issues. Their pharmacy fills about 200 prescriptions each day.

PARTICIPANTS

- *Information about the senior and seniors' organization representative will be provided tomorrow.*

ATTACHMENTS

- Your remarks
- 

**NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION**

(Formerly NARD)

205 Daingerfield Road

Alexandria, VA 22314

Date: November 5, 1999

Pages including cover sheet: 2

TO: Shazia B.

Phone:

Fax: (703) 356-5557

FROM: *John M. Rector, Sr. VP
Government Affairs and
General Counsel
NCPA (formerly NARD)*

Phone: (703) 683-8200

Fax: (703) 683-3619

If you have not received all pages, please contact
Shazia Noreen at (703) 838-2695

REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please Comment

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Thank You.

Brand vs. Generic Pricing

Product name (generic)	Brand Price	Generic Price
Xanax 0.5mg (Alprazolam)	\$86.12	\$12.50
Proventil inhaler (1 unit) (Albuterol inh)	\$27.75	\$12.71
Tenormin 50mg (Atenolol)	\$100.59	\$9.92
Tegretol 200mg (Carbamazepine)	\$42.73	\$16.09
Klonopin 1mg (Clonazepam)	\$77.96	\$42.36
Tylenol #3 (Acetaminophen with codeine)	\$34.60	\$10.49
Keflex Capsules 500mg #40 (Cephalexin)	\$121.71	\$12.78

NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION

(Formerly NARD)

205 Daingerfield Road
Alexandria, VA 22314

Date: November 5, 1999

Pages including cover sheet: 2

TO: Juruba B.

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NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION
(Formerly NARD)
205 Daingerfield Road
Alexandria, VA 22314

Date: November 5, 1999

Pages including cover sheet: 2

TO: Suzanne B.

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FROM: *John M. Rector, Sr. VP
Government Affairs and
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If you have not received all pages, please contact
Shazia Noreen at (703) 838-2695

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