NLWJC - Kagan

DPC - Box 028 - Folder 017

Health - FDA Reform

Health - FDA, general

FDA Success Stories in Clinton Administration

- Tobacco
- Drug Approval
- Food Safety/Seafood HACCP
- Biotechnology
- AIDS (drugs, blood, test kits, vaccines)
- REGO
- Pediatric Labeling
- Mammography
- High Profile Food Additives (BST, Olestra, Sucralose, Meat Irradiation)
- BSE

FDA

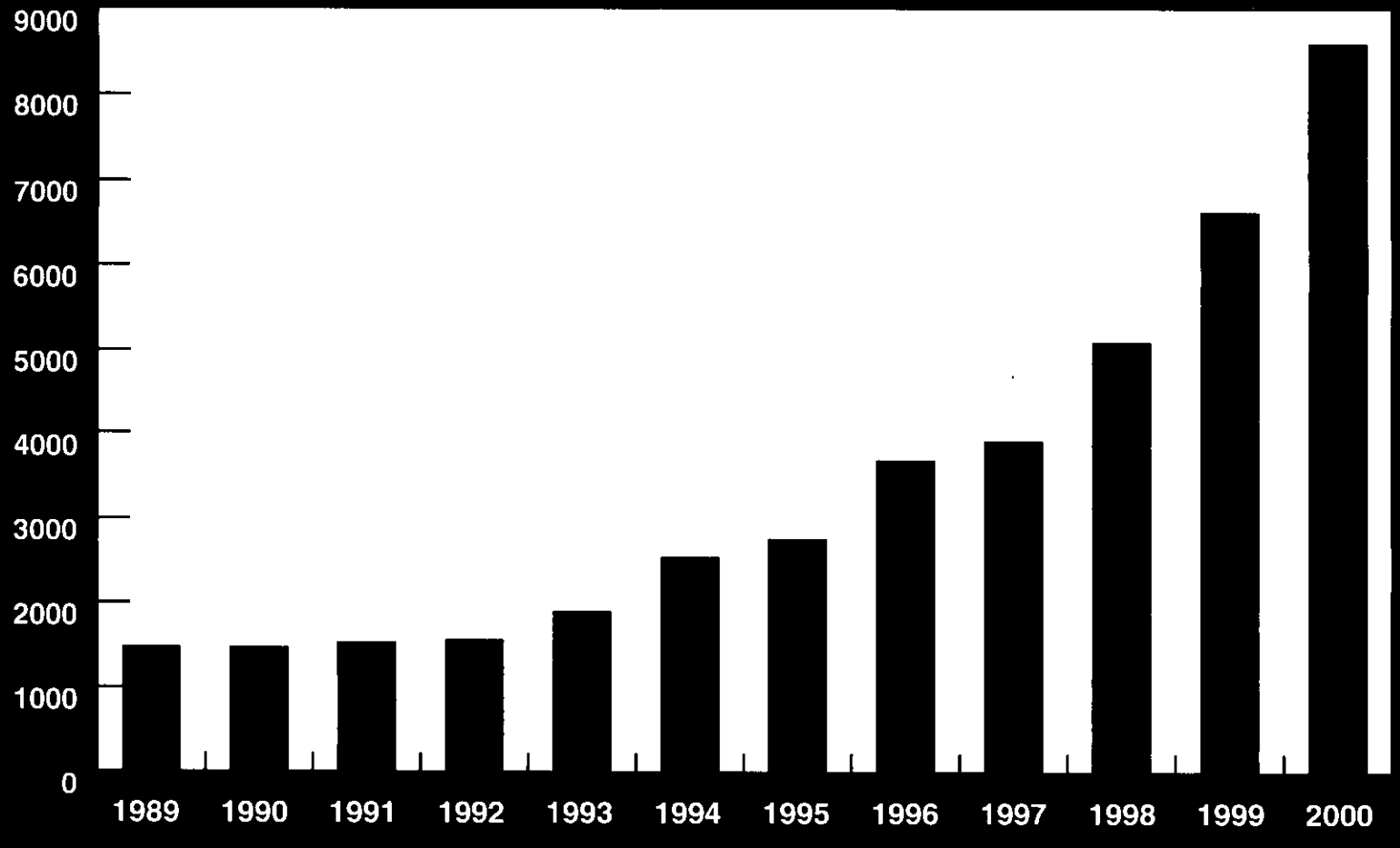
Crushing New Responsibilities

- Soaring Workload Increases for each of last 5 years
  - 12% Annual Increase in Product Applications
  - 24% Annual Increase in Imports
  - 25% Annual Increase in Injury Reports
  - 5% Annual Increase in Regulated Firms
- Complex New Products/Technologies
  - Genetic Testing
  - Gene Therapy
  - Tissue Transplantation (Human and Xeno)
  - Cloning
  - Anti-Viral Drugs
  - Computerized Devices/Manufacturing Processes
  - Novel Foods
  - Biotechnology

Crushing New Responsibilities

- New Challenges
  - Blood Safety
  - New Diseases (AIDS, BSE, HUS, CJD)
  - Emerging Pathogens
  - Counterfeiting
  - Tampering
  - Dietary Supplements
  - Drug Promotion in Managed Care/On Internet
  - International Harmonization
  - Home Test Kits
- New Statutory Responsibilities
  - 10 Major New Laws Since 1990
- FDA Modernization Act
  - 100 new regs, guidances, etc.
- Presidential Initiatives
  - Tobacco
  - Food Safety
  - REGO
  - Bioterrorism

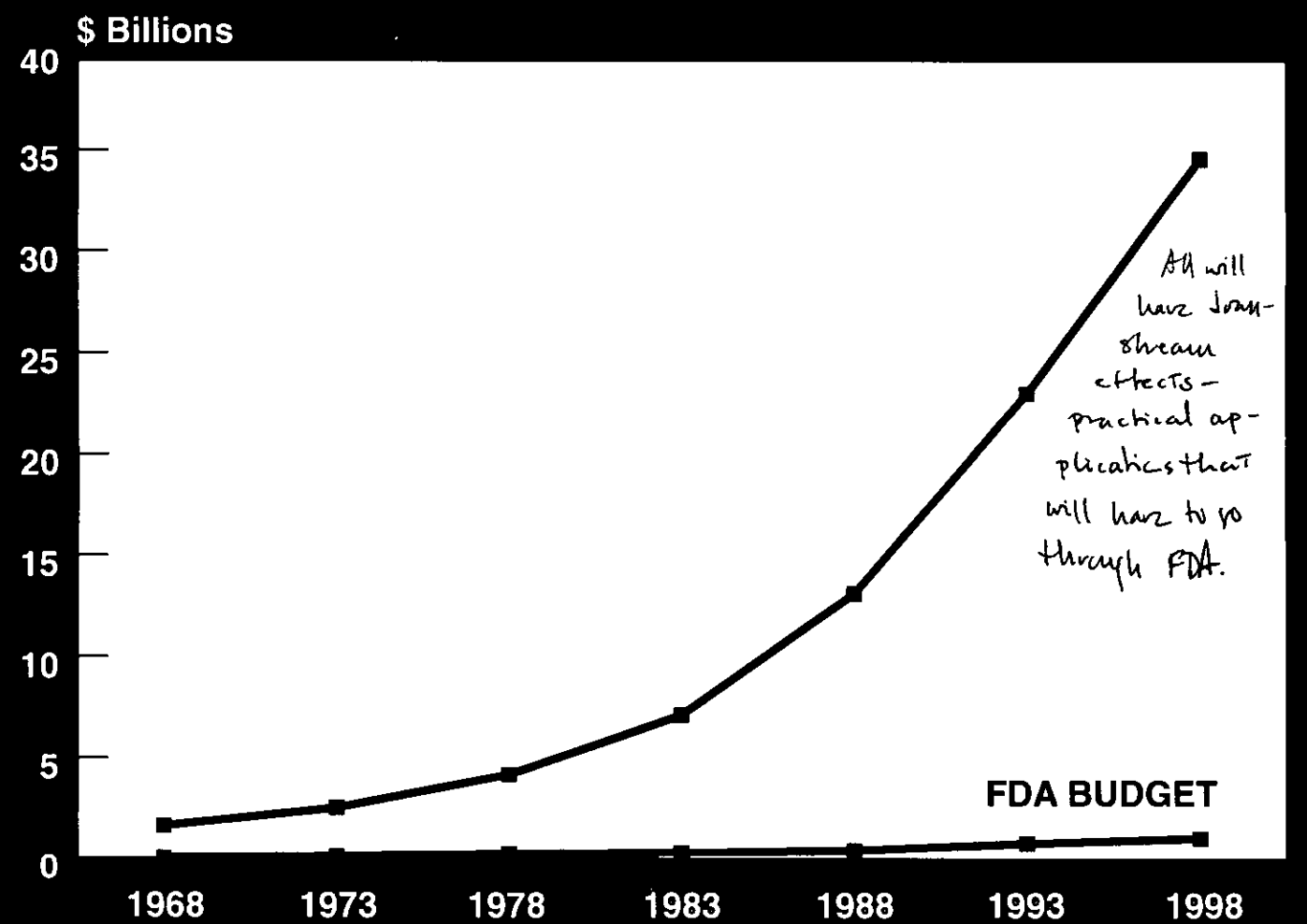
FDA Import Entries



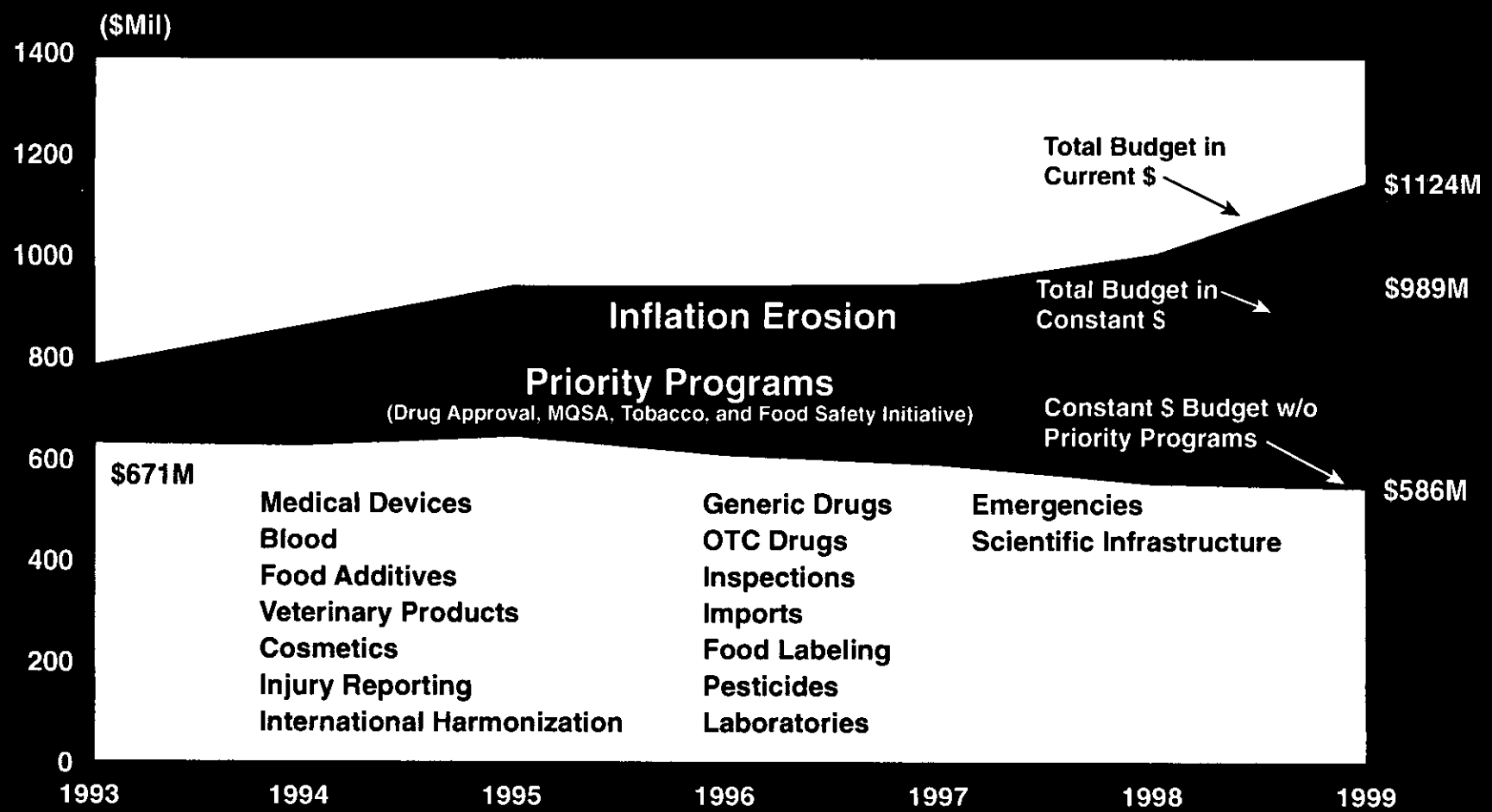
Note: The numbers for the years 1998, 1999 and 2000 are projected

US Biomedical R&D Expenditures

Public (NIH) + Private (PhRMA)



The Shrinking FDA



What Does This Mean?

- Failure of Import Program
  - Will inspect less than 1% by 2000
- Inspections at Historically Low Levels
  - General food inspections (filth) no longer done
  - Food inspections down to 5,000 (vs. 21,000 in 1981)
  - Only 10% of foreign drug firms inspected annually
  - Only 50% of highest risk device manufacturers inspected within statutory interval (virtually no low risk)
  - Only 33% of veterinary drug manufacturers inspected within statutory interval
  - Tissue and organ banks rarely inspected
- Product Recalls Doubled in Recent Years

FDA

What Does This Mean?

- Many Products Virtually Unregulated
  - Dietary supplements
  - Cosmetics
  - Medical products purchased overseas
  - Elimination of foreign pesticide monitoring/phase out of U.S. field sampling
- Health fraud and economic fraud enforced only for outrageous violations
- New products/technologies slowed to market
- Adverse event reports 250,000/year and increasing
- Citizen petition backlog of 600 petitions

What Can Be Done?

Focus FY 2000 Budget Priorities to Strengthen Four Critical Areas

- Adverse Event/Injury Reporting
  (Lower the enormous cost in dollars and lives)
  - reduce injuries and healthcare costs by 15%
- Product Safety Assurance
  - meet 95% of statutory inspection obligation; reduce rising industry recall rates
- Product Review
  (Speed products to consumers; enhance industry competitiveness)
  - review 90% of product applications in statutory time frames
- Food Safety
  - achieve a 50% reduction in food borne illness

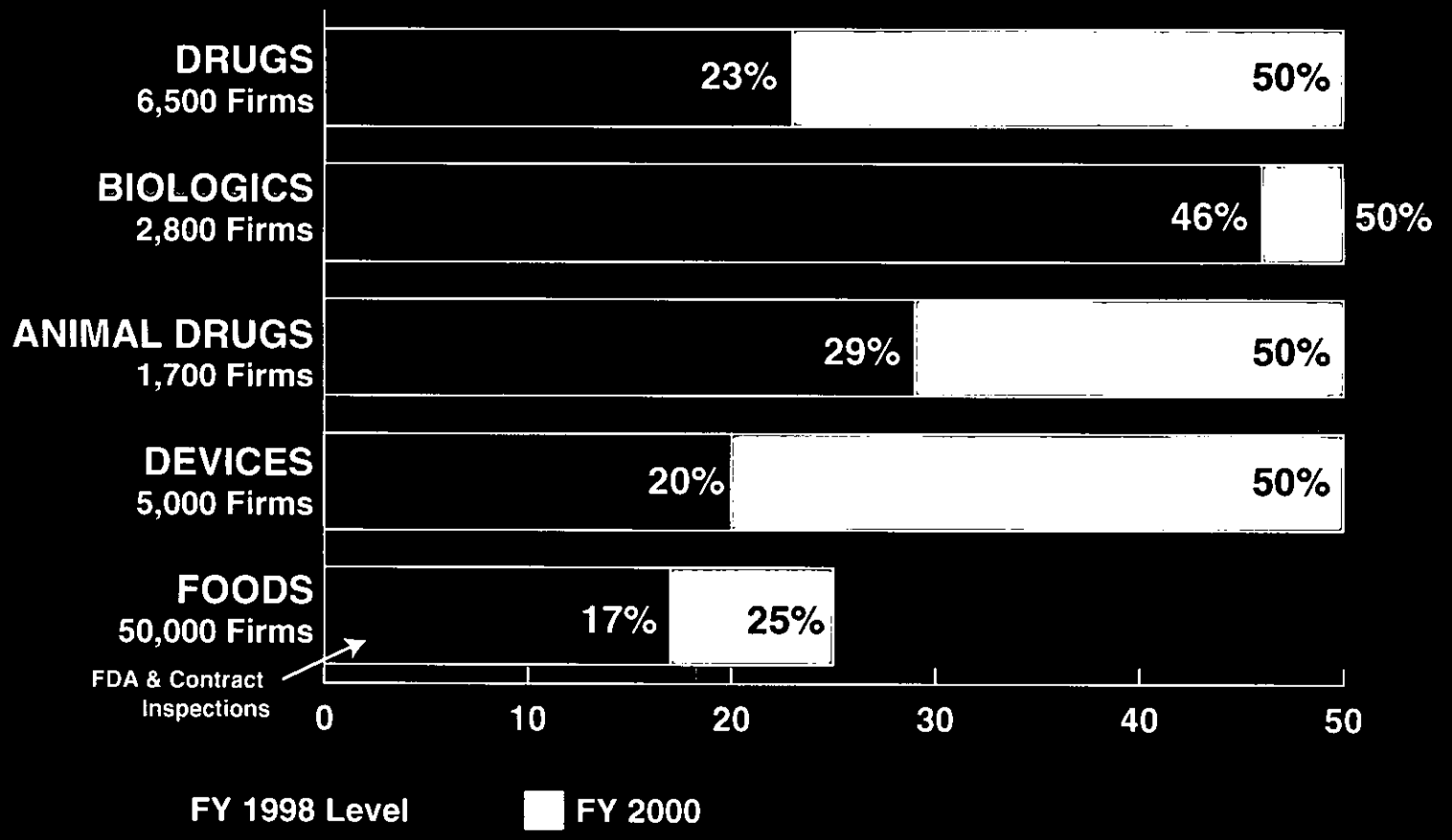
FDA

Injury Reporting:

What is the Problem?

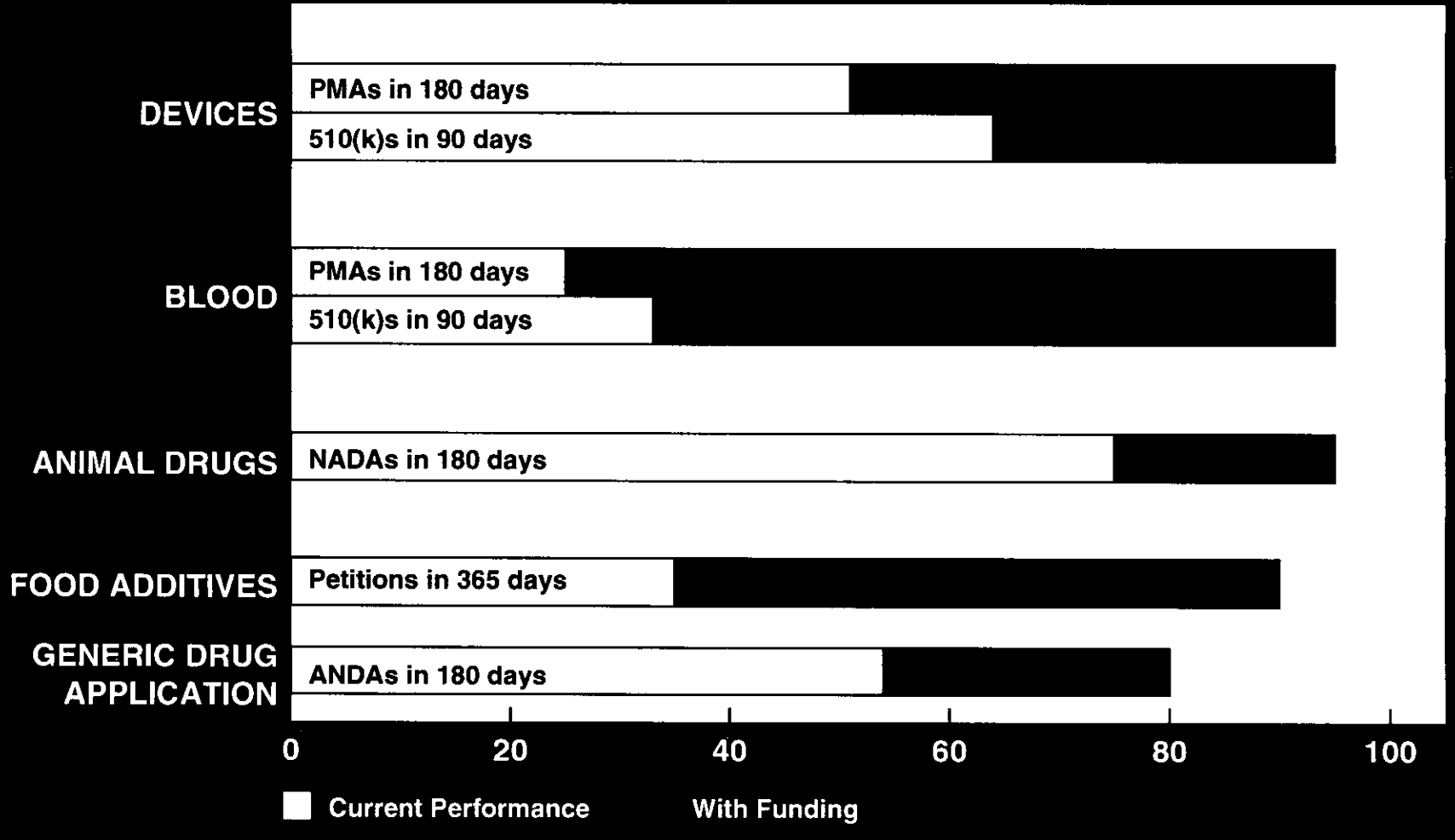
- Estimated > 100,000 deaths and 1.3 million serious injuries/year in the U.S. (one of the top 6 causes of death)
- 10% of all hospital admissions from drug-related problems
- Drug-related illness and death in the U.S. cost approximately $80 billion annually
- Drug-related illness and death costs U.S. government approximately $26 billion annually

Inspection Coverage



New Product Approvals

Filling the Public Health Need



Health - FDA reform

PRESIDENT CLINTON SIGNS LAW TO STRENGTHEN AND MODERNIZE THE FOOD AND DRUG ADMINISTRATION

November 21, 1997

Today, President Clinton signed into law "the FDA Modernization Act of 1997, "critical legislation that will improve the regulation of food, medical products and cosmetics, and prepare the FDA for the 21st century. This new law represents the culmination of several years of effort by the Administration and Congress to reach common ground on how to amend the drug, device, and food laws. The Act, the first major food and medical products reform legislation in 35 years, includes numerous initiatives championed by the Clinton Administration that will ease the regulatory burden on industries, protect consumers, and cut red tape, making government operations faster and more efficient.

STRENGTHENING FDA MODERNIZATION INITIATIVES. The new law builds on FDA modernization efforts already underway which have reduced drug and medical device approval times to record lows while maintaining consumer protections. The new law also expands the resources available to the FDA to carry out its mission. Key provisions of the new law include:

- **Reauthorizing the Prescription Drug User Fee Act.** The Act reauthorizes for five more years the Prescription Drug User Fee Act of 1992, under which FDA uses fees from manufacturers to accelerate the review of new drugs and biological products. This user fee program, developed in close cooperation with the pharmaceutical industry and Congress, has cut the average drug review time in half -- from 30 months before user fees to 15 months today -- bringing safe and effective new medicines to patients much more quickly than ever before.

- **Reinventing Government.** The law enacts many FDA initiatives undertaken in recent years under the Vice President's Reinventing Government program. The codified initiatives include measures to modernize and streamline the regulation of biological products; increase patient access to experimental drugs and medical devices; and accelerate review of important new medications.

- **Increasing Access to Experimental Therapies.** The new law streamlines the filing and approval for new therapies for serious or life-threatening conditions. It also codifies current FDA regulations and practices designed to ensure patient access to therapies for serious and life-threatening conditions before they are approved for marketing. At the Administration's urging, the law provides for an expanded database on clinical trials of experimental treatments for serious and life-threatening conditions so that patients may have access to the results of important clinical studies.

- **Streamlining Medical Product Approval.** The Act reduces requirements and simplifies the review process for manufacturers of pharmaceutical products and medical devices, while maintaining the FDA's high standards of consumer protection. The Act also protects consumers by specifying that FDA may ban devices produced in a seriously deficient manner, and by giving the agency explicit authority to take preventive action if

the technology of a device suggests that it is likely to be used "off-label" for a potentially harmful, unapproved use.

- **Expanding Consumer Access to Information on Unapproved or "Off-label" Drug Uses.** This Act seeks to ensure that health care providers find out quickly about new uses for approved products by explicitly allowing manufacturers to distribute information about unapproved uses of drugs and medical devices. This provision will allow manufacturers to disseminate reliable information about off-label uses provided they commit to conducting appropriate research and to filing a supplemental application for approval of these uses so that this information is available in the official product labeling.

- **Strengthening Risk-Based Regulation of Medical Devices.** The Act complements and builds on FDA's recent measures to match the level of medical device regulations to the level of risk posed by the products. Under the Act, manufacturers are no longer required to alert the FDA before they market certain low-risk devices. The new law also expands a program under which low-risk products can be initially reviewed for safety and effectiveness by FDA-accredited outside experts. In terms of devices already on the market, the Act directs FDA to focus on implantable, life-supporting, life-sustaining, and other types of high-risk devices.

- **Ensuring Accurate Food Labeling.** The Act expands procedures under which FDA can authorize health and nutrient content claims -- which link a health benefit to a particular food component -- without weakening the current requirement that the information be truthful and scientifically valid.

BUILDING ON PREVIOUS CLINTON ADMINISTRATION INITIATIVES. Under the Clinton Administration, the FDA has made significant progress in streamlining its review processes to ensure that consumers gain access to important new drugs and medical devices as quickly as possible. At the same time, the FDA has continued to protect consumers by working with public and private sector partners to ensure that the foods, drugs, cosmetics, and medical products consumers buy are the safest available.

As a result of innovations led by the FDA, Americans with cancer, AIDS, Alzheimer's disease, multiple sclerosis, and other serious conditions now have access to major innovative drugs much sooner. To date, the agency has cut new drug approval times nearly in half, while the number of new drugs approved in a year has doubled.

In recognition of its innovations of the U.S. drug approval process, the FDA was named a 1997 winner of the prestigious Innovations in American Government Awards Program, sponsored by the Ford Foundation and Harvard University's John F. Kennedy School of Government. In addition, in August 1997, the FDA unveiled a new regulation that will protect children by requiring drug manufacturers to study the safety and appropriate dosage levels of medications for pediatric populations. The regulation also requires proper labeling of drugs for use by children.

Health - FDA reform

THE WHITE HOUSE AT WORK
Friday, November 21, 1997

PRESIDENT CLINTON SIGNS LAW TO STRENGTHEN AND MODERNIZE THE FDA

"The FDA has served America well. Today, with a bill I'm about to sign into law, we can ensure that it will serve America well into the 21 century, and I hope serve as a model again for how we can maintain our goals of pursuing the public interest and adjust our means to the possibilities and the challenges of a dramatically new era."
-- President Clinton, 11/21/97

Today, President Clinton signed into law "the FDA Modernization Act of 1997," critical legislation that will improve the regulation of food, medical products and cosmetics, and prepare the FDA for the 21st century. This new law represents the culmination of several years of effort by the Administration and Congress to reach common ground on how to amend the drug, device, and food laws. This Act, the first major food and medical products reform legislation in 35 years, includes numerous initiatives championed by the Clinton Administration that will ease the regulatory burden on industries, protect consumers, and cut red tape, making government operations faster and more efficient.

CONTINUING TO MODERNIZE THE FDA

FDA modernization efforts already underway have reduced drug and medical device approval times to record lows while maintaining consumer protections. Under the President's leadership, the FDA has also ensured that the unique needs of children are protected. The law President Clinton signed today not only builds on this effort, but also expands the FDA's resources. Key provisions of the new law include:

- **Getting Drugs Approved Faster.** The law reauthorizes for five years the Prescription Drug User Fee Act of 1992, which ensures that the cost of reviewing and approving drugs is shared between industry and government. Since 1992, these additional revenues have helped FDA hire some 600 more employees, cutting drug approval time in half -- from 30 months to 15.

- **Reducing Requirements and Simplifying the Review of New Drugs and Medical Devices.** The law enacts many FDA initiatives undertaken in recent years under the Vice President's Reinventing Government initiative, reducing the requirements and simplifying the review process for new drugs and medical devices without compromising safety.

- **Offering Hope to Critically Ill Americans**. The law offers new hope to critically ill Americans by expanding access to drugs and therapies whose FDA approvals are still pending. Because for many patients experimental treatments represent their best chance for recovery, this bill writes into law current FDA policies that allow doctors and patients to use new drugs before they are formally approved. Already, thousands of AIDS, cancer and Alzheimer patients have found new hope with these experimental therapies. At the Administration's urging, the law also expands the database on clinical trials of drugs that fight serious illnesses so that patients can keep track of their progress.

- **Protecting Consumers.** The Act also protects consumers by specifying that the FDA may ban devices produced in a seriously deficient manner, and by giving the agency explicit authority to take preventive action if a device is likely to be used "off-label" for a potentially harmful, unapproved use.

- **Ensuring Accurate Food Labeling.** The Act expands procedures for the FDA to authorize health and nutrient content claims -- which link a health benefit to a particular food component -- without weakening the current requirement that the information be truthful and scientifically valid.

Health - FDA reform

Document No. [redacted]

WHITE HOUSE STAFFING MEMORANDUM

DATE: 11/20/97 ACTION/CONCURRENCE/COMMENT DUE BY: 11/21/97 8:00AM

SUBJECT: FDA Bill Signing Remarks

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	✓	☐	McCURRY	☐	✓
BOWLES	✓	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
PODESTA	✓	☐	RADD	☐	☐
MATHEWS	✓	☐	REED	✓	☐
RAINES	✓	☐	RUFF	☐	☐
BLUMENTHAL	✓	☐	SMITH	☐	☐
BERGER	☐	☐	SOSNIK	✓	☐
ECHAVESTE	☐	☐	SPERLING	✓	☐
EMANUEL	✓	☐	STREETT	☐	☐
GIBBONS	☐	☐	TARULLO	☐	☐
HILLEY	✓	☐	VERVEER	☐	☐
IBARRA	☐	☐	WALDMAN	✓	☐
KLAIN	☐	☐	YELLEN	☐	☐
LEWIS	✓	☐	BEGALA	✓	☐
LINDSEY	☐	☐	Elena Kagan →	✓	☐
MARSHALL	✓	☐	Chris Jennings	✓	☐
			Barry Toiv	✓	☐

REMARKS:

Comments to Staff Sec.

RESPONSE:

Staff Secretary
Ext. 6-2702

Draft 10 pm

PRESIDENT WILLIAM J. CLINTON
REMARKS FOR FDA MODERNIZATION AND ACCOUNTABILITY ACT OF 1997
THE WHITE HOUSE
NOVEMBER 21, 1997

Acknowledgments: VP Gore; Sec. Shalala; Members of Congress; Sally Katzen

The FDA Modernization and Accountability Act of 1997 represents the latest step we must take to give America a government that is truly prepared for the challenges of the 21st century. Over the past five years, we've weeded out useless regulations, decreased paperwork, and cut the employee rolls. We've made regulatory agencies a partner with the business and private organizations they oversee. And we've accomplished this while honoring and strengthening our government's fundamental commitment to protecting the health and safety of our people.

American families have come to enjoy the peace of mind that comes with knowing that the food we eat, and the medicine we use, are safe and effective. This has been possible -- in large part -- because of our Food and Drug Administration. For nearly a century, since it was created by President Theodore Roosevelt, the FDA has protected our people. But as times change, the way government protects people must change. And we must ensure that -- as new innovations in biotechnology and hopeful discoveries in medical research take shape -- the FDA continues to act vigorously to protect the public without standing in the way of progress

Today, I am proud to sign into law comprehensive reforms -- the first in a generation -- to strengthen, streamline and improve the FDA, to ensure that the latest breakthroughs in medical treatment reach Americans quickly, while meeting our highest safety standards.

This bill is the product of three years' hard work by Vice-President Gore and my Administration, by Congress, by patient and industry groups. At the beginning of this process, all sides stood worlds apart on FDA reform. But by thinking through our differences and refusing to give up until we had built a true bipartisan consensus, we crafted a bill that sailed through Congress. This is the right way to serve the American people.

Everyone wins with this new law. American families win because safe, effective and life-saving drugs and treatments will now be available sooner. Our drug companies -- one of America's fastest growing industries -- win because they will profit from their latest discoveries sooner and stay ahead of their global competition. And all America wins because these reforms will strengthen the health of our people even as they strengthen the health of our economy.

Let me highlight just a few of the bill's provisions. First, we will continue working with the business community to get more drugs approved faster. We have reauthorized the Prescription Drug User Fee Act for five more years, ensuring that the cost of reviewing and

approving drugs is shared between industry and government. Since 1992, these additional revenues have helped the FDA hire some 600 more employees, cutting drug approval time in half.

Second, this bill writes into law many of the Reinventing Government measures introduced by the FDA a few years ago. It reduces the requirements and simplifies the review processes for new drugs and medical devices, without compromising safety. I congratulate Vice-President Gore for leading this effort. This is an example, one of the best examples, of reform the right way.

Third, we will offer new hope to critically ill Americans by expanding access to drugs and therapies whose FDA approvals are still pending. We know that for many patients, experimental treatments represent their best chance for recovery. That is why this bill writes into law current FDA policies allowing doctors and patients to use new drugs before they are formally approved. Already, thousands of AIDS, cancer and Alzheimers patients have found new hope, even new life, with these experimental therapies.

It has been said that this century has been an age of physics; that the 21st century will be an age of biology, perhaps yielding cures to diseases we once thought incurable. As the Vice-President noted, we are already witnessing the medical possibilities of the future. This fall alone, the FDA has approved new drugs and treatments for everything from HIV to breast cancer, cardiovascular disease to cystic fibrosis; Parkinson's disease to epilepsy.

The FDA has served America well. And today, with the bill I am about to sign into law, we can ensure that this essential institution will continue to meet the challenges of the 21st century.

Health – ~~CCS~~ FDA Reform

FDA Reform 7/30/97 Telecon w/ R. Tarplin

Pdufa trigger –

OMB: trigger is incentive w/ budget plan for FDA

Imp. to industry – doesn't matter much in practice

Only time raised – letter to Tetlinds

NEJA

KMcGinty – learned of it last week – decided it was major problem.

Never raised before in this Cong

Sally has lead / Josh involved / Chris + Tracy

Health - FDA reform

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAY 27 1997

The Honorable James M. Jeffords
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

Thank you very much for your recent letter regarding your plans for reauthorization of the Prescription Drug User Fee Act (PDUFA) and Food and Drug Administration (FDA) reform. I think we have a unique opportunity to achieve constructive, bipartisan consensus reform in drugs and biologics with the reauthorization of PDUFA. You have my commitment to work with you toward that goal.

As you know, FDA and HHS staff have participated in an extensive series of meetings with your staff and other Labor Committee staff, and industry representatives. These meetings have included discussion of a range of legislative proposals and exchange of legislative language, or comments thereon. We have tried, in particular, to be responsive to Congressional staff requests for assistance in drafting legislative language for the specific proposals on which they wished to focus. I understand that we have made progress toward our mutual goal of identifying consensus issues that can form the basis for constructive bipartisan reform.

While we look forward to continuing to work with you on these issues, I am becoming concerned that timely reauthorization of the PDUFA program could be at risk. There were a number of issues discussed at the staff meetings that are not, in our view, consensus issues. While obviously we do not know which items will be included in the Committee's draft proposal, I am concerned that inclusion of non-consensus issues in the Committee's draft could result in a protracted and contentious debate. This would not serve our mutual goal of timely reauthorization of PDUFA and passage of constructive, consensus, bipartisan FDA reform.

As I indicated above, I think we have made great progress up to now, and I hope we can continue to move ahead.

Sincerely,

Donna E. Shalala

Donna E. Shalala

Health –
FDA reform

committee chairmen in the past and that before they did use the authority they would consult with the ranking minority member on the committee before issuing subpoenas or taking depositions. Massachusetts Democrat Joe Moakley said investigators for Burton's committee "don't seem to be out to get the facts; they seem to be out to get Democrats." Wisconsin Democrat Thomas Barrett said the committee is out to "intimidate anybody who gave money to the Democrats." But Burton responded, "We are not going to try to intimidate anybody," and Republicans argued it would be impractical to require Burton to conduct committee votes every time he wants to call a witness. Ohio Republican Deborah Pryce said the authority granted to Burton will allow the House to "guard against any dilatory tactics that may be employed by those opposed to the investigation." Burton today listed those whom he called "major contributors with foreign ties who have now fled the country or taken the Fifth Amendment." The list included former Democratic fundraiser and Commerce Department official John Huang.

o **Congress Takes More Moderate Approach To FDA Reform.** Following this week's markup of FDA reform legislation in the Senate Labor Committee, Chairman Jim Jeffords and other lawmakers are pushing for floor consideration "as soon as possible; hopefully by July," according to a Senate GOP source. After contentious disagreements derailed last year's FDA reform bill, senators this year "have worked closely with FDA on this," the GOP source said, adding: "They didn't necessarily get everything they wanted and we didn't necessarily take their point of view on everything, but certainly they were in the room when we were talking out various issues of the bill. The process has been much more collaborative." An FDA official acknowledged that "compared to last year, this is much milder," but added: "You still have to understand the implications for carrying out reforms, and the importance of the mission of FDA." Although those familiar with the measure appear to agree that Jeffords' bill is less controversial than last year's FDA bill, several floor amendments are likely when the full Senate takes it under consideration.

For example, Jeffords' bill contains no language on the issue of off-label uses. A GOP committee source said the bill is "silent" on whether drug companies should be allowed to tell doctors the results of studies that indicate a certain drug is effective for a use other than the one for which it was originally intended. Sen. Connie Mack has been a leading advocate for distributing such information, and an aide said Mack is "keeping his options open" and "working with his colleagues" on the issue. Sens. Frist, Dodd, Mikulski and Wyden have been involved in Mack's efforts, the aide said, adding: "We want to make sure we put together an acceptable bipartisan bill that will have some meaningful reforms and some support. We want to allow pharmaceutical companies to disseminate information about studies on off-label uses of drugs to doctors, as long as those uses have been peer reviewed and published in well-known medical journals."

Floor amendments are also considered likely in areas such as third-party review, alternative medicine practices, and food labeling. The GOP Senate source said Sens. Kennedy and Harkin are considered likely to seek changes in Jeffords' third-party review language. "We give FDA very controlled authority over the use of third-party reviewers," the GOP source said, adding, "Kennedy and Harkin are concerned about that and they may seek restrictions...although we feel we've done it in a way that really keeps FDA in the driver's seat. Under our plan, the FDA would certify [outside reviewers]; any reviews they do come back to FDA, and FDA would decide how to use them, if at all." Harkin may also introduce an amendment on alternative treatments, such as acupuncture. The source said Harkin "wants to permit treatment by any health care practitioner requested by the individual [patient]."

During markup, Sen. Judd Gregg saw passage of his two amendments on food labeling, but a GOP source said Gregg's amendments were "kind of modest and not as far reaching as Gregg would like," so he may seek further changes on the floor. However, an FDA official called this effort one of the Administration's "main concerns" with FDA reform, adding: "The legislation as proposed tends to undercut the food labeling law that people worked so hard on at FDA. We went to a great deal of effort, and industry and FDA look at the Nutrition, Labeling and Education Act as a great deal of success. It took a great deal of effort to get that through and there would be a lot of concern about efforts to water that down."

Meanwhile, FDA reform appears to be on the back burner in the House, where legislation would move

through the Commerce Committee. A House source said Commerce Chair Tom Bliley and other lawmakers "are still mulling" their approach to FDA reform for this year, adding: "There have been some discussions, but nothing definite has been decided as of yet. Action is not imminent. We have other things to work on right now." Although the Senate proposals are included in one comprehensive bill, the Senate source said the House is likely to move several separate bills, "instead of having a single bill." Another GOP source said FDA reform "remains high on the list of priorities" for Bliley, and it is likely to be "up there on the agenda" sometime after the Fourth of July recess.

- **Gingrich May Remove Minimum Wage Language From Reconciliation Bill.** Speaker Newt Gingrich has tentatively decided to remove language allowing states to avoid paying the minimum wage to newly hired workers off welfare roles, according to a House GOP leadership source. Another House GOP leadership source said the decision was based on a desire to avoid Byrd Rule complications in the Senate, adding that the House will take up the measure separately later in the year.

  According to a House GOP leadership source, "At a leadership meeting yesterday afternoon, [Gingrich] was almost convinced to keep the minimum wage in there because [Rep. John] Linder had met with some of the most vulnerable members, and they were adamant that they didn't want to gut welfare reform." Governors have complained that if President Clinton is successful in forcing employers to pay the minimum wage, as opposed to a training wage, for newly hired employees coming off welfare, it will destroy most of the benefits from the recently passed welfare reform law. And while there may be procedural reasons for pulling the minimum wage language from the bill, one leadership source noted that Republicans did not fare very well politically the last time they fought Clinton on the minimum wage issue.

- **Armey Supports MFN; Ashcroft To Oppose.** Last night, House Majority Leader Dick Armey announced that he will support granting MFN status to China, though he said he does so with deep reservations. The issue threatens to split the Republican Conference in the House, and a House GOP leadership source said this morning that the issue is not and will not be whipped, because of the difficult nature of the decision members have to make. The leadership source added that while circumstances have changed since the last vote on MFN, nonetheless the margin then was so large that it is likely MFN will still pass the House this year. Several sources contend, however, that the vote will be quite close when the House votes on it next week, particularly since many members may view this as a "free vote," meaning they know the Senate will not reject MFN and can accordingly be on the record opposing the goverment of China without causing any harm to US-Chinese trade. The scheduling of the House vote was a matter of debate last night, as it was battered back and forth between competing political arguments. Opponents of MFN argued for a delay in the vote, particularly as House Republicans were preparing for a vote on taxes, in an effort to present a unified conference for tax cutting week. Some suspect MFN opponents were also hopeful for more time to develop votes, fearing they did not have enough to reject MFN.

  Meanwhile, an aide to Sen. John Ashcroft said that Ashcroft will come out against MFN next week. Ashcroft's opposition and Armey's support underscore how the issue divides conservatives.

- **Chambliss, Armey Feud Punctuates Week Of GOP Infighting.** GOP insiders are talking this morning about a fracas on the House floor between House Majority Leader Dick Armey and Republican Rep. Saxby Chambliss over military depot/base closing issues in the Defense authorization bill. One observer said Chambliss was so angry he called Armey a "liar" and "almost got into a fight on the House floor." After the confrontation, Chambliss issued a one-sentence statement, saying, "This isn't about the GOP leadership – this is about poor leadership from one man in Texas. Dick Armey is two-steppin' with Bill Clinton and two-timing his Republican conference members."

  An aide to Chambliss said, "We got blindsided by Mr. Armey on this," explaining Chambliss felt he had a commitment from Mr. Armey to leave in language that would close down two depots, one in Texas and one in California -- as called for by the 1995 BRAC effort -- with the result that jobs from those depots would be spread among the three remaining depots, including one in Chambliss' district.

Health - FDA reform

The Honorable James M. Jeffords
Chairman, Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510

Dear Senator Jeffords:

For the past several months the Administration has been working with the Senate Labor and Human Resources Committee on legislation to improve the performance and accountability of the Food and Drug Administration (FDA or the Agency), while preserving and enhancing the Agency's ability to protect and promote the public health. I appreciate the efforts that you, Senator Kennedy, and the other members of the Committee have made in this regard and believe that considerable progress has been made toward these goals.

The Food and Drug Administration Modernization and Accountability Act of 1997, S. 830, includes approximately 20 provisions that represent significant consensus reforms. Among the provisions that we all agree on are those that set forth the Agency's mission, codify reforms to the regulation of biotechnology products, provide expedited authority for the adoption of third party performance standards for device review and for the classification of devices, and streamline submission requirements for manufacturing changes and marketing applications for drugs and biologics.

I must emphasize that these provisions represent very significant reform, on which all parties have worked hard to reach consensus, and which I hope will not be jeopardized by insistence on other provisions on which we have not reached agreement.

Unfortunately, the Chairman's substitute to S. 830, also includes a number of provisions which as drafted do not reflect consensus and about which I have very significant concerns. Also, the current version is not "balanced" in that it does not take advantage of significant opportunities to strengthen current law so FDA can more effectively protect the public health. The most significant of the non-consensus provisions, summarized on the enclosed list, would undermine the public health protections that the American people now enjoy, by: 1) lowering the review standard for marketing approval; 2) allowing distribution of experimental therapies without adequate safeguards to assure patient safety or completion of research on efficacy; 3) allowing health claims for foods and economic claims for drugs and biologic products without adequate scientific proof; 4) requiring third party review even for devices that require clinical data; and 5) burdening the Agency with extensive new regulatory requirements that will detract resources from critical Agency functions without commensurate enhancement of the pubic health.

In addition, we believe the provision on pediatric labeling can be improved to assure appropriate testing of drugs for pediatric use before they are prescribed for children.

I want to commend you and members of the Committee on both sides of the aisle on the progress we have made together to develop a package of sensible, consensus reform provisions that are ready for consideration with reauthorization of the Prescription Drug User Fee Act (PDUFA). We are interested and prepared to continue working with the Committee to reach consensus on additional issues -- and have proposed acceptable alternative approaches to many of the objectionable provisions. My concern is the time for reauthorization of PDUFA is running perilously short. As I indicated in my recent letter to you, I am concerned that the inclusion of non-consensus issues in the Committee's bill will result in a protracted and contentious debate. This would not serve our mutual goal of timely reauthorization of PDUFA and passage of constructive, consensus bipartisan FDA reform.

Sincerely,

Attachment

cc: The Honorable Edward M. Kennedy
Ranking Member, Committee on Labor
and Human Resources

Members of the Labor and Human Resources Committee

an's Substi

Concerns

1. **Cumulative Regulatory Burdens/No Provisions to Promote Public Health**

- many new regulatory burdens are being imposed on FDA (list enclosed) and little that can be advanced as promoting public health

2. **Third Party Review of Devices (Sec. 204)**

- expansion of FDA's existing pilot project for review of medical devices (includes devices that require clinical data) by organizations accredited by FDA

3. **Approval Standard for Drugs/Biologics/Devices (Secs. 404/409/609/610/611/619)**

- effectiveness standard for drugs and biologics needs further clarification; for supplements (applications for new uses) lowers standard such that they might not ever require a single investigation
- limits FDA authority to evaluate clinical outcomes for devices
- lowers approval standard for radiopharmaceuticals, including PET drugs

4. **Health Claims For Foods (Sec. 617)**

- health claims not approved by the FDA but consisting of information published by authoritative government scientific bodies (e.g., NAS or NCI) would be permitted for use by companies in the labeling of food products, even if it is very preliminary

5. **Expanded Access to Investigational Therapies (Sec. 102)**

- would allow drug and device companies to sell an investigational product for any serious disease or condition without FDA approval and without appropriate protections for clinical investigations

6. **Device Modifications (Sec. 601)**

- would allow companies to make manufacturing changes that affect a device's safety and effectiveness without FDA agreement

7. **Health Economic Claims (Sec. 612)**

- would allow industry to discuss health economic claims given to managed care organizations under a lower evidentiary standard and without FDA review, even if the claim compared the safety or efficacy of two drugs

8. **Pediatric Labeling**

- would provide an incentive of six months of market exclusivity to encourage pharmaceutical companies to conduct necessary clinical trials for FDA approval of their products for children

- might undercut FDA's ability to use other means such as regulations and raise health care costs.

B. Other Significant Concerns

1. Expanded Humanitarian Use of Devices (Sec. 103)
2. Device Collaborative Determinations/Review (Secs. 301/302)
3. Limitations on Initial Classification Determinations (Sec. 407)
4. Evaluation of Automatic Class III Designation (Sec. 604)
5. PMS (Sec. 606)

C. Currently In The Bill - No Language Provided Yet

1. Off-Label Use of Drugs (floor amendment expected)
2. Drug Compounding (amendment expected)

Health - FDA reform

Ellen S. Seidman 05/19/97 01:52:45 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: AIDS vaccine and torts

I thought it was interesting that the pharmaceutical companies' response on the AIDS vaccine proposal was they need tort reform and more money for FDA new drug approval, BUT NOT FDA reform. Is this the time to get some commitments on protecting the FDA new drug approval process? ellen

Message Sent To:

Elena Kagan/OPD/EOP
Bruce R. Lindsey/WHO/EOP
Jennifer D. Dudley/WHO/EOP
Kathleen M. Wallman/WHO/EOP
Elizabeth Drye/OPD/EOP

1/10/96 FDA Reform

We need — (at any price??)
Pour they also need

Try to separate from PDUFA - so not to delay PDUFA

HHS/FDA to meet w/ ind ≤ drug ind / device ind — harder to work on consumer

starting next wk

Who controls paper - who does the draft?

Small wkg grp - committee process

Reach out to Hill — say want bipart bill / tell process / seek input

Most in Hill: If you can get a deal w/ industry, good bless you.

SK: Any issues of the task? - Things we can't accept

e.g. — off-label

Also - Things not part of last bill that we need/want?

HHS: Very difficult — but ⊙ of the task

1st - see where ind is. If it moderates, we should put anything on!

Our budget proposals may have consequences — in user fees/device fees - like kicking someone's dog on way into poker game.

SK: We should be supportive - but backbench —
Not involved publicly / or even as to lobbyists
Get together in early Feb.

FILE: FDA Reform

012110BX.txt

From: CHENOK_D@A1@CD@LNGTWY
*To: Jonathan D. Winer@eop@LNGTWY@EOPMRX@LNGTWY
*To: John F. Morrall III@eop@LNGTWY@EOPMRX@LNGTWY
*To: Sally Katzen@eop@LNGTWY@EOPMRX@LNGTWY
*To: DRYE_E@A1@CD@LNGTWY
*cc: Michael A. Fitzpatrick@eop@LNGTWY@EOPMRX@LNGTWY
Date: 1/16/97 9:01am
Subject: User Fee, FDA Reform Bills Head List Of Legislative Prio
riti
User Fee, FDA Reform Bills Head List Of Legislative Priorities, P
hRMA
Reauthorization of the Prescription Drug User Fee Act of 1992 and
passage
of legislation reforming the Food and Drug Administration are top

priorities
for members of the Pharmaceutical Research and Manufacturers of A
merica in
1997, officials from the trade association said at a Jan. 15 brie
fing.
Reauthorization of the user fee act fits in with the association'
s goal of
expediting the availability to consumers of safe, effective new d
rugs,
according to Sidney Taurel, PhRMA's chairman-elect and president
and chief
executive officer for Eli Lilly and Co. PhRMA has been participat
ing in
negotiations with FDA and Congress that should lead to reauthoriz
ation of
the
user fee act, he said.
To further the goal of expediting the availability of drugs, PhRM
A also is
prepared to support legislation that would ``break down barriers
to the
dissemination of information,'' and efforts by the International
Conference on
Harmonization that would streamline drug approvals and establish
common
standards on drug development throughout the world, Taurel said.
Under the heading of creating an environment that promotes innova
tion,
PhRMA's other priorities for 1997 include seeking a permanent ext
ension of
the

research and development tax credit, strengthening U.S. intellect
ual
property
protections, and enforcing international property protection laws
. PhRMA
also
will support legislation that improves the Clinton administration
's
ability to
negotiate trade agreements as part of its goal to promote open ma
rkets and
free trade, Taurel said. ``We will strive to convince foreign gov
ernments
that
the best way to contain health-care costs is through free-market
competition,'' he added.
Second Phase, New Goal
Under the user fee act, FDA promised to meet certain deadlines fo
r
reviewing and approving drug applications in exchange for additio
nal
revenues
generated by industry's user fees, which were dedicated to paying
for the
personnel and supporting activities necessary to complete the rev
iews in a
timely fashion.
A second phase of the user fee act, known colloquially as PDUFA I
I, should
``build on the progress already made in reducing approval times a
nd make
similar progress in cutting overall drug development times,'' Tau
rel said
in a
statement.
Since the first phase of the user fee act has been successful in
improving
review times, industry is focusing its reauthorization negotiatio
ns on
lessening overall drug development times. Drug companies ``are ma
king
internal
improvement to speed drug development and improve the productivit
y of the
process--and there are improvements we can make,'' Charles A. Hei
mbold

Jr.,
PhRMA board chairman and chairman and CEO of Bristol-Myers Squibb Co.,
said.
However, ``we continue to need the support and cooperation of government
to
make a meaningful impact. If meetings are required between a pharmaceutical
company and the FDA, they should be set promptly. Extraneous meetings
should
be eliminated. Written protocols on aspects of the development process
should
be created by the FDA. Drug development remains highly regulated and
requires
the closest partnership between government and industry to shorten it. We
hope
to do just that in 1997,'' Heimbold added.
Alan F. Holmer, PhRMA president, said, according to FDA, drug reviews, a
period extending from the time a company files a new drug application to
the
time it receives FDA approval, actually have decreased from 2.5 years to
1.5
years since the user fee act was implemented. By contrast, the overall
time
spent on clinical development has increased from 5.5 years for drugs
approved
between 1990 and 1993 to 7.2 years for drugs approved in 1994 and 1995,
Holmer
said, citing the findings of a study by Tufts University Center for Drug
Development.
The amount spent on research and development in 1997 by research-based
drug
and biotechnology companies will reach a new high of $18.9 billio

n, PhRMA
said, which represents a 11.5 percent increase from 1996. Of the total
$18.9
billion, approximately $15 billion will be spent in the United States.
Expressed as a ratio of R & D to sales, pharmaceutical companies will
spend
about 21.2 percent of their revenues on R & D in 1997 compared to an
average
of 4 percent for all industries, Heimbold said.
According to Heimbold, ``countries everywhere look to the United States
and
its pharmaceutical industry to discover many of the new drugs and do much
of
the significant new research for new medicines.'' He pointed out that, in
addition to a record level of R & D investment, research-based drug
companies
in 1996 introduced 53 new medicines to U.S. patients that were designed to
treat more than 40 diseases, including drugs for AIDS, Alzheimer's
disease,
various cancers, glaucoma, and multiple sclerosis.
Reform, User Fees?
PhRMA also will concentrate its energies on ensuring passage of
legislation in 1997 that would bring about improvements at FDA. The
principal
focus at PhRMA over the past few months has been addressing the technical
issues included in the reauthorization of the user fee act, Holmer said.
However, there are many other issues about improvements that could be made
beyond the scope of user fees that PhRMA would like to take up with FDA,
he
said.
For example, PhRMA supports efforts aimed at revising the agency'

s
policies
about dissemination of information about prescription medicines.
The
policies
governing distribution of scientific information should be less
proscriptive,
particularly for pharmacoeconomic data and off-label uses of appr
oved
drugs,
Holmer said.
As for indications that House Commerce Committee Chairman Thomas
J. Bliley
Jr. (R-Va) will tie user fee reauthorization to FDA reform, Holme
r merely
said
the question of how these issues are approached by Congress shoul
d be left
to
congressional leaders. Both are high priorities for PhRMA. ``We h
ope they
happen this year,'' he said.
Mike Collins, communications director for the House Commerce Comm
ittee,
told BNA that Bliley believes the reauthorization and reform issu
es are
``joined at the hip'' and already has informed Health and Human S
ervices
Secretary Donna E. Shalala that user fee reauthorization will be
taken up
in
the context of FDA reform. However, for a bill to get the preside
nt's
signature, it must be both popular with the president and hugely
bipartisan,
so it cannot be an extreme measure, he said.
The measures introduced in the 104th Congress were not very extre
me, had
broad bipartisan support, and came very close to being passed, wh
ich has
had a
profound impact on FDA operations, according to Collins. The job
should be
less complicated this session, he said.
FDA