

delay any ruling until further investigation into this matter has been made.

Yours truly,

BILL MAGRUDER,
Vice President, Pharmacy Program.

NATIONAL ASSOCIATION OF
CHAIN DRUG STORES,
Alexandria, VA, April 26, 1995.

Hon. DAVID KESSLER,
Commissioner, Food and Drug Administration,
Rockville, MD.

DEAR DR. KESSLER: On behalf of the National Association of Chain Drug Stores (NACDS), I am writing to strongly urge that the Food and Drug Administration (FDA) recognize pre-GATT patent expiration dates for pharmaceuticals, and allow the approval of ANDAs for generic prescription pharmaceutical preparations where the sponsor of such application has made a "substantial investment" in the product prior to June 8, 1995, the date of implementation of the General Agreement on Tariffs and Trade (GATT). We understand that the FDA is currently considering whether GATT's implementing legislation provides such statutory authority. NACDS believes that it does.

NACDS represents America's chain drug store industry, and includes more than 160 chain companies in an industry that operates 30,000 retail community pharmacies. Chain pharmacy is the largest component of retail pharmacy practice, providing practice settings for more than 66,000 pharmacists. Our membership base fills over 60 percent of the more than two billion prescriptions dispensed annually in the United States.

We understand and support the importance of having generic prescription drugs available to consumers as soon as possible. Everyday, the availability of generic drugs enables the pharmacists who practice in our stores to help reduce overall prescription medication costs for populations that do not have prescription drug insurance. Among those who benefit from access to generic drugs are millions of older Americans and working poor, publicly-funded prescription drug programs such as Medicaid, and other third party prescription drug plans.

The impact that a misapplication of the GATT implementing legislation could have on the American public is significant. A recent study by the PRIME Institute at the University of Minnesota found that GATT provisions could result in an additional \$6 billion in prescription drug expenditures in the United States because of the additional patent protections granted to brand name products, and the relative unavailability of lower-cost generic versions.

In summary, NACDS believes that the GATT agreement should not preclude the manufacturers of generic prescription drugs from bringing their products to market during the period of extended patent protection provided by GATT for brand name prescription drug products.

Sincerely,

RONALD L. ZIEGLER,
President and Chief Executive Officer.

NATIONAL PHARMACEUTICAL ALLIANCE,
Alexandria, VA, April 26, 1995.

Hon. DAVID PRYOR,
U.S. Senate, Washington, DC.

DEAR SENATOR PRYOR: The National Pharmaceutical Alliance (NPA) is an association of over 165 manufacturers and distributors of pharmaceutical preparations for human and veterinary use. Our members are dedicated to providing safe and affordable alternatives to the American public whenever health needs dictate the use of pharmaceutical products.

In December of last year, the congress ratified the Uruguay Round Agreements Act

[P.L. 103-465] (URAA) of the General Agreement on Trade and Tariffs (GATT). This agreement created some fundamental changes to be made in U.S. patent law. The new law provides for patents to be in force 20 years from the date of application as opposed to the historical law of the United States which provided for patents to be in force for 17 years from date of approval. Congress, realizing that such a change would cause a financial hardship on companies that expected to enter the marketplace at the expiration of the old patent date, provided a remedy to allow competing products on the market.

Under H.R. 5110, the implementing language of GATT, companies that could show that a substantial investment had been made in a product could enter the marketplace at the pre-GATT expiry date. The respective companies then would work out an "equitable remuneration" during the life of the patent extension. This remedy will work for every industry except the generic pharmaceutical industry due to its regulation by the Food and Drug Administration. Since approvals for Abbreviated New Drug Applications (ANDAs) are governed by the Drug Price Competition and Patent Term Restoration Act of 1984, known as Hatch/Waxman, failure to change its provisions could prevent the FDA from granting approvals until after the patent extension has expired. We do not believe that Congress intended to treat the drug industry differently than other industries.

If the 109 generic pharmaceutical products inversely affected by GATT are kept off the market, the result could be an increased cost to the American consumer of over \$6 billion and a cost of over \$1.2 billion to Federal and State governments in higher Medicare and Medicaid costs. In 1995 alone, drugs such as alclometrasone dipr. (Alclovat), captopril (Capoten), and ranitidine HCl (Zantac) could be unavailable to consumers in a generic version. Zantac alone could represent an additional cost to the consumers in excess of \$1 billion during the time of the patent extension. At a time when both healthcare costs and government budgets are strained to the limit, it makes no sense for government to take any action that would fuel the growth in these expenditures.

In the ten years since its passage, the Hatch/Waxman legislation has done remarkably well at balancing the interests of proprietary drug companies and the generic drug industry. The public also has come to not only expect, but to rely upon, timely access to high quality, low cost alternatives to monopolistic priced name brand drugs.

NPA is pleased to see that members of Congress, such as yourself, are taking steps to correct this inequity in the law. Your actions are to be applauded and your decision to stand up for the American consumer is appreciated.

Sincerely,

CHRISTINE SIZEMORE,
Executive Director.

INTERSTATE TRANSPORTATION OF MUNICIPAL SOLID WASTE ACT

The Senate resumed consideration of the bill.

The PRESIDING OFFICER (Mr. THOMAS). The pending business is the Jeffords amendment No. 867.

The Senator from Michigan.

Mr. LEVIN. Mr. President, I ask unanimous consent I be allowed to proceed as in morning business for 3 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator may proceed.

THE NATIONAL RIFLE ASSOCIATION

Mr. LEVIN. Mr. President, our friend from Arkansas has brought to our attention the fact that former President Bush has decided to resign from the National Rifle Association because of its refusal to repudiate some statements which were made by a vice president of NRA in a fundraising letter. I join Senator PRYOR in commending former President Bush for his action. I am sure it is a difficult one for the President, as a decades-long member of the NRA and as someone who believes in so many of its programs and efforts to protect rights under the second amendment.

But what President Bush reacted to is what I think most Americans who have read this letter reacted to, which is a statement by Mr. LaPierre, among others, that the Clinton administration has authorized law enforcement personnel to murder law-abiding citizens.

Those are the words in the letter. It is an outrageous allegation about any American President or any American administration. I do not think 1 percent of the members of the NRA believe that the Clinton administration has authorized its agents, its Treasury agents, its FBI agents, its law enforcement agents, to murder law-abiding citizens. I wrote a letter to Tom Washington, whom I know. He is a resident of Michigan who was president of the National Rifle Association, urging him to retract that statement and some other allegations in that letter which are, I think, equally offensive, but at least that statement.

In his response to me, which I put in the RECORD yesterday or the day before yesterday, he really did not respond to the request. He simply acknowledged that sometimes fundraising letters have exaggerated rhetoric. But this is not a case of just exaggerated rhetoric. This is an allegation by one of the Nation's largest organizations that this administration has given the go-ahead to law enforcement personnel to murder—I am using the word murder because that is exactly the word that they used; indeed the letter underlines it, italicizes it, emphasizes it—to murder law-abiding citizens.

I do not think, again, anybody on this floor would think there is truth to that statement. I do not think 1 percent of the members, as I said, of the NRA believes there is truth to that statement. It is that kind of a statement, of a wild statement, of an irresponsible statement by a major organization, which is creating an unacceptable climate in this country, I believe. Is it the only statement? Of course not. Others have made outrageous statements, too. Do they have a right to make that statement under the first amendment? They do. I will defend it.

They may have a right to make that statement, but that does not make it right to make that kind of a statement. It should be retracted.

I commend President Bush and I hope other members of the NRA, in one way or another, would let their leadership know that kind of rhetoric is unacceptable about an American administration. Like any other administration, it, I am sure, has agents who make mistakes from time to time. There is a place to rectify them. It is called a court. But to make that allegation from an organization the size of the NRA I think is unacceptable, it is irresponsible, and it still should be retracted.

I thank my friend from Arkansas for his continuing effort to try to bring some kind of calmer normalcy into the general climate in this country.

I yield the floor.

Mr. LOTT. Mr. President I just want to observe that the managers of the pending legislation I understand are working on some agreements hopefully that will make it possible to wrap up this legislation before the day is out. Therefore, at this time, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. COATS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. COATS. Mr. President, I would like to ask the Chair what the pending business is.

The PRESIDING OFFICER. The pending business of the Senate is the Hatch amendment numbered 755.

Mr. COATS. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. ROTH. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. GREGG). Without objection, it is so ordered.

THE NUCLEAR NON-PROLIFERATION TREATY

Mr. ROTH. Mr. President, just a couple of hours ago, the Nuclear Non-Proliferation Treaty—the single most important component of the international effort to prevent the spread of nuclear weapons—was enshrined for all time by an overwhelming decision made by more than 170 countries party to the treaty. The decision to make the NPT permanent was accomplished without any conditions or qualifications.

This is a truly historic day in our ongoing efforts to make ours a safer and more peaceful world. The security of all countries, weapons States and non-weapons States alike, has been strengthened.

The NPT has established the norm prohibiting the further acquisition of nuclear weapons. Indefinite extension of the NPT will help improve the climate of trust conducive to more restrictive controls over weapons-grade nuclear materials and related technologies and activities. It also provides momentum for addressing the dangers posed by other weapons of mass destruction.

Making the NPT permanent, of course, will not end the global nuclear proliferation threat. Treaty membership is never a guarantee of compliance. Yet, when backed by strong national policies, the NPT advances the security interests of all countries. Indeed, it has helped to keep the number of declared nuclear weapons States and so-called “threshold” States at five and three respectively.

Clearly, the world remains a dangerous place. Iran, North Korea, and the theft of fissile materials present immediate nuclear proliferation perils. Much progress on controls over other weapons of mass destruction remains to be made. Moreover, as the tragic bombing in Oklahoma has shown, determined terrorists can accomplish their contemptible intentions with even the crudest of weapons.

But today is a time for celebration. We have achieved a critical victory in making the post-cold-war period safer and more secure. This is a victory for all the world's people. I believe this body deserves a measure of credit for the unanimous adoption of a resolution in March calling for permanent, unconditional extension of the NPT. It is also a testament to the hard work of Tom Graham who took the lead in the negotiations. The chairman of the conference held in New York, the Honorable Jayantha Dhanapala of Sri Lanka, also deserves our thanks for his particularly skilled leadership. Happily, Mr. Dhanapala will be returning to Washington within a few days to resume his post as Ambassador of his country to the United States.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. THURMOND. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

THE NON-PROLIFERATION TREATY AND U.S. SECURITY

Mr. THURMOND. Mr. President, 26 years ago, the Senate provided its advice and consent to ratification of the Nuclear Non-Proliferation Treaty [NPT]. In considering the treaty, Chairman Fulbright prevailed on the Members of the Senate to ratify the NPT, because without it, the world would face a wide array of potential nuclear horrors—such as developing

nations acquiring nuclear weapons to elevate their status or national power; regional powers resorting to the use of nuclear weapons to settle their differences; or ethnic or religious differences being settled with nuclear weapons. He foresaw a world where major powers like the United States might be held hostage by small, poor countries who possess a few nuclear weapons and the means to deliver them, or, become drawn into a nuclear confrontation brought about by these small nations through a miscalculation or an accident.

At the time the NPT was negotiated there were relatively few countries who had tested or possessed nuclear weapons. Those countries were the United States, the United Kingdom, Russia, France, and China. They became known as the nuclear weapons states. All other states who did not possess or had not tested nuclear weapons became known as non-nuclear weapons states.

Back in 1969, when the Senate voted to provide its advice and consent to ratification of the NPT, I was one of the 15 members who voted against ratification of the treaty. I voted against it because I had grave reservations about the treaty's goals and whether they could be achieved. I was concerned that if the United States ratified the NPT, it would be unable to fulfill its NATO responsibilities and commitments. I feared that the NPT would also foreclose the ability of NATO members to participate fully in the operations of the Alliance. Lastly, I was concerned that the nuclear weapons states, and in particular, the United States, would bear the huge costs of transferring nuclear technology for peaceful uses to the non-nuclear weapons states.

Mr. President, the overall goal and purpose of the NPT is to stop the spread of nuclear weapons, and to prohibit the transfer, or acquisition and manufacture of nuclear weapons by non-nuclear weapons states. However, there are no enforcement mechanisms to prevent a non-nuclear weapons state from becoming a nuclear weapons state in the NPT. There are no sanctions for violations of the treaty. While the NPT requires the parties to pursue negotiations to end the nuclear arms race and bring about nuclear disarmament, the NPT cannot force an end to the race for nuclear weapons, nor can it force the destruction of all nuclear weapons.

For that matter, the NPT cannot ensure that parties to the Treaty, whether nuclear weapons states or non-nuclear weapons states, do not withdraw from the Treaty if they decide they wish to acquire or develop a nuclear arsenal for their own national security reasons. In fact, the NPT has a withdrawal clause.

The NPT only covers countries that have ratified the Treaty. For example, take the so-called threshold states which have developed nuclear weapons,