

# Withdrawal/Redaction Sheet

## Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Tom Loranger to Chris Jennings re: Biden Amendment (3 pages)	9/24/96	P6/b(6)

### COLLECTION:

Clinton Presidential Records  
Domestic Policy Council  
Chris Jennings (Subject File)  
OA/Box Number: 23752 Box 9

### FOLDER TITLE:

Food and Drug Administration Modernization [8]

gf18

### RESTRICTION CODES

#### Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

#### Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

**Note to Chris**

This provision was inserted in the insurance reform bill by Trent Lott as a special favor for American Home Products. It provides for a 2-year patent extension for Lodine, an anti-inflammatory drug they manufacture. This is the second patent extension for Lodine (it was extended 3 years by GATT).

It would appear (we are double checking) that this extension will have the effect of making a slight bit of money for Medicaid through the rebate program. This will presumably be more than made up by AHP in the prices they charge their private pay customers, such as Medicare beneficiaries. The extension will also have the effect of delaying introduction of generic substitutes in the market. FDA is prohibited from saying whether or how many applications may be pending for generic licenses.

Dingell and Stark are at Rules now making a fuss about this provision. I have not called around to see whether anyone in the Senate is exercised about it because I don't want to create any waves before checking with you. Please call on my beeper 668-7317. Thanks.

KP

F:\EGG\HCR96\CONF\TITLE2.001

1 (B) A seller or issuer of a health insurance policy may  
2 substitute, for the disclosure statement described in clause (vii)  
3 of such section, the statement specified under section  
4 1882(d)(3)(D) of the Social Security Act (as in effect before  
5 the date of the enactment of this Act), without the revision  
6 specified in such clause.

### 7 Subtitle H—Patent Extension

#### 8 SEC. 281. PATENT EXTENSION.

9 (a) IN GENERAL.—Any owner on the date of the enact-  
10 ment of this Act of the right to market a non-steroidal anti-  
11 inflammatory drug that—

12 (1) contains a patented active agent,

13 (2) has been reviewed by the Federal Food and Drug  
14 Administration for a period of more than 96 months as a  
15 new drug application, and

16 (3) was approved as safe and effective by the Federal  
17 Food and Drug Administration on January 31, 1991,  
18 shall be entitled, for the 2-year period beginning on February  
19 28, 1997, to exclude others from making, using, offering for  
20 sale, selling, or importing into the United States such active  
21 agent, in accordance with section 154(a)(1) of title 35, United  
22 States Code.

23 (b) INFRINGEMENT.—Section 271 of title 35, United  
24 States Code, shall apply to the infringement of the entitlement  
25 provided under subsection (a) to the same extent as such sec-  
26 tion applies to infringement of a patent.

27 (c) NOTIFICATION.—Not later than 30 days after the date  
28 of the enactment of this Act, any owner granted an entitlement  
29 under subsection (a) shall notify the Commissioner of Patents  
30 and Trademarks and the Secretary for Health and Human  
31 Services of such entitlement. Not later than 7 days after the  
32 receipt of such notice, the Commissioner and the Secretary  
33 shall publish an appropriate notice of the receipt of such notice.

34 (d) OFFSET.—An owner described in subsection (a) shall  
35 pay the amount of \$10,000,000 to the Secretary of Health and  
36 Human Services in each of the fiscal years 1997 and 1998 as

LODINE"  
ETODOLAC

*Handwritten notes:*  
A  
Proton  
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Agent?

1.90-8425

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1 a condition for being eligible to qualify for the entitlement  
2 under subsection (a). As a further condition for eligibility, such  
3 owner shall enter into a legally binding agreement with the Sec-  
4 retary of Health and Human Services which shall provide a  
5 means for ensuring that the entitlement under subsection (a)  
6 shall not create any net costs to the States under the medicaid  
7 program under title XIX of the Social Security Act.

DAVID PRYOR  
ARKANSAS

RUSSELL SENATE OFFICE BUILDING  
WASHINGTON, DC 20510  
(202) 224-2352

ARKANSAS OFFICE:  
3030 FEDERAL BUILDING  
LITTLE ROCK, AR 72201  
(501) 324-6336

## United States Senate

WASHINGTON, DC 20510-0402

September 25, 1996

COMMITTEES:  
AGRICULTURE, NUTRITION, AND  
FORESTRY  
FINANCE  
GOVERNMENTAL AFFAIRS  
SPECIAL COMMITTEE ON AGING

The Honorable Donna Shalala  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Shalala:

I am writing to express concern over congressional efforts to overturn a key Federal Court of Appeals decision and grant private relief to a handful of prescription drug companies. If these last-minute efforts are successful, a few companies will receive patent protection which is unjustified as a matter of law and unfair to American consumers as a matter of policy. It is my hope that your Department and the Administration will continue to oppose any attempts to include such patent provisions in a FY 1997 continuing resolution or omnibus appropriations bill.

Earlier this year, an amendment was offered to the Defense Authorization bill which called for reversing the Federal Court of Appeals ruling in Merck v. Kessler. The amendment provided a few drug manufactures with the "win-win" outcome of receiving patent extensions under the GATT agreement in addition to extensions granted under the 1994 Waxman-Hatch amendments. As you know, such an outcome was strongly opposed by the Patent and Trademark Office (PTO) and the Food and Drug Administration (FDA) during the Federal court's deliberations.

It is this amendment which reportedly is now being endorsed by the prescription drug industry for inclusion in FY 1997 appropriation measures. My concern is that the provision would guarantee that consumers would wait up to three additional years for generic equivalents to as many as 20 best-selling brand drugs. There is currently no estimate of the potential costs to the public, HMOs, state Medicaid programs, and other drug purchasers - but it is certain to reach hundreds of millions of dollars.

In light of separate efforts to include patent extensions for the drugs Lodine, Relafen, and Claritin into the final legislative business of the 104th Congress, I urge you to oppose this and all other special-interest measures relating to pharmaceutical patents. If you have any questions, please contact Kenneth Cohen of my Aging Committee staff at 224-6018.

Sincerely,



David Pryor

cc: The Honorable Thomas Daschle  
The Honorable Trent Lott



# United States Senate Special Committee on Aging

Senator David Pryor, Ranking Member

628 Hart Senate Office Building, Washington, D.C. 20510  
Phone (202) 224-1467 ~ Fax (202) 224-9926

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FROM:	Paul Kim
TO:	Chris Jennings White House
FAX:	202 456 7431
DATE:	Thursday, August 1, 1996
PAGES (INCL. COVER):	6

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Chris,

Here's the lowdown on the Lodine patent extension. Attached is a letter from our boss and Senator Chafee, and below are our reasons for opposing the patent extension:

1. It costs \$10 million, which should be spend on agriculture programs. The States and consumers would bear this expense directly.
2. Lodine has *already received a 2 year patent extension* under the 1984 Waxman-Hatch amendments. Congress specifically passed the 1984 law to preempt special case-by-case reviews of patent term extensions like this. The 1984 law automatically extends drug patent to compensate for any regulatory delays at FDA. In fact, *the original Lodine patent expired in 1995* -- Lodine is currently protected by a *Waxman-Hatch extension* which runs until February 1997.
3. In 1993, the GAO issued a report *specifically about the Lodine patent*. GAO concluded that *there was no basis for recommending a patent term extension*. Lodine's approval was delayed for public health reasons:
  - (1) it is a "me-too" drug which provided no significant public health benefit or therapeutic breakthrough, which would justify expedited review (such as AIDS or cancer drugs);
  - (2) concerns about Lodine's carcinogenicity were raised both in Canada and the United States, which had to be resolved before the drug could be approved;
  - (3) FDA found that the Lodine submission was "piecemeal, voluminous, disorganized and based on flawed clinical studies."
  - (4) The Lodine submission to FDA did not contain "enough data to prove efficacy until September 1989" -- *almost seven years after the submission was made to FDA.*

4. No hearings or deliberations of any kind have been held in either the House or Senate on whether any public purpose is served by granting this extension.
5. If the Lodine extension is approved, it will create an untenable precedent by overturning the Congressional intent expressed in the carefully crafted 1984 Waxman-Hatch compromise. Moreover, the extension would further encourage manufacturers -- who already benefit from a statute which has successfully address their concerns for 12 years -- to bypass committees of jurisdiction in seeking unjustified relief. *The fact that Schering Plough is already seeking a patent extension for Claritin is proof that this will lead to a cascade of additional, unwarranted patent extensions.*
5. In a July 23 letter, Congressmen Bliley and Dingell, chairman and ranking member of the House Commerce Committee, stated that the Lodine extension (as part of a package of patent modifications before the House) "has not had the benefit of full Commerce Committee consideration or adequate hearings."
6. An extension of the Lodine patent term would also overturn the constitutionally-based "reasonable investment-backed expectations" of generic companies who invested significant time and money to secure FDA approval of generic versions of Lodine, based on the current date of patent expiration.
7. With respect to unfunded mandates, as you know, Medicaid recipients are entitled to coverage by the States for covered, medically necessary services, including prescription drugs. States then receive matching funds from the Federal government, which are calculated by a formula which accounts for States' per capita income.

Medicaid is *the* largest outpatient prescription drug program in the United States. Annual Medicaid drug expenditures exceed \$7 billion and States rely heavily on rebates (discounts) gathered by the Federal government to subsidize their Medicaid programs and, in some cases, State budgets.

Lodine is a member of a class of drugs called non-steroidal anti-inflammatory drugs (NSAID). These are anti-inflammatory painkillers like ibuprofen. Lodine was a "me-too" drug which came onto the market after a large number of comparable drugs were already available. In 1995, Lodine had sales of \$274.4 million -- *more than a quarter of a billion dollars.*

Under Medicaid, the States would be forced to pay directly "out of pocket" for a more expensive drug for an additional two years. Generic versions of Lodine are ready to go to market at 30 to 50 percent less. If these generic are blocked from market by a patent extension, the difference will be paid for by consumers and taxpayers subsidizing Medicaid, Veterans and Defense health programs, community health centers and other Federal health programs.

# United States Senate

WASHINGTON, DC 20510

July 26, 1996

Senator Thad Cochran  
Senator Dale Bumpers  
Senate Appropriations Subcommittee  
on Agriculture, Rural Development  
and Related Agencies

Dear Senators Cochran and Bumpers:

We are writing to express our concerns about section 731 of the House version of H.R. 3603, the Agriculture, Food and Drug Administration and Related Agencies appropriations bill for Fiscal Year 1997. This provision would grant a 2-year patent extension for a prescription drug called Lodine.

First, we would note that no hearings or deliberations of any kind have been held in either the House or Senate as to whether any public purpose would be served by granting this extension.

Second, we understand the manufacturer of Lodine has already received the maximum patent term extension to which it is entitled under the 1984 Hatch-Waxman amendments, which allowed drug manufacturers to receive patent term extensions to compensate for regulatory delays. Congress approved Hatch-Waxman expressly to preempt special case-by-case reviews of patent term extensions. Therefore, this provision would create a poor precedent by overturning congressional intent and by encouraging manufacturers to bypass committees of jurisdiction in seeking unjustified relief.

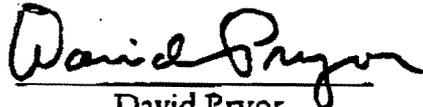
Third, an extension of the Lodine patent would appear to undermine the constitutionally-based "reasonable investment-backed expectations" of generic companies who invested significant time and money to secure FDA approval of generic versions of Lodine based on the current date of patent expiration.

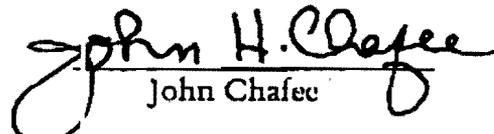
Finally, according to the Congressional Budget Office, the Lodine patent extension will cost the Federal government and taxpayers \$10 million. These resources would be far better applied to urgent needs under the subcommittee's jurisdiction.

We understand that others also have raised concerns about Senate action on this provision, including the leadership of the House Commerce Committee.

Because of these serious concerns, we urge you to exclude this provision from the conference agreement on the Agriculture Appropriations bill.

Sincerely,

  
David Pryor

  
John Chafee

07/26/96 16:51

002/002

# GDEC Generic Drug Equity Coalition

P.O. Box 27911  
Washington, DC 20006  
202 842-1656  
FAX: 202 408-1134

July 26, 1996

Chair  
James P. Firman, Ed.D.  
President  
National Council on the Aging

National Council on the Aging  
Gray Panthers  
National Consumers League  
United Seniors Health Cooperative  
U.S. PIRG  
American College of Nurse-Midwives  
Pasequid  
National Pharmaceutical Alliance,  
Manufacturers Division  
Consumers for Quality Care  
Newpharm  
Geneva Pharmaceuticals  
MOVA Laboratories  
People's Medical Society  
National Association of  
Pharmaceutical Manufacturers  
Roya Laboratories  
Public Citizen  
National Women's Health Network  
Citizens Advocacy Center  
United Homeowners Association  
Center For Health Care Rights  
Mylan  
National Council of Senior Citizens  
National Black Women's Health Project  
National Committee to Preserve  
Social Security and Medicare  
Generic Pharmaceutical  
Industry Association

The Honorable Thad Cochran, Chairman  
The Honorable Dale Bumpers, Ranking Member  
Subcommittee on Agriculture, Rural  
Development and Related Agencies  
Washington, D.C. 20510

Dear Senators Cochran and Bumpers:

The Generic Drug Equity Coalition urges you to oppose in conference Section 732 of the House-passed agriculture appropriations bill. Section 732 would grant a two-year patent extension to the anti-inflammatory, pain killing drug Lodine manufactured by Wyeth-Ayerst.

Wyeth-Ayerst has already received patent term restoration for Lodine under the Hatch-Waxman Act of 1984 which balances the interests of innovator companies, generic manufacturers and consumers. Section 732 provides two additional years of monopoly sales with no corresponding benefit whatsoever to consumers, taxpayers or generic drug manufacturers.

The Congressional Budget Office estimates that Section 732 of the House bill will cost taxpayers \$10 million.

Consumers and seniors will pay tens of millions more than they should as Wyeth-Ayerst enjoys hundreds of millions in monopoly sales over the two year patent extension period.

Please oppose Section 732 of the House bill.

Sincerely,

  
James P. Firman, Ed.D.  
Chair

cc: Members, Subcommittee on Agriculture, Rural  
Development and Related Agencies

1993 F-D-C Reports / The Pink Sheet 1993; 55(22): 5-6 / May 31, 1993 / WYETH-AYERST'S 97-MONTH LODINE NDA REVIEW ATTRIBUTED BY GAO REPORT TO INCREASE IN AVERAGE FDA NSAID REVIEW TIMES, DIFFICULT DATA, FALSE CARCINOGENICITY SCARE

FDA's 97-month premarket review of Wyeth-Ayerst's Lodine NDA is attributed to an increase in the average time required by the agency to review nonsteroidal anti-inflammatory drugs (NSAIDs), the difficulty of reviewing data on Lodine (etodolac) and a carcinogenicity concern that ultimately proved groundless, the General Accounting Office maintains in a recently-released report.

The report was requested by House Judiciary/Intellectual Property Subcommittee Chairman Hughes (D-N.J.), Senate Judiciary/Patents Subcommittee Chairman DeConcini (D-Ariz.) and Sen. Lautenberg (D-N.J.). The report was completed April 12 and released May 12.

The legislators requested the report on FDA's review of the Lodine NDA to help determine whether Congress should grant Wyeth-Ayerst's request for legislation to extend the product's patent.

GAO pointed out that it "did not determine whether it would be appropriate to extend the patent term for Lodine." The report largely summarizes FDA's and Wyeth-Ayerst's sometime divergent "characterization of events" during the NDA review. The Lodine patent was granted in February 1978 and was scheduled to expire in 1995; the NDA was filed in December 1982, and the product was approved in January 1991. The patent term was extended two years to February 1997 under the 1984 Waxman/Hatch law.

Wyeth-Ayerst asked Congress for a patent extension of 70 months. Such an extension would restore market exclusivity for all but 27 months of the patent term for Lodine consumed during FDA's 97-month review of the NDA. The average NDA review time for NSAIDs before December 1982 was 27 months.

However, GAO said that when the NDA was filed "events were occurring that doubled this average," including FDA's receipt of serious adverse reaction reports connected with the use of four approved NSAIDs. Furthermore, the review of Lodine was a low priority because there were already 10 NSAIDs on the market. "Whereas the average approval time for all NSAIDs jumped from 27 to 53 months, the average approval time for [low-priority NDAs for NSAIDs] like Lodine jumped from 31 to 73 months," the report states. "The Lodine NDA took 24 months longer than the 73-month average because of other mitigating circumstances."

FDA told GAO "that the Lodine submissions were piecemeal, voluminous, disorganized and" were based on "flawed" clinical studies, the report states

The NDA filed in 1982 did not contain "enough data to prove efficacy until September 1989," agency officials told GAO. "Of the more than 2,100 volumes submitted by the company, over 1,400 were part of amendments to the original application," the report states. Wyeth-Ayerst told GAO that the submissions constituted updates from ongoing testing. "The company maintains that these additional submissions provided FDA with updated clinical results, rather than supplementing the original application," the report notes.

Regarding the quality of data, the report states that "Wyeth-Ayerst officials agreed that problems did exist with the clinical trial methodology and that FDA did considerable work to obtain interpretable results." However, GAO said the company "believes that these problems occurred after 1986 -- a time period that the company believed that FDA was diligently reviewing the Lodine NDA."

Two events further delayed FDA's review of Lodine. In May 1984, Canada's Health Protection Branch, which also was conducting a premarket review of Lodine, raised a concern that the NSAID may be carcinogenic in animals. FDA waited until 1986 to review Canada's analysis and ultimately determined etodolac was not carcinogenic. A medical reviewer was not assigned to the NDA until the animal carcinogenicity issue was resolved.

In 1986 FDA received an anonymous letter "alleging that Wyeth-Ayerst was manipulating its Lodine clinical trial results," the report states. FDA consequently took "additional time to look at the data more carefully." GAO noted that "FDA inspectors could not prove the allegation but concluded that the company's internal controls over the trial results were not adequate to assure that the data could not be manipulated."

Congress requested the report in 1992, when it was considering legislation to extend the patents for a number of products, including Lodine and Upjohn's NSAID Ansaid (flurbiprofen). GAO conducted a similar study of FDA's review of the Ansaid NDA last year. In that report GAO also avoided a recommendation as to whether the patent in question should be extended through legislation; however, the agency concluded that the arguments for extension of the Ansaid patent were "probably strongest" with regard to the two-year period 1984-1986 during which FDA review activities "took longer" than usual ("The Pink Sheet" April 13, 1992, T&G-4). Other products for which Congress considered patent extension legislation last year are U.S. Bioscience's chemoprotective agent Ethyol and Procter & Gamble's fat substitute Olestra.

# Withdrawal/Redaction Marker

## Clinton Library

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**This marker identifies the original location of the withdrawn item listed above.  
For a complete list of items withdrawn from this folder, see the  
Withdrawal/Redaction Sheet at the front of the folder.**

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Chris Jennings (Subject File)  
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# American Medical Association

Physicians dedicated to the health of America



1101 Vermont Avenue, NW  
Washington, DC 20005  
(202) 789-7400

Date: Sept. 25

To: Chris Jennings

From: Rich Deem

Message: Medical + Surgical procedure patent  
language, negotiated with Bio + PhRMA, is  
included in the continuing Resolution  
I am very concerned about the possible  
reaction from the Patent and Trade Office  
(see attached) to this legislation. Please  
call me ASAP to discuss  
202-789-7413

Total pages (Including cover sheet)

**3**

Reply Fax Number: (202) 789-7485

# Fax Transmission

is after From: Ed Pickam 9-18-96 2:32pm p. 8 of 18  
SEP-18-96 18:30 From: F D C REPORTS INC 8018847288 T-288 P.06/10 Job-481

Health News Daily Thursday, September 19, 1996

The agreement to exempt silicone breast implant litigation from biomaterials liability protection sporadically is what opened the door for the possible Senate action. Plaintiffs attorneys involved in litigation against silicone breast implant manufacturers are said to have played a role in sidetracking efforts to introduce legislation in the Senate by charging that the measure would reduce damages awards in the ongoing disputes.

The House, led by Rep. George Gekas (R-Penn.), also has agreed to the exclusion language. If the Senate is successful in adding the biomaterials amendment to an appropriations measure, the House would adopt the revision in conference. Gekas introduced a stand-alone biomaterials bill (HR 3468) in the House after broad product liability legislation was vetoed by President Clinton earlier this year.

Aside from the new provision on silicone breast implants, the biomaterials amendment is said to be identical to language included in the product liability bill vetoed by President Clinton. Intended to thwart the reported wishes of manufacturers from the medical implant materials market due to concerns over product liability, the legislation would shield bulk component and raw material suppliers from liability as long as they delivered the "product described in the contract" with the finished device manufacturer. The measure also would establish "expeditious procedures to dispose of unwarranted suits against the supplier."

President Clinton singled out the biomaterials liability protection component of the product liability bill as a section worthy of enactment. Despite the presidential endorsement and the recent agreement, however, the Senate may encounter difficulty in adding the language to an appropriations measure given the time pressures as the 104th Congress draws to a close. Senate staffers are optimistic, pointing to the measure's bipartisan support, including co-sponsorship from Senate Majority Leader Trent Lott (R-Miss.).

**GENERIC INDUSTRY AMENDMENT TO HATCH OMNIBUS PATENT ACT** would prohibit additional patent term restoration for pharmaceutical companies receiving Hatch/Waxman extensions. Senate Judiciary Committee Chairman Orrin Hatch's (R-Utah) S 1961, which is expected to be marked up Sept. 19, grants restoration for patent terms shortened by administrative delay at the Patent and Trademark Office. A similar measure pending in the House (HR 3460) is sponsored by Rep. Pat Schroeder (D-Colo.).

In a Sept. 18 letter to Senate Judiciary Committee members, Generic Pharmaceutical Industry Association President Robert Waspe states that "GPIA must oppose the bill in its present form. It is our concern that [the patent extension provision in S 1961] does not provide adequate protection against delay and manipulation by patent applicants, nor does it prevent an applicant from obtaining an extension under both the Hatch/Waxman Act and this legislation."

GPIA is seeking a sponsor for its amendment, which states that holders of Hatch/Waxman extensions are ineligible for an extension under S 1961. GPIA's letter was written, in part, to signal the association's opposition in principle to the creation of a new category of patent extensions. Prospects for the generic amendment will be aided by the short timeframe for action on the legislation: at a Sept. 18 hearing on the Omnibus Patent Act, Sen. Hatch indicated that he would consider taking controversial provisions out of the bill for consideration in future sessions.

The Hatch bill could be considered as a vehicle for other patent-related provisions. With prospects for the passage of a comprehensive FDA reform bill this session fading, Sen. Nancy Kassebaum (R-Kan.) is said to be looking for another vehicle for a pediatric research incentive that would grant a six-month patent extension to companies who submit pediatric study data with an NDA.

In other patent issues, Patent and Trademark Office Commissioner Bruce Lehman raised concerns at the Sept. 18 hearing regarding legislation that would ban the issuance of patents for medical procedures. That bill has been added as an amendment by Rep. Greg Ganske (R-Iowa) to the Commerce Appropriations bill; compromise language drafted to address the concerns of the Biotechnology Industry Organization and the Pharmaceutical Research & Manufacturers of America could be introduced when Commerce Appropriations legislation is discussed on the Senate floor.

Lehman told the committee that the Clinton Administration opposes "any variation" of the Ganske amendment. "We are quite concerned about the Ganske amendment and the implications of that for the patent

From: Ed Picken 9-19-96 2:32pm p. 7 of 10

SEP-19-96 10:31 From: F D C REPORTS INC 3018047200 T-200 P.07/10 Job-001

Thursday, September 19, 1996 Health News Daily . 7 .

system at large. It would really be quite tragic if we were to find that a very large loophole were to be opened in the patent system, that would cause investment in some of the most important technology, not from an economic point of view but from a lifesaving point of view, to cause that investment to dry up."

A coalition of generic manufacturers and consumer groups has cited the Orphan provision during efforts to prevent the enactment of individual pharmaceutical patent extensions this session. In a Sept. 13 memo, the coalition notes that the amended provision "would preclude enforcement of medical procedure patents, although it would allow them to be issued.... Since Congress seems to have bought off on the idea of precluding enforcement of certain patent rights, we should give consideration to preparing an amendment to the Orphan compromise that would bar enforcement of any extended pharmaceutical patents."

Patent extensions being sought on Capitol Hill by brand-name manufacturers are said to include Wyeth-Ayerst's *Lodges*, Schering Plough's *Claritin* and SmithKline Beecham's *Relafen*. Generic manufacturers also are seeking to roll back a two-year extension of the patent for Searle's *Daypro* until Oct. 29, 1999 that was secured as part of the FY 1996 budget agreement.

**POPULATION COUNCIL'S MIFEPRISTONE MANUFACTURING LABELING INFORMATION NEEDED** needed before final approval of the abortifacient drug can be granted, FDA said. FDA issued an "approvable" letter Sept. 18 to the Population Council for mifepristone (RU-486), when used in combination with Searle's *Cytotec* (misoprostol), for the termination of early pregnancy.

The agency "has determined that the submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when under close supervision, but additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made," FDA said in a same-day "Talk Paper."

On July 19, FDA's Reproductive Health Drugs Advisory Committee voted 6-0 with two abstentions that the results of two French clinical studies establish that the benefits outweigh the risks of the mifepristone/misoprostol regimen. A U.S. study of the combination was also conducted by Population Council.

The advisory committee reviewed special conditions for RU-486 use, including direct distribution to providers, instead of pharmacies. At that time, proposed labeling stipulations included requiring that providers be physicians trained in determining gestational age, able to diagnose ectopic pregnancy, and capable of performing surgical abortion with access to emergency treatment. Draft labeling presented to the committee required that patients reside and work within one hour of an emergency facility, be able to comply with a multi-visit regimen, and remain under observation for four hours following misoprostol administration.

The proposed regimen of RU-486 involves oral administration of 600 mg of mifepristone (three 200 mg tablets) within 49 days of the beginning of the last menstrual period, followed by oral administration of 400 mg of misoprostol two days later.

RU-486 first became available in France in 1989, where it is manufactured by a division of Hoechst. The Population Council was given U.S. rights to RU-486 under an agreement brokered by the Clinton Administration. The drug is also available in China, Sweden and the U.K.

**CLIA GENETIC TESTING STANDARDS SHOULD BE "SORTED UP."** National Center for Human Genome Research Director Francis Collins, MD/PhD, asserted Sept. 17 at a hearing before the House Technology/Science Subcommittee. "Certainly one could argue that...[the Clinical Laboratory Improvement Amendments of 1988] could be substantially improved," Collins said. "At the present time there is no genetics speciality at all at CLIA, and the kind of inspection that a laboratory offering genetic testing goes through to pass the certification...really is not all that relevant to the specifics of the genetic test."

"At the present time," Collins continued, "just by the nature of the way that CLIA is carried out...and the lack of very many inspectors who really have any experience in genetics it's just not possible" to assure laboratory quality control. "That may, however, lead to a false sense of security that everything is fine."

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FACSIMILE TRANSMISSION SHEET

CLIENT:

PAGE 1 of 2

DATE:

9-25-96

TO:

CHRIS JENNINGS, ASST to the PRESIDENT for HEALTH POLICY

FROM:

TOM LORANGER

SUBJECT:

PRYOR LETTER to HON. DONNA SHALALA

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SPECIAL COMMITTEE ON AGING

## United States Senate

WASHINGTON, DC 20510-0402

September 25, 1996

The Honorable Donna Shalala  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Shalala:

I am writing to express concern over congressional efforts to overturn a key Federal Court of Appeals decision and grant private relief to a handful of prescription drug companies. If these last-minute efforts are successful, a few companies will receive patent protection which is unjustified as a matter of law and unfair to American consumers as a matter of policy. It is my hope that your Department and the Administration will continue to oppose any attempts to include such patent provisions in a FY 1997 continuing resolution or omnibus appropriations bill.

Earlier this year, an amendment was offered to the Defense Authorization bill which called for reversing the Federal Court of Appeals ruling in Merek v. Kessler. The amendment provided a few drug manufacturers with the "win-win" outcome of receiving patent extensions under the GATT agreement in addition to extensions granted under the 1994 Waxman-Hatch amendments. As you know, such an outcome was strongly opposed by the Patent and Trademark Office (PTO) and the Food and Drug Administration (FDA) during the Federal court's deliberations.

It is this amendment which reportedly is now being endorsed by the prescription drug industry for inclusion in FY 1997 appropriation measures. My concern is that the provision would guarantee that consumers would wait up to three additional years for generic equivalents to as many as 20 best-selling brand drugs. There is currently no estimate of the potential costs to the public, HMOs, state Medicaid programs, and other drug purchasers - but it is certain to reach hundreds of millions of dollars.

In light of separate efforts to include patent extensions for the drugs Lodine, Relafen, and Claritin into the final legislative business of the 104th Congress, I urge you to oppose this and all other special-interest measures relating to pharmaceutical patents. If you have any questions, please contact Kenneth Cohen of my Aging Committee staff at 224-6018.

Sincerely,



David Pryor

cc: The Honorable Thomas Daschle  
The Honorable Trent Lott

DAVID PRYOR  
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SPECIAL COMMITTEE ON AGING

**United States Senate**  
WASHINGTON, DC 20510-0402

September 25, 1996

The Honorable Thomas Daschle  
United States Senate  
Washington, DC 20510

Dear Mr. Leader:

I am writing to urge your opposition to secretive, last-minute lobbying by a handful of pharmaceutical companies to obtain costly and unjustified patent extensions for the drugs Lodine, Claritin, and Relafen. Failure on our part to halt this special interest campaign will force American consumers to subsidize a multimillion dollar windfall to underserving companies seeking protection from fair market competition.

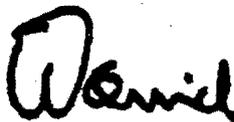
Just prior to the August recess, a two year patent extension for the drug Lodine was inserted into the Kennedy-Kassebaum health insurance conference report - despite the fact that it had already been categorically rejected by both the Defense and Agriculture appropriations conferees. Thanks to the efforts of Senators Wellstone and Kennedy, the offending provision was struck from the conference report on a voice vote.

This week, I have heard reports that the manufacturer of Lodine is trying yet again to slip its multimillion dollar windfall past our body in the waning hours of the 104th Congress. This is despite the fact that Lodine is already enjoying a 2 year patent extension under a law intended to preempt such special interest lobbying, the 1984 Waxman-Hatch Act.

Two other drug companies have joined reportedly Lodine's manufacturer in seeking their own patent extensions for the drugs Claritin and Relafen. Incredibly, these drugs have patent protection until 2002 and 2009, with projected 1996 sales of \$1 billion and \$400 million, respectively. In Claritin's case, the Agriculture conferees have already rejected the notion of a patent extension.

I ask you to join me in preventing this lobbying campaign from succeeding. If you have any questions, please contact Kenneth Cohen of my Aging Committee staff at 4-6018.

Sincerely,



David Pryor

cc: L. Panetta

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SPECIAL COMMITTEE ON AGING

United States Senate  
WASHINGTON, DC 20510-0402

September 25, 1996

The Honorable Trent Lott  
United States Senate  
Washington, DC 20510

Dear Senator Lott:

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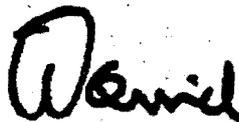
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Sincerely,



David Pryor

cc: L. Panetta

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## FACSIMILE TRANSMISSION

Sender's Direct  
 Fax 202/234-3550

**TO:** Chris Jennings  
**COMPANY:** \_\_\_\_\_  
**FAX #:** 456-7431  
**FROM:** Marshall L. Matz  
**SENT BY:** \_\_\_\_\_  
**DATE:** 9/27/96 Total Number Of Pages 3

### COMMENTS

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OF COUNSEL  
MICHELE F. CROWN

MEMORANDUM

September 27, 1996

BY TELECOPY

TO: Senator David Pryor  
Attn: Kirk Robinson

FROM: Marshall L. Matz  
Karen A. Reis  
Counsel to the  
National Association of Pharmaceutical Manufacturers

RE: Generic Drugs

---

In the final hours of the 104th Congress, the generic drug industry, once again, is coming under attack from brand name pharmaceutical companies. Branded companies are pushing three proposals that are harmful to the generic drug industry and the public. Cumulatively, the impact of these proposals could be disastrous. Congress has not held hearings on any one of these proposals. A brief summary of each follows:

**Private-Relief Patent Extensions:** Complaining of FDA delays in approval of certain drugs, brand name companies are proposing to extend the patents on widely used drugs -- Lodine (American Home Products' Etodolac), Claritin (Shering's Loratadine), Relafen (SmithKline Beecham's Nabumetone), and Taxol (Bristol's paclitaxel). If enacted, these Congressionally-mandated extensions would set a dangerous precedent for further patent extensions and effectively nullify the Hatch-Waxman Amendments. Each of these private-relief proposals is likely to be attached to the Continuing Resolution (CR).

**Further GATT Patent Extensions:** Senator Biden may offer an amendment reversing current law by allowing more drugs to receive patent extensions under GATT. The Biden amendment would provide GATT patent extensions to drugs with patents that were effective on June 8, 1995 only by virtue of the Waxman-Hatch extension. This is a likely candidate for the CR.

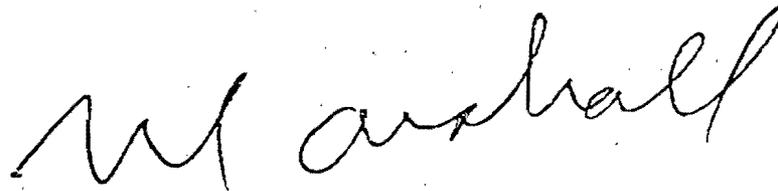
Memorandum to Senator David Pryor  
September 27, 1996  
Page 2

**Pediatric Study Patent Extensions:** Senators Kassebaum and Kennedy are likely to offer legislation that would grant a brand name drug company an additional six months of non-patent marketing exclusivity if the company performs pediatric studies during drug development. There has been no showing of how, if at all, such an incentive would affect pediatric research, nor has there been consideration of alternate incentives for spurring such research. Senator Kassebaum may offer this as a free-standing bill. Otherwise, we expect this proposal to be included on the CR.

We would appreciate Senator Pryor doing everything he can to oppose each of these amendments.

Thank you very much. You are always there for the generic industry.

cc: Chris Jennings

A handwritten signature in cursive script, appearing to read "M Marshall". The signature is written in dark ink and is positioned in the lower right quadrant of the page.