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FDA FAILS TO PROTECT PUBLIC FROM THE DANGERS OF NEW DRUGS, HOUSE REPORT CONCLUDES

Washington, D.C. -- The Food and Drug Administration is not protecting the pub from the dangers of new drugs, according to a Government Operations Committee repor released today entitled "FDA's Regulation of Zomax." Last month the Committee detailed several deficiencies in FDA's regulation of Oraflex, another new drug.

The reports were prepared by the Intergovernmental Relations and Human Resourc Subcommittee, chaired by Rep. Ted Weiss (D-N.Y.), and issued by the House Committeé on Government Operations, chaired by Jack Brooks (D-Tex.). Chairman Weiss said:

> "Our examination of FDA's regulation of Oraflex and Zomax raises serious questions about FDA's ability and willingness to protect the public from the serious and sometimes fatal side effects of new drugs."

A pain reliever, Zomax was withdrawn from the market on March 4, 1983, by its manufacturer, McNeil Pharmaceutical, a subsidiary of Johnson and Johnson, because c a large number of serious allergic/anaphylactoid reactions, including deaths, associated with its use. Anaphylactoid reactions generally involve rapid onset (within 20 minutes of taking the drug) of rash, itching, swelling, lowered blood pressure, breathing difficulty, and sometimes cardiovascular collapse and loss of consciousness. FDA has received approximately 2,200 reports of Zomax-associated allergic/anaphylactoid reactions, 503 of which it has classified as life-threateni and now believes it has sufficient information to attribute 14 or 15 reported deat to such reactions.

Chairman Weiss stated:

> "In light of the information available to FDA, it is disturbing that FDA permitted Zomax to be marketed in 1980. It is equally disturbing that FDA is considering whether to permit the drug's return to the market without the scientific evidence it had determined would be needed to support Zomax's remarketing."

FDA scientists found that Zomax caused tumors in animals at extremely low dos (substantially below those intended for humans) and concluded that the drug posed cancer risk to humans. FDA nevertheless approved Zomax for marketing without requiring evidence that its painkilling benefits outweighed its carcinogenic risk.

Chariman Weiss said:

> "At a time when we are spending vast amounts of public funds in a natior effort to detect and control cancer-causing agents, it is distressing that FI is not minimizing the public's unnecessary exposure to substances with cance causing potential."

The report also found that FDA referred the question of whether Zomax should

remarketed to its Arthritis Advisory Committee without first obtaining the scientifi evidence the agency determined was needed to support the drug's remarketing. In view of Zomax's higher risks, FDA had testified during the subcommittee's hearings in April that it would not permit Zomax to be remarketed unless studies showed that there was a patient population for whom Zomax was better than other drugs in its class. Yet, in August, FDA asked the advisory committee to decide whether to recommend that drug's remarketing even though the agency had received no evidence proving the existance of such a patient population. In fact, one FDA official had urged the advisory committee to recommend remarketing without such evidence. "In seeking an advisory committee recommendation on the Zomax remarketing issue," Chairman Weiss said, "FDA totally disregarded its sworn testimony before the subcommittee."

The report also found that FDA's monitoring and analysis of adverse reactions reported for new drugs were deficient. Because the agency has not been adequately processing incoming reports of such reactions, FDA officials were unaware of the large number of serious Zomax anaphylactoid reactions that had been reported and did not realize that Zomax may have had a higher incidence of such reactions than other drugs in its class.

The committee also found that FDA disregarded important evidence suggesting tha sudden and serious anaphylactoid reaction was not only more frequent with Zomax, but also more unpredicatble. Patients suffering anaphylactoid reactions to Zomax were much less likely to have similarly reacted to Zomax or similar drugs than patients experiencing wuch reactions to other drugs in its class. Although the manufacturer was aware by March 1982 that serious and sudden anaphylactoid reaction to Zomax was often unpredictable, the report found that it never warned physicians of this danger

Despite claims by FDA and McNeil that Zomax-associated anaphylactoid reactions were rare events which only occurred after the drug was approved, the committee four reports of serious and, in one case, life-threatening anaphylactoid reactions which had been reported during the pre-market Zomax clinical trials.

Members of the subcommittee in addition to Chariman Weiss are: John Conyers, Jr. (D-Mich.), Sander M. Lavin (D-Mich.), Buddy MacKay (D-Fla.), Adolphus Towns (D-N.Y.), Ben Erdreich (D-Ala.), Robert S. Walker (R-Pa.), Alfred A. (Al) McCandles (R-Calif.), and Larry K. Craig (R-Idaho), Jack Brooks (D-Tex.) and Frank Norton (R-N.Y.) are Ex Officio members.

Div. File
18-217

Memorandum of Meeting

May 18, 1987

NDA 18-217

Suprofen

Between

Patrick Seay, M.D., McNeil Pharmaceutical

And

John Harter, M.D., HFN-150
Sandy Barnes, HFN-150

Dr. Seay came by to deliver two submissions, one submission notifies FDA that the sales of Suprofen have been suspended and contains a copy of the letter to physicians and pharmacists notifying them of the suspension. The other submission contains a copy of the presentation which was made by McNeil Pharmaceutical to the European Communities Committee for Propriety Medicinal Products on MAy 12, 1987.

Dr. Harter suggested that Dr. Seay deliver desk copies of the first submission to Ken Feather in the Drug advertising and to the Press Office.

Dr. Harter also indicated we would probably have a memo for McNeil later this afternoon.

Sandy Barnes
CSO, HFN-150

cc NDA 18-217
Div. file
HFN-150 Cobb
HFN-150 SBarnes

Today: High 58. Low 40.
Wednesday: Variably cloudy with chance of showers. High 56.
Yesterday: AQI: 35 Temp. range: 49-66. Details on Page B2.

111TH YEAR ... No. 325

PUBLIC COURTS, PRIVATE JUSTICE

Third of Four Articles

Drug Firm's Strategy: Avoid Trial, Ask Secrecy

Records Reveal Story of Zomax Recall

By Benjamin Weiser
and Elsa Walsh
Washington Post Staff Writers

In mid-January 1985, an important memorandum began circulating to top officials at McNeil Pharmaceutical, a major subsidiary of the Johnson & Johnson company, the maker of Band-Aids and Tylenol.

The memo was both a warning and a reminder of a difficult period in McNeil's history. Nearly two years earlier, on March 4, 1983, McNeil had withdrawn its prescription painkiller Zomax after only 28 months on the market. The decision came after reports of hundreds of severe allergic reactions to the drug, a top seller. After the recall, the company faced nearly 600 lawsuits, many alleging that McNeil had failed to adequately warn the medical community about Zomax's risks—an allegation the company has strongly disputed in court.

The Jan. 14, 1985, memo, written by McNeil legal aide Herman Lutz, listed 18 lawsuits that "presented McNeil with the most exposure or had sensitive problems." Many of the cases involved patients who had taken Zomax during periods when the company had decided to issue stronger warnings, but had not yet done so. The memo, sent to company President Jack O'Brien, also noted other factors, including the potential testimony of several witnesses that might prove worrisome.

To defend itself against these lawsuits and dozens of others that McNeil's lawyers regarded as serious, the company adopted a strategy that it has pursued vigorously during five years of Zomax litigation in 43 states.

It has used court secrecy procedures—called protective orders—to prevent the disclosure of information that McNeil turned over during the course of the lawsuits. It has taken only three cases to trial, choosing instead to settle cases outside the courtroom without admitting any liability. As part of these settlements, it has obtained confidentiality agreements that prohibit opposing lawyers and their clients from revealing what they have learned about Zomax.

What McNeil's attorneys consistently have managed to keep out of the courtroom are documents and testimony that might have provoked a public debate about whether McNeil withheld information from the medical community about the risks of Zomax. The U.S. Food and Drug Administration concluded in 1985 that the drug was probably a factor in 14 deaths and 403 life-threatening allergic reactions. The material also did not reach congressional investigators who, a month after the recall, held two days of hearings

See COURTS, A12, Col. 1

protection is secrecy," the company has said in court papers.

The Washington Post, as part of a lengthy examination of secrecy in the civil courts, has reviewed much of this still-confidential material. It provides an inside look at how McNeil tested and marketed Zomax, then struggled to understand why the drug—which was being taken safely by millions of people—also was causing unpredicted and life-threatening reactions in some patients.

According to the documents, there were indications during premarketing testing that Zomax might cause a severe allergic reaction known as anaphylaxis, which can lead to seizures and respiratory failure. McNeil said the results were not conclusive enough to include in Zomax's package insert—the primary way that a company warns prescribing doctors of harmful side effects.

A warning about anaphylaxis was first included nine months after the drug went on the market, following several reports of anaphylactic reactions, but one internal memorandum to McNeil's president criticized the company for not acting sooner. "We resisted too much and waited too long," wrote Patrick Seay, McNeil's longtime head of regulatory affairs in a Sept. 8, 1984, critique of the company's overall performance in marketing drugs.

Another internal document is a Feb. 26, 1982, memo sent to the company's sales force immediately after a case of anaphylactic shock was reported in the Journal of the American Medical Association. The memo said, "This information is being sent to you so you will be fully prepared to respond to a physician or pharmacist who initiates discussion on the article. You should not bring up the subject."

Six weeks later, other documents show, the company launched a high-pressure sales campaign shortly after McNeil had sent out a special warning letter to 200,000 physicians. As the letter was being drafted, a McNeil researcher gathered data that suggested Zomax might be riskier for some patients than previously believed.

Concerns within McNeil climaxed in a series of tense weekend meetings on Feb. 5 and 6, 1983, at the firm's headquarters in Spring House, Pa. Three of the company's four top doctors told McNeil's president they no longer had confidence in the drug's safety, according to one of the doctors, James A. Dale. The company considered various options, including a recall, before deciding instead to strengthen its package warning.

As the new warning was being prepared, two people died of anaphylactic reactions allegedly related to Zomax use, and the company took the drug off the market. "They were avoidable deaths," Dale, then McNeil's associate medical director and now in private practice, said in an interview.

uments in publicly filed legal briefs in Miami and Seattle. As part of those settlements, judges in both cases ordered that the entire file be sealed from public view.

During four hours of interviews and in 22 pages of written responses to questions submitted in advance, officials at McNeil and its parent company, Johnson & Johnson, strongly defended both their legal strategy and their handling of Zomax.

"The strategy was to dispose of the Zomax cases as expeditiously and as cheaply as possible," said Roger Fine, associate general counsel of Johnson & Johnson, which handles the legal work for all the company's subsidiaries.

According to Fine, secrecy orders were necessary to guard the company's chemical formulas and marketing methods, as well as to prevent others from using documents to suggest unfairly that McNeil did not care about the safety of its products. The company settled cases, he said, for a variety of reasons, not just concern over documents and testimony.

James E. Burke, chairman of Johnson & Johnson, said in an interview that he was proud of the company's handling of Zomax and rejected any suggestion that the company should have withdrawn the drug immediately after the Feb. 5 and 6 meetings. Once the company decided to recall the drug, he said, "I think we did a good thing—I don't see how you could do it any faster."

Dr. Patricia Stewart, McNeil's head of medical research, said her staff carefully monitored adverse reactions to Zomax for the entire time that it was on the market. McNeil officials said the company's decision to issue a stronger warning after the Feb. 6 meeting was a prudent course of action given what was known at the time.

Lawrence G. Foster, Johnson & Johnson's vice president for public relations, said, "As we demonstrated in response to the Tylenol poisonings and again in the way we managed Zomax, our first responsibility under our credo is to our customers. Anybody who manages a business for the long term, as we do, knows that putting the customer first is the only way to increase sales."

Foster said that nearly 15 million patients used Zomax without incident, and that the recall of Zomax was not an admission that the drug was unsafe for everyone. "Decisions regarding Zomax labeling had to be made based on fragmentary information about possible adverse reactions experienced by a small number of patients out of the millions who actually used the medication," he said. "This is hardly an exact science . . . . And warning of every conjectural side effect, no matter how thin the evidence, results in a label so expansive and indiscriminate that it in effect warns of nothing . . . ."

The company revised its warning labels whenever it had enough information to warrant it, Foster said.

solved that medical dilemma by requiring drug companies [illegible] as well as its benefits, [illegible] full and accurate warnings about possible adverse side effects. If a company complies, the courts have ruled, it usually cannot be held liable for an adverse reaction [illegible]

Seay, in his 22-page internal critique written 18 months after Zomax was recalled, voiced his belief that the company had failed, at times, to meet its own high standards. "We can do little about the past," he wrote, "but we should perform now strictly according to the letter and spirit of the regulations and to ethical principles to preserve the good name of J&J [Johnson & Johnson]."

Conflicting Interests

The information in this article is drawn from internal McNeil records made available by sources, and from interviews with present and former McNeil employees, lawyers who have sued McNeil and officials at McNeil and Johnson & Johnson.

McNeil's attorneys agreed to discuss some aspects of their legal strategy and to comment on internal documents that The Post had obtained elsewhere. They declined to disclose settlement amounts or to release internal records.

A handful of plaintiffs' attorneys agreed to a limited discussion of their impressions of McNeil's legal strategy. A few other lawyers consented to interviews on the condition that they not be identified by name. Most plaintiffs' attorneys, however, declined to make any comment, saying they feared it might be construed as a violation of court-imposed protective orders or a breach of the confidentiality agreements they have signed with McNeil.

Some of the plaintiffs' attorneys, while acknowledging that they agreed to McNeil's requests for secrecy, took issue with the company's statements about its need for confidentiality.

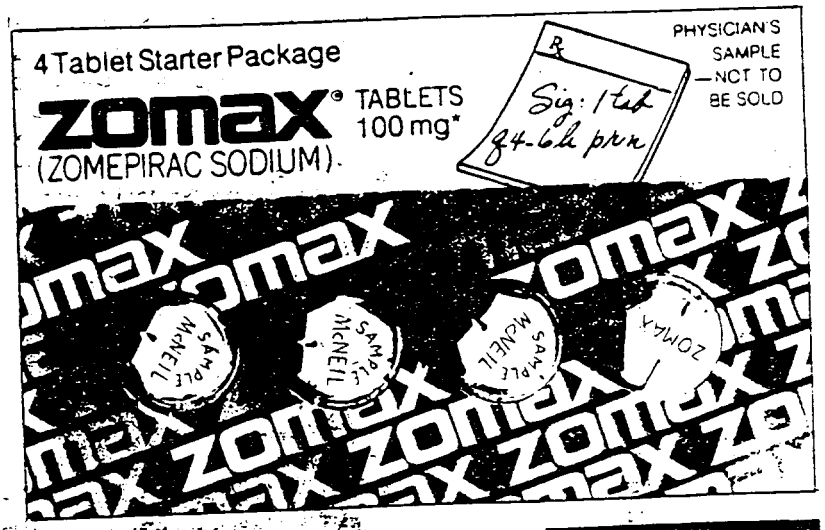
Allan Kanner, a lawyer in Philadelphia who has represented several clients in Zomax settlements, said, "What they are trying to do is not be accountable to the vast majority of the public for what they've done . . . . They paid my clients a ton of money for me to shut up."

Maryland lawyer Steven Nemeroff, who settled a Zomax lawsuit in Baltimore, said generally of lawsuits involving drugs, "The problem is that they have a gun to your head. The client is concerned about being compensated in full. The lawyer must abide by the concerns and wishes of his client . . . not the fact that [information will remain secret or] other victims may be injured."

For some of Zomax's alleged victims and their families, the legal process left them ambivalent. They agreed to financial settlements—in which the company admitted

PUBLIC COURTS, PRIVATE JUS

THE CORPORATE PHILOSOPHY

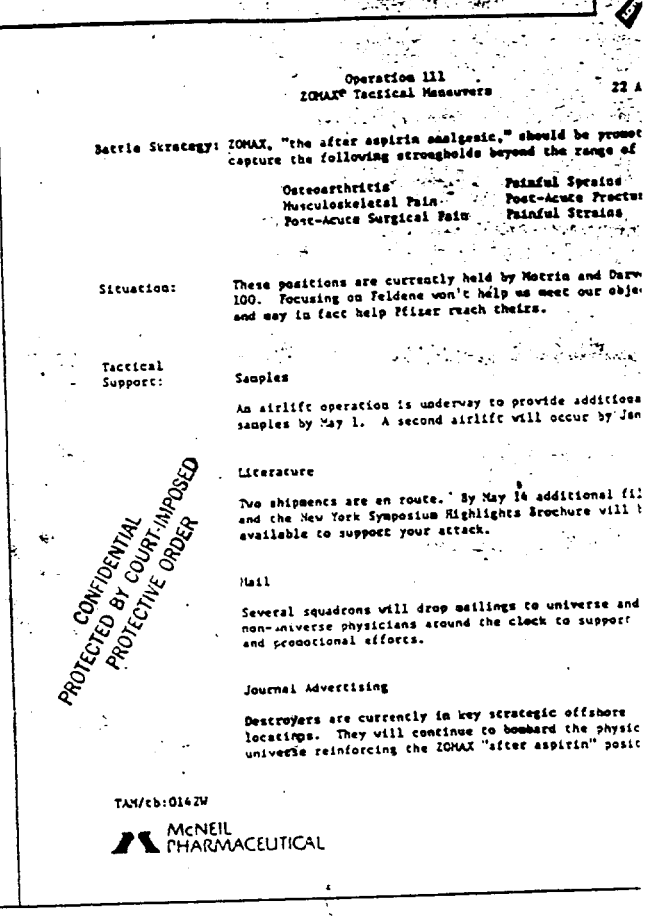


A physician's sample of Zomax, developed by McNeil Pharmaceutical

"I think we did a good thing —I don't see how you could do it any faster."

— James E. Burke, chairman of Johnson & Johnson, rejecting any suggestion that the company should have withdrawn Zomax sooner

OPERATION ONE-ELEVEN



Operation 111
ZOMAX® Tactical Maneuvers

Battle Strategy: ZOMAX, "the after aspirin analgesic," should be promot capture the following strongholds beyond the range of

Osteoarthritis — Painful Sprains
Musculoskeletal Pain — Post-Acute Fractu
Post-Acute Surgical Pain — Painful Strains

Situation: These positions are currently held by Motrin and Darv 100. Focusing on Feldene won't help us meet our obje and may in fact help Pfizer reach theirs.

Tactical Support:

Samples

An airlift operation is underway to provide additiona samples by May 1. A second airlift will occur by Jan

Literature

Two shipments are en route. By May 14 additional fil and the New York Symposium Highlights Brochure will available to support your attack.

Mail

Several squadrons will drop mailings to universe and non-universe physicians around the clock to support and promotional efforts.

Journal Advertising

Destroyers are currently in key strategic offshore locations. They will continue to bombard the physic universe reinforcing the ZOMAX "after aspirin" posit

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PROTECTIVE ORDER

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McNEIL PHARMACEUTICAL

Drug Label Warnings at Issue in Suits

COURTS, From A1

that centered on the FDA's role in regulating Zomax, and not the company's internal procedures.

McNeil officials, pointing out that drugs are inherently unsafe, said in interviews that they promptly alerted doctors or the FDA whenever they had solid data about Zomax's risks. They sought broad secrecy orders, they said, to prevent disclosure of trade secrets that would be valuable to competitors and because some documents might be misinterpreted. "McNeil's only protection is secrecy," the company has said in court papers.

The Washington Post, as part of a lengthy examination of secrecy in the civil courts, has reviewed much of this still-confidential material. It provides an inside look at how McNeil tested and marketed Zomax, then struggled to understand why the drug—which was being taken safely by millions of people—also was causing unpredicted and "They were avoidable side effects . . . . I felt guilty . . . . We met and had the opportunity to take action . . . . We could have done something sooner."

Dale has never testified in any Zomax lawsuit. In several instances where his testimony has been sought, McNeil has settled before he could appear for a deposition, sworn pretrial testimony that is taken outside the courtroom. Information about the Feb. 5 and 6 meetings has never become public.

McNeil also moved quickly to settle two cases in which opposing lawyers had unexpectedly referred to sensitive McNeil documents in publicly filed legal briefs in Miami and Seattle. As part of those settlements, judges in both cases ordered that the entire file be sealed from public view.

During four hours of interviews and in 22 pages of written responses to questions submitted in advance, officials at McNeil and its parent company, Johnson & Johnson, strongly defended both their legal strategy and their handling of Zomax.

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Responding to Seay's criticism that McNeil had not issued a warning about anaphylaxis soon enough, Foster said the company's decision was reasonable at the time.

The adequacy of McNeil's warnings is the central issue in the Zomax lawsuits. The courts have long recognized that prescription drugs are inherently unsafe, that what is enormously beneficial for some people may not be for others. Federal law has resolved that medical dilemma by requiring drug companies to assess a drug's risks, as well as its benefits, and issue full and accurate warnings about possible adverse side effects. If a company complies, the court have ruled, it usually cannot be held liable for an adverse reaction.

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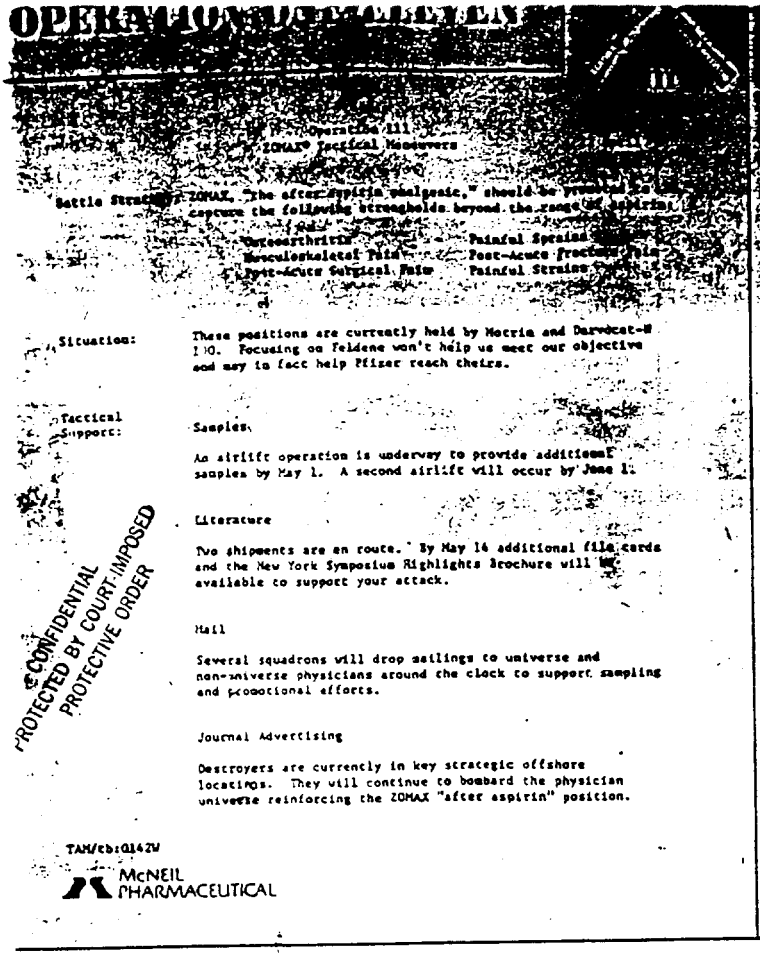

Operation 111
ZOMAX Tactical Maneuvers

Battle Strategy: ZOMAX, "the after-aspirin analgesic," should be promoted to capture the following strongholds beyond the range of aspirin:

Osteoarthritis	Painful Sprains
Musculoskeletal Pain	Post-Acute Fracture Pain
Post-Acute Surgical Pain	Painful Strains

Situation: These positions are currently held by Motrin and Darvocet-N 100. Focusing on Feldene won't help us meet our objective and may in fact help Pfizer reach theirs.

Tactical Support:

Samples:

An airlift operation is underway to provide additional samples by May 1. A second airlift will occur by June 1.

Literature

Two shipments are en route. By May 14 additional file cards and the New York Symposium Highlights Brochure will be available to support your attack.

Mail

Several squadrons will drop mailings to universe and non-universe physicians around the clock to support sampling and promotional efforts.

Journal Advertising

Destroyers are currently in key strategic offshore locations. They will continue to bombard the physician universe reinforcing the ZOMAX "after aspirin" position.

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McNEIL PHARMACEUTICAL

CONFIDENTIAL
PROTECTED BY COURT-IMPOSED PROTECTIVE ORDER

Under our credo is to our customers.

—Lawrence G. Foster, Johnson & Johnson vice president for public affairs, relations, who said that nearly 15 million patients used Zomax without incident.

A portion of the corporate philosophy of Johnson & Johnson's founder, below.

Johnson & Johnson

"The evidence on this point is clear . . . institutions, both public and private, exist because the people want them, believe in them, or at least are willing to tolerate them. The day has passed when business was a private matter — if it ever really was. In a business society, every act of business has social consequences and may arouse public interest. Every time business hires, builds, sells, or buys, it is acting for the . . . people as well as for itself, and it must be prepared to accept full responsibility for its acts . . ."

Excerpt from "Or Forfeit Freedom" by General Robert Wood Johnson, 1947

McNeil marketing strategy memo, left, has a military motif. The paper, sealed as part of a lawsuit, bears a "confidential" stamp.

Issue in Suits

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no fault—and found themselves with important unanswered questions.

Carol Sawyer, whose lawsuit alleged that her 42-year-old husband Michael died of anaphylaxis after taking Zomax, said she settled the case without knowing of the Feb. 6 meeting at which Dale said he and two other McNeil doctors had declared their lack of confidence in Zomax's safety.

Michael Sawyer was one of two people to die of anaphylactic reactions allegedly caused by Zomax in the four-week period between that meeting and Zomax's recall. "That's very upsetting to know, that [his death] might have been prevented," she said. "I just can't believe [McNeil] would take a chance and wait and see."

Devra L. Davis, a Washington toxicologist who settled with McNeil after suffering a near-fatal anaphylactic reaction, said she believes court secrecy impairs "free scientific inquiry and the right of the public to know specific information about drugs it consumes."

If independent scientists could make a thorough study of what happened with Zomax, Davis said, they might be able to learn lessons that would help others in the future.

McNeil's attorneys dispute these characterizations, saying that the civil courts are primarily intended to be a place to resolve private disputes—and, therefore, not the proper forum for a public debate on McNeil's performance. "We don't really have anything to hide in this thing," said David F. Dobbins, of Patterson, Belknap, Webb & Tyler, the New York law firm that has represented McNeil in court throughout the Zomax litigation.

Code Name: Operation 111

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McNeil's Foster said, "With hinds one can debate whether the label sh have been changed a month or two ear but not earlier than that.

Another memo shows McNeil's gro concern as anaphylactic reactions esca through 1981 and into 1982. "Zomax gic reactions are continuing to be rep at a relatively high rate and need close veillance," wrote Dr. Stewart, Mcl medical research chief, on Feb. 18, 19

A month later, the company learn the first fatal anaphylactic reaction in tient who had taken Zomax. Because th tient was allergic to aspirin and shoul have been given a prescription for Z the company decided to issue a s "Dear Doctor" letter to the medical munity to call attention to the aspirin ing already in the package insert.

As the Dear Doctor letter was drafted with the aid of FDA officials company undertook a study of the 1 lergic and anaphylactic reactions tha been recorded since Zomax was introc The results surprised some membe McNeil's medical staff.

Of the 84 reactions that clearly r bled anaphylaxis, most of the patient no known allergy to aspirin, accordin March 31, 1982, memo from rese Thomas Teal to McNeil president O' Instead, the study found a pattern o phylactic reactions in patients who Zomax intermittently—starting, sto starting again. It made no conclusions these statistics.

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In large part, the information contained in McNeil's internal records and in still-confidential depositions shows a side of the drug industry that the public rarely sees: the inevitable tension between the medical staff and the marketing division, the sometimes flawed relationship between a drug company and its regulators at the FDA, and the high-pressure sales tactics used to promote a drug to doctors and hospitals.

When Zomax was approved for sale in October 1980, McNeil called the painkiller a breakthrough, as strong as a narcotic but not addictive. The drug was an immediate success, capturing 11 percent of the new prescription analgesic market within four months, according to McNeil records.

Zomax's initial package insert cautioned that doctors should not prescribe the drug for patients with allergies to aspirin or similar medication, but it made no mention of anaphylactic reactions.

The first reports of anaphylactic reactions—none of which had resulted in death—surfaced soon after Zomax was launched. In July 1981, the company revised its package insert to include a statement that "anaphylactoid reactions have been reported."

Seay, in his internal critique, suggested that the package insert should have been revised sooner. He faulted the company for allowing its marketing division to gain "a greater role in the content and changes of the package insert," an area traditionally left to the medical side.

Pointing out that several severe allergic reactions occurred in 1978 during the premarketing testing of Zomax, Seay said an argument could be made that the company should have interpreted them as anaphylactic—an argument the company rejects. Seay also cited reports of anaphylatic reactions to another McNeil drug, Tolectin. "We knew the chemical relationship of Zomax to Tolectin and we knew that Tolectin produced

March 31, 1982, [illegible] Thomas Teal to McNeil president O'Brien. "Instead, the study found a pattern of anaphylactic reactions in patients who took Zomax intermittently—starting, stopping, starting again. It made no conclusions about these statistics.

Intermittent users were Zomax's largest market, about 75 percent. They took Zomax like aspirin, whenever necessary. If they were at risk, that might require a broad warning.

A few days after Teal presented his study to McNeil management, documents show an explicit paragraph-long warning was drafted for the proposed Dear Doctor letter, specifically citing risks for intermittent users who had no previous problems with Zomax. In the final draft, however, this word "intermittent" was dropped and the warning shortened to a single sentence: "Hypersensitivity upon re-exposure or extended use cannot be ruled out."

In recent interviews, McNeil and Johnson & Johnson officials stood by the letter's final wording. They said the Teal study, while worthy of consideration, was based on fragmentary information. At that point, they said, intermittent use was still an "unproven risk factor."

On April 9, the less explicit version was mailed to 200,000 prescribing doctors.

Seven days later, internal documents show, McNeil instructed its sales force to undertake a major new marketing campaign. An April 16 Mailgram said, "We're calling it 'Operation One-Eleven.' Now, if that sounds like war, well, in our world of selling that's what it is."

It was being called Operation 111, the Mailgram said, because McNeil hoped to garner $111 million in annual sales for Zomax and its sister drug, Tolectin. To do so, the Mailgram instructed the sales force to concentrate exclusively for 10 weeks on those two drugs.

During the duration of the sales campaign, McNeil sent memo after memo to its sales force, all written in mock military language and styled as if they were military intelligence reports. At the top of each was the Operation 111 insignia: crossed rifles. The sales reps received new stationery,

See COURTS, A13, Col. 1

VIEWPOINTS

"That's very upsetting to know, that [her husband's death] might have been prevented."

— Carol Sawyer, who sued McNeil after her husband, Michael, 42, died of anaphylaxis after taking Zomax

Court secrecy [illegible]

Staff Doctors Voice Concern At Tense Weekend Meetings

COURTS, From A12

adorned with pictures of a tank, a cannon and a fighter plane.

An April 22 memo to the sales force, titled "Operation 111 War Bulletin," warned of a competing drug firm's plans to introduce its own painkiller. It began:

"Situation: Be advised, the invading forces of Pfizer are currently amassing on our borders. Intelligence reports that no aggressive actions have taken place thus far. Each day Pfizer delays gives us more time to make preemptive strikes.

"Mission: We will not only hold our ground but continue to increase our strength by aggressive pursuit of current competitors.

"Strategy: Immediate deployment to all territory representatives and hospital representatives for strengthing the Zomax . . . flanks has begun . . . .

"Tactical support: Our factories have been converted to increase production of samples, direct mail, literature, and journal ads."

Halfway through Operation 111, a memo went out reminding the sales force that "high volume prescribers" of Zomax should be called a minimum of four times before the campaign was over. Each sales representative had been sent a list of these physicians in their area.

At McNeil headquarters, some medical staffers were upset about the sales campaign, believing that it had probably increased sales to intermittent users, according to Dale.

McNeil officials said Operation 111 was a typical sales campaign that had been conceived to respond to the introduction of Pfizer's new drug. They stressed that the sales force also had been sent copies of the Dear Doctor letter, which in their view contained the best warning statements that could be written at that time.

The Demise of Zomax

The internal documents also contain revealing insights into McNeil's dealings with the FDA and provide new details about the company's decision to recall the drug.

By law, drug companies are required to forward all reports of adverse reactions to the FDA. In 1982, documents show, Seay informed the FDA that McNeil had inaccurately reported the seriousness of several adverse reactions to Zomax. According to an April 21, 1982, internal memo by Seay, who was the company's liaison with the FDA, several cases described simply as allergic reactions "should have been designated" as the more serious anaphylactic.

It is clear from Seay's 1984 critique that he considered accurate reporting to the FDA to be of paramount importance. Not naming any specific drugs, he recounted one McNeil official's complaint that the company was "reporting too many adverse reactions on our drugs." Responded Seay, "We must report every adverse drug reaction that is received by us . . . . The requirements are clear."

Seay's critique also criticized other McNeil officials who paid visits to the FDA commissioner's office, which Seay said were seen by the FDA "as a form of pressure" to win favorable decisions. "We are having some difficulty in maintaining credible relations with FDA," he wrote.

Another internal memo criticized Dr. John Harter, the FDA official in charge of regulating Zomax. Robert Z. Gussin, McNeil's vice president for scientific affairs, described Harter as someone who "seems to have a different cause celebre every week, and we would go out-of-our-minds if we seriously followed up every one," according to his Jan. 25, 1982, memo to a McNeil colleague.

McNeil officials told The Post that Gussin's "colorful choice of words" does not reflect McNeil policies. They said the company took all FDA requests seriously.

By early 1983, with Johnson & Johnson still reeling from the highly publicized Tylenol poisonings in the fall of 1982, a task force was appointed at McNeil to study the deaths associated with Zomax use. At a meeting of McNeil officials, "It was pointed out . . . that this is a sensitive issue which can become the focus of immediate attention," according to minutes of the Jan. 21, 1983, meeting.

The issue came to a head at the Feb. 5 and 6 weekend meetings. At a Sunday session, McNeil president O'Brien heard for the first time that three of his four highest-

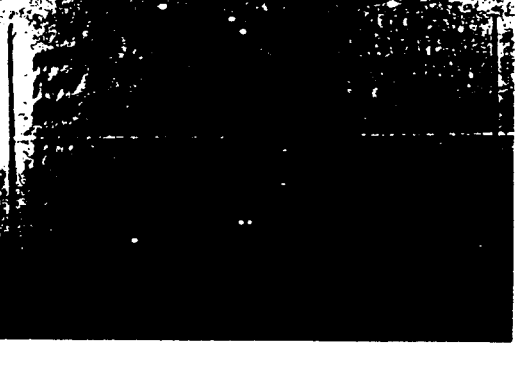
Settlements Kept Former Drug Salesm

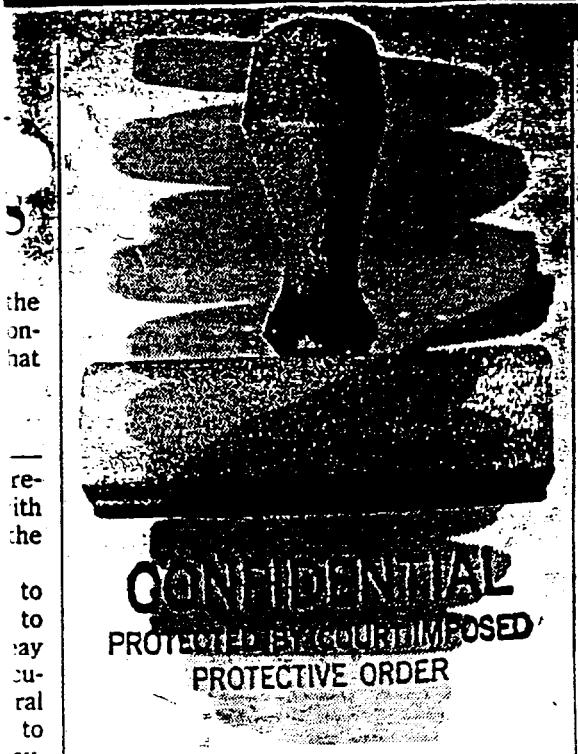
Jody Perez, a former sales representative for McNeil Pharmaceutical, went to his garage in June 1984, retrieved some documents stored there and took them to a law office in downtown Lubbock, Tex.

He was an important witness in several lawsuits against McNeil, which had been filed by alleged victims of Zomax, a prescription painkiller that McNeil pulled

Very appreciative. They usually have to pry notepads from Lilly rep."

He treated doctors to college football games and boxing matches, delivered pizzas to their offices and took doughnuts to their surgical suites. He gave samples to medical students and medical residents for their headaches, hangovers and menstrual cramps. He flattered nurses and receptionists to gain access to





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The issue came to a head at the Feb. 5 and 6 weekend meetings. At a Sunday session, McNeil president O'Brien heard for the first time that three of his four highest-ranking medical staffers were sufficiently concerned that they would not prescribe the drug for a patient, according to Dale, one of those who participated. His account was confirmed by another McNeil employee who attended the meeting with O'Brien.

McNeil officials differ over what happened next. Dale said there was a consensus that the company should recall the drug and immediately publicize its concerns. Foster, of Johnson & Johnson, said: "The possibility of voluntarily withdrawing the drug from the market was considered, but it is incorrect to state that the medical personnel concluded that a recall should take place."

The company decided to strengthen its package insert again. As it was being prepared, McNeil learned of three cases in which patients with no known allergy to aspirin had died of anaphylactic shock. Then, on March 3, a Syracuse, N.Y., television station carried a report of several nonfatal anaphylactic reactions in that city, the first time the issue had surfaced in the general media.

The next day, Johnson & Johnson announced the nationwide recall.

Troubling Witnesses

From the filing of the first lawsuits, after the wide publicity about the recall, McNeil's lawyers divided the cases into two categories. Many cases were considered frivolous or involved mild reactions that caused no long-term injuries. These were typically settled for less than $20,000, according to McNeil, and involved no extensive exchange of documents or secrecy orders.

The second category were cases deemed more difficult to defend for a variety of reasons, including the severity and timing of the injury, as well as the company's desire to prevent sensitive documents from emerging or certain witnesses from testifying.

One such witness was Jody Perez, a former McNeil sales representative in Texas who had resigned in 1982 because he believed the sales campaign downplayed Zomax's risks. Perez is listed as one factor in some cases on the list of 18 sensitive cases that circulated inside McNeil in January 1985.

McNeil's lawyers said Perez was only on factor in their decision to settle, and neve the most important one. "We looked at th cases in the total spectrum . . . the injurie involved, the jurisdiction, all the thing which go into evaluating a case, and a tempted to negotiate a settlement," sa Roger Christiansen, another Johnson Johnson attorney.

McNeil was more concerned about ano ymous notes that began mysteriously arri ing in 1986 at the offices of attorneys suin McNeil. The notes urged that they "not b deflected" from taking depositions of thre McNeil employees—Dale, Seay and E ward Lemanowicz, one of Seay's deputies.

The depositions never took place.

One note went to lawyer W. Thom Smith. He was the attorney for Carol Sa yer and the children of Michael Sawye whose death had occurred in the four-we interval between the Feb. 6 meeting a the recall. The Sawyer lawsuit, filed in Bo ton federal court, was on McNeil's list of sensitive cases.

Another note went to Florida attorn James Gray, who was representing Higir Acosta, a 41-year-old construction work who had a severe reaction on the same day Sawyer.

Both cases were settled soon after Smi and Gray sought to take the depositior Under the terms of the settlements, t attorneys said they could not discuss t cases. In the Acosta case, the entire file the Miami federal court has been sealed accordance with certain confidential a ye ments," according to an Oct. 2, 1986, or by Judge Thomas E. Scott.

McNeil's attorneys said they settl these two cases for a variety of reasons a not because they feared the testimony potential witnesses.

Referring to the three men, Fine sa "They were not the best spokespeople f the company. It was as simple as that."

Staff researcher Melissa Mathis contribute to this report.

NEXT: A sealed dispute

r Drug Salesman's Story Under Wraps

In early March, McNeil's head of medical research, Dr. Patricia Stewart, flew to Texas to investigate the reactions. She met with doctors and one of the people who had an anaphylactic reaction. On her return to McNeil headquarters in Spring House, Pa., she wrote a memo to her superiors, citing Perez for his "outstanding" performance in helping to reassure the Lubbock medical community. "Without his stabilizing influence the situation there would be much more

was a possible side effect for occasional users. "The attached letter need not be the focus of a Zomax presentation," an April 8 memo said. "However, the issues it raises should be communicated as part of a balanced presentation to physicians and pharmacists . . . . Zomax business is excellent. We are ahead of our sales forecast to date. Keep up the good work!"

A few days later, the company sent another announcement to its sales force, launching a major 10-week sales

McNeil officials said in recent interviews that their sales tactics, including Operation 111, are typical of the industry. "The communications to the sales force that are designated 'Operation 111' represent nothing but an unexceptional effort to compete in the marketplace with a resourceful competitor," said Lawrence G. Foster, vice president for public relations at Johnson & Johnson.

As Perez made his rounds to carry out

N 18,236

FDA
TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
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T83-11
March 4, 1983

William Grigg or Chris Smith
(301) 443-4177

REACTIONS TO ZOMAX

There have been cases reported of allergic reaction to a prescription drug Zomax. The following may be used in answering questions:

Zomax is a prescription drug widely used for severe and/or chronic pain. The physicians' labeling includes a warning which says in part, "As with other nonsteroidal anti-inflammatory drugs, anaphylactoid reactions have been reported." The warning goes on to describe the treatment, including the use of antihistamines, to counter this reaction.

FDA and the manufacturer, McNeil Pharmaceutical, have been working on a stronger warning for the drug. Over the past year and a half, two deaths have been reported in aspirin-sensitive persons among the 15 million persons who have been prescribed the drug. Three deaths have been reported in individuals who stopped and then were re-started on Zomax; these were anaphylactic shock cases — similar to the situation in which a bee sting sensitizes a person, immunological sensitivity develops and a second bee sting produces a violent reaction. There are also about 1000 reports of non-fatal allergic reactions, some quite severe.

McNeil Pharmaceuticals decided late today to conduct a market withdrawal the drug until the labeling can be rewritten. The company requests that any consumer having Zomax return the drug to the drugstore.

FDA believes that the allergic reactions to Zomax are fewer than with penicillin. Zomax may sometimes be used to replace narcotics in relieving severe pain.

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10TH ITEM of Level 1 printed in FULL format.

Congressional Record -- House

Monday, August 3, 1992

102nd Cong. 2nd Sess.

138 Cong Rec H 7201

REFERENCE: Vol. 138 No. 112

TITLE: PROVIDING POLICIES WITH RESPECT TO APPROVAL OF BILLS PROVIDING FOR PATENT TERM EXTENSIONS

SPEAKER: Mr. COBLE; Mr. FAWELL; MR. FISH; Mr. HUGHES; MR. MOORHEAD; Mr. STARK; MR. WOLPE; Mr. WYLIE

TEXT:
Text that appears in UPPER CASE identifies statements or insertions which are not spoken by a Member of the House on the floor.

{*H7201} Mr. HUGHES. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5475) providing policies with respect to approval of bills providing for patent term extensions, and to extend certain patents, as amended.

The Clerk read as follows:

H.R. 5475

BE IT ENACTED BY THE SENATE AND HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA IN CONGRESS ASSEMBLED,

SECTION 1. STATUTORY EXTENSION OF PATENT TERMS.

(a) In General. -- The Congress finds that, in the future, any bill providing for the extension of the term of a patent should not be approved by the Congress unless the requirements set forth in subsection (b) or (c) are met.

(b) Requests based on Delay in Premarket Approval. -- When the basis for a bill providing for a patent extension is delay in premarket regulatory approval of a patented invention, the following requirements should be met before the bill is approved by the Congress:

(1) Governmental misconduct. -- (A) Delay in the approval process must have been beyond the control of the patent holder and directly caused by governmental misconduct.

(B) For purposes of this paragraph, governmental misconduct is established by presentation of adequate proof of --

(i) dishonest or deceitful conduct,

(ii) vindictive or retaliatory action,

(iii) arbitrary, capricious, or grossly negligent performance of governmental duties, or

(iv) serious failure to perform governmental duties,

by the Federal Government.

(C) Unusual or unexpected delay alone does not constitute governmental conduct for purposes of this paragraph.

(2) Unjustified injury to the patent holder. -- The governmental misconduct under paragraph (1) must have caused a substantial inequity to the patent holder who, without the extension of the patent term, will suffer material harm directly attributable to the delay in the approval process. The unjustified harm to the patent holder if relief is not granted must outweigh any harm to the public (such as through higher prices) or to competitors that will result from extension of the patent.

(3) Expired patents. -- Expired patents shall not be revived and extended, except under the most extraordinary and compelling circumstances. In no such case shall an extension be granted unless the patent holder exercised due diligence to prevent the invention from entering the public domain.

(4) Intervening rights. -- In the event extraordinary circumstances justify the revival and extension of an expired patent, intervening rights shall be extended to persons using the subject matter of the patent after its expiration. Such rights shall not be provided in the case of statutory extension of unexpired patents, except that, in a case in which extreme injustice would result from the failure to provide such rights, they may be extended to persons who have, in good faith expectation of the expiration of the patent, made substantial preparation for use of the subject matter of the patent after its expiration.

(c) Other Requests. -- When the basis for a bill providing for a patent term extension is other than delay in premarket regulatory approval, the following requirements should be met before the bill is approved by the Congress:

(1)(A) Either governmental misconduct (as described in subjection (b)(1)), or action or inaction by the United States Government, contributed substantially to significant injury to the patent rights of the person requesting extension of the patent.

(B) For purposes of subparagraph (A), the action or inaction by the Government need not constitute governmental misconduct (as described in subsection (b)(1)), but must be of such a nature as to create a moral or ethical obligation on the part of the Government to provide relief to a person whose patent rights have been substantially injured by the action or inaction by the Government. Such action or inaction may include altering, by statute or rule, the regulatory approval procedures, standards, or requirements in a case in which there has been material reliance by an applicant on the prior procedures, standards, or requirements.

[*H7202] (2) The requirements set forth in paragraphs (2) through (4) of subsection (b) are met, except that --

(A) the reference in subsection (b)(2) to "governmental misconduct" shall be deemed to include, as applicable, the action or inaction by the Government described in paragraph (1) of this subsection, and

(B) the reference in subsection (b)(2) to "delay in the approval process" shall be deemed to refer to "governmental misconduct", which shall be deemed to include, as applicable, the action or inaction by the Government described in paragraph (1) of this subsection.

(d) Lack of Due Diligence. -- Notwithstanding the preceding provisions of this section, in no case should the Congress approve a bill providing for the extension of the term of a patent in the case of delay attributable to a lack of due diligence by the patent holder.

SEC. 2. PATENT EXTENSION FOR NONSTEROIDAL ANTI-IN-FLAMMATORY DRUGS.

(a) In General. -- The terms of United States patents numbered 3,793,457 and 4,076,831 shall each be extended for a period of 2 years beginning on the date of its expiration.

(b) Limitation on Rights. -- The rights derived from any patent which is extended by this section shall be limited during the period of such extension to any use for which the subject matter of the patent was approved by the Food and Drug Administration before the date of the enactment of this Act.

SEC. 3. PATENT TERM EXTENSION FOR OLESTRA.

The terms of United States patents numbered 4,005,195, 4,005,196, and 4,034,083 (and any reissues of such patents) shall each be extended for a period beginning on the date of its expiration through December 31, 1997.

SEC. 4. EXTENSION OF PATENT FOR INSIGNIA.

A certain design patent numbered 29,611, which was issued by the United States Patent Office on November 3, 1989, which is the insignia of the United Daughters of the Confederacy, and which was renewed and extended for a period of 14 years by the Act entitled "An Act granting an extension of patent to the United Daughters of the Confederacy", approved November 11, 1977 (Public Law 95-168; 91 Stat. 1349), is renewed and extended for an additional period of 14 years beginning on the date of the enactment of this Act, with all the rights and privileges pertaining to such patent.

SEC. 5. PATENT TERM EXTENSIONS FOR AMERICAN LEGION.

(a) Badge of American Legion. -- The term of a certain design patent numbered 54,296 (for the badge of the American Legion) is renewed and extended for a period of 14 years beginning on the date of the enactment of this Act, with all the rights and privileges pertaining to such patent.

(b) Badge of American Legion Women's Auxiliary. -- The term of a certain design patent numbered 55,398 (for the badge of the American Legion Women's Auxiliary) is renewed and extended for a period of 14 years beginning on the date of the enactment of this Act, with all the rights and privileges pertaining to such patent.

(c) Badge of Sons of the American Legion. -- The term of a certain design patent numbered 92,187 (for the badge of the Sons of the American Legion) is renewed and extended for a period of 14 years beginning on the date of the enactment of this Act, with all the rights and privileges pertaining to such

patent.

SEC. 6. INTERVENING RIGHTS.

The renewals and extensions of the patents under sections 4 and 5 shall not result in infringement of any such patent on account of any use of the subject matter of the patent, or substantial preparation for such use, which began after the patent expired but before the enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey [Mr. Hughes] will be recognized for 20 minutes, and the gentleman from North Carolina [Mr. Coble] will be recognized for 20 minutes.

The Chair recognizes the gentleman from New Jersey [Mr. Hughes].

Mr. HUGHES. Mr. Speaker, I yield myself such time as I may consume.

(Mr. HUGHES asked and was given permission to revise and extend his remarks.)

Mr. HUGHES. Mr. Speaker, H.R. 5475 is the product of almost a year's work by the Subcommittee on Intellectual Property and Judicial Administration. It grew out of a group of nine separate bills referred to the committee, each of which would extend the term of a patent or patents.

Following a hearing on these bills last October, the Subcommittee on Intellectual Property and Judicial Administration determined that at least two of them involved substantial factual disputes. We therefore asked the General Accounting Office to do some factfinding analysis regarding the Food and Drug Administration review of the ansaid (H.R. 2255) and olestra (H.R. 2805) products.

After some 4 months, the GOA provided the subcommittee with reports which helped clarify the facts regarding FEA review of ansaid and olestra.

The subcommittee then met and decided to defer action on the specific bills until we first develop a set of standards which must be met before we will favorably consider any bill providing for a patent term extension.

We also agreed that any bill favorably reporting a patent term extension should be a public and not a private bill.

As a reflection of these decisions, H.R. 5475 is a public bill which tablishes standards for the consideration of future patent extension bills.

We decided not to apply these standards retroactively to the bills already pending. I doubt if any of the separate extension bills which are incorporated in this bill would qualify under these new, stricter standards. However, we feel that fairness dictates that these petitions be judged by preexisting standards, not by ones we formulated after these bills were introduced. Indeed, in our hearing last October on these bills, proponents and opponents alike quite properly focused their presentations on whether the particular fact situations in question met the 1984 standards developed by our committee.

The central requirement of the new standards is that the patent rights of the patentee who is seeking an extension were materially harmed by governmental

138 Cong Rec H 7201, *H7202

action or inaction.

If the claim is that the harm resulted from unjustified delay in the regulatory approval process -- and almost all cases are -- the governmental action or inaction must constitute misconduct on the part of the Government. Mere delay in the regulatory process is not sufficient basis for a patent extension.

The bill enumerates various types of Government action which might constitute misconduct. In addition to egregious acts, such as deceitful, vindicative, or retaliatory action, misconduct can also be found in grossly negligent performance of governmental duties, or serious failure to perform those duties.

In examining the history of special legislation to grant statutory patent relief, we determined that, on some rare occasions, relief is appropriate even though there is no governmental misconduct. Examples are found in the governmental taking or curtailing of patent rights during time of war or national emergency. In these circumstances, the Government has not been guilty of misconduct -- but nonetheless the patent owner was seriously harmed by governmental action, and there is a moral if not a legal obligation on the part of the Government to provide relief.

In addition to the formulation of standards for future cases, H.R. 5475 provides for patent term extensions in the case of five product patents and four design patents.

Deciding these individual cases was the tougher part of our work on these issues, and among the most difficult I have worked on in my 18 years in the House.

First, the facts were in serious dispute. After we sorted out the facts as best we could, we had to decide what was fair and in the public interest.

On the one hand is the interest of developers of these products, their stockholders and employees in seeing that they are given the opportunity to market their products and recover their investments.

These investments are massive. For example, the three products involved in this bill required from $100 to $230 million to develop. Without a fair chance to bring their drug or food product to market, these investments would not be made, and we would all suffer.

On the other hand, patent terms have always been limited, and for good reason. The inventor receives exclusive rights to make and market the invention for a limited period of time in exchange for full disclosure of how it is made, so that others may enter the competition when the term expires. This benefits not only competitors who wish to enter the market, but also, frequently, the public at large in the form of lower prices. Generic drugs are a prime example.

Let me describe for you what we decided on the individual patents, and why:

1. ANSAID AND LODINE

Patents for these two products, both nonsteroidal anti-inflammatory drugs, are each extended for 2 years. Both the Upjohn new drug application for Ansaid

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and the American Home Products [*H7203] NDA for Iodine encountered delays of more than 78 months before approval. This is three times the average review period at the time these applications were filed.

The delays were caused in part by FDA concern over serious results, including nerous deaths, which resulted from the use of other, previously approved drugs of the same category. Nonetheless there was a troublesome 2-year period during which it appears that, without reasonable explanation, no action at all was taken by the FDA. In short, I believe the FDA, stung by criticism of the approval of the earlier drugs, froze up and shut down work on these drugs for about 2 years.

Eventually -- after 78 months in the case of ansaid and 96 months in the case of Iodine -- the FDA determined that both ansaid and Iodin are safe and effective, and have none of the defects found in the earlier approved drugs. Under these circumstances, some short term of extension is appropriate. H.R. 5475 provides for a 2-year extension of each of these patents.

2. OLESTRA

Consideration of the appropriate review and approval process for this ground breaking product has vexed the FDA and Procter & Gamble, the company which developed it, for 20 years. One of the four patents involved in the olestra application, which has not yet been approved, has already expired. The patents cover various aspects of the noncaloric cholesterol-free sucrose polyester compound knows as olestra. Olestra is a fat replacement product that can be used to flavor and texture food.

I do not believe that there is any justification for reviving the expired patent, or for granting the company's other request for an open-ended 10-year extension of the existing patents, to run from the time, if ever, that the FDA approves the food additive petition.

However, some relief is appropriate. The bill before us would extend the three unexpired olestra patents until December 31, 1997. This amounts to an extension of about 4 years for two of the patents, and 3 1/2 years for the third.

If and when the FDA petition is approved, the company would be entitled to a 2-year extension under the Patent Term Restoration Act of 1984. However, if we enact this bill, it will take away that 2 years. The net effect of this bill is, therefore, an extension of only 1 1/2 to 2 years.

We refused to provide and extension for the patent for an antiradiation drug eveloped under contract to the U.S. Army in the 1960's and known as WR 2721. That drug shows substantial potential for additional useful development.

However, we don't think that, standing alone, potentiality for future development is a proper basis for patent extension. The company -- U.S. Bioscience -- which owns the patent rights acquired those rights in 1987. The company bases its request for an extension upon the claim that, for many years, information regarding the potential for the drug was unavailable because of national security classification.

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We checked with the Army, however, and found that the information was classified for no more than a 4-year period, and that this classification was lifted in 1965. The Army further reports that it in fact encouraged publication and development of the potentialities of the drug, beginning in the 1970's.

Furthermore, we don't think a company which bought patent rights in 1987 has a legitimate claim against the Government for something the Government may have done in the 1960's, long before the company bought into the patent, and even before it was issued.

DESIGN PATENTS FOR INSIGNIAS AND BADGES

Section 4 of the bill would renew and extend the design patent for the insignia for the United Daughters of the Confederacy.

Section 5 would renew and extend the design patents for the badges of the American Legion, the American Legion Women's Auxiliary, and Sons of the American Legion.

All of these four design patents have expired, and would be renewed and extended for a period of 14 years beginning on date of enactment. Intervening rights would be recognized to prevent infringement actions against any persons who began use of the subject matter of these patents after their expiration and before the effective date of this act.

H.R. 5475 is a good bill. It lays down clear and appropriately tough standards for future statutory patent extensions.

It deals fairly with the bills filed under the old rules. It grants short extensions for products which were bogged down for excessive amounts of time in bureaucratic delay, and thus encourages the extremely expensive research and development that is necessary to bring beneficial new medicines and food products to consumers.

I urge your support.

Mr. Speaker, I reserve the balance of my time.

Mr. COBLE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to express my strong support for passage of H.R. 5475, a bill to create new standards regarding patent extension approvals. My primary interest in this legislation concerns that section of the bill involving the cronutrient called olestra, which has been developed by the Procter & Gamble Corp.

Mr. Chairman, I first want to commend the chairman of the Subcommittee on Intellectual Property and Judicial Administration, the gentleman from New Jersey [Mr. Hughes], and the ranking minority member of the subcommittee, the distinguished gentleman from California [Mr. Moorhead], for their patience and thoughtful contributions during our work on this project. Mr. Speaker, these two gentleman provided the leadership necessary to craft a fair and innovative bill which will extend certain patients for a brief period of time while creating a new standard to be applied to future extension requests.

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In addition to olestra, those products receiving patent extensions are two anti-inflammatory drugs, one licensed to the Upnohn Co., called ansaid; and the other owned by American Home Products, called lodine. Both drugs will receive 1-year extensions. Design patents for badges and insignia used by the United Daughters of the Confederacy and the American Legion will also be extended for 4 years.

The most important feature of the bill, Mr. Speaker, is the creation of new criteria to judge the merits of future requests. In brief: when a request for a patent term extension involves regulatory delay, the delay must have been beyond the control of the patent holder and directly caused by governmental misconduct. Unusual or unexpected delay alone will not constitute governmental misconduct. Further, the governmental misconduct must have caused a substantial inequity to the patent holder who will suffer material harm in the absence of an extension. Expired patents shall not be revived and extended, except under the most extraordinary and compelling circumstances. Requests based on circumstances other than regulatory delay need not constitute misconduct but must be of a nature to create a moral obligation on the part of the Government to supply relief.

No one involved in this process walked off with all of what he or she wanted. But the finished product in my opinion is something in which the subcommittee, especially its leadership, can take pride.

Mr. Speaker, I made the statement, you may recall, in full committee, I was reminded of a ship charting dangerous waters as we went through this with Mr. Hughes and Mr. Moorhead, who led the subcommittee through what I call procedural waters infested with rocks on the one hand, reefs on the other, and shoals somewhere in the middle. But thanks to their leadership, and I will again use the word patience, we negotiated this very difficult course and, I think, came up with a very worthwhile finished product.

Mr. Speaker, as noted, I am most interested in obtaining relief for olestra. By way of background, olestra is a calorie-free fat substitute that looks, cooks, and tastes like ordinary fat, but adds no fat or calories to the diet. Procter & Gamble has been testing olestra since 1971, the year its first patent for the substance was granted. Since that time, Procter & Gamble has invested more than $180 million in research and development in the project, but because of the unique nature of olestra, has been unable to secure Food and Drug Administration approval of [*H7204] the product. The company plans to spend another $50 million over the next 2 years to obtain the necessary regulatory clearance.

The last point, I believe, Mr. Speaker, is crucial in understanding why extended patent protection for olestra is warranted. Back in the early seventies, some testing indicated that olestra contained cholesterol-reducing properties. Neither Procter & Gamble nor the FDA had ever encountered a substance like this one that processed the attributes of a drug, on the one hand, as well as a food additive, on the other.

There was a total absence of any precedent to guide Procter & Gamble as it sought to establish the proper testing protocols for olestra, or to enable the FDA to provide other guidance in the matter. Stated differently, the FDA was compelled to develop the rules of the game as it went along. Understandably -- and after the fact -- this resulted in a 20-year-plus delay in approval that

persists to this day.

Mr. Speaker, we all know that patent extension bills are rarely approved. To do routinely would encourage monopolistic behavior and ultimately hurt consumers through higher prices. They should only be granted under exceptional circumstances. Under the standard which has governed patent extension requests, however, Procter & Gamble's situation would more than justify the assistance contained in H.R. 5475.

The company initially requested a 10-year extension for four patents -- one of which has already expired -- from the date of regulatory approval. But the legislation before us only extends the unexpired patents for 3 1/2 to slightly less than 4 years -- at most -- after expiration. The expired patent -- the most important of the four -- will not be extended at all. But this is still an equitable result, Mr. Speaker; Procter & Gamble will receive some protection for its exercise of good faith and commitment to regulatory compliance. As a simple matter of equity, it would otherwise be unfair to allow competitors to piggy-back on a $180 million investment when this corporation has exercised due diligence as it navigated, and continues to navigate, the regulatory maze at FDA, and I do not say there is fault against FDA, but it is, nonetheless, a regulatory maze.

Finally, Mr. Speaker, I think we have before us a fair, balanced, equitable bill, and I urge its passage.

Mr. Speaker, I reserve the balance of my time.

Mr. HUGHES. Mr. Speaker, I yield 2 minutes to the gentleman from California [Mr. Stark].

Mr. STARK. Mr. Speaker, I thank the distinguished gentleman from New York [Mr. McHugh] for yielding this time to me. He has yielded to me knowing that I have some reservations on the bill.

Mr. Speaker, H.R. 5475 deserves thoughtful consideration by every Member of the House. It is not without controversy, unfortunately, or differences of opinion on what is arguably a very complex subject.

First, Mr. Speaker, I would like to commend the thoughtful approach of the Committee on the Judiciary in establishing new strict standards for granting private patent extensions. Passage of this bill will have a significant effect on the normal course of business for thousands of American companies and their workers, not to mention millions of consumers.

Having said that, however, I think that what the bill gives with the one hand it immediately taketh away, and it grants special patent extensions to three companies without actually applying the new standards, and granting those extensions has been opposed by a variety of consumer interests: Public Citizen, Center for Science in the Public Interest, Citizens for Public Action on Blood Pressure and Cholesterol, Consumer Federation of America, Consumers Union and the National Consumers League. It would be my hope that that portion of this bill would have been dropped had the bill been brought to the floor with a rulemaking in order an amendment to eliminate that portion of it. It seems to me that without the debate necessary to determine whether billions of dollars should be given away to three of the largest, most profitable pharmaceutical

manufacturers in this country who already enjoy generous research and development tax credits, 936 credits for manufacturing in Puerto Rico, which gives almost $3 billion a year in taxpayer awards to these pharmaceutical companies, and they have just announced, in some cases, some 27 percent increase some of the drugs covered under this bill.

How much are we going to ask the consumers of this country who are already burdened by the lack of decent cost containment of their medical expenses to bear? I think that is a topic worthy of debate.

I would like to see H.R. 5475 passed by this House. I would like to see it amended, and I would like to see the amendment discussed after thorough discussion of these particular issues.

Mr. COBLE. Mr. Speaker, I yield 2 minutes to the gentleman from Illinois [Mr. Fawell].

Mr. FAWELL. Mr. Speaker, I thank the gentleman from North Carolina [Mr. Coble] for yielding this time to me.

Mr. Speaker, I come before this body not deeply knowledgeable in reference to all the aspects of this bill, and I commend the committee for certainly coming up with new recommendations, new concepts, in regard to patent approvals.

However, Mr. Speaker, I have had contact from various groups, one within my 13th Congressional District, where they pointed out that they had relied upon the fact that a certain patient, described in this bill, would be expiring. This pertains to Olestra, the fat substitute which indeed is quite a concept. They have spent approximately $40 million in research of Olestra, assuming that there was a date certain when the patents pertaining to Olestra would be terminated. So it does appear to me that there is controversy here and that perhaps it was not a bill that should be on the Suspension Calendar.

I did want to express my concern. I think somewhere along the line there should be some open debate on this subject because I am sure there are many others who have some of the concerns that I do have.

Mr. Speaker, I thank the gentleman very much for having yielded to me.

Mr. COBLE. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from Ohio [Mr. Wylie].

(Mr. WYLIE asked and was given permission to revise and extend his remarks.)

Mr. WYLIE. Mr. Speaker, I thank the gentleman from North Carolina [Mr. Coble] for yielding this time to me, and, Mr. Speaker, I want to compliment the gentleman from New Jersey [Mr. Hughes], the gentleman from California [Mr. Moorhead], and the gentleman from North Carolina [Mr. Coble] for the extraordinary good work they have done in bringing together this bill which is very complicated, to say the least.

I know that the gentleman from North Carolina [Mr. Coble] has done a splendid job in explaining the reason why I am here to extend the patent for Olestra. The gentleman has mentioned that Olestra is unique. It has taken Procter & Gamble over 20 years of research and uninterrupted dialog with the FDA. Procter &

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Gamble has invested somethingin the neighborhood of $185 million to research for Olestra in pursuit of this innovation. It is a unique new food additive, and because it is unique, the Food and Drug Administration has been a long time in allowing for approval. Procter & Gamble has been diligent in pursuing FDA approval from the start, and, without the extension, Procter & Gamble will lose of its key patent rights by expiration through early 1994, about the same time that FDA would be expected to approve its use.

So, Mr. Speaker, I rise in support of this legislation. I think it is good legislation, but I especially think it is desirable because of the patent extension for Olestra. There is a foreign-based competitor, I submit, ready, willing and able to pick up where Procter & Gamble is about to leave off if this extension is not granted. I think a failure to extend the extension of the patent for Olestra would be unfair and a deterrent to long-term research and development.

[*H7205] Mr. HUGHES. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I want to say to my colleagues in California and Illinois that I understand the argument. I understand that there is a foreign corporation which is based in Rotterdam that has also invested a lot of money in this product, not nearly as much as has Procter & Gamble, and obviously they are opposed to the legislation because they stand to gain from this patent going into the public domain.

But let us just take Olestra. The basic patent is already expired. It has been 20 years. We grant a 17-year patent. Putting aside the 2-year extension available under certain circumstances, we grant 17 years. That means that they have 17 years basically to receive the recoupment for that money. In the instance of Procter & Gamble, they have spent $180 million.

Now, while on the one hand once the patent falls into the public domain we benefit through the generic industry in particular in lower costs, but if companies will not invest because they cannot recoup their investment, then we do not get the patent to begin with and we do not get the products. That is the balancing we have had to do.

In the instance of Olestra, the Food and Drug Administration did not know what to do with it. They had a macronutrient and they did not know what it was about and we did not have testing protocols in place. So it took all those years to get to the point where we are just moving that through the process now.

Just recently the Food and Drug Administration mandated new tests on pigs. It was a brew requirement. In the meantime, 20 years have gone by and their basic patent has expired.

Is that fair? I do not think that is fair.

In the instance of ansaid, ansaid was a closer call for us. Iodine, not so much. But ansaid, there was a 2-year period of time when apparently the FDA did very little if anything in processing that drug. It took a total of 78 months, when the average time should take 26 months. Is that fair? In the instance of Iodine, it took 36 months. It is a very similar product.

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Mr. Speaker, that takes away from the company's basic investment and makes it that much more difficult for those companies to recoup their investments.

We talk about industries having a hard time surviving in this economic [illegible]ate today and competing with other companies around the world. Here is an [illegible]ance basically where there is a basic unfairness. So we get down to the standard.

Mr. Speaker, I think my colleague is right. We agonized over whether to apply this tough new standard, but we thought to ourselves, is that fair to take a tougher new standard and apply it to pending cases?

We took testimony on the basis of a standard which says if you have delay and you have harm, that is a sufficient basis for a patent extension. Is it fair to change the rules in the middle of the game after you have taken testimony?

Mr. Speaker, I do not think so. That is where the subcommittee came down, that is where the full committee came down, and, Mr. Speaker, I think the subcommittee and the full committee in working their will came up with a fair and balanced bill to all concerned. Not just to the companies, but also to the public interest, which is served by getting these products on the market so we can benefit from these new medicines.

MR. FISH. MR. SPEAKER, I RISE IN SUPPORT OF H.R. 5472.

I WOULD LIKE TO COMMEND THE GENTLEMAN FROM NEW JERSEY [MR. HUGHES] AND THE GENTLEMEN FROM CALIFORNIA [MR. MOORHEAD], AND NORTH CAROLINA [MR. COBLE] FOR THEIR PAINSTAKING WORK AND THOUGHTFUL ANALYSIS ON THESE DIFFICULT ISSUES. OUR PATENT LAWS HAVE SERVED THIS COUNTRY WELL. PATENT PROTECTION PROVIDES THE INCENTIVES TO MAKE INVESTMENTS AND BRING NEW PRODUCTS TO MARKET. IT'S IMPORTANT TO PROTECT AND ENCOURAGE THIS INVESTMENT BUT WE MUST AT THE SAME TIME BE SENSITIVE TO THE RIGHTS OF OTHERS WHOSE COMPETITIVE COMMERCIAL INTEREST MAY BE ADVERSELY AFFECTED BY THE EXTENSION OF A PATENT. TO BALANCE THESE INTERESTS CAN BE A VERY DIFFICULT ASSIGNMENT. UPJOHN, AMERICAN HOME PRODUCTS, AND PROCTER & GAMBLE MADE A FAIR AND REASONABLE CASE BEFORE THE SUBCOMMITTEE.

EXTENDING THE TERM OF A PATENT, EVEN ONE THAT HAS EXPIRED IS SOMETHING THE CONGRESS CAN AND HAS DONE FOR OVER 200 YEARS. THE USE OF SPECIAL RELIEF LEGISLATION WAS ADOPTED BY THE FIRST CONGRESS, WHICH PASSED THE FIRST TWO PRIVATE BILLS IN 1789. THE FIRST PRIVATE PATENT EXTENSION WAS ENACTED IN 1808. THE ACCEPTANCE OF THIS SPECIAL LEGISLATIVE FUNCTION BY CONGRESS MET WITH OPPOSITION EARLY ON -- JOHN QUINCY ADAMS REGARDED IT AS A CONTRADICTION OF THE [illegible]PARATION OF POWERS. HE THOUGHT THAT "A DELIBERATIVE ASSEMBLY IS THE WORST OF [illegible], TRIBUNALS FOR THE ADMINISTRATION OF JUSTICE." I AM SURE SOME OF YOU WOULD [illegible]REE WITH HIM, BUT MY POINT IS THAT H.R. 5475 REPRESENTS A METHOD OF JUSTICE THAT'S AS OLD AS THE PROCESS ITSELF. IT'S NOT AN EASY METHOD, IT'S NOT A POPULAR METHOD AND IT MAY NOT BE THE BEST METHOD, BUT THE JUDICIARY COMMITTEE AND ITS SUBCOMMITTEE HAVE DONE THIS HOUSE AND THE CONGRESS AN IMPORTANT SERVICE BY NOT ONLY CAREFULLY CONSIDERING THE VARIOUS BILLS CURRENTLY BEFORE IT, BUT ALSO IN DEVELOPING GUIDELINES THAT WILL AID IN THE CONSIDERATION OF FUTURE PROPOSALS. FOR THIS WE ARE GRATEFUL AND I URGE SUPPORT FOR H.R. 5475.

MR. GRADISON, MR. SPEAKER, I RISE IN SUPPORT OF H.R. 5475, A BILL PROVIDING POLICIES WITH RESPECT TO APPROVAL OF BILLS PROVIDING FOR PATENT TERM EXTENSIONS. AT THE OUTSET, I WANT TO COMMEND THE CHAIRMAN OF THE SUBCOMMITTEE [MR. HUGHES]

AND THE RANKING REPUBLICAN MEMBER [MR. MOORHEAD] FOR THEIR COOPERATION, FAIRNESS, AND DELIBERATE CONSIDERATION OF THE ISSUES RAISED IN THIS LEGISLATION.

SUBSTANTIAL CONGRESSIONAL AND JUDICIAL PRECEDENT EXISTS FOR THE EXTENSION OF NT TERMS. HOWEVER, THIS LEGISLATION REPRESENTS THE FIRST INSTANCE IN WHICH GRESS WILL ESTABLISH STATUTORY STANDARDS BY WHICH REQUESTS FOR PATENT TERM EXTENSIONS ARE TO BE JUDGED. THESE PROVISIONS ARE REASONABLE AND THEY DESERVE THE SUPPORT OF THE HOUSE. IT WOULD, HOWEVER, BE UNREASONABLE TO APPLY THESE STANDARDS RETROACTIVELY.

H.R. 5475 ALSO INCORPORATES THE PROVISIONS OF H.R. 2805, AS AMENDED, WHICH I INTRODUCED LAST YEAR. H.R. 2805 WOULD HAVE EXTENDED THE TERMS ON PATENTS RELATED TO OLESTRA, A NONCALORIC, NONABSORBABLE FAT REPLACEMENT, INVENTED BY THE PROCTER & GAMBLE MANUFACTURING CO.

DUE TO THE UNIQUE PROPERTIES OF OLESTRA, ITS USE AS A FOOD ADDITIVE HAS NOT YET BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION. THE UNIQUE CHARACTER OF OLESTRA HAS REQUIRED THE DEVELOPMENT OF A NEW REGULATORY REGIME WHICH WAS NOT FORESEEN WHEN CURRENT LAW WAS WRITTEN. AS A RESULT, NO PRACTICAL RELIEF CAN BE GRANTED TO THE COMPANY UNDER THE PATENT RESTORATION ACT OF 1984. HENCE, THE NEED FOR CONGRESSIONAL ACTION.

MR. SPEAKER, THE SUBCOMMITTEE, AFTER DELIBERATE CONSIDERATION, CHOSE NOT TO EXTEND THE EXPIRED PATENT ON OLESTRA. THE EXTENSIONS THE SUBCOMMITTEE DID GRANT ON THE THREE REMAINING PATENTS ARE FOR A PERIOD OF 3 YEARS.

IN MY VIEW, THIS WILL PROVIDE SOME RELIEF TO THE COMPANY AND WILL ALSO SUPPORT AN IMPORTANT PUBLIC POLICY INTEREST. OUR INTEREST IN THIS HOUSE SHOULD BE IN SUPPORTING AND ENCOURAGING INNOVATION. DEFEAT OF THIS LEGISLATION WOULD NOT ONLY DEFEAT THE STANDARDIZATION OF PATENT TERM EXTENSION REQUESTS, AS WELL AS IMPORTANT PATENT PROTECTIONS FOR THE AMERICAN LEGION AND THE UNITED DAUGHTERS OF THE CONFEDERACY, IT WOULD SEND A SIGNAL THAT THIS HOUSE IS NOT PREPARED TO GIVE MINIMAL SUPPORT TO INNOVATION. IT IS A SIGNAL THIS HOUSE SHOULD NOT SEND.

I URGE MY COLLEAGUES TO SUPPORT THE BILL.

MR. MOORHEAD. MR. SPEAKER, I RISE IN SUPPORT OF H.R. 5475.

I WOULD LIKE TO COMMEND THE GENTLEMAN FROM NEW JERSEY [MR. HUGHES] AND THE GENTLEMAN FROM NORTH CAROLINA [MR. COBLE] FOR THE WORK PRODUCT THEY BRING BEFORE US TODAY. THE EXTENSIONS PROVIDED FOR IN THIS BILL ARE, IN MY OPINION, FAIR AND JUST.

NO ONE RECEIVED ALL OF WHAT THEY ASKED FOR BUT HAVING REVIEWED THE RECORD JSELY, WE DID TRY AND PROVIDE A FAIR EXTENSION OF THOSE WHO, I THINK, MADE A GOOD CASE.

THE IMMEDIATE PROBLEM FOR THE SUBCOMMITTEE AND THE JUDICIARY COMMITTEE WAS TO DEAL FAIRLY WITH A GROUP OF VERY DIFFICULT PATENT EXTENSION BILLS THAT WE FOUND BEFORE US. AND ALL OF THESE BILLS ARE DIFFICULT. BECAUSE EACH OF THE APPLICANTS FEELS THAT THEY HAVE A HARDSHIP, THAT THE PATENT TERM IS NOT SUFFICIENT TO GET THEIR PRODUCT APPROVED BY THE FOOD AND DRUG ADMINISTRATION AND THEIR PATENTS ARE GOING TO EXPIRE BEFORE THEY HAVE HAD AN OPPORTUNITY TO PUT THEIR PRODUCT ON THE MARKET, OR BEFORE THEY COULD RECOVER ANY OF THE COSTS OF THEIR RESEARCH AND DEVELOPMENT.

OBVIOUSLY, THE PURPOSE OF OUR PATENT SYSTEM IS SO THAT PEOPLE WHO SPEND THEIR MONEY ON RESEARCH AND DEVELOPMENT OF A PRODUCT AND TAKE THE RISK WILL HAVE AN OPPORTUNITY TO TRY AND RECOVER THEIR COSTS AND MAKE A PROFIT BEFORE THEIR PATENT PIRES. AND THE DELAYS THAT HAVE TAKEN PLACE IN MANY INSTANCES, IN GETTING IR PRODUCTS TO MARKET, HAVE BEEN SO LONG THAT THEY HAVEN'T HAD A CHANCE TO AND GET ANY RETURN ON WHAT ARE SUBSTANTIAL INVESTMENTS.

WE HAVE STRUGGLED OVER ALL OF THESE INDIVIDUAL BILLS FOR A NUMBER OF MONTHS. AND IN THE [*H7206] END, I TOTALLY AGREE ON THE RESULT CONTAINED IN H.R. 5475.

WHAT'S IMPORTANT ABOUT THIS LEGISLATION ARE THE STANDARDS WE HAVE DEVELOPED FOR FUTURE CONSIDERATION OF PATENT TERM EXTENSIONS. TO STATUTORIZE STANDARDS BY WHICH TO MEASURE FUTURE LEGISLATION IS UNPRECEDENTED. NEVER BEFORE IN THE HISTORY OF PATENT TERM EXTENSIONS HAS A COMMITTEE RECOMMENDED A MECHANISM FOR DEALING WITH THESE IMPORTANT AND DIFFICULT CASES. THESE STANDARDS ARE INTENDED TO BE HIGH, AND DIFFICULT TO MEET, BUT THEY WOULD ALSO PROVIDE THE SUBCOMMITTEE WITH THE NEEDED FLEXIBILITY TO DEAL WITH THE EXTENSIONS THAT ARE MERITORIOUS.

I THINK IT IS NECESSARY THAT AT LEAST SOME LEEWAY BE THERE. BUT WE WANT THESE RULES TOUGH ENOUGH SO THAT WE DON'T HAVE A FLOOD OF BILLS FROM PEOPLE WHOSE PATENTS ARE EXPIRING, WHO THINK THAT THEY CAN COME TO CONGRESS AND RECEIVE AN EASY EXTENSION OF THEIR PATENT.

OUR JOB IS TO TRY TO BRING SOME DEGREE OF FAIRNESS TO THESE SITUATIONS. AND I BELIEVE THAT THIS IS WHAT H.R. 5475 DOES, AND I CERTAINLY HOPE THAT IT IS ADOPTED. IF THERE ARE CHANGES THAT ARE LATER NEEDED DOWN THE LINE IN THE STANDARDS, THEY MAY BE MADE BY A FUTURE CONGRESS. BUT FOR TODAY, I THINK THIS IS A GOOD BILL, AND GOOD POLICY AND URGE A FAVORABLE VOTE.

MR. WOLPE. MR. SPEAKER, I AM ONE OF THE ORIGINAL COSPONSORS OF LEGISLATION TO EXTEND THAT PATENT FOR ANSAID, AN ANTI-INFLATIONARY DRUG USED TO TREAT DISEASES LIKE RHEUMATOID ARTHRITIS. ANSAID IS MANUFACTURED BY THE UPJOHN CO., WHICH IS HEADQUARTERED IN MY DISTRICT AND WHICH HAS BEEN AN OUTSTANDING CORPORATE CITIZEN DURING THE MORE THAN 100 YEARS SINCE ITS FOUNDING.

H.R. 5475 PROVIDES SOME PATENT RELIEF FOR ANSAID, AND I SUPPORT THE BILL. I BELIEVE THAT THE FACTS OF THE ANSAID CASE UNEQUIVOCALLY INDICATE THIS RELIEF IS WARRANTED, AND I HAVE A LENGTHY STATEMENT THAT I WOULD LIKE TO SUBMIT FOR THE RECORD WHICH LAYS OUT THOSE FACTS IN SIGNIFICANT DETAIL.

I INVITE MY COLLEAGUES -- THOSE OF YOU WHO HAVE NOT BEEN AS CLOSELY INVOLVED THIS BILL AS I HAVE -- TO EXAMINE THE FACTS. THESE FACTS HAVE BEEN EXAMINED AUSTIVELY BY THIS BODY, BY OUR SENATE COUNTERPARTS, BY THE FDA AND BY THE ATENT AND TRADEMARK OFFICE, AND, IN AN UNPRECEDENTED STEP, BY THE GAO. THESE FACTS INDICATE THAT, THROUGH NO FAULT ON THE PART OF THE COMPANY, THE ANSAID APPLICATION WAS SUBJECT TO EXTRAORDINARY REGULATORY DELAY.

BILL HUGHES, THE CHAIRMAN OF THE INTELLECTUAL PROPERTY SUBCOMMITTEE OF THE JUDICIARY COMMITTEE, AND THE RANKING MINORITY MEMBER OF THAT SUBCOMMITTEE, CARLOS MOORHEAD, LOOKED AT THESE FACTS. THEY LOOKED ALSO AT THE MANNER IN WHICH WE HERE IN CONGRESS DEAL WITH PATENT EXTENSION REQUESTS, A ROLE WHICH EXTENDS BACK TO THE EARLIEST DAYS OF THIS BODY. THE SUBCOMMITTEE CAME UP WITH STANDARDS TO EVALUATE PATENT EXTENSION LEGISLATION IN THE FUTURE, BUT AGREED THAT IT WOULD BE INEQUITABLE, BASED ON THE FACTS OF THE ANSAID CASE, TO DENY RELIEF.

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I THINK THAT THE FACTS OF THE ANSAID CASE ARE COMPELLING. I BELIEVE THAT H.R. 5475 IS A BALANCED AND EQUITABLE BILL, AND I ENCOURAGE MY COLLEAGUES TO VOTE YES.

THE FACTS OF THE ANSAID CASE

I. THE DEVELOPMENT OF ANSAID

For many decades, medical researchers have sought safe and effective treatments for the inflammatory diseases which affect large segments of the U.S. population. These diseases include rheumatoid arthritis, degenerative joint disease, bursitis and tendinitis, and they afflict virtually all Americans, from the elderly to the best trained athletes.

Aspirin has long been recognized as a potent anti-inflammatory drug and is still the drug of choice for many patients. Because of the serious gastrointestinal effects of aspirin, however, research continued in an effort to find a safer agent. Research conducted in the late 1950's and early 1960's resulted in the discovery of compounds now classified as "non-steriodal anti-inflammatory drugs" ("NSAIDs"). As a group, these drugs have anti-inflammatory properties comparable to aspirin but with fewer adverse gastrointestinal effects.

Indicin, a product of Merck Sharp & Dohme, was the first of these drugs to be approved, in 1965, but the approval of Motrin, an Upjohn product, in 1974 opened the gates for the introduction of fifteen more of these drugs over the next fourteen years. The NSAID field is now among the most competitive and consumer-oriented fields in the pharmaceutical marketplace. The development of Ansaid represents the next step in the progress of this important line of drugs.

II. THE ANSAID APPROVAL PROCESS

The Upjonn Company submitted its NDA for Ansaid (flurbiprofen) on March 29, 1982. At that time, the average period for approval of an NDA for an NSAID such as Ansaid was approximately two years. From 1974 through 1982, eight out of ten NSAIDs had been approved in 27 months or less. n1

n1 Footnotes at end of article.

The animal studies and clinical trials of Ansaid had shown the drug to be both effective for the treatment of rheumatoid arthritis and osteoarthritis and remarkably free of serious side effects. The drug's profile was, in fact, quite similar to what was anticipated for drugs of this class. Upjonn therefore reasonably expected that its NDA would not present significant problems and that it would be approved within the two-year period required for approval of other NSAIDs in the 1974-1982 period.

Shortly after the Ansaid NDA was submitted, however, a series of events relating to other drugs unfolded, which dramatically lengthened the approval time for Ansaid. After approving ten NSAIDs in the immediately preceding eight years, the FDA did not approve ANY drugs of this class in 1983 or 1984, and only one in each of the next three years. Average NSAID approval times soared from slightly more than two years for drugs approved in 1982 and earlier to almost six years for those approved after that time. Because of these delays, Upjonn didnot reach marketing approval for Ansaid until October 31, 1988, more than

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six years after its NDA was submitted.

These delays were caused by events pertaining to other NSAIDs, principally Oraflex, Feldene, Lomax, and Suprol. As a result of issues raised by those drugs, FDA slowed its new NSAID approvals for two primary reasons. First, significant Agency resources were devoted to resolving the questions raised by these particular drugs and were thus unavailable for reviewing new NSAID applications. Second, when FDA did turn to reviewing the pending NADs for this class of drugs, it gave them much closer scrutiny in light of the problems with other NSAIDs, and this also lengthened the time needed for approval.

In sharp contrast to the drugs and events described below, Ansaid has been used safely by millions of people in the United States and internationally. The safety of the product was never under any dispute at any time during the course of FDA review of the application for approval.

A. Oraflex

On April 19, 1982, FDA approved the NDA for Oraflex (Benoxaprofen), an NSAID indicated, like Ansaid, for treatment of reneumatoid arthritis and osteoarthritis. The Oraflex NDA was submitted in 1980, and approval followed 27 months later, the average time then expected for NSAIDs. Almost immediately after this approval, however, FDA was forced to devote substantial resources to reviewing new information on the drug and reassessing its labeling, dosage, and risk-benefit ratio.

On April 24, 1982, The Lancet, a British medical publication, published a letter to the editor noting jaundice in three patients using benoxprofen in the United Kingdom. n2 A few weeks later, on May 8, 1982, the British Medical Journal published a "short report" describing the death of six elderly patients, all of whom had been taking benoxaprofen, from a liver disorder known as cholestatic jaundice. n3 FDA also received a letter on May 27, 1982, from a British government medical official pertaining to adverse events associated with benoxaprofen. n4

n2 "Jaundice associated with the use of benoxaprofen," Lancet 959 (Apr. 24, 1982). SEE THE REGULATION OF NEW DRUGS BY THE FOOD AND DRUG ADMINISTRATION: THE NEW DRUG REVIEW PROCESS, Hearings Before a Subcomm. of the House Comm. on Gov't Operations, 97th Cong., 2d Sess. 105 (1982) (hereinafter cited as NEW DRUG HEARINGS).

n3 Taggart and Alderice, "Fatal cholestatic jaundice in elderly patients taking benoxaprofen," 284 Brit. Med. J. 1372 (May 8, 1982). SEE NEW DRUG HEARINGS, SUPRA, at 104.

n4 SEE "Deficiencies in FDA's Regulation of the New Drug 'Oraflex,' " Fourteenth Report by the House Comm. on Gov't Operations, H.R. Rep. No. 811, 98th Cong., 1st Sess. 3 (1983) (hereinafter cited as "Oversight Report").

These events and other reports prompted FDA to reconsider the labeling of Oraflex, especially as it concerned liver and kidney dysfunction, as well as the appropriate dosage for elderly patients. Senior FDA officials gave this matter their personal attention from the outset. n5 In addition, FDA personnel conducted careful investigations into the voluminous clinical data concerning the safety of Oraflex. n6 As part of its overall review, the Agency considered

whether certain adverse events raised medical and scientific questions for NSAIDs as a class, in addition to whether they necessitated changes with respect to Oraflex in particular. The Agency also implemented changes in its DNA review procedures to ensure that medical officers based their decisions on the most rent safety data available. n7

n5 SEE, E.G., NEW DRUG HEARINGS, supra, at 108 (memorandum of phone conversation concerning Oraflex between FDA's Acting Director, Office of New Drug Evaluation, and Lilly physician); id. at 112-113 (memorandum of meeting concerning Oraflex; attendees included FDA's Director and Associate Director, Bureaus of Drugs and Biologics).

n6 SEE, E.G., id. at 98-99 (setting forth FDA memorandum concerning benoxaprofen adverse event reporting).

n7 SEE ID. at 526-527 (setting forth memorandum from Dr. Temple concerning review of investigational files prior to NA approval).

FDA devoted a meeting of its Arthritis Advisory Committee on June 3-4, 1982, to the issue of liver toxicity for all NSAIDs. At the meeting, the Director of the FDA division responsible for NSAID approvals indicated his belief that almost all NSAIDs were associated with liver abnormalities and that additional information was needed to help develop classwide labeling revisions. n8 This association had not previously manifested itself as a significant clinical problem. n9

n8 Adv. Comm. Transcript, pp. 156-157.

n9 SEE, E.G., ID. at 106.

Following this meeting, FDA reviewed proposed revised labeling for Oraflex. It ultimately approved revisions on July 12, 1982. n10 Reports continued, however, concerning the use of benoxaprofen overseas. Later that month, for example, the regulatory authorities in Denmark decided to restrict the drug to hospital use. n11

n10 SEE "Oversight Report," supra, at 3.

n11 SEE ID.

At the same time, the Oraflex controversy continued to receive widespread public and media scrutiny in the United States. n12 The Health Research Group, a consumer advocacy organization, petitioned the Secretary of Health and Human rvices to remove Oraflex from the market. n13 Six weeks later, the American sociation of Retired Persons also petitioned the Secretary to ban the drug. n14 These organizations, joined by the National Council of Senior Citizens, sued the Departme t of Health and Human Services in federal court shortly thereafter in an attempt to force FDS to rescind the approval for Oraflex. n15 Responding to these efforts required substantial Agency resources.

n12 SEE, E.G., "Oraflex Case Seen Changing Drug Industry," Wall St. J., Sept. 20, 1982, at 33.

n13 SEE "Warning About Using Anti-Arthritis Drugs Is Urged by U.S. Panel," Wall St. J., June 18, 1982, at 32.

n14 SEE "Arthritis Drug Stirs Ban Effort," Wash. Post, July 31, 1982, at A-4.

n15 SEE "3 Groups Suing To Bar Arthritis Drug Oraflex," Wash. Post, Aug. 3, 1982, at A-13.

n August 3 and 4, 1982, the Intergovernmental Relations and Human Resources Subcommittee of the House Committee on Government Operations held oversight hearings on FDA's regulation of new drugs. n16 The [*H7207] hearings concentrated almost exclusively on matters relating to Oraflex and Feldene (piroxicam), another NSAID (see below). Even before the hearings were held, FDA

n16 SEE NEW DRUG HEARINGS, SUPRA.personnel had responded to congressional staff inquiries concerning Oraflex. n17

n17 SEE, E.G., ID. at 119 (memorandum of telephone conversation between Dr. Harter of FDA and Mr. Siglerman of the Subcommittee staff).

FDA Commissioner Arthur Hull Hayes, Jr., M.D., and other FDA officials gave extensive testimony at these hearings. In fact, FDA officials were the only persons who testified during the two days of hearings. In discussing the NDA approval process, Commissioner Hayes noted that even the two years required for approval of Oraflex was a "lengthy" period, which was required because the NDA was particularly "complicated." n18 More straightforward NSAID applications presumably would take less time to approve.

n18 ID. at 16.

FDA continued responding to congressional requests for information concerning Oraflex after the hearings were concluded. n19 Meanwhile, the manufacturer of Oraflex voluntarily suspended the sale and distribution of the drug on August 5, 1982. n20

n19 SEE, E.G., ID. at 532, 559-561 (letters from Commissioner Hayes to Representative Fountain).

n20 SEE ID. at 564.

After several months of investigation, the House Committee on Government Operations released a report concerning Oraflex and recommending changes in FDA's adverse event reporting requirements and NDA review procedures. n21 On October 12, 1984, FDA Commissioner Frank E. Young, M.D., provided detailed responses to the Committee's recommendations. n22 In this response, Commissioner Young noted that the Agency had proposed changes in its new drug regulations in October 1982 and June 1983. n23 Those changes included modification of the reporting requirements.

n21 SEE "Oversight Report," SUPRA, at 3.

n22 SEE letter from Commissioner Young to Representative Weiss (Oct. 12, 1984).

n23 SEE ID.; 47 Fed. Reg. 46622 (Oct. 19, 1982) (NA regulations); 48 Fed. Reg. 26720 (June 9, 1983) (investigational new drug, or "IND," regulations). The revised regulations became final in 1985 and 1987. SEE 50 Fed. Reg. 7452 (Feb. 22, 1985) (NA regulations); 52 Fed. Reg. 8798 (Mar. 19, 1987) (IND

regulations).

In addition, FDA continued its own investigation of Oraflex. Following an extensive review, FDA referred the matter to the Justice Department in May 1983. A grand jury was later convened, and the manufacturer ultimately pleaded guilty to misdemeanor violations of the Federal Food, Drug, and Cosmetic Act on August [illegible], 1985.

B. Feldene

A substantial part of the August 1982 oversight hearings were devoted to FDA's approval of another antiarthritic NSAID, Feldene (piroxicam). n24 This drug was approved on April 6, 1982, following extensive FDA review of the clinical trial data in the NDA. Questions were raised at the hearing with respect to the effectiveness of the drug and certain press announcements concerning the drug. n25 Again, senior FDA management testified and responded to the Subcommittee's questions.

n24 SEE, E.G., NEW DRUG HEARINGS, supra, at 367.

n25 SEE, E.G., ID. at 368-404, 508-512.

In the same report in which it discussed Oraflex, the Committee noted issues pertaining to Feldene as well. n26 As stated by the Committee, an FDA supervisory medical officer investigating Oraflex also raised questions pertaining to Feldene adverse event reporting. n27 The Subcommittee subsequently "brought this matter to the attention of senior FDA managers," and further FDA review ensued. n28 Thus, as with Oraflex, FDA officials spent considerable time investigating the facts pertaining to Feldene. More than a year after the hearing, FDA was still reviewing the reporting of adverse events associated with Feldene and responding to congressional inquiries on this matter. n29

n26 SEE "Oversight Report," SUPRA, at 7, 21-22.

n27 SEE ID. at 7.

n28 ID. at 21.

n29 FDA'S REGULATION OF ZOMAX: HEARINGS BEFORE A SUBCOMM. OF THE HOUSE COMM. ON GOV'T OPERATIONS, 98th Cong., 1st Sess. 440-447 (1983) [hereinafter cited as Zomax Hearings].

C. Zomax

In the spring of 1983, as FDA continued its Oraflex and Feldene investigations, the Agency found itself facing yet another controversy involving another NSAID, Zomax (zomepirac sodium). After approval in 1980, Zomax was withdrawn from the market by its manufacturer on March 4, 1983, "because of fatal and near fatal adverse reactions to the drug." n30

n30 ID. at 2.

For at least a year prior to the removal of Zomax from the market, FDA medical officials with responsibility for new drugs in general and NSAID's in particular had devoted considerable time and effort to reviewing data on Zomax

and considering changes in the drug's labeling. n31 During this period, and especially after the market withdrawal, issues pertaining to Zomax "received a good deal of publicity." n32

n31 SEE, E.G., ID. at 108-119, 125-127.

n32 ID. at 91. As Dr. Harter of the FDA explained with respect to the withdrawal of Zomax from the market, "I think the news media got more interested; it got more publicity than one might expect, because the Tylenol thing had preceded it, and here was a company with a similiar -- not the same problem -- but from the news people's viewpoint a similar problem, deaths from a drug." Transcript of Arthritis Advisory Committee Meeting, May 12, 1983, at 9 [hereinafter cited as Advisory Comm. Tr.].

The Intergovernmental Relations and Human Resources Subcommittee held oversight hearings concerning Zomax on April 26 and 27, 1983. n33 Commissioner Hayes again appeared before the Subcommittee, accompanied by several other senior FDA officials. n34 In his testimony, the Commissioner discussed FDA's adverse event monitoring systems, and in particular a newly developed system that "logs all reports *** regardless of source and tracks the review process until the report is entered

n33 SEE ZOMAX HEARINGS, SUPRA.

n34 SEE ID. at 85, 124.into the [Drug Experience Information System] file." n35 The Commissioner also noted that the adverse events associated with Zomax were considered in light of the drug experience profiles for NSAIDs as a class, and that the Agency carefully considered overall drug experience patterns for the NSAIDs in this context. n36

n35 ID. at 88.

n36 SEE ID. at 89. An FDA official explained to the Arthritis Advisory Committee that while it may seem to "be an easy thing" to review the relevant epidemiologic data, "it is clear that it is not" because the "reaction is rare enough that it is hard to get the noise out so you can start seeing the reaction you are really interested in." Advisory Comm. Tr., SUPRA, at 10.

The removal of Zomax from the market prompted intense FDA scrutiny of all NSAIDs. For example, FDA prepared an extensive "summary of [adverse drug experience] reports, by year, for all nonsteroidals on the basis of market share." n37 In addition, Agency officials analyzed reports pertaining to several NSAIDs to determine whether those drugs were associated with the same type of hypersensitivity or anaphylactic [allergic] reactions that led to the withdrawal of Zomax. n38 FDA was particularly concerned with the possibility that "the apparent increase in hypersensitivity [to Zomax] * * * [was not] really different from other NSAID drugs used the same way," and that "if other NSAIDs were used intermittently, they too would have a greater frequency of hypersensitivity reactions." n39 FDA therefore conducted an "indepth analysis * * * by examining all nonsteroidal exposed patients" in a data base of records from 300,000 Medicaid patients." n40 In addition, the Agency developed tabulations of more than 18,000 adverse events for all NSAIDs from 1969 through 1983, and presented these to the Subcommittee during the hearings. n41

n37 ZOMAX HEARINGS, SUPRA, at 89.

n38 SEE ID.

n39 ID. at 90.

n40 ID. at 89.

n41 SEE ID. at 102-104.

The Commissioner and other FDA officials also responded to extensive questioning from the Subcommittee. Most fundamentally, the Subcommittee was concerned whether FDA was "really doing an objective job," or instead "trying to find justification for having approved a product." n42 Commissioner Hayes responded that the Agency was not "seeking a justification but rather * * * trying to find the right answer" in light of all available "scientific data." n43 While the discussion focused primarily on Zomax, the Subcommittee emphasized that "[w]e are really talking about appropriate policy and procedures of the Agency, including questions of adequate staffing and effective management practices." n44

n42 ID. at 96 (Mr. Weiss).

n43 ID. at 97.

n44 ID. at 124 (Mr. Weiss).

In this regard, the Subcommittee pointed to a 1982 report of the General Accounting Office concerning areas in which FDA's adverse event monitoring systems could be improved, and asked what steps had been taken to implement the recommendations contained in that report. n45 The Commissioner responded that Agency officials "have addressed and continue to address" these issues. n46 For example, considerable FDA resources were devoted to maintaining and improving FDA's computer tracking system. n47 FDA officials also explained that an indepth epidemiological study of adverse event information for even a single drug is an especially "labor intensive" undertaking. n48 The Subcommittee questioned whether a computer system could be implemented specifically to track adverse events reported with respect to NSAIDs. n49 FDA responded that the issues involved in any tracking system are "very complicated" and its system in particular is "complex." n50 Resources also were devoted to answering inquiries from the Subcommittee about specific Zomax adverse event reports and other issues. n51 Finally, the Subcommittee reviewed documents pertaining to two NSAIDs with NDAs then pending at FDA to determine whether they raised safety issues related to Zomax. n52

n45 SEE ID. at 132-134.

n46 ID. at 133.

n47 SEE ID.

n48 ID. at 283, 285.

n49 SEE ID. at 285 (Mr. Weiss).

n50 ID. at 286.

n51 SEE ID. at 327-333, 509-532.

52 SEE ID. at 533-555.

On December 2, 1983, the House Committee on Government Operations issued a report concerning "FDA's Regulation of Zomax." n53 Among other things, the Committee recommended that "FDA establish procedures for prompt processing, review, and analysis of all adverse reaction reports for marketed drugs." n54 The controversial nature of the entire Zomax episode and of certain of the Committee's findings is reflected in the numerous dissenting and additional views accompanying the report. n55

n53 "FDA'S REGULATION OF ZOMAX," Thirty-First Report by the (House Comm. on Gov't Operations, H. Rept. No. 884, 98th Cong., 1st Sess. (1983).

n54 ID. at 27.

n55 SEE ID. at 29-36.

D. Suprol

After a virtual moratorium on NSAID approvals, FDA finally approved a new NSAID, Suprol (suprofen), on December 24, 1985. A few months later, however, the drug's manufacturer began receiving reports of unusual adverse kidney effects, frequently combined with flank pain, associated with Suprol. Sales of the drug ultimately were halted on May 18, 1987, in the face of mounting criticism. n56

n56 SEE FDA'S REGULATION OF THE NEW DRUG SUPROL, Hearing Before a Subcomm. of the House Comm. on Gov't Operations, 100th Cong., 1st Sess. 417-418 (1987).

Reports of the flank pain syndrome associated with Suprol had begun to appear almost immediately after the drug was approved for marketing. n57 Subsequently, numerous reports were made to FDA, and the Agency became occupied with reviewing new and revised labeling for the drug. An article also appeared in the June 1986 edition of the FDA Drug Bulletin. n58 In addition to the Agency itself, Advisory Commission reviewed Suprol in light

n57 SEE ID. at 35-36.

n58 SEE ID. at 36-41.of the new adverse events reports. n59 FDA resources were also devoted to responding to a petition filed in September 1986 seeking removal of Suprol from the market. n60

n59 SEE ID. at 42.

n60 SEE ID. at 364.

Once again, FDA officials testified at a House oversight hearing devoted to examining the Agency's NSAID regulatory processes. Among the issues raised by the House Subcommittee at the hearing were whether FDA adequately investigated the drug sponsor's reporting of adverse drug events and whether the Agency had properly weighed the risks and benefits of the drug. n61 The overall goal of the hearing was to use the case of Suprol to evaluate "whether or not our current

system of drug regulation and surveillance works." n62

n61 SEE ID. at 2.

n62 ID. at 3.

At the hearing, FDA officials emphasized the difficulty of detecting rare adverse events in the clinical trials prior to NDA approval, since those trials are generally limited to a few thousand patients. n63 Following the hearing, FDA supplied a detailed chronology of events relating to Suprol, as well as written responses to certain questions raised at the hearing. n64 FDA had also answered questions from the Subcommittee chairman prior to the hearing. n65

n63 SEE ID. at 364.

n64 SEE ID. at 412-433.

n65 SEE ID. at 336-366.

E. Contrast: The Approval of Ocufen

Review of the case of FDA approval of Ocufen, an ophthalmic solution containing flurbiprofen sodium -- a salt of the active ingredient in Ansaid -- suggests that the delay in approving Ansaid was due to events relating to other NSAIDs, and not to the nature of the product itself.

The NADA for Ocufen for use in the inhibition of intraoperative miosis was submitted [*H7208] by Allergan on December 19, 1984 -- more than two years after the NDA for Ansaid. It was approved in just two years, on December 31, 1986 -- almost two years before Ansaid would be approved.

The review time for Ocufen was similar to the mean review time (22 months) for all new molecular entities reviewed by the Division of Anti-Infective Drugs during the period 1980 through 1988. Thus, flurbipofen was approved for ophthalmic use without significant regulatory delay. The delay in approving Ansaid, by contrast, can be viewed as directly associated with the crises involving other orally administered NSAIDs.

III. CONGRESSIONAL REVIEW OF ANSAID PATENT EXTENSION LEGISLATION

H.R. 5475 includes a set of standards by which Congress can evaluate future patent extension request. The bill has been criticized for expanding several patents, under previously existing standards of equity and extraordinary circumstances, and applying the new standards only prospectively. The assumption underlying this argument is that because the new standards were not use, the extensions in H.R. 5475 were granted without regard to any standard or process. In the case of Ansaid, however, nothing could be further from the truth.

Ansaid legislation has been considered by this Congress for well over a year. It was introduced in May of last year, with 28 original co-sponsors. It has been the subject of hearings in three Committee, including: the Intellectual Property Subcommittee of the House Judiciary Committee; the Health and the Environment Subcommittee of the House Energy and Commerce Committee; and the Patent and Trademark Subcommittee of the Senate Judiciary committee. The Patent Office and the FDA testified at all of those hearings.

At the request of Representative Bill Hughes, Chairman of the Intellectual Property subcommittee of the House Judiciary Committee, and Senator Dennis DeConcini, Chairman of the Patent and Trademark Subcommittee of the Senate Judiciary Committee, the GAO conducted an unprecedented investigation into the facts of the FDA's approval of Ansaid. The Upjohn Company cooperated completely with GAO investigators.

The following outline indicates the nature and extent of the Congressional consideration of the Ansaid patent term extension.

1. H.R. 2255 introduced May 8, 1991.

29 Cosponsors, including 16 Democrats and 13 Republicans.

Cosponsors: Bonior, Broomfield, Bryant, Camp, Carr, Coble, B. Collins, Conyers, R. Davis, Feighan, Fish, W. Ford, Gekas, Henry, Hertel, Hoagland, Kildee, M. Levine, S. Levin, McCollum, Moorhead, Pursell, Richardson, Schiff, Synar, Traxler, Upton, Vander Jagt and Wolpe

2. Hearing held on August 1, 1991 on S. 1165 (Senate counterpart of H.R. 2255) by the Patents, Copyrights and Trademarks Subcommittee of the Senate Committee on the Judiciary

Testimony by Theodore Cooper, M.D., Ph.D., Chairman and CEO, The Upjohn Company; Harry F. Manbeck, Jr., Commissioner of Patents and Trademarks; Stuart Nightingale, M.D., Associate Commissioner, FDA

3. Hearing held on October 31, 1991 on H.R. 2255 by the Intellectual Property and Judicial Administration Subcommittee of the House Committee on the Judiciary

Testimony by Theodore Cooper, M.D., Ph.D., Chairman and CEO, The Upjohn Company; Stuart Nightingale, M.D., Associate Commissioner, FDA

4. Hearing held on February 20, 1992 by the Health and Environment Subcommittee of the House Committee on Energy and Commerce

Testimony by Theodore Cooper, M.D., Ph.D., Chairman and CEO, The Upjohn Company

5. Markup of S. 1165 held on May 21, 1992 by the Patent Subcommittee

6. Markup of H.R. 2255 held June 11, 1992 by the Intellectual Property Subcommittee: H.R. 2255 reported out as part of a clean bill, H.R. 5475

7. Markup of H.R. 5475 held July 22, 1992 by the full House Judiciary Committee: bill reported favorably to the full House, without amendment (voice vote)

This lengthy process of review was based on a standard that has evolved over the long course of Congressional consideration of patent extensions, which, as Representative Fish pointed outduring the full Judiciary Committee markup of H.R. 5475, Congress has approved since its inception.

That standard has been stated in a variety of ways, but it is fundamentally one of equity: Congress has in the past weighed the merits of each individual

case, and has made a decision based on the equities. The new standards enunciated in H.R. 5475 are a reasonable attempt to make this general concept of equity more specific. But as Chairman Hughes explained at the markup, it is not fair to require a company which has invested a great many resources in making a [illegible] under an older standard to make another case under a new standard.

It would be particularly unfair to Upjohn. The patent for Ansaid expires in February of 1993. Application of the new standards would require additional hearings, another review by the Patent Office and by FDA, a new GAO report, and reconsideration by the appropriate Congressional committees. In light of the lengthy consideration this bill has already had, and the short time remaining on the patent, applicable of the new standards would not be equitable.

IV. THE GAO REPORT

The GAO conducted an investigation of the circumstances of the FDA delay in the approval of the Ansaid application. This unprecedented step, never before included in a Congressional review of a patent extension request, resulted in a report which was, in part, the basis for the relief granted in the Intellectual Property Subcommittee's bill. The extensions in H.R. 5475 have nevertheless been criticized as unsupported by the GAO report.

As the following excerpts indicate, however, this is a completely specious charge.

Upjonn's preparation of the NDA: No unusual delay.

"From our review of agency and company documentation and our own analysis, it appears that Upjohn did not unnecessarily delay submitting its NDA." GAO Report at 5.

Application reviews take longer; May 1984 through May 1986

"Upjonn's primary arguments *** to support its claim that the patent term for Ansaid should be extended are most relevant to this 2-year period. FDA acknowledges that, during this time, it reviews took longer." GAO Report at 8.

The impact of unusual circumstances on the FDA

"FDA did indeed face an unusual set of events from 1982 through 1987, which affected its operations. ... Compared with the pre-1982 approval time, the average time taken to approve NSAID NDAs nearly doubled." GAO Report at 8.

V. CONCLUSION: THE PUBLIC POLICY REASONS FOR SUPPORTING A PATENT EXTENSION FOR ANSAID

There are general public policy reasons for patent extensions which concern adequate reward for innovation. Congress has traditionally served as a safety valve in the rare situations in which the rigidities of our otherwise effective patent system would prevent appropriate compensation for inventors.

But in the case of Ansaid, there is also a more specific public health reason for supporting the Ansaid extension. The Upjohn Company is sponsoring research into additional uses for Ansaid. Promising work is being done in a variety of areas, including post-surgical pain, fractures, and gout. Upjohn is also

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supporting research by Dr. Tom Aufdemorte, who is working at the UT Health Science Center in San Antonio. Dr. Aufdemorte has discovered some interesting possibilities for the use of Ansaid in treating osteoporosis, a disease which seriously diminishes the quality of life of many elderly women. Without additional market exclusivity, however, Upjohn will not be able to afford to continue this support.

In summary: H.R. 5475 is a balanced and equitable bill. The case of Ansaid has been meticulously made and documented in several Congressional forums. The legislation has been subject to hearings and public markup. There are sound public policy reasons for this extension. The bill is worthy of support.

FOOTNOTES

n1 This is illustrated in the following table:

Year of approval	Name of drug	Approval time (months)
1974	Motrin (ibuprofen)	18
1976	Nalfon (fenoprofen calcium)	22
1976	Naprosyn (naproxen)	23
1976	Tolectin (tolmetin sodium)	20
1978	Clinoril (sulindac)	27
1980	Meclomen (meclofenamate sodium)	39
1980	Zomax (zomepirac sodium)	22
1982	Feldene (piroxicam)	48
1982	Oraflex (benoxaprofen)	27
1982	Dolobid (diflunisal)	22

However, only five NSAIDs were approved from 1983 through 1988, and only three of those are currently being marketed. Suprol (suprofen) was approved in 1985 following an 86-month review period, and was withdrawn from the market in May 1987. Orudis (ketoprofen) was approved in 1986 after 46 months. Voltaren (diclofenac) was approved in 1987 after 85 months. Remedial (karprofen) was approved in 1988 after 87 months, but has not been marketed. Ansaid was approved in 1988 after a 79-month review period.

Mr. COBLE. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. HUGHES. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. Mazzoli). The question is on the motion offered by the gentleman from New Jersey (Mr. Hughes) that the House suspend the rules and pass the bill, H.R. 5475, as amended.

The question was taken.

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Mr. STARK. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to the provisions of clause 5, rule I, and the Chair's prior announcement, further proceedings on this motion will be postponed.