

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 29, 1996

REMARKS BY THE PRESIDENT
AT CEREMONY FOR ANTI-CANCER INITIATIVE

The East Room

3:06 P.M. EST

THE PRESIDENT: Mr. Vice President, Secretary Shalala, Dr. Kessler, Congressman Richardson, welcome. To all of you who are here, I welcome you and I thank you, each in your own way, for the power of your example.

I thank Stacy, too, especially for being here and telling us her story, and doing it in the way that she did. We know we can thank modern medicine, but you saw a little bit of her steel and grit when she was talking, and it's a great testimony to her faith and to her inner strength. I think that we ought to ask her parents to stand since she mentioned them.

Would you stand up, please, Mr. and Mrs. Oller? Thank you. (Applause.) Thank you very much.

Perhaps more than any other health statistic in America, cancer touches virtually every family. My mother and my stepfather succumbed to cancer; the Vice President lost his sister. Just before coming here today I proclaimed April Cancer Control Month over in the Oval Office, and I was there with several cancer patients and their families. They're all over here, and I want to thank all of them for coming to visit with me, the children and the adults alike, the parents, the brothers, the sisters. As families, they are fighting for a way to win this battle, and the rest of us owe it to them to give them every chance they can to win. That's why we're here today; we want to have more people like Stacy.

More than ever before, we know from the sheer statistics that cancer is treatable and beatable. We know that early detection and prevention are critical. We have, therefore, put more resources in to mammograms for women over 50, and we have

taken a very strong stand against the use of tobacco by young people, and against any attempt to induce them to use it.

When cancer does strike, we have an ever-growing arsenal of new drugs and cutting-edge therapies to fight it. But before any treatment can get to patients, we need to make sure it is safe and effective. The development and approval process can take years. When a member of a family gets cancer, the whole family bears the pain, and years are sometimes far, far too long. These families should not also suffer from the stress of knowing that there may be better remedies already out there, but they're somehow not quite available.

So I'm happy today to say to those patients and to their families, the waiting is over. Today, we announce a major new initiative to speed new cancer therapies to our people. These changes will affect at least 100 drugs now being studied. Dozens of them will get to the market sooner, and that means they can help Americans suffering from cancers of the breast, lung, ovary, prostate and colon, among others. For these Americans, we cannot guarantee miracles, but at least now new hope is on the way.

With our reforms, cancer patients won't have to leave the country to look for promising treatments. If a drug does demonstrate effectiveness, patients will have access to it here even while the drug continues to undergo tests for approval. Let me emphasize, these steps will speed cancer drugs to patients who need them when they need them. They will help to save lives. They will give cancer patients a better chance. They will do all this by cutting red tape, but they will not -- they will not -- cut corners on safety. We are doing this the right way and it is the right thing to do.

This initiative is part of our National Performance Review, popularly known as REGO, Reinventing Government. This remarkable effort has been chaired brilliantly by the Vice President, and it will, among other things, now cut the development time for drugs by as much as several years. At the same time, the FDA will cut its review time for these drugs from 12 months to six months.

The initiative contains four major proposals. First, we propose to accelerate approval for cancer drugs by allowing companies to apply to market a treatment that is still being tested. In other words, if a drug shows promise by shrinking tumors, for example, it can be considered for approval. That could cut several years off the time needed to get a drug to market.

Second, we propose to expand access to drugs that are already approved in other countries. The FDA will encourage the sponsors of these experimental drugs to apply for permission to distribute the drug to eligible cancer patients before final drug approval is granted here in the United States.

Third, we propose that cancer patients be better represented in FDA advisory meetings. These committees play a major role in policy and product decisions. And cancer patients who have valuable insights and the most at stake should be at the table when these decisions are made.

Fourth, we propose fewer applications for additional uses of approved cancer drugs. Often, these applications are for uses the drug maker does not even intend to market. By cutting out these unnecessary applications we will free investigators from paperwork and allow them to devote more time to cancer research.

These four steps are the results of listening to patients, to their families, to their advocates, to the pharmaceutical industry, the doctors, and the researchers. This initiative shows what we can do when we work together.

Since 1938, our nation has looked to the FDA to protect and improve the public health by making sure that medicines we take help us, not harm us. Our commitment to safety must never waver. Under Commissioner David Kessler, the FDA has reinforced that commitment while working to speed drug approval in the right way. In 1987 it took an average of 33 months to approve new drug applications. In 1994 96 percent of new drug applications were acted on within 12 months.

On AIDS drugs the United States was the first to approve five of the six antiviral treatments for the disease. The most recent of these drugs was approved in 42 days -- a record. And the FDA has been the first to approve new drugs for ovarian cancer, for lymphocytic leukemia, for cystic fibrosis, for multiple sclerosis, for Lou Gehrig's Disease and Alzheimer's. Under Dr. Kessler, more than ever, the FDA is a place where advance science and common sense work together for the American people.

Now, using the principles of the National Performance Review, we have an opportunity to help more Americans conquer cancer. These four steps will make a big difference, and we are glad to give them to the American people today.

Now I'd like to ask the Vice President to come up here and talk just a few moments about the reinventing of these regulations -- how we did it, what we hope will happen. And let me say, again, how grateful I am to Secretary Shalala, to Dr. David Kessler and to the Vice President, and to all the other good people at FDA. We can keep our people safe and save more lives, and that's exactly what we're determined to do.

Thank you, God bless you all.

Mr. Vice President, please come up. (Applause.)

END

3:15 P.M. EST

To: Roslyn Miller

From: Kay Hamer

As requested, these are
Mr. Kesler's remarks.

301-827-2410 work
301-443-2100 fax

Remarks by

David A. Kessler, M.D.

Reinventing Government: Oncology Drug Approvals

at

The White House

March 29, 1996

WHAT IT ALL MEANS

The four initiatives announced today have a single, significant meaning:

American cancer patients, from now on, will have faster and easier access to more promising therapies.

Here, in a nutshell, is the importance of each of our four proposals:

First, for patients with refractory -- hard to treat -- cancer, instead of requiring evidence of clinical benefits -- such as survival -- FDA will rely on objective evidence of tumor shrinkage as a basis for initial approval. This will allow reliance on smaller, shorter studies for initial approval of drugs. This accelerated procedure, which will be followed up by further studies of clinical safety and effectiveness in larger groups of patients, should simplify and speed up the evaluation and approval of drugs for advanced stages of solid tumors.

Second, we will expedite the availability of promising medications that have been approved in certain other countries. If there is a promising drug approved in a foreign market, we will invite the manufacturer to submit to us the **same** information that made possible the approval abroad and, whenever possible, use it as basis for making such therapy available to critically ailing patients in this country. Use of similar approaches to drug evaluation, in our experience with AIDS therapies, has been powerful stimulus to the development of new agents.

Third, we will include representatives of cancer patients in FDA's cancer-related advisory committees, and thereby make sure that their views are heard when it comes to recommending approval or non-approval of new cancer drugs.

And fourth, we will eliminate unnecessary paper work that used to delay or discourage cancer research by non-commercial clinical investigators.

Two more points about these initiatives are of importance:

(1) They are designed to accomplish their aims without lowering FDA's high standards of drug safety and effectiveness, or reducing the amount of information available to physicians.

And

(2) They are not to be seen as one-time measures, but rather as part of a continuing FDA effort to improve the quality and availability of drugs for all people with serious and life-threatening diseases.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 29, 1996

BRIEFING BY THE VICE PRESIDENT
AND DR. DAVID KESSLER, FEDERAL DRUG ADMINISTRATION

The Briefing Room

3:44 P.M. EST

VICE PRESIDENT GORE: I'm going to make a statement about some figures that were released by the CBO very late last night. I'm going to say a few words about the promises kept. And I'm going to turn this briefing over to Dr. David Kessler, who will elaborate on the announcement the President just made in the East Room and respond to your questions about that.

But first of all, let me talk just a bit about the new CBO figures released last night. When Bill Clinton campaigned for the presidency, he promised that he would cut the federal budget deficit in half during his first four years in office. He put that promised in writing in the book that he and I put out during the campaign, called Putting People First.

In fact, I think I might be able to find it right here. "Our plan will cut the deficit in half within four years and assure that it continues to fall each year after that," on page 4 of Putting People First. Yesterday, late last night, the Congressional Budget Office, using its traditionally conservative estimates, released brand new figures projecting that the budget deficit at the end of the current fiscal year will be half -- actually less than half -- of the deficit that President Clinton and I inherited. Bill Clinton made good on his promise.

When Bill Clinton campaigned for the presidency, he also promised eight million new jobs would be created in America by the end of his first four years in office. Earlier this month, the Bureau of Labor Statistics reported that we have crossed the eight-million job threshold. Since Bill Clinton became President, the American economy has added more than 8.4 million new jobs. Bill Clinton made good on his promise. And incidentally, more than half of these new jobs have wages higher than the average wage in the economy.

If you will look at this, from the day that President Clinton took office, the economy has created 8.4 million new jobs.

**PHOTOCOPY
PRESERVATION**

And from the day he took office, the deficit has come down from \$290 billion to the new figure of \$140 billion at the end of this fiscal year.

Paul Volker, former chairman of the Federal Reserve Board, was recently quoted as saying, "The deficit has come down and I give the Clinton administration and President Clinton himself a lot of credit for that, and I think we're seeing some benefits."

The Congressional Budget Office in 1994, in its Economic and Budget Outlook, on page 13, said, the dramatic improvement in the deficit since last January is largely the result of the enactment in August of the Omnibus Budget Reconciliation Act of 1993. You may remember that measure passed a one-vote margin in the House, went to the Senate where it was tied 50 to 50, causing momentary despair -- (laughter) -- and then due to a provision in the Constitution I was

able to vote. In any event we're very happy with these new figures, because the deficit has indeed been cut in half, and it will, as promised, continue to go down in the years ahead, because we're on the way to a balanced budget.

Incidentally, on this same page, I was noticing as I went through this material that just above the promise that I cited on cutting the deficit in half, was the promise that we would revolutionize government by cutting 100,000 federal jobs. As you may know, we have eliminated 205,000 federal jobs. Seven of the 14 Cabinet departments have had personnel reductions of more than 10 percent. Every single Cabinet department has had dramatic reductions except for the Justice Department, because there we are adding more personnel as part of the anti-crime bill.

Also, on the very same page, is the pledge to provide affordable quality health care by, among other things, reducing paperwork. And we talked about reinventing government in this same list of promises to the American people four years ago. And in the event in the East Room just concluded, the President announced the result of the National Performance Review effort at FDA, run by the people at FDA and run by Dr. David Kessler, which is resulting in much speedier approval of new drugs, new medications, new life-saving treatments -- in this case for cancer patients, but for all patients really.

And you have seen the difference for AIDS patients and for cancer patients particularly. And the announcement was one that was particularly moving for anyone who is part of a family that has been touched by cancer. And, again, as the President did earlier, I want to express gratitude to Dr. David Kessler and Secretary Donna Shalala, who was here earlier, and their whole team for the tremendous work that they have done.

And now I would like to turn over the podium to Dr. Kessler, who will elaborate on that announcement.

**PHOTOCOPY
PRESERVATION**

8/9/96

Chris,

Bill Schultz asked me to send the attached info to you re: progress in drug reviews by FDA. The most important points may be that:

- o Drug approvals times have dropped since the beginning of the Clinton Administration from almost 3 years on average to just over a year in 1995.
- o By next year, virtually all breakthrough drugs will be approved within 6 months, all others within a year;
- o Three different studies have found that U.S. drug approvals are now as fast or faster than any other industrialized country;
- o Most important new drugs (e.g., that are a real medical advance and/or provide treatment that didn't exist before) are approved first in the United States; and
- o These accomplishments have been achieved without additional appropriated funds (thanks to user fees paid by industry) and while also reducing regulatory burden on the industry through the REGO initiatives.

Call if you need more, at 301-827-3360.

Bill Hubbard/FDA

P.S. I know you may be disinterested or skeptical, but the FDA appropriations bill the President signed this week makes patient information (Medication Guides) statutory. If those leaflets are effective, they will address the approximately \$20 billion in wasted health care costs each year due to misuse of medications. Under the statute, the industry must begin implementing the effort to get the leaflets in patients hands before the end of the year.



FDA: A Record Of Accomplishment

Faster Drug Approvals

- 82 new drugs approved in 16.5 months (median) in Calendar Year (CY)1995, compared with 62 new drugs approved in 19 months in 1994.
- 28 of the 1995 approvals were new molecular entities (NMEs)—brand new drugs as opposed to new formulations—and were approved in 15.9 months (median), compared with 22 NMEs approved in 17.5 months in 1994
- 15 of the 1995 approvals were “priority” drugs—having important therapeutic value—and were approved in 6 months (median), compared with 17 “priority” drugs approved in 15 months in 1994
- 13 of the 1995 “priority” approvals were user fee drugs approved in 5.9 months (median), compared with 12 “priority” user fee drugs approved in 10.4 months in 1994

Improved Device Reviews

- 5,594 510(k)s (which account for about 98% of medical devices) reviewed by FDA in 138 days (mean) in Fiscal Year (FY) 1995, compared with 5,498 in 182 days in FY 1994
- 27 PMAs (premarket applications for certain Class III devices) reviewed by FDA in 20.2 months (mean) in FY 1995, compared with 26 PMAs in 21.6 months in FY 1994

The Record on Reinvention

As part of Vice President Gore's National Performance Review, the FDA has announced more than 30 FDA regulatory reinvention initiatives since March 1995. These initiatives will reduce regulatory burdens and streamline the regulatory process, while maintaining vital public health safeguards and speeding the marketing of safe and effective new drugs and medical devices. Following is a partial listing of these initiatives:

- Speed up approval process for cancer drugs by using tumor shrinkage as surrogate marker for accelerated approval decisions
Impact: Cut years off development times and months off FDA review

- **Expand patient access to experimental cancer drugs approved in other countries**
Impact: Make it easier for patients to have access to promising but still experimental therapies
- **Increase patient representation on cancer drug advisory committees**
Impact: Give patients more of a voice in the drug review process
- **Clarify requirements for doctors studying already approved cancer drugs**
Impact: Reduce paperwork for doctors and free FDA staff for other priorities
- **Eliminate Establishment License Application (ELA) for most biotech drugs**
Impact: Reduce paperwork burden for industry and speed up marketing of biotech drugs
- **Eliminate lot release requirement for biotech drugs**
Impact: Save time and resources of industry and FDA
- **Commit FDA to respond to clinical hold submissions on drugs, including biotech drugs, within 30 days**
Impact: Speed up drug development
- **Harmonize application forms for drugs and biologics**
Impact: Improve quality of submissions and reduce paperwork for industry and FDA
- **Eliminate preapproval requirement for promotional labeling for biotech drugs**
Impact: Speed up marketing of products and free FDA staff for other priorities
- **Allow companies to distribute certain textbooks and journal articles that discuss unapproved uses of drugs and devices**
Impact: Increase access to important scientific information without threatening effectiveness standard
- **Allow companies to submit toxicology findings based on first analysis of studies and reduce manufacturing data needed to begin drug tests in humans**
Impact: Speed up drug development
- **Develop pilot program for review of low- to moderate-risk medical devices by outside organizations**
Impact: Determine if outside review speeds up process and if integrity of review process can be maintained while allowing FDA to focus resources on higher risk-devices
- **Collect user fees for medical device reviews**
Impact: Speed up device reviews using program similar to one already achieving success for drug reviews
- **Expand opportunities for export of unapproved drugs and medical devices to industrialized countries**
Impact: Widen industry markets for products and encourage American companies to keep operations in United States

- **Exempt up to 125 categories of low-risk medical devices from premarket review, adding to 441 categories already exempted**
Impact: Speed up marketing of medical devices and free FDA staff for other priorities
- **Allow manufacturers of biological drugs to get licenses for pilot facilities instead of having to build full-scale manufacturing plants**
Impact: Reduce manufacturers' start-up costs and speed up marketing of drugs
- **Exclude drug and biologics manufacturers from requirements for most environmental assessments**
Impact: Reduce industry costs in preparing assessments FDA has found unnecessary

The International Record

- **The General Accounting Office reported in October 1995 that approval times for NMEs were shorter in the United States than in the United Kingdom.**
 - in FY 1994, 32 NMEs were approved in the United Kingdom in a median time of 30 months
 - in CY 1994, 22 NMEs were approved in the United States in a median time of 18 months
- **FDA's median approval time for new drugs approved in CY 1994 and 1995 was as fast as that in the United Kingdom and faster than those in France, Spain, Germany, Australia, Japan, Italy and Canada according to preliminary data from the Centre for Medicines Research (CMR), an industry-funded, not-for-profit research group in the United Kingdom. The median review time in the United States and the United Kingdom was approximately 1.3 years according to *CMR News*, Spring 1996.**
- **The United States has had more first launches of worldwide NMEs than any single European country since 1990. In fact, analysis of worldwide NMEs launched in the United States and Europe showed the United States has had a higher percentage of first launches than the top three European countries combined, according to *CMR News*, Spring 1996.**
 - **United States: 33%**
 - **United Kingdom: 14%**
 - **France: 9%**
 - **Germany: 7%**

#

Chris
Pitt

THE WHITE HOUSE

WASHINGTON

October 3, 1996

David A. Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

I am writing regarding the Food and Drug Administration's (FDA's) policy on home drug test kits. I understand that FDA's approach to reviewing and approving home testing kits, including those for illegal drugs, was developed during the administrations of Presidents Reagan and Bush. The President is pleased that you intend to re-evaluate this policy as it applies to home tests for illegal substances.

As you know, The President is committed to ensuring parents have the tools they need to prevent their children from using illegal substances. He has supported drug testing of high school athletes and has fought Congress's efforts to cut funds for the Safe and Drug-Free Schools Act. This administration has encouraged states to adopt a "zero tolerance" standard for drivers under the age of 21 who drive while intoxicated. You and the President have worked together to end children's tobacco use.

The President believes parents should also have access to safe and effective home drug test kits. Of course, neither he nor I state a view as to whether the FDA should approve any particular home drug testing product as safe and effective. The President believes, however, that safe and reliable tests should be available to parents, and parents should be able to use such tests if they choose.

As parents seek to raise their children drug-free, it is important to make all potentially useful tools available to them. The President would want you to keep this in mind as FDA reviews its criteria for evaluating home drug test kits.

Sincerely,



Carol H. Rasco
Assistant to the President
for Domestic Policy

THE PATIENTS' COALITION

An Independent Coalition of Patients With Serious And Life-Threatening Diseases Working Together For Responsible FDA Reform

February 12, 1997

The Honorable Donna Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 615F
Washington, DC 20201

Dear Secretary Shalala:

As organizations representing patients, many with serious or life-threatening conditions, and consumers in general, we are very concerned about continuing attempts to weaken the Food and Drug Administration through legislative and budgetary actions. As the 105th Congress begins its work, we urge you to maintain a steadfast commitment to protecting public health through a strong, well-funded FDA. There are four areas of special concern to us.

► **The President's FY 98 Budget**

The president's budget request includes an FDA budget that relies upon medical device and import user fees to cover portions of the FDA's "base" budget. Not only does the agency not have the statutory authority to collect such fees, but the fees outlined would be used to pay for basic FDA functions, rather than enhancements. Under the PDUFA regulations, the precedent for FDA user fees, all user fees must be used to pay for enhancements, not to support the agency's core public health functions. The medical device and import user fees in the FY 98 budget appear to be a deficit-reduction mechanism with the serious consequence of weakening the FDA. To include these fees in the budget without authorizing legislation at a time when some of the agency's fundamental responsibilities are already being questioned by Congress is especially troubling. We urge you to work with the FDA, the Office of Management and Budget, and Congress to ensure that the FDA's full budget needs are met through appropriated dollars and authorized user fees.

► **The Prescription Drug User Fee Act (PDUFA)**

PDUFA must be reauthorized without any FDA-"reform"-type amendments to the Food, Drug and Cosmetic Act (FD&C Act). All stakeholders agree that PDUFA has been extremely successful and should be reauthorized quickly to ensure that the program is not disrupted. Any attempts to change the standards by which drugs are approved or marketed through amending the FD&C Act as part of the PDUFA reauthorization process are unwise and unacceptable. In addition to any harm that might result from the amendments themselves if passed, their presence on the bill will certainly slow down and might well derail the reauthorization process itself.

► **FDA "Reform" Legislation**

We are also concerned about the Administration's efforts to move forward with drafting FDA

"reform" legislation. Many of the necessary changes at the FDA can be made without changes to the FD&C Act. While there are some changes that are needed to update portions of the FD&C Act, no one within the Administration has yet to articulate why comprehensive, FDA-"reform" legislation is necessary. After the FDA "reform" debate in the 104th Congress, we fear that any FDA-related legislation wades into dangerous territory and may well include, either in its original form or through amendment, provisions that will threaten the basic public health safeguards in the FD&C Act. We will continue to vocally oppose attempts to weaken the statutory threshold for the approval and marketing of drugs and devices.

There is in fact legislation that would improve the FDA review process. An example is legislation that would authorize medical device and import user fees. The administration has clearly demonstrated its support for such programs by including these fees in its FY 98 budget request. The administration could show genuine leadership on this issue by supporting authorization legislation for medical device and import user fees designed to provide enhancements to the FDA's core public health responsibilities. The absence of strong leadership on these user fees would be a clear signal that the fees in the budget are included for political expediency rather than good public health.

► **The New FDA Commissioner**

The new Commissioner must be, first and foremost, a strong public health advocate with a proven track record on public health issues. The Commissioner's primary responsibility is to protect the health and safety of the American public and we are confident you will select an individual who fully understands and supports this mission. As consumer and patient advocates we are keenly interested in this appointment and we want to play an active role in the process of selection.

We trust you share our commitment to the nation's public health and hope you and your staff will work closely with us to ensure that the FDA remains the strong, well-resourced agency that its mission demands. Representatives of our organizations request a meeting with you as soon as possible to discuss these pressing issues and will contact your staff to arrange such a meeting.

If you need further information please contact Gary Rose of AIDS Action Council at (202) 986-1300 ext. 3026 or Michael Langan of NORD at (202) 479-6694.

Sincerely,

AIDS Action Council
AIDS Interfaith Network
AIDS National Interfaith Network
American Foundation for AIDS Research
American Public Health Association
Association of Schools of Public Health
Center for Medical Consumers
Childrens Leukemia Foundation
Citizen Action
Committee for Children
Consumer Federation of America
Gay Men's Health Crisis

Grass Roots the Organic Way (G.R.O.W.)
Health Emergency Lifeline Programs (H.E.L.P.)
National Association of People With AIDS
National Association of Protection and Advocacy Systems (NAPAS)
National Episcopal AIDS Coalition
National Latino/a Lesbian & Gay Organization
National Minority AIDS Council
National Puerto Rican Coalition
National Organization for Rare Disorders (NORD)
National Women's Health Network
New York Coalition for Alternatives to Pesticides
Osteogenesis Imperfecta Foundation
The TMJ Association, Ltd.
Tourette Syndrome Association, Inc.
Treatment Action Group
United Parkinson Foundation and International Tremor Foundation
Wilson's Disease Association

cc: William Corr - Department of Health & Human Services
Mary Pendergast - Food & Drug Administration
William Schultz - Food & Drug Administration

THE PATIENTS' COALITION

An Independent Coalition of Patients With Serious And Life-Threatening Diseases Working Together For Responsible FDA Reform

June 9, 1997

The Honorable James Jeffords
Chair, Committee on Labor and Human Resources
U.S. Senate
SH-728 Hart Senate Office Building
Washington, DC 20510

Dear Senator Jeffords:

As representatives of patients with serious and life-threatening diseases, and consumers in general, we call on you to hold public hearings on your bill to amend the Food, Drug & Cosmetic Act prior to any committee mark-up.

This proposed legislation seeks to make significant changes to the federal Food, Drug and Cosmetic Act, one of the nation's most important and fundamental pieces of consumer protection legislation. The process used by the Labor Committee staff to draft the bill excluded patients and consumers, those with the most to gain or lose from the outcome, from the discussions and negotiations with the other stakeholders (industry, the FDA, and Congress).

These vitally important issues impact the health of all Americans and demand far more public discussion than the two general hearings the committee held this spring. The translation of "reform" proposals and concepts into legislative language is a complicated process in which patients and consumers deserve the opportunity to comment publicly on the specific legislative proposals.

We are extremely concerned about a number of these proposals, which would dramatically lower the standards and processes used to approve new drugs and devices. Among our gravest concerns are provisions that will:

- lower the effectiveness standard for new drugs, allow approvals of new drug indications based solely on anecdotal evidence, and allow for marketing approval of new drugs based on surrogate endpoint studies, without any enforceable mechanism for confirmatory clinical evidence;
- eliminate or weaken most regulatory protections against unsafe medical devices by allowing manufacturers to select and pay for-profit reviewers to certify that their products are safe and effective, letting companies make what they consider to be "minor" changes in the manufacturing process without notifying the FDA, and by repealing mandatory tracking and post-market surveillance for all devices;

- weaken restrictions on food health claims; and
- limit FDA's authority related to health economic claims, despite the acknowledged lack of standards and clarity by all stakeholders, including industry, on the parameters and implications of this uncertain and evolving area of product marketing.

Finally, we remain deeply troubled by the threat that these controversial provisions pose to the reauthorization of the Prescription Drug User Fee Act (PDUFA). PDUFA is largely responsible for the significant improvements in the FDA's review and approval of new drug applications and faster patient access to promising new therapies. PDUFA should be reauthorized immediately and without any link to controversial legislative provisions so that PDUFA's life-saving benefits to the American people are not threatened.

You have proven yourself to be a committed advocate for the needs of the American people and we hope that you will continue in that tradition as you move forward with legislation to change the Food, Drug and Cosmetic Act, one of the nation's most important pieces of consumer protection legislation.

Sincerely,

Daniel Zingale, Executive Director
AIDS Action Council

Carol Webb, Director
AIDS Council of West Virginia

David C. Harvey, Executive Director
AIDS Policy Center for Children, Youth, and Families

Stephen Conn, Executive Director
Alaska Public Interest Research Group

Sandra K. Brandley, Executive Director
Alpha National Association

Stephen McConnell, Senior Vice President for Public Policy
Alzheimer's Association

Dr. Arthur Ammann, President
American Foundation for AIDS Research

M. Doreen Croser, Executive Director
American Association on Mental Retardation

Kenneth J. Benner, President
American Council on Consumer Awareness, Inc. (MN)

Phyllis Rowe, President
Arizona Consumers Council

Libby Hill, Organizer
Arkansas Public Policy Panel

Hollie Swain, President
Association for Glycogen Storage Disease

Alison Wojciak, MPH, Director of Practice Programs
Association of Schools of Public Health

Peter A. Brigham, President
Burn Foundation

Arthur A. Levin, MPH, Director
Center for Medical Consumers

Donald Rounds, Executive Director
Center for Public Interest Research (MI)

Martin B. Scharf, PhD, Clinical Director
Center for Research in Sleep Disorders

Rhonda Connolly, Co-President
Children's PKU Network

Cathy Hurwit, Deputy Director
Citizen Action

J. Scott Douglas, Director
Committee for Children

Barbara Simmat, President
Connecticut TMJ Association

Laura Cordes, Director
Connecticut Public Interest Research Group

June Harper, Executive Director
Consortium of MS Centers

Cher McIntyre, Director of Advocacy
Consumer Action (CA)

Dr. Richard L.D. Morse, President
Consumer Education and Protection Association for Kansas

Senator Howard M. Metzenbaum (Retired), Chairman
Consumer Federation of America

Walter Dartland, Executive Director
Consumer Fraud Watch (FL)

Melissa Burkholder, Executive Director
Consumer Law Center of the South (GA)

Rosemary Shahan, President
Consumers for Auto Reliability & Safety (CA)

Laurie Pace, President
Cushing Support & Research Foundation

Albert Sterman, Secretary – Treasurer
Democratic Processes Center (AZ)

Nora Cody, Executive Director
DES Action

Ann Mulligan, National Coordinator
DES Cancer Network

Lenore F. Roseman, Executive Director
Dysautonomia Foundation, Inc.

Dr. Valerie F. Levitan, Executive Director
Dystonia Medical Research Foundation

Denis Cranson, Executive Director
Eastern Maine AIDS Network

Judy Braiman, President
Empire State Consumer Association

Audrey N. Lewis, Executive Director
Families of Spinal Muscular Atrophy

Thomas E. Roden, Executive Director
Friends for Life AIDS Resource Center

Chris Weidner, President
Grass Roots the Organic Way (GROW)

Estelle Benson, Executive Director
Guillain-Barre Syndrome Foundation International

Margit A. Krikker, MD, Medical Director
Hemochromatosis Foundation, Inc.

Nancy Wexler, President
Hereditary Disease Foundation

Helen Kay-Kreizenbeck, Executive Vice President
Idaho Consumer Affairs, Inc.

Rose Marie Silva, Executive Director
International Joseph Diseases Foundation, Inc.

Renee Glass, President
Jaw Joints and Allied Musculo-Skeletal Disorders Foundation

Debra M. Adkins, President
Latex Allergy News

Deirdre Cummings, Consumer Program Director
Massachusetts Public Interest Research Group

Lorraine Teel, Executive Director
Minnesota AIDS Project

Chris Newbold, Executive Director
Montana Public Interest Research Group

Marie Capobianco, President
MPS Society, Inc.

Joseph Interrante, Executive Director
Nashville Cares

Glen Sutcliffe, Director of Government Affairs
National Association of Protection and Advocacy Systems

Ted Karpf, Executive Director
National Episcopal AIDS Coalition

Mary K. Richter, Executive Director
National Foundation for Ectodermal Dysplasias

Raymond W. Stanhope, President
National Hemophilia Foundation

Lydia Buki, PhD., Director of Programs
National Hispanic Council on Aging

Martin Ornelas-Quintero, Executive Director
National Latino/a Lesbian and Gay Organization

Abbey S. Meyers, President
National Organization of Rare Disorders (NORD)

Lisa Cox, Program Director
National Women's Health Network

Shelley Moskowitz, Legislative Director
Neighbor to Neighbor

Henry Segal, Administrator
New York Consumer Assembly

Dr. Ellen DeWind, Director
Niagara Frontier Consumers Association (NY)

Steven B. Johnson, Director of Public Policy
Northwest AIDS Foundation

Marion Gray, Co-President
Older Women's League – Green Mountain Chapter (VT)

Leanna Jackson, Director
Osteogenesis Imperfecta Foundation

Jeannie Darneille, Executive Director
Pierce County (WA) AIDS Foundation

Frank Clemente, Congress Watch Director
Public Citizen

Stephen Barrett, M.D., Executive Director
Quackwatch, Inc. (PA)

Ellen H. Taggart, Executive Director
Rural Vermont

Bill Welsch, President
Safe Alternatives For Our Forest Environment

Skip Roberts, Acting Director Legislation Department
Service Employees International Union, AFL-CIO, CLC

Judith Filler, Executive Director
Texas Alliance for Human Needs

Terrie Cowley, President
TMJ Association

Judit Unger, Executive Director
Tourette Syndrome Association (TSA)

Gregg Gonsalves, Policy Director
Treatment Action Group

Paula Brazeal, President
United Leukodystrophy Foundation

Judy Rosner, Executive Director
United Parkinson Foundation / International Tremor Foundation

J.C. Carter, Policy Director
Vermont Public Interest Research Group

Joyce W. Graff, Chair
VHL Family Alliance

Carol Renza, Connecticut Representative
We the People, Connecticut

H. Ascher Sellner, MD, President
Wilson's Disease Association

James Brown, President
Wisconsin Consumers League

August 27, 1997

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

Dear Secretary Shalala:

We respect the commitment that you and other Administration officials have made to preserve important public health protections during the negotiations on S. 830, "The FDA Modernization and Accountability Act of 1997," but are deeply troubled by a number of recent agreements reached with members of the Senate Labor and Human Resources Committee. Indeed, our belief that these agreements will have devastating consequences for public health is so strong that representatives from our organizations urgently met last week with HHS Chief of Staff Bill Corr, FDA Deputy Commissioner Bill Schultz, FDA Associate Commissioner Diane Thompson, and FDA Policy Analyst Peggy Dotzel.

It appears that the Administration's strategy has been only to minimize the negative consequences of proposed provisions rather than actively pursuing legislation that would benefit American consumers. As a result, pro-consumer and pro-patient reforms are almost completely missing from S. 830. There is no provision in the bill for stronger FDA enforcement powers, consumer right-to-know and safeguard provisions, or sufficient resources to fund the FDA's core public health functions or additional new responsibilities.

Instead, S. 830 contains numerous provisions that will lower standards for proving new drugs and devices safe and effective, permit medical device companies to pay private, for-profit firms to review their products, eliminate mandatory tracking and postmarket surveillance of high-risk medical devices such as heart valves, and permit drug companies to make health economic claims based on scientifically untested methodology.

We are especially troubled by the agreement that will allow manufacturers to promote unproven, off-label uses for three years, with a possible extension up to five years. In testimony delivered in the Senate just last year, Mr. Schultz stated, "Permitting companies to promote drugs and devices for off-label use could have a number of devastating consequences for the quality of medical care in this country." Yet, the FDA has now agreed to a provision that will permit just such promotion. This agreement undermines the basic premise upon which the nation's entire drug and device approval system is based: drugs and devices must be proven safe and effective before they are marketed. The supposed requirements for companies to conduct research on the new use during this period are essentially meaningless absent the FDA resources, staff and authority necessary to monitor and enforce company performance.

In response to questions regarding FDA resources and staff available to complete the extensive reviews of off-label information to be disseminated and monitor manufacturers' progress in completing clinical studies, we were told that the agency will have no new resources available to

fulfill this function and that the Lead Deputy Commissioner has committed to shifting resources from other, as yet undetermined, FDA functions.

We reference this "zero-sum" funding approach to off-label promotion not because funding the provision could in any way mitigate its dangerous impact on public health - it would not - but to highlight the further damage it will do by shifting already inadequate resources and staff away from core public health functions. It is imperative that Congress and the public be told what other FDA activities will be cut in order to fund off-label promotion.

Once again, we appreciate the efforts the Administration has made to at least partially mitigate the impact of S. 830's numerous non-PDUFA provisions. However, while a number of individual sections have been slightly improved, taken as a whole S. 830 seriously damages the basic structure of health and safety protection for American consumers and patients. Given the importance of these issues it is especially disturbing that to date there has been no public hearing on S. 830 and a final copy of the bill still remains elusive.

When negotiations on S. 830 and House legislation resume after Labor Day, we strongly urge the Administration to publicly call for a public hearing and to actively pursue positive protections for patients and consumers. It is essential that there be sufficient new resources to fund the new mandates and effective enforcement, right-to-know, and consumer and patient safeguards. We are preparing a list of pro-patient and pro-consumer provisions that would constitute meaningful FDA reform, which we will send you in the near future.

Thank you for your attention and consideration.

Arthur Ammann, M.D.
American Foundation for AIDS Research

Mary Rouleau
Consumer Federation of America

Jeff Bloom
Project Inform

Sidney Wolfe, M.D.
Public Citizen Health Research Group

Abbey Meyers
National Organization for Rare Disorders

Daniel Zingale
AIDS Action Council

Cindy Pearson
National Women's Health Network

cc: Bill Corr
Michael Friedman
Bill Schultz
Diane Thompson
Peggy Dotzel

FDA Reform R4

4 September 1997

The Honorable James M. Jeffords
728 Hart Senate Office Building
United States Senate
Washington, DC 20510

Dear Senator Jeffords:

As national organizations representing a broad spectrum of American patients, consumers, and health care professionals, we are extremely concerned about S. 830, the "Food and Drug Administration Modernization and Accountability Act of 1997," and its potentially harmful impact on the health of millions of Americans.

The FDA protects public health by safeguarding our nation's drugs, biological products, medical devices, blood supply, and many foods. S. 830 would erode the FDA's ability to properly evaluate drugs and medical devices before and after marketing and would also allow companies to make claims about drugs and food products without sufficient evidence.

All parties agree that the Prescription Drug User Fee Act of 1992 (PDUFA) has led to speedier review times of new drugs at the FDA. We believe that Congress should reauthorize PDUFA immediately. American patients cannot afford further delay due to attempts to attach very controversial and even dangerous statutory "reforms" aimed solely at weakening the agency.

We are especially concerned about the following dangerous "reforms" found in and possible amendments to S. 830:

Third-Party Review of Medical Devices – This provision presents a clear conflict of interest encouraging a race-to-the-bottom for review standards, putting Americans at risk for faulty medical devices. We urge you to reject this attempt to privatize core FDA functions.

Drug Company Promotion of Unproven "Off-Label" Drug Use – A new provision of S. 830 would let drug companies promote unproven uses of FDA approved therapies, likely exposing patients to ineffective and unsafe drugs while reducing incentives for firms to do crucial clinical research.

Preemption of States' Rights, "National Uniformity" – S. 830 would nullify state and local consumer protection laws such as California's Proposition 65 and other laws requiring labeling of certain products like raw shellfish, cosmetics, and dietary supplements.

Unproven Health Claims on Foods – S. 830 would allow food and dietary supplement firms to make scientifically unsubstantiated health and nutrition claims about their products, claims currently prohibited by the Nutrition Labeling and Education Act (NLEA).

Use of Health Economic Information – Under S. 830, drug companies would be permitted to make health economic claims about drugs based on scientifically untested methodology to large

purchasers such as HMOs and mail order pharmacies. This would deny patients and physicians access to certain approved life-saving therapies by cutting drug availability.

The FDA, through a strong Food, Drug, & Cosmetic Act, has enhanced the public health by safeguarding our nation's drug, medical devices, and foods. Unless major changes are made, S. 830 will strip the agency of essential regulatory oversight and authority. This legislation is not responsible reform and the case for its necessity has not been made.

Sincerely,

AIDS Action Council
AIDS Legal Referral Panel
AIDS Policy Center for Children, Youth and Families
Alaska Public Interest Research Group
American Council on Consumer Awareness, Inc.
American Foundation for AIDS Research
American Public Health Association
Americans for Democratic Action
Arizona Consumer's Council
Arizona Consumer's Union
Arkansas Public Policy Panel
Arkansas Seniors Organized for Progress
Association for Gerontology and Human Development in Historical Black Colleges and Universities
Bazelon Center for Mental Health Law
Center on Disability and Health
Center for Medical Consumers
Center for Public Interest Research (MI)
Center for Research on Sleep Disorders
Center for Science in the Public Interest
Center for Women Policy Studies
Children's Leukemia Foundation of Michigan
Citizen Action
Citizen Advocacy Center
Coalition for the Homeless
Committee for Children
Consortium of Multiple Sclerosis Centers
Consumer Action (CA)
Consumer Education and Protection Association for Kansans
Consumer Federation of America
Consumer Fraud Watch (FL)
Consumer Law Center of the South (GA)
Consumers for Auto Reliability and Safety (CA)
Consumers Union
Democratic Processes Center (AZ)
DES Cancer Network
Doris Day Animal League

Dysautonomia Foundation
Dystonia Medical Research Foundation
Eldercare America, Inc.
Empire State Consumer Association
Families of Spinal Muscular Atrophy
Florida AIDS Action Council
Foundation for Ichthyosis and Related Skin Types
Gray Panthers
G.R.O.W., Inc.
Guillain Barre Syndrome Foundation International
Hemochromatosis Foundation
Human Rights Campaign
Idaho Consumers Affairs, Inc.
Immune Deficiency Foundation
International Tremor Foundation
Minnesota AIDS Project
Montana Public Interest Research Group
Mothers' Voices
Myositis Association of America
Narcolepsy Network
National Association of Protection and Advocacy Systems
National Association of School Psychologists
National Association of Social Workers
National Black Women's Health Project
National Caucus and Center on Black Aged, Inc.
National Citizens' Coalition for Nursing Home Reform
National Foundation for Ectodermal Dysplasias
National Health Care for the Homeless Council
National Hemophilia Foundation
National Hispanic Council on Aging
National Incontinentia Pigmenti Foundation
National Latino/a Lesbian and Gay Organization
National Lesbian and Gay Health Association
National Lymphedema Network
National Organization for Rare Disorders (NORD)
National Parent Network on Disabilities
National Task Force on AIDS Prevention
National Women's Health Network
Neighbor to Neighbor
NETWORK: A National Catholic Social Justice Lobby
New York Coalition for Alternatives to Pesticides
New York Consumer Assembly
Niagara Frontier Consumers Association (NY)
Northwest AIDS Foundation
Older Women's League – Green Mountain Chapter
Osteogenesis Imperfecta Foundation

Pennsylvania Citizens Consumer Council
Project Inform
Project on Government Oversight
Public Citizen
Quackwatch, Inc
Rural Vermont
Safe Alternatives for Our Forest Environment
Service Employees International Union, AFL-CIO, CLC
Sturge-Weber Foundation
Texas Alliance for Human Needs
The ARC
The MPS Society
The TMJ Association, Ltd.
Tourette Syndrome Association
Treatment Action Group
Union of Needletrades, Industrial and Textile Employees
United Church of Christ, Office for Church in Society
United Parkinson Foundation
United Leukodystrophy Foundation
We the People
Wilson's Disease Association
Wisconsin Consumer's League
Women's AIDS Network

FDA Reform - 1997

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NICK LITTLEFIELD, MINORITY STAFF DIRECTOR AND CHIEF COUNSEL

<http://www.fda.gov/compliance/lobby.html>

United States Senate

COMMITTEE ON LABOR AND
HUMAN RESOURCES

WASHINGTON, DC 20510-6300

TO: Chris Jennings

FAX NUMBER: 202-456-5557

FR: David Nexon

NUMBER OF PAGES: _____ COVER + 3

RETURN FAX NUMBER: (202) 224 - 3533

IF THERE IS ANY TROUBLE RECEIVING THIS FAX, PLEASE CALL
(202) 224 - 7675.

MESSAGE:

*- Memo to Elena re Abortion?
2 apology
Carasol*

*Memo
- ~~memo~~ to Bruce, Elena, Cathy re their
letter*

FAX NUMBER: _____

TO: Chris Jennings

From: David

Attached is our list. The most important issues are in bold, but the other issues are also important. We and the FDA have offered compromises on every remaining issue--and compromise should be possible if there is the will to compromise on the other side. In general, industry is taking a softer line than the Jeffords staff.

As we discussed, we think the most helpful steps would be:

--a call to Jeffords telling him that he needs to work these issues out with Kennedy and the FDA and that this should be doable.

--Administration support for any agreement is conditional on a commitment, which Jeffords would need to get Lott to participate in, that this agreement has to hold through conference, unless all parties agree to changes.

DEVICE ISSUES

STATUS

Third party review	Extensive discussion. Tentative agreement to exclude class III devices and high-risk class II devices. Remaining issue is total number of devices to be included in the pilot. FDA has offered 40% and is willing to allow the majority to specify particular device categories if they want. We are awaiting Jeffords/Coats response. Close to agreement.
Manufacturing changes	Had agreement on language which would 1) exempt manufacturing changes that do not affect safety or effectiveness from FDA review; 2) give FDA 30 days to review other proposed changes; 3) would allow manufacturers to go ahead with such changes unless FDA affirmatively found that the changes proposed a sufficient risk to require additional review. Jeffords staff backed away from agreement because of Coats objections. FDA is reviewing Coats counter proposal which would accept proposal but shorten review times for higher risk manufacturing changes. Close to agreement
Post marketing surveillance	Had agreement to make post market surveillance discretionary; Had agreement in principle on length of time allowed in cases where surveillance was necessary. Jeffords staff backed off of agreement after Coats raised objections. FDA will provide additional information.
Eliminate automatic class III designation for novel but low risk devices	We and FDA support provision but had agreement in principle on legislative history to clarify standards of review for such devices. Jeffords failed to abide by agreement. We are awaiting Jeffords response.
Prohibit FDA from taking GMP violations into account in determining whether to approve a product (reference list)	We agreed to the concept with an exception in cases where GMP applied to the specific product and the violation was sufficiently severe where the product could not be considered substantially equivalent. Jeffords refuses to compromise, although industry has indicated flexibility to us.
Prohibit FDA from taking into account anything other than proposed labeling claim in reviewing a device	We have accepted this proposal with the exception that the proposed claim not be false or misleading. Jeffords staff and industry have accepted this exception for class III devices but not for 510(k) devices.
Humanitarian devices	We have accepted proposed changes but want to allow FDA adequate time to review the devices.

DRUG ISSUES

Pharmacoeconomic claims Proposals have been exchanged by FDA, industries.
Agreement between FDA and the industry seems likely.

Enforcement of agreements between companies and FDA to carry out post-approval trials (phase IV) Jeffords reviewing our proposal.
Critically important to patients groups.

Expanded access to unapproved drugs Jeffords reviewing FDA proposal which would retain current restrictions that expanded access is generally available only in cases where clinical trials are ongoing for the particular illness for which use of the drug is sought. This issue is not important to industry.

PET pharmaceuticals Jeffords/Stevens reviewing our proposal.

CROSS-CUTTING ISSUES

Health claims for foods We believe we are close to agreement.
Jeffords/Gregg reviewing our proposal.

Agency plan We are close to agreement.

Contracts for expert review We have accepted the concept of mandatory contracting out under certain circumstances. The issue is defining those circumstances to assure that health and safety are protected and that the agency is only required to contract out when it would truly be advantageous to do so.
Jeffords/Gregg reviewing our proposal.

OTC/cosmetic preemption Discussions have been inconclusive.



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

File FDA reform

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

JUN 1 1997

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 public health. Another significant nonconsensus item is the set of adjustment provisions in sections 703 and 704, which together require significant increases in FDA's appropriations levels over FY 1998 through 2002 (almost \$100 million above the FY 1998 Budget with

#5

levels rising thereafter). We recognize that the ability of the FDA to commit to specific performance goals under PDUFA depends on the resources it will have available. We would support a user fee proposal that is consistent with our FY 1998 Budget proposal, but we are concerned that the proposal to collect user fees in this legislation imposes additional pressure on the fixed level of discretionary resources agreed to under the Bipartisan Budget Agreement.

We note the inclusion of the provision on pediatric labeling in the most recent version of the Committee mark. We believe it should be revised to assure a more appropriate system for testing 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.

A copy of this letter is also being sent to the ranking Minority member, Senator Kennedy, and the other members of the Senate Labor and Human Resources Committee.

Sincerely,



Donna E. Shalala

Enclosure

S. 830 (Chairman's Substitute)

needs to be a negotiated process.

A. Major Concerns

too many

→ 5 yrs.

#5 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

law

2. Third Party Review of Devices (Sec. 204) degree volume

expansion of FDA's existing pilot project for review of medical devices (includes devices that require clinical data) by organizations accredited by FDA They have excluded class 3 devices. we'll do pilot. if manageable.

sk- advisory committee

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

1/3 of S-10 K program → how much can you add a year. Pilot never ends.

- 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

#3 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. court action or rule. FDA burden of proof showing that fraudulent. 553 rule. court action - otherwise they can announce

#2 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

where is S. Kennedy? who wants this - not patients, not providers
→ experimental matter
waive for specific use, indi
so why expanded access.
this got fixed last time.

* - real problem

slight modification
never have to come to
industry agrees not
a problem to go to
FDA.

FDA to
change
efficacy
minor
modifications

6. Device Modifications (Sec. 601)

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

#3

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

Process issue, lang not OK. It goes beyond lifestyle - ~~give them what they want~~. resolution.

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
- doesn't assure that necessary labeling for children will be included.
- might undercut FDA's ability to use other means such as regulations

B. Other Significant Concerns

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

kind of data required.
certainty in process
legit. but need
agreement on
protocol

C. Currently In The Bill - No Language Provided Yet

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

Imprecise, etc

DRAFT ----- DRAFT ----- DRAFT ----- DRAFT ----- DRAFT

Raines/Administration letter regarding S. 830

Dear Senator Jeffords,

I am writing regarding the Food and Drug Administration and Accountability Act of 1997, S. 830, which was reported by the Labor and Human Resources Committee on June 18, 1997. I understand that the bill includes a significant number of provisions that represent constructive, consensus reform designed to improve the performance and accountability of the Food and Drug Administration (FDA or Agency). We appreciate the efforts that you, Senator Kennedy and the other members of the Committee have made in this regard. As you know, improving the performance of Executive branch agencies, while preserving and enhancing our ability to protect health, safety and the environment, has been one of this Administration's highest priorities.

Unfortunately, I understand that the bill as reported contains a number of provisions which would undermine the public health protections on which the American public relies. The

that go beyond the consensus reform.

~~provisions of greatest concern to the Administration were outlined in Secretary Shalala's letter to you dated June 11, 1997. Our concerns have not been addressed in the bill reported by the~~

While progress has been made during the Committee's consideration of the bill, our concerns have not been addressed in the bill reported by the

~~Committee. The Administration is prepared to continue to work with you, Senator Kennedy, and the other members of the Committee on a package of consensus reforms that could be enacted~~

~~with reauthorization of the Prescription Drug User Fee Act (PDUFA). Please understand~~

~~however, that our concerns are significant and the President could not sign this FDA reform~~

~~legislation without those concerns being addressed. Moreover, I must reiterate the Secretary noted in her letter, that time for reauthorization of (PDUFA) is running perilously short.~~

Administration could not sign this bill

these provisions. In particular we have serious problems with (a) _____ + (b) _____

I hope we will not jeopardize the opportunity before us to enact the PDUFA reauthorization with strong, constructive consensus reform because there continue to be issues on which consensus does not exist. Working together I am confident that we can achieve our mutual goal of FDA improvements that enhance performance and the Agency's ability to promote and protect the public health.

Sincerely,

S:\wp\diane\fdare\raines.dft



B A C K G R O U N D E R

U.S. FOOD & DRUG ADMINISTRATION

FDA: A Record Of Accomplishment

Faster Drug Approvals

- 82 new drugs approved in **16.5 months** (median) in Calendar Year (CY)1995, compared with 62 new drugs approved in **19 months** in 1994
- 28 of the 1995 approvals were new molecular entities (NMEs)—brand new drugs as opposed to new formulations—and were approved in **15.9 months** (median), compared with 22 NMEs approved in **17.5 months** in 1994
- 15 of the 1995 approvals were “priority” drugs—having important therapeutic value—and were approved in **6 months** (median), compared with 17 “priority” drugs approved in **15 months** in 1994
- 13 of the 1995 “priority” approvals were user fee drugs approved in **5.9 months** (median), compared with 12 “priority” user fee drugs approved in **10.4 months** in 1994

Improved Device Reviews

- 5,594 510(k)s (which account for about 98% of medical devices) reviewed by FDA in **138 days** (mean) in Fiscal Year (FY) 1995, compared with 5,498 in **182 days** in FY 1994
- **27 PMAs** (premarket applications for certain Class III devices) reviewed by FDA in **20.2 months** (mean) in FY 1995, compared with 26 PMAs in **21.6 months** in FY 1994

The Record on Reinvention

As part of Vice President Gore’s National Performance Review, the FDA has announced more than 30 FDA regulatory reinvention initiatives since March 1995. These initiatives will reduce regulatory burdens and streamline the regulatory process, while maintaining vital public health safeguards and speeding the marketing of safe and effective new drugs and medical devices. Following is a partial listing of these initiatives:

- Speed up approval process for cancer drugs by using tumor shrinkage as surrogate marker for accelerated approval decisions
Impact: Cut years off development times and months off FDA review

- Expand patient access to experimental cancer drugs approved in other countries
Impact: Make it easier for patients to have access to promising but still experimental therapies
- Increase patient representation on cancer drug advisory committees
Impact: Give patients more of a voice in the drug review process
- Clarify requirements for doctors studying already approved cancer drugs
Impact: Reduce paperwork for doctors and free FDA staff for other priorities
- Eliminate Establishment License Application (ELA) for most biotech drugs
Impact: Reduce paperwork burden for industry and speed up marketing of biotech drugs
- Eliminate lot release requirement for biotech drugs
Impact: Save time and resources of industry and FDA
- Commit FDA to respond to clinical hold submissions on drugs, including biotech drugs, within 30 days
Impact: Speed up drug development
- Harmonize application forms for drugs and biologics
Impact: Improve quality of submissions and reduce paperwork for industry and FDA
- Eliminate preapproval requirement for promotional labeling for biotech drugs
Impact: Speed up marketing of products and free FDA staff for other priorities
- Allow companies to distribute certain textbooks and journal articles that discuss unapproved uses of drugs and devices
Impact: Increase access to important scientific information without threatening effectiveness standard
- Allow companies to submit toxicology findings based on first analysis of studies and reduce manufacturing data needed to begin drug tests in humans
Impact: Speed up drug development
- Develop pilot program for review of low- to moderate-risk medical devices by outside organizations
Impact: Determine if outside review speeds up process and if integrity of review process can be maintained while allowing FDA to focus resources on higher risk-devices
- Collect user fees for medical device reviews
Impact: Speed up device reviews using program similar to one already achieving success for drug reviews
- Expand opportunities for export of unapproved drugs and medical devices to industrialized countries
Impact: Widen industry markets for products and encourage American companies to keep operations in United States

- Exempt up to 125 categories of low-risk medical devices from premarket review, adding to 441 categories already exempted
Impact: Speed up marketing of medical devices and free FDA staff for other priorities
- Allow manufacturers of biological drugs to get licenses for pilot facilities instead of having to build full-scale manufacturing plants
Impact: Reduce manufacturers' start-up costs and speed up marketing of drugs
- Exclude drug and biologics manufacturers from requirements for most environmental assessments
Impact: Reduce industry costs in preparing assessments FDA has found unnecessary

The International Record

- The General Accounting Office reported in October 1995 that **approval times for NMEs were shorter in the United States than in the United Kingdom.**
 - in FY 1994, 32 NMEs were approved in the United Kingdom in a median time of 30 months
 - in CY 1994, 22 NMEs were approved in the United States in a median time of 18 months
- FDA's median approval time for new drugs approved in CY 1994 and 1995 was **as fast as** that in the United Kingdom and **faster than** those in France, Spain, Germany, Australia, Japan, Italy and Canada according to preliminary data from the Centre for Medicines Research (CMR), an industry-funded, not-for-profit research group in the United Kingdom. The median review time in the United States and the United Kingdom was approximately 1.3 years according to *CMR News*, Spring 1996.
- The United States has had **more first launches** of worldwide NMEs than any single European country since 1990. In fact, analysis of worldwide NMEs launched in the United States and Europe showed the United States has had a higher percentage of first launches than the top three European countries combined, according to *CMR News*, Spring 1996.
 - United States: 33%
 - United Kingdom: 14%
 - France: 9%
 - Germany: 7%

#