

WHITE HOUSE STAFFING MEMORANDUM

9:30 a.m.

DATE: 1/23/97 ACTION/CONCURRENCE/COMMENT DUE BY: 1/24/97SUBJECT: Radio Address (Food Safety)

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	McCURRY	☐	☒
BOWLES	☒	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
PODESTA	☒	☐	QUINN	☒	☐
MATHEWS	☒	☐	RASCO	☐	☐
RAINES	☒	☐	REED	☒	☐
BAER	☒	☐	SOSNIK	☐	☐
	☐	☐	LEWIS	☒	☐
EMANUEL	☒	☐	YELLEN	☐	☐
GIBBONS	☐	☐	STREETT	☐	☐
HALE	☐	☐	SPERLING	☐	☐
HERMAN	☐	☐	HAWLEY	☐	☐
HIGGINS	☒	☐	WILLIAMS	☐	☐
HILLEY	☐	☐	RADD	☒	☐
KLAIN	☒	☐	<u>T.J. Glauthier</u>	☒	☐
BERGER	☐	☐	<u>Sally Katzen</u>	☒	☐
LINDSEY	☐	☐	☒ <u>Nancy - Ann Min</u>	☒	☐
			<u>Waldman</u>	☒	
			<u>Elizabeth Dye</u>	☒	

REMARKS:

Comments to David Shipley.

RESPONSE:

1/23/97

PRESIDENT WILLIAM J. CLINTON
WEEKLY RADIO ADDRESS
THE WHITE HOUSE
JANUARY 25, 1997

'97 JAN 23 PM5:11

Good morning. Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

Almost a week ago, in my inaugural address, I told the American people in broad terms what our vision must be -- to lead this country into the 21st century with the American Dream alive for all our children; with the American promise of a more perfect union a reality for all our people; with America's bright flame of freedom illuminating the world.

I believe we will make real this vision by doing what we have always done in moments of great change: By holding fast to our enduring values. Central among these is the belief that Americans are entitled to clean air, safe food, pure water. Hard-working American parents deserve the peace of mind that comes from knowing that the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State and in 2 other Western states this fall. Apple juice contaminated with a deadly strain of E Coli bacteria reached supermarket shelves. More than a dozen children -- some as young as 2 -- were hospitalized. One child died.

I'm sure just about every parent in America remembers what E Coli can do. Four years ago this month, tragedy struck hundreds of families in the Western United States when they took their children to fast-food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children lost their lives.

My administration has made it a top priority to protect the health and safety of all Americans. I signed into law legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. We put in place strong new protections to ensure that seafood is safe. And we announced steps to modernize our meat and poultry food safety system for the first time in 90 years. Those new safety rules will begin to take effect next week. From now on, all meat and poultry plants will be required to test for E Coli.

We have built a solid foundation of health security for our families. But, clearly, we must do more. No parent should have to think twice about the juice they pour their children at breakfast or a hamburger ordered during a dinner out. That is why today I am announcing new steps to keep our food safe and to protect our children from deadly bacteria.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the Centers for Disease Control, the Food and Drug Administration, and the Agriculture Department sponsor 5 centers across the country whose mission is ^{actually} ~~to post a look-out~~ ^{Set out} for food-borne diseases -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will increase the number of these sites from 5 to 8. And we will link them to other state health agencies. This expanded early-warning system will enable us to catch outbreaks sooner, and give us the data that will help us prevent outbreaks from happening in the first place.

Second, we will see to it that the early-warning system uses state-of-the-art technology to keep our food safe. We will increase the number of expert disease detectives to investigate and control food-borne disease outbreaks. We will give these experts the technology to use sophisticated new DNA fingerprinting methods to trace infectious agents to their source. We will create a permanent fingerprint library, so we can immediately recognize an illness ^{if it reappears} ~~if it reappears~~. And we will use advanced communications networks to speed outbreak information to hospitals and public health agencies around the country. ^{actually}

Third, I am directing the Secretaries of Agriculture and Health and Human Services, as well as the Administrator of the Environmental Protection Agency, to work with communities, farmers, businesses, consumer protection groups, and all levels of government to come up with additional measures to improve food safety. I want them to pay special attention to research and public education efforts. I want them to focus on what sort of ~~public-private~~ ^{public-private} partnerships ~~we can develop~~ to meet our goals. And I want them to report back to me with their findings within 90 days. ^{The gov't can form with the private sector}

Finally, let me add that these new public health investments are paid for line-by-line, dime-by-dime in the balanced budget I will officially send to Congress next month.

With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children. Together, we will see to it that our people find a land of new promise in the 21st century.

Thanks for listening.

*These sites -- CA, OR, MN, GA, and CT --
actually track outbreaks of illnesses
caused by contaminated food.*

WHITE HOUSE STAFFING MEMORANDUM

DATE: 1/23/97 ACTION/CONCURRENCE/COMMENT DUE BY: 1/24/97 ^{9:00 a.m.}SUBJECT: Presidential Directive on Food Safety

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	McCURRY	☐	☒
BOWLES	☒	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
PODESTA	☒	☐	QUINN	☒	☐
MATHEWS	☒	☐	RASCO	☐	☐
RAINES	☒	☐	REED	☒	☐
BAER	☒	☐	SOSNIK	☐	☐
	☐	☐	LEWIS	☒	☐
EMANUEL	☒	☐	YELLEN	☐	☐
GIBBONS	☐	☐	STREETT	☐	☐
HALE	☐	☐	SPERLING	☐	☐
HERMAN	☐	☐	HAWLEY	☐	☐
HIGGINS	☒	☐	WILLIAMS	☐	☐
HILLEY	☐	☐	RADD	☒	☐
KLAIN	☒	☐	<u>T. J. Glauthier</u>	☒	☐
BERGER	☐	☐	<u>Sally Katzen</u>	☒	☐
LINDSEY	☐	☐	<u>Clerk</u>	☒	☐
			<u>Nancy-Ann Min</u>	☒	
			<u>Drye, Elizabeth</u>	☒	

REMARKS:

Comments to this office.

RESPONSE:

Memorandum on Improving the Safety of the Nation's Food Supply
January 25, 1996
Memorandum for the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency.

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better in our efforts to eliminate disease caused by microorganisms and other contaminants. Americans still suffer thousands of food-related deaths and millions of food-related illnesses.

The 21st century will present new and greater challenges in this area. Novel pathogens are emerging. Long-understood pathogens are growing resistant to treatment. Americans eat more foods prepared outside the home, and we consume record levels of imported food -- some of which moves across the globe overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention, research, and education.

My Administration has already taken a number of steps to improve food safety. We modernized the meat, poultry, and seafood safety systems. I signed into law new legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. Today I announced a new national early warning system for foodborne illness. The system will allow us to respond more quickly to disease outbreaks and to better prevent them in the future.

But we need to do more. Government, consumers and industry must work together to further reduce foodborne disease, and to ensure our food supply is the safest in the world.

I hereby direct that you work with consumers, producers, industry, states and the public to identify additional ways to improve the safety of our food supply through government and private sector action, including public-private partnerships. Your recommendations should identify steps to further improve surveillance, inspections, research, risk assesment, education, and coordination among local, state, and federal health authorities. You should report back to me with in 90 days with your recommendations.

NOTE TO BRUCE AND ELENA

FROM: Elizabeth Drye

SUBJECT: 7:30 Meeting / Food Safety

Frank is expecting DPC to raise at 7:30 whether and how to discuss 98 budget numbers in the food safety radio address and accompanying materials. He may just want a straight decision on whether to give any numbers, but his staff tell me he may want to discuss details. Here is my quick assessment of the options:

1. Give no numbers. Simply say we'll give numbers when we release budget. Pros: consistent with general policy. Cons: event is less newsworthy, invites speculation, wrong numbers have already been in trade press.
2. Give total number for initiative, \$42 million. Pros: better information. Cons: not much better.
3. State that we'll request \$42 million total -- \$11.5 million for early warning system and the remainder for seafood safety inspectors, research, education, and training. (Current draft fact sheet). Don't elaborate on allocation. Pros: much more concrete, leaves HHS room to make further adjustments, keeps focus on early warning system. Cons: still ambiguous.
4. Spell out how USDA/FDA/CDC will allocate \$42 million among early warning system, inspectors, education, research and training. Pros: more detail for reporters. Cons: HHS may need to adjust allocation later.

I like option 3.

Thanks for your help.

WHITE HOUSE STAFFING MEMORANDUM

10:30 a.m.

DATE:

11/1/96

ACTION/CONCURRENCE/COMMENT DUE BY:

11/2/96

SUBJECT:

Presidential Directive on Food Safety

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	McCURRY	☐	☒
PANETTA	☒	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
ICKES	☒	☐	QUINN	☒	☐
LIEBERMAN	☒	☐	RASCO	☒	☐
RAINES	☐	☐	REED	☒	☐
BAER	☒	☐	SOSNIK	☐	☐
CURRY	☐	☐	STEPHANOPOULOS	☒	☐
EMANUEL	☐	☐	STIGLITZ	☐	☐
GIBBONS	☐	☐	STREETT	☐	☐
HALE	☐	☐	TYSON	☐	☐
HERMAN	☐	☐	HAWLEY	☐	☐
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HILLEY	☐	☐	<u>Clerk</u>	☒	☐
KLAIN	☒	☐	<u>Nancy Ann Min</u>	☒	☐
LAKE	☐	☐	<u>Sally Katzen</u>	☒	☐
LINDSEY	☐	☐	<u>T.J. Glanville</u>	☒	☐
			<u>E. Dye</u>	☒	☐

REMARKS:

Comments to this office.

RESPONSE:

11/1/96 FINAL

**PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS TO THE NATION
NOVEMBER 2, 1996**

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

I believe this is a positive and hopeful time...an age of enormous possibility...a chance for us to build a country and a world that is stronger and safer and full of more possibility than any that existed before.

The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. Several children, some as young as 2, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria.

I imagine just about every parent in America remembers what E Coli can do. In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Food and Drug Administration, we stopped this week's outbreak of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. The Centers for Disease Control and Prevention notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get its juice off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. Now, of the 5 children who were hospitalized in Seattle, all are recovering.

This quick response is part of our larger effort to protect the health and safety of all our people. Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us. We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90 years. I signed into law legislation to keep harmful pesticides off our fruits and vegetables --

and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of food safety we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the CDC sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of "disease detectives" to investigate and control food-borne disease outbreaks...to give health experts state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will do everything in our power to make sure that the world's most bountiful food supply is also the safest.

By protecting the public health, by bringing our people together around our basic values of opportunity, responsibility, and community, we will surely make this an age of possibility for all Americans.

Thanks for listening.

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Thanks for listening.

DRAFT 11/1/96

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The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. Several children, some as young as TK, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria.

I imagine just about every parent in America remembers what E Coli can do. In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Food and Drug Administration, we stopped this week's outbreak of E. Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. We worked with the manufacturer to get its juice off supermarket shelves in all 7 states where it was available. And we put doctors and hospitals across the country on alert for symptoms of E Coli infection. Now, of the 4 children who were hospitalized, all but one has gone home. And XX is expected to be released any day.

This quick response is part of our larger effort to protect the health and safety of all our people. Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us. We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90

Here's what we'd like to be able to say
on early warning system

years. I signed into law legislation that protects our fruits and vegetables from harmful pesticides -- and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of health security we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria.

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Second, we will use state-of-the-art technology to keep our food safe. We will increase the number of expert disease detectives to investigate and control food borne disease outbreaks. We will give these experts the technology to use revolutionary new DNA fingerprinting methods to trace infectious agents to their source, and create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use cutting-edge communications networks to speed outbreak information from these centers to hospitals and public health agencies all across the country.

Third, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to ensure the safety of our food.

With these initiatives we say, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children.

Today, in America, no parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

11/1/96 FINAL

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Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Food and Drug Administration, we stopped this week's outbreak of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. The Centers for Disease Control and Prevention notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get its juice off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. Now, of the 5 children who were hospitalized in Seattle, all are recovering.

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Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of "disease detectives" to investigate and control food-borne disease outbreaks...to give health experts state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

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Thanks for listening.

Before chair

DRAFT 11/1/96

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Thanks for listening.

Jean Logan
632-0390

N T
N T

EXECUTIVE OFFICE OF THE PRESIDE
EXECUTIVE OFFICE OF THE PRESIDE

16-Jan-1997 09:29am

TO: (See Below)

FROM: Elizabeth E. Drye
Domestic Policy Council

SUBJECT: Tuesday food safety event

We are planning to do a food safety announcement Tuesday afternoon. An outline of the event is below. It's very similar to the announcement we prepared in October. POTUS will announce early warning system, note other items in 98 food safety budget request, and direct Secretaries to work with industry and consumer groups to suggest further steps.

I'm hosting a 1:30 mtg today, Thursday, to brief you or your staff on the event. Notice of that meeting to follow. Please call me if you have any questions, suggestions, comments. 6-5573.

OUTLINE OF EVENT

The President would:

1. Take credit for progress:

- Acknowledge it is the 4 year anniversary of the western e-coli outbreak that killed several children and made hundreds sick;
- Note that since then we've revolutionized meat and poultry rules, and that this week slaughter houses will start testing for e-coli;
- Note that for seafood, as well as meat and poultry, we've moved to a science-based preventive approach;

2. State that we need to do more.

- Announce a new national early warning system to catch outbreaks early, prevent illness and death, and gather data we need to further our prevention efforts (we're still clearing the exact language with CDC, but expect to use the language we wanted to use earlier regarding DNA fingerprinting, disease detectives, etc.).

- State that we have already begun to put system in place, and will ask Congress for additional funds to complete the job.
 - Announce 98 budget will also contain money for seafood inspectors (FDA), research (USDA/FDA) and education (USDA).
3. Ask gov't, industry, consumers, and the public to work together to ensure we continue to have the worlds safest food supply.
- Direct Secretaries and EPA Administrator to (1) work with cooperatively industry and consumer groups to identify

additional steps to improve food safety, and (2) report back in 120 days on additional steps.

Participants

- VP, Shalala, Glickman, Browner, Kessler, Satcher (CDC)
- Families of kids who died from e-coli
- a few industry types (e.g. meat packers and food processors)

Agenda

- ^{group}POTUS would make remarks, sign directive, won't answer questions. Still need to sort out how to handle Q & A, whether to do stakeout w/families and/or industry.

Remaining substantive issues:

- CDC still has to clear specifics of early warning system; our goal is to reach closure by mid-morning.
- Need to clear overall announcement w/OMB in a.m. also.

Distribution:

TO: T J. Glauthier
TO: Nancy-Ann E. Min
TO: Sally Katzen

CC: Alecia Ward
CC: Mark A. Weatherly
CC: Richard J. Turman
CC: Jim R. Esquea
CC: K. Lisa Grove
CC: Michael A. Fitzpatrick
CC: Adrienne C. Erbach

OFFICE OF THE STAFF SECRETARY

Fax Transmittal Sheet

TO: Elizabeth Dye

Fax Number: 6-4028

Phone Number: 6-5573

FROM: Helen Howell

SUBJECT:

DATE: 1/15/97

NUMBER OF PAGES (including cover sheet): 2

MESSAGE:

If all pages are not received, please call 202/456-2702

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MEMORANDUM TO: Bruce Reed
Jack Quinn
T.J. Glauthier
Nancy Ann Min
Sally Katzen

receding
11:12 am

FROM: Elizabeth Drye, 456-5573

SUBJECT: Draft Presidential Directive on Food Safety

FOR YOUR IMMEDIATE REVIEW
---- DRAFT 10/31/96 ----

Memorandum on Improving the Safety of the Nation's Food Supply
November 2, 1996

Memorandum for the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency.

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better in our efforts to eliminate disease caused by microorganisms and other contaminants. Americans still suffer thousands of food-related deaths and millions of food-related illnesses.

The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to treatment. Americans consume record levels of imported food, some of which moves across the globe overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention, research, and education.

My Administration has already taken a number of steps to improve food safety. We modernized the meat, poultry, and seafood safety systems. I signed into law new legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. Earlier today I announced a new national early warning system for foodborne illness. The system will allow us to respond more quickly to disease outbreaks and to better prevent them in the future. But we need to do more.

I hereby direct that you report back to me within 60 days and recommend additional measures to improve the safety of our food. Your recommendations should include ways to improve surveillance, inspections, research, education and coordination among local, state, and federal health authorities. In particular, I direct you to consider ways to: increase the number of experts investigating food-borne disease outbreaks; give health experts state-of-the-art technology to trace infectious agents to their source; and use advanced communications networks to speed outbreak information to health authorities across the country.

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MEMORANDUM TO: Amy Busch, HHS
Eric Olsen, USDA
Lyn Goldman, EPA

FROM: Elizabeth Drye, 456-5573

SUBJECT: Draft Presidential Directive on Food Safety

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[Handwritten signature]

MEMORANDUM TO: Bruce Reed
Jack Quinn ✓
T.J. Glauthier ✓
Nancy Ann Min
Sally Katzen

FROM: Elizabeth Drye, 456-5573

SUBJECT: Draft Presidential Directive on Food Safety

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In particular, these recommendations should also

THE WHITE HOUSE

WASHINGTON

December 3, 1996

MEMORANDUM TO LEON PANETTA
DON BAER

FROM: Elizabeth Drye, DPC

SUBJECT: Possible Food Safety Radio Address or Event

Bruce Reed asked that I forward to you a copy of the food safety radio address and Presidential directive we prepared last month (attached). The address announces a new early warning system for food-borne illness, and directs USDA, HHS, and EPA to recommend additional food safety improvements.

We previously worked out the language and policy in the address with Secretary Shalala's staff. However, Secretary Shalala does not want to go forward with the radio address at this time. She instead wants to announce a broader food safety initiative in the State of the Union Address (she just sent OMB an amendment to her 1998 budget request asking for an additional \$96 million for food safety). The early warning system we would announce in the address is a small part of her FY98 request and requires a commitment of \$2-3 million in FY97 funds. We would have to firm up funding commitments from USDA, FDA, CDC, and OMB on the early warning system before making an announcement (HHS and USDA previously agreed to fund the FY97 cost with existing funds).

Attachments

WHITE HOUSE STAFFING MEMORANDUM

5:00 P.M.

DATE: 11/1/96 ACTION/CONCURRENT COMMENT DUE BY: 11/1/96SUBJECT: Radio Address

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☒	☐	McCURRY	☐	☒
PANETTA	☒	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
ICKES	☒	☐	QUINN	☐	☐
LIEBERMAN	☒	☐	RASCO	☒	☐
RAINES	☐	☐	REED	☐	☐
BAER	☒	☐	SOSNIK	☐	☐
CURRY	☐	☐	STEPHANOPOULOS	☒	☐
EMANUEL	☐	☐	STIGLITZ	☐	☐
GIBBONS	☐	☐	STREETT	☐	☐
HALE	☐	☐	TYSON	☐	☐
HERMAN	☒	☐	HAWLEY	☐	☐
HIGGINS	☒	☐	WILLIAMS	☐	☐
HILLEY	☐	☐	<u>Toiv</u>	☒	☐
KLAIN	☒	☐	<u>E. Drye</u>	☒	☐
LAKE	☐	☐		☐	☐
LINDSEY	☐	☐		☐	☐

REMARKS:

Comments to David Shipley or Jonathan Prince.

RESPONSE:

11/1/96

**PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS TO THE NATION
NOVEMBER 2, 1996**

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

I believe this is a positive and hopeful time...an age of enormous possibility...a chance for us to build a country and a world that is stronger and safer and full of more possibility than any that existed before.

The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. Several children, some as young as 2, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria.

I imagine just about every parent in America remembers what E Coli can do. In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Centers for Disease Control and Prevention and the Food and Drug Administration, we stopped this week's outbreak of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. We notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get it off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. Now, of the 5 children who were hospitalized, all are expected to make a full recovery.

This quick response is part of our larger effort to protect the health and safety of all our people. Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us. We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90 years. I signed into law legislation that protects our fruits and vegetables from harmful

pesticides -- and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of food safety we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the CDC sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of "disease detectives" to investigate and control food-borne disease outbreaks...to give health experts state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will do everything in our power to make sure that the world's most bountiful food supply is also the safest.

By protecting the public health, by bringing our people together around our basic values of opportunity, responsibility, and community, we will surely make this an age of possibility for all Americans.

Thanks for listening.

MEMORANDUM TO: Bruce Reed
Jack Quinn
T.J. Glauthier
Nancy Ann Min
Sally Katzen

received 11-1-96
6:12 p.m.

FROM: Elizabeth Drye, 456-5573

SUBJECT: Draft Presidential Directive on Food Safety

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THE WHITE HOUSE

WASHINGTON

October 31, 1996

MEMORANDUM TO LEON PANETTA

FROM: Elizabeth Drye, DPC

SUBJECT: Saturday Food Safety Radio Address

This memo provides an update on the Odwalla apple juice E-Coli outbreak, describes the proposed content for this Saturday's radio address, and discusses outstanding funding issues for Saturday's announcement.

Status of Outbreak

As you know, apple juice produced by Odwalla, Inc., a juice company based in Half Moon Bay, California, has been linked to at least ten cases of illnesses caused by E. Coli 0157:H7 (the same bacteria that contaminated Jack in the Box hamburger meat and caused hundreds of illnesses and some deaths in 1993). All of the confirmed cases are in the Seattle area. Several children were hospitalized with hemolytic uremic syndrome, a life threatening condition. Only one remains hospitalized and none has died.

FDA worked with Odwalla yesterday evening to arrange a voluntary recall of Odwalla's apple juice-containing products. The company had distributed the products to 7 states -- CA, CO, NV, NM, OR, TX and WA -- and British Columbia. The company removed these products from store shelves this morning.

CDC and FDA are continuing to investigate. CDC is working with affected states to identify additional cases, and has identified 3-4 possible cases in Colorado and one in California. FDA is looking into the cause of the contamination. FDA had inspected Odwalla's apple juice line in July, 1996 and found only minor violations. Today, five FDA field inspectors visited the plant again. FDA expects to have better information within the next few days on the outbreak's cause. Odwalla is cooperating fully.

Food Safety Radio Address

The President would talk about steps he has already taken to strengthen food safety, announce a new national early warning system for foodborne illness outbreaks, and direct the Secretaries of Health and Human Services and Agriculture and the Administrator of the EPA to suggest additional measures within 60 days. The new early warning system would help identify outbreaks early and would gather the data we need to prevent future

occurrences. Specifically, the President would announce:

- 1) doubling the number of "sentinel" surveillance sites currently in operation from five to ten (\$3 million);
- 2) creating an electronic and communication network among sites (\$1.3 million);
- 3) introducing state-of-the-art lab capabilities like "DNA fingerprinting" to identify the causes of disease outbreaks (\$1.7 million);
- 4) and increasing the number of "disease detectives" -- epidemiologists -- to investigate outbreaks (\$1.9 million).

Outstanding Issues

HHS (CDC and FDA) would fund most of the initiative. Secretary Shalala has committed to funding the five new sentinel sites out of her 1997 budget. She is asking that we commit to funding the other components in the 1998 budget. Nancy Ann Min will take the request to Frank Raines first thing in the morning. USDA already contributes to the sentinel site program, and will contribute additional funds to this initiative. Bruce Reed and I will work with the two departments and OMB to iron out funding details Friday morning.

cc: Carol Rasco



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FACSIMILE TRANSMISSION

OFFICE OF
THE ADMINISTRATOR

TO: Elizabeth Dye phone 456-5573
fax -7028

FROM: Lynn Goldman 260 2902 (P)
260 1847 (F)

COMMENTS: For Presidential directive/letter
on food safety

PAGES IN THIS TRANSMISSION, INCLUDING COVER SHEET: 2

DATE: 11/1/96

TIME: 3:15 pm

Office of the Administrator
1200 West Tower (AO; M.C. 1101)
401 M Street, S. W.
Washington, D. C. 20460

Facsimile: 202/260-0279; Telephone: 202/260-4700

11/1/96

Elizabeth:

Points to make for directive.

1. I want the agencies to

a. develop new tools to identify and ~~reduce~~ eliminate harmful levels of environmental pollutants in our food and drinking water

b. coordinate efforts to implement requirements of the Food Quality Protection Act of 1996 and new standards to ensure that our meat, poultry and fish are safe

2. "Food borne disease outbreaks" includes outbreaks from contaminants other than pathogen (eg lead, pesticides food additives) and thus our efforts should also include bolstering capabilities to trace noninfectious harmful agents to the source and speed information about outbreaks to the public.

Lynn Golden
EPA OOPTS



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

DEC 13 1996

MEMORANDUM FOR THE PRESIDENT

SUBJECT: New Initiative to Protect Americans' Food Supply

PURPOSE

We wanted to let you know about a joint initiative we are proposing, to reduce death and disease caused by food poisoning. This food safety initiative, which is now under consideration as part of the FY 1998 budget process, would affect every American but would involve only a modest amount of new funding (about \$100 million).

BACKGROUND

Last month's outbreak of E. coli-contaminated apple juice sickened dozens and killed one child. There was a similar outbreak involving hamburger in the northwest during the early days of your Administration. Although those outbreaks received nationwide publicity, the reality is that every year millions of Americans are sickened, and an estimated 9,000 die, from E. coli, Salmonella, Cryptosporidium and other foodborne "pathogens."

Hospitalization costs alone for these illnesses are over \$3 billion a year, and costs for lost productivity have been estimated to range, for seven specific pathogens, between \$6 and \$9 billion; total costs for all food poisonings are likely to be much higher. In August, you announced that USDA was adopting modern requirements to make meat and poultry safer. Last year, HHS adopted similar requirements for seafood. This initiative would strengthen those programs and implement important measures to make the rest of the food supply safer.

Today, our understanding of many pathogens is limited; for some, we do not even know how much must be present in food to cause illness. The public health system has limited means to identify and track the causes of foodborne illness; and Federal, State, and local food safety agencies need to improve coordination for more effective response to outbreaks of illness. Years go by before most non-meat plants receive an FDA or State inspection, and increasing quantities of imported foods flow into this country daily with little scrutiny by FDA inspectors. And food processors, restaurateurs, supermarket managers, and consumers often lack basic understanding of the threat of foodborne contaminants and how to protect against them.

Page 2

During the past three months, experts at our two departments and the EPA have worked intensively to develop a highly targeted initiative to address this issue; a summary has been shared with your staff. OSTP and State health officials have also been involved in the development of this plan, which addresses one of the initiatives identified in your recent report, "Meeting the Challenge: A Research Agenda for America's Health, Safety, and Food (1996)."

PROPOSAL

The good news is that we have the scientific talent and wherewithal to reduce the number of illnesses that do occur and to ensure that the United States will have a safer food supply. We believe that this Administration should launch a major new initiative next year that will positively affect the lives of all Americans. We would work through this initiative to reinvent the currently inadequate system devised by Theodore Roosevelt at the turn of the century into one that incorporates the science and technology of the 21st Century. Moreover, these gains can be achieved with a relatively small investment in new resources--around \$100 million--that can yield enormous benefits in health and public confidence in the food supply. Indeed, it is estimated that we can prevent 2 to 9 million illnesses, head-off up to 3,000 deaths, and save society billions of dollars in preventable health care costs each year.

The proposed interagency food safety initiative includes the following actions:

- o Build up the "early warning" and surveillance systems for foodborne illnesses and track them to their cause.
- o Increase FDA's inspections of food processors and imported foods, and improve collaboration with States in that area.
- o Better coordinate when disease outbreaks occur, including electronic communication among Federal, State, and local health authorities.
- o Expand education of food processors, retailers, restauranteurs, and consumers about the latest safe food processing, storage, and handling techniques.
- o Improve risk assessment for food pathogens, so that regulators can make the most cost-effective decisions.
- o Expand and better coordinate Federal research efforts on pathogens that pose the highest risk to the public.

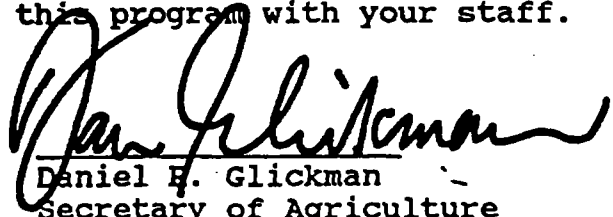
In addition, we recognize that fundamental change of the food safety system is necessary, and we propose the development of a comprehensive, strategic plan to improve the food safety infrastructure through broad-based discussions involving all stakeholders.

Page 3

A number of industry, academic, and other reports, such as those of GAO and NAS, have indicated that such reforms are necessary. We believe, therefore, that this initiative will be well received by the food industry and the general public. This interagency food safety initiative can be a significant feature of your domestic agenda for the coming year, and will accomplish an historic advance in public health. If you concur, we will coordinate further preparation of this program with your staff.



Donna E. Shalala
Secretary of
Health and Human Services



Daniel F. Glickman
Secretary of Agriculture

FOOD AND DRUG ADMINISTRATION

Appeal Item #1) Restore Base Resources & Eliminate Unauthorized User Fees (Dollars in Millions)

	1996	1997	1998		
	<u>Enacted</u>	<u>Enacted</u>	<u>Amended Request</u>	<u>OMB</u>	<u>Appeal #1</u>
BA	\$876.9	\$887.6	\$1,104.1	\$727.1	+\$167.1
Prog. Level	\$979.9	\$995.9	\$1,235.2	\$1,015.1	-\$167.1
Outlays	\$875.3	\$923.9	\$1,046.1	\$758.8	\$127.5

Description of OMB Passback: OMB is proposing user fees beyond the \$131.1M FDA has already included in its budget request. These new user fees are not directly linked to any specific program enhancement or industry benefit as required by the general user fee statute and are meant to offset budget authority (BA) reductions made to our base resources. The resulting program level of \$1,015.1M (which includes BA plus user fees) is held constant through FY 2002, but BA is further reduced by about another 2.2% per year and replaced with additional user fees.

Description of Appeal: FDA is appealing for \$167.1M to restore the BA eliminated by these proposed user fees in order to maintain our funding at the FY 1997 enacted level. This is not the user fee model that OMB itself recognizes as successful. If the appeal is not upheld, it would be catastrophic for FDA.

OMB's proposal runs counter to Congressional direction, and therefore would dramatically effect current negotiations with the Congress on FDA reform and PDUFA reauthorization. This proposal will force the kind of FDA reform long opposed by the Administration. If we send a budget to the hill with a \$170 million gap to be filled by new user fees, Congress may instead choose to make it up by giving product review responsibility to third parties. This will jeopardize the quality of FDA's review of products, and in turn, threaten the public health.

We have worked hard for several years to convince industry that user fees should be supported. The industry has been split down the middle as to whether to accept such fees. The drug industry has finally accepted them, for new reviews, and is paying millions of dollars. There is optimism that other industries can be brought along for licensing fees to get new products on the market. However, if we push for user fees for enforcement, industry will see it as purely a tax, which they have adamantly opposed. That approach might well unify industry against all user fees, undermine the negotiations with the drug industry on reauthorizing prescription drug user fees, and negate any hope of getting other industries to accept such fees.

Given Congress' and the industry's opposition, the likelihood of enacting legislation for non-additive user fees in the coming Congress is virtually zero. If Congress is forced to fill the \$170M gap from appropriated funds, it will greatly harm the Administration's chances to add new funding in high priority areas such as tobacco and food safety.

The magnitude and risk of the reduced appropriation levels contained in the OMB passback would lead to an overall reduction of 20% for FDA core public programs in FY 1998. These cuts would cripple the Agency and destroy its ability to protect the public health. Given the lack of support for these kinds of user fees in the past, FDA would be forced to plan for the worst-case scenario, absorbing the 20% reduction in funding. **Beginning in FY 1997**, we would be forced to implement draconian and dangerous cuts to programs and personnel, eliminating essential programs and drastically cutting others. Some examples of the negative public health consequences follow:

- The safety of the Nation's blood supply would be jeopardized. Blood bank inspections would be reduced and resources available to review and approve blood license applications would plummet.
- Frequency and effectiveness of food safety evaluations and establishment inspections would be reduced, leading to increased incidence of microbiological and chemical hazards. Over the past 10 years, the number of inspections has dropped significantly, and recalls have increased dramatically.
- Improvements in the device review process would be negated; review times would revert to pre-FY 1995 levels which are unacceptable to Congress and the Administration.
- Under current law, PDUFA would not be triggered. FDA could not collect fees and approval times would revert back to pre-1992 drug approval times.
- A virtual shut-down of the Animal Drug review process would occur. The result would be increased animal drug/feed contamination -- a threat to the safety of the nation's food supply.

The Administration has commended FDA for its efforts to reduce teen smoking; for its reinvention initiatives in the areas of foods, drugs and medical devices; and, for reducing the burden on industry while improving agency efficiency. FDA has worked hard with both industry and Congress to forge FDA reform proposals that are acceptable to both parties without jeopardizing the health of American consumers. FDA has serious concerns about the inclusion of unauthorized user fees in its budget proposal to Congress. However, FDA is keenly aware of the value of additive user fees to the accomplishment of its mission. The implementation of this type of user fee in the form of PDUFA has had exemplary results. Benefits of the program are wide-spread. Industry gets a faster, more predictable process, FDA accomplishes its mission through improved performance without sacrificing quality, and consumers receive safe and effective products more quickly. Also, FDA has advanced similar user fee proposals for medical device review and the processing of imports, which have not been authorized by the Congress in the past.

FOOD AND DRUG ADMINISTRATION

Appeal Item #2) Provide Funding for Food Safety Inter-Agency Initiatives (Dollars in Millions)

	1996	1997	1998		
	<u>Enacted</u>	<u>Enacted</u>	<u>Amended Request</u>	<u>OMB</u>	<u>Appeal #2</u>
BA	\$876.9	\$887.6	\$1,104.1	\$727.1	+\$53.4 ^{1/}
Prog. Level	\$979.9	\$995.9	\$1,235.2	\$1,015.1	+\$53.4
Outlays	\$875.3	\$923.9	\$1,046.1	\$758.8	\$40.7

Description of OMB Passback: No funding is provided for FDA's role in the Interagency Food Safety Initiative.

Description of Appeal: FDA is appealing \$53.4 million and 293 FTEs for its part of the multi-agency (CDC, USDA, EPA and FDA) Food Safety Initiative. President Clinton and Vice-President Gore have begun an important and overdue restructuring of our nation's food safety programs. The President signed landmark pesticide legislation and revolutionized meat, poultry, and seafood safety regulations. These were important steps forward. Funding this initiative will help to completely fulfill their vision by providing resources to improve **coordination** between Federal and State agencies in the management of response to foodborne illness; enhance the infrastructure for **inspections** and **early warning system/surveillance** activities to strengthen regulatory capabilities; and improve **education, risk assessment, and research** efforts. Also, funding would be provided for premarket activities to enhance the review processes for new animal drug applications and for new food additives petitions.

Early Warning System/Surveillance -- \$4.680 million and 15 FTEs. Improve strategies to ensure rapid and early detection of foodborne illness outbreaks and dissemination of information to facilitate response, thereby decreasing the total number of cases of foodborne related deaths and illness by 2 percent. This funding would also create a national electronic network for comparison of bacterial "fingerprints", expand the Sentinel Site project to assure appropriate geographic diversity of the network, cover a greater portion of the nation's population and larger spectrum of foodborne pathogens, increase the number of experts to investigate and control foodborne disease outbreaks, and enhance surveillance for foodborne pathogens in food animals and feed, monitor laying hens and egg products before pasteurization for Salmonella.

^{1/} In addition, we are seeking \$19.1 million to fund 190 HACCP FTEs which should be transferred to HHS from the Department of Commerce.

Coordination -- \$1.000 million and 2 FTEs. Unify the considerable existing expertise of Federal, State, and local health authorities, by creating a Federal emergency response system designed to better manage outbreaks, ensure interagency collaboration, and provide advanced communications networks with the capability to speed information to experts nationwide, and enhancing infrastructure for foodborne illness surveillance and coordination at State health departments.

Inspections -- \$27.602 million and 201 FTEs. Establish an effective infrastructure for a nationwide HACCP-based system for seafood, and expand Federal/State inspection partnerships to monitor the nation's food supply. Twenty percent of all foodborne related deaths and illness can be eliminated via this enhanced inspection partnership program. Funding would also enhance foodborne pathogen testing by all HACCP programs, provide a greater coverage of the ever-increasing imported food-product supply, and upgrade food inspection programs by transferring 190 inspectors from the National Marine Fisheries Service.

Education -- \$7.030 million and 23 FTEs. Launches an educational campaign focused on preventive measures for improved food safety. More than 50 percent of food related deaths and illnesses may be caused by unsafe preparation practices. This portion of this initiative could reduce food related death and illness by 1 percent per year. Our focus is to improve food safety education campaigns targeted to consumers, retail, institutional and food services, veterinarians and producers, the transportation industry, and laboratory scientists in state and local health departments.

Risk Assessment -- \$10.330 million and 21 FTEs. Develop methodology to evaluate surveillance plans, risk reduction strategies, implementation of HACCP practices, and research programs. The result is a more focused critical control point and far less costly than the current "scattershot" approach. Further, funding would establish an interagency risk assessment consortium to further develop and strengthen food safety risk assessment research and methods development, ensure development of high-quality, high-priority biological data and develop/validate exposure data and models, initiate research on the use of biomarkers of exposure and effect, and initiate research on target-dose toxicokinetics.

Bioscience Research -- \$13.870 million and 31 FTEs. Enhance research science capabilities to develop new and improved methods for rapid testing of microbial and chemical contaminants, and better understanding of antibiotic resistance. Research activities are pivotal to the success of the Inspection and Risk Assessment parts of the initiative. Funding would also strengthen scientific programs to achieve a more comprehensive collaborative food safety program, improve methods to detect, control, reduce and eliminate foodborne pathogens, and develop data for strategies to counter development of antibiotic resistance in pathogens.

Premarket Activities -- \$8 million. Enhance activities required to process applications for new food animal drugs and for petitions for new food additives.

Americans rightly expect to have the world's safest food supply. Although it is among the safest, it is not safe enough. There is a growing risk that a serious outbreak of food-borne illness such as the one that recently made thousands ill across Japan could strike the U.S. The Centers for Disease Control and Prevention (CDC) estimates that 9,000 deaths and 33 million illnesses in the U.S. each year are food-related.

The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to the treatments we have relied upon. Lowering of trade barriers has led to record levels of food imports. Rapid delivery services routinely move food from the furthest reaches of the world to the American meal table overnight. These changing circumstances require greatly strengthened systems of prevention, surveillance, research, targeted illness reduction, coordination, and education.

More than 30 million U.S. citizens are considered to be at high risk for diseases from foodborne microorganisms. Every hour of every day, one American dies from *preventable* foodborne diseases. These 'high-risk' individuals include the portion of the population age 65 or older, and those who are chronically ill. Full implementation of the Food Safety Initiative can save up to the lives of 2,600 American citizens every year, and reduce the number of foodborne illness by 8.8 million every year.

FOOD AND DRUG ADMINISTRATION

Appeal Item #3) Provide Funding for the President's Tobacco Initiatives (Dollars in Millions)

	1996	1997	1998		
	<u>Enacted</u>	<u>Enacted</u>	<u>Amended Request</u>	<u>OMB</u>	<u>Appeal #3</u>
BA	\$876.9	\$887.6	\$1,104.1	\$727.1	+\$55.0
Prog. Level	\$979.9	\$995.9	\$1,235.2	\$1,015.1	\$55.0
Outlays	\$875.3	\$923.9	\$1,046.1	\$758.8	\$42.0

Description of OMB Passback: The FDA passback provided \$5M to fund the President's tobacco initiatives.

Description of Appeal: On August 23, 1996, President Clinton announced his Administration's plan for the regulation of nicotine-containing tobacco products. FDA is appealing \$55M and 54 FTEs for the costs associated with implementing, and enforcing the final rule on this regulation.

The President is committed to a goal of decreasing young people's use of tobacco 50% over seven years. In four years, at the end of his term, the President will be judged on how well this goal was achieved. Even under the best circumstances, this goal is ambitious and will be difficult to reach. However, without these resources, we will not be able to even begin moving toward the goal.

Every year, another 1 million young people become regular smokers, and one-third of them will eventually die prematurely as a result of their smoking. Smoking is the leading preventable cause of death in the United States. Tobacco products are responsible for more than 400,000 deaths annually due to cancer, respiratory illness, heart disease, and other health problems. According to CDC, health care costs associated with smoking soared to more than \$50 billion in 1993.

FDA's continued investments in promoting and protecting the health of our youth is essential to the future of our nation's well-being, and will be accomplished through reduced availability and appeal of tobacco products to children and teenagers, and education of young people about the health risks of tobacco use. FDA plans to carry out a major portion of this initiative through State contracts amounting to about \$30M.

THE FOOD AND DRUG ADMINISTRATION

Food Safety

QUESTION:

Why can't this initiative be done using user fees? Especially seafood?

ANSWER:

- User fees of this type are not the type which are authorized under the general User Fee statute. This statute authorizes regulations to collect fees for product approvals, but not general public benefit activities such as inspections and other activities which are intended to be funded from appropriations at large.
- We have worked hard for several years to convince industry that user fees should be supported. The industry has been split down the middle as to whether to accept such fees. The drug industry has finally accepted them, for new reviews, and is paying millions of dollars. There is optimism that other industries can be brought along for licensing fees to get new products on the market. However, if we push for user fees for enforcement, industry will see it as purely a tax, which they have adamantly opposed. That approach might well unify industry against all user fees, undermine the negotiations with the drug industry on reauthorizing prescription drug user fees, and negate any hope of getting other industries to accept such fees.
- For seafood, the Commerce Department's National Marine Fisheries Service offers a "voluntary" inspection program on processed seafood. This voluntary, fee for service program in which only about 20 percent of seafood processors participate, is perceived by the regulated industry as fundamentally different than the mandatory public health seafood inspection program performed by the FDA.

THE FOOD AND DRUG ADMINISTRATION

Food Safety

QUESTION:

Why is it important to do the Food Safety Initiative now?

ANSWER:

- President Clinton and Vice-President Gore have begun an important and long overdue restructuring of our nation's food safety programs. The President signed landmark pesticide legislation and revolutionized meat, poultry, and seafood safety regulations.
- The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to the treatments we have relied upon. Lowering of trade barriers has led to record levels of food imports. Rapid delivery services routinely move food from the furthest reaches of the world to the American meal table overnight.
- Today, we are not ready -- We are prime for the same type of foodborne illness outbreak that hit the Japanese.

KEY INFORMATION:

- Funding this initiative will complete these initial steps by providing resources to improve **coordination** between Federal and State agencies in the management of response to food borne illness; **enhance the infrastructure for inspections and early warning system/surveillance** activities to strengthen regulatory capabilities; and improve **education, risk assessment, and research** efforts. Funding would be provided for premarket activities to enhance the review processes for new animal drug applications and for new food additives petitions.
- Americans rightly expect to have the world's safest food supply. Although it is among the safest, it is not safe enough. There is a growing risk that a serious outbreak of food-borne illness such as the one that recently made thousands ill across Japan could strike the U.S. The Centers for Disease Control and Prevention (CDC) estimates that 9,000 deaths and 33 million illnesses in the U.S. each year are food-related.
- More than 30 million U.S. Citizens are considered to be at high risk for diseases from food borne microorganisms. Every hour of every day, one American dies from *preventable* food borne diseases. These 'high-risk' individuals include the portion of the population age 65 or older, and those who are chronically ill. Full implementation of the Food Safety Initiatives can save the lives of 2,600 American citizens every year, and reduce the number of food borne illness by 8.8 million every year.

THE FOOD AND DRUG ADMINISTRATION

Food Safety

QUESTION:

The food safety initiative includes a request to transfer 190 FTEs (their seafood inspectors) from the Department of Commerce to HHS. Is the Department of Commerce on board with this?

ANSWER:

- We have discussed transfer of the FTEs only, not any funding for the program. In reality, since the current DOC program is based on a voluntary user fee program, there are no dollars that would transfer to pay these inspectors. Our proposal includes funding for these FTEs.

KEY INFORMATION:

- The Commerce Department's National Oceanographic and Atmospheric Administration (NOAA) oversees the National Marine Fisheries Service (NMFS). NMFS has various programs to assist and regulate marine resources, including marine laboratories and the protection of offshore fishing grounds from pollution. Another is a seafood inspection program, under which NMFS inspectors "grade" (i.e., provide a Commerce seal of quality) on processed seafood and inspect for safety (under the new HACCP safety procedures). The inspection program is a voluntary one in which about 20% of seafood processors participate. They pay a fee to NMFS for the service, which is supposed to be self-supporting.
- Although the NMFS inspection program is structured to pay for itself through user fees, it has been unable to recruit enough "customers" to do so, and the program began its first Reduction-in-Force this year. As a result, NOAA has offered the program to both FDA and USDA, neither of which had excess FTEs to absorb the approximately 190 FTEs that operate the program. However, those inspectors are skilled seafood experts who could carry out FDA's seafood inspection program, freeing up FDA inspectors to inspect other commodities that are currently under-inspected (e.g., canned goods, fruit juices, dairy products and many others).
- NOAA officials have had repeated conversations with FDA relative to FDA's absorption of these inspectors, and NOAA has seen a draft of our food safety report. Their response thus far is that they have no objection to the proposal, although they have not sought an official concurrence from the Secretary of Commerce.

THE FOOD AND DRUG ADMINISTRATION**Tobacco****QUESTION:**

Why can't this initiative be done using user fees?

ANSWER:

- The implementation and enforcement activities planned by FDA for tobacco are not the type for which fees are authorized under the general User Fee statute. This statute authorizes regulations to collect fees for product approvals, but not general public benefit activities such as inspections, outreach, enforcement, and education, which are intended to be funded from appropriations at large.
- Also, it is not clear to whom such user fees would be assessed. Tobacco producers, retailers and users would view any such fee as a tax.

THE FOOD AND DRUG ADMINISTRATION**Tobacco****QUESTION:**

Why does this cost so much? When we began discussing this, we didn't believe it would cost so much.

ANSWER:

- In terms of potential lives saved and the reduction in medical costs, this proposal is very inexpensive.
- The scope of the problem is enormous and successfully dealing with it is costly.
- Additionally, the original figure was a mere placeholder because FDA had not yet devised its implementation and enforcement plan for the final rule.

KEY INFORMATION:

- Our final rule is aimed at tackling the leading preventable cause of death and disease in the United States. Annual health care costs associated with treating tobacco-related diseases is around \$50 billion. Even if we reduce this by one percent -- a conservative estimate -- we have avoided health care costs of \$500 million, nearly 10 times the amount of our proposed investment of \$60 million investment.
- Half of the request is for funds that go directly to the states for implementation and enforcement of the final rule. To effectively enforce this rule, we need to have coverage across the nation and have enough of a presence to provide a deterrence effect.

THE FOOD AND DRUG ADMINISTRATION**Tobacco****QUESTION:**

Why are we doing this?

ANSWER:

- The President is committed to a goal of decreasing young people's use of tobacco 50% over seven years. Without these resources, we will not be able to even begin moving toward the goal. We need to fund this initiative to support the President's courageous stand taken shortly before the election.

KEY INFORMATION:

- The tobacco initiative is one of the President's major domestic accomplishments. But there is unfinished business. We now have a final rule to implement and enforce. In four years the President needs to be able to point at his accomplishments in reducing young people's tobacco use. The only way he will be able to do that is by adequately funding the implementation and enforcement of FDA's final rule starting right now.

THE FOOD AND DRUG ADMINISTRATION

User Fees

QUESTION:

Even if the OMB plan is ambitious, why not send it up to let Congress fix the budget problem, like in past years?

ANSWER:

- The OMB plan runs counter to Congressional direction and strong opposition to deficit reduction user fees to fund FDA's core programs. It dilutes the credibility of the budget and threatens the public health.
- This plan places Congress in the position of robbing Peter to pay Paul, thus exacerbating an already cumbersome process.
- This proposal jeopardizes the current FDA reform negotiations underway with industry and Congress.
- This passback will alienate industry negotiators working with FDA to reauthorize PDUFA.

KEY INFORMATION:

- Reducing FDA's base and promoting deficit user fees is neither reasonable nor feasible. Based on the voice of Congress, this is a failed strategy that threatens funding for important public health programs if reduced appropriations occur, but user fee legislation does not pass.
- FDA is working hard with both industry and Congress to forge an FDA reform that is acceptable to both parties without jeopardizing the health of the American consumers. The Administration and Congress have commended FDA for its efforts to reduce teen smoking, for its reinvention initiatives in the area of foods, drugs, and medical devices, and reducing the burden on industry while improving agency efficiency. Investment resources provided by PDUFA have resulted in the U.S. approving products as fast or faster than any country in the world. The user fee proposal runs the risk of diminishing these innovative models for improvements and undermines the work already accomplished with industry and Congress -- instead it provides a further opportunity for FDA opponents who would rather bash the Agency than engage in a meaningful dialogue on ways to improve FDA's performance.
- Should Congress accept the reduced appropriation levels contained in the OMB passback for FDA, it will mean an overall reduction of 21% for FDA core programs. These cuts will cripple the Agency and destroy its ability to protect the public health.

- The safety of the Nation's blood supply would be jeopardized, blood bank inspections would be reduced and resources available to review and approve blood license applications will be reduced.
- Evaluations and establishment of inspections for food safety would be dramatically lessened, thus increasing the incidence of microbiological and chemical hazards.
- Improvements in the device review process would be eliminated and review times would revert to pre-FY 95 levels which are unacceptable to Congress.
- Under current law PDUFA would not trigger, thereby disallowing FDA from collecting fees and reverting back to the exceedingly long pre-1992 approval times.

THE FOOD AND DRUG ADMINISTRATION

User Fees

QUESTION:

Why does everything have to be additive, this is a difficult budget year if we are going to balance the budget. Don't we have to look ahead to make industry pay for these services?

ANSWER:

- A guiding principal of PDUFA, and key to industry and Congressional support, is the additive nature of the user fee resources. This model improved public health programs, while at the same time yielded economic benefits to the regulated industry in the form of improved and predictable performance. OMB's user fee passback runs counter to the lessons of PDUFA.
- We believe the user fee passback will bolster industry's long held suspicion that additive user fees lead to deficit reduction user fees. Industry will merely step up its opposition to any user fee proposal, even additive user fees.
- The passback would have the immediate effect of alienating industry negotiators working with FDA to reauthorize PDUFA.

KEY INFORMATION:

- Negotiations currently underway with industry to reauthorize PDUFA indicate they are adamant about maintaining the additive nature of the fees and the current proportion to total program costs (36% industry, 64% FDA). Industry is only supportive of additional user fees for increased performance -- not the agency's base. Industry would immediately oppose such fees in Congress, endangering the success FDA and industry have achieved over the last 5 years.
- If PDUFA is not reauthorized, FDA would be forced to eliminate 700 FTE which would quickly return the program to 30 month review times. Backlogs would reappear and many of the innovative initiatives and incentives created under PDUFA would erode.
- Industries' opposition to replacing base resources with user fees, is the same whether it's the Pharmaceutical companies, food manufacturers, device manufacturers or animal drug manufacturers:
 - The food industry has consistently opposed the idea of paying user fees. This position is reflected in a statement issued by the Grocery Manufacturers of America (GMA),

Master Copy

#'s on Odwalla

USDA -
HHS -Government can't do
anything, but there's
this suit has to go.

1/23/97

**PRESIDENT WILLIAM J. CLINTON
WEEKLY RADIO ADDRESS
THE WHITE HOUSE
JANUARY 25, 1997**

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

Almost a week ago, in my inaugural address, I told the American people in broad terms what our vision must be -- to lead this country into the 21st century with the American Dream alive for all our children; with the American promise of a more perfect union a reality for all our people; with America's bright flame of freedom illuminating the world.

I believe we will make real this vision by doing what we have always done in moments of great change: By holding fast to our enduring values. Central among these is the belief that Americans are entitled to clean air, safe food, pure water. Hard-working American parents deserve the peace of mind that comes from knowing that the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State and in 6 other Western states this fall. Apple juice contaminated with a deadly strain of E Coli bacteria reached supermarket shelves. Several children -- some as young as 2 -- were hospitalized. One child died.

I imagine just about every parent in America remembers what E Coli can do. Four years ago this very week, tragedy struck hundreds of families in the Western United States when they took their children to fast-food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children lost their lives.

There's simply no excuse for this. Though America has the world's safest food supply, as many as 33 million Americans are made sick by food-borne diseases every year. As many as 9,000 people die.

That's why my administration has made it a top priority to protect the health and safety of all Americans. We strengthened the Community Right to Know law, which requires industries to tell our citizens what chemicals are being released into our neighborhoods. I signed into law legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. We put in place strong new protections to ensure that seafood is safe. And we announced steps to modernize our meat and poultry inspection system for the first time in 90 years. Those new safety rules will begin to take effect next week. From now on,

①

Food safety

technical
~~slaughter~~ *slaughter*
 [all meat and poultry plants will be required to test for E Coli.]

(to target these disease-causing bacteria)
and improve the safety of floor meat and poultry.

We have built a solid foundation of health security for our families. But, clearly, we must do more. *(No parent should have to think twice about the juice they pour their children at breakfast or a hamburger ordered during a dinner out.)* That is why today I am announcing new steps to keep our food safe and to protect our children from deadly bacteria.

First, we will put in place a nationwide early warning system for food-borne illness. Right now, the Centers for Disease Control sponsors 5 centers across the country whose mission is to post a look-out for food-borne diseases -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will increase the number of these sites from 5 to 8. And we will link them to other state health agencies. This full-scale early-warning system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

The early warning system
 Second, we will use state-of-the-art technology to keep our food safe. We will increase the number of expert disease detectives to investigate and control food-borne disease outbreaks. We will give these experts the technology to use sophisticated new DNA fingerprinting methods to trace infectious agents to their source. We will create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use advanced communications networks to speed outbreak information to hospitals and public health agencies around the country.

Third, I am directing the Secretaries of Agriculture and Health and Human Services, as well as the Administrator of the Environmental Protection Agency, to work with communities, *farmers*, businesses, consumer protection groups, and all levels of government to come up with additional measures to improve food safety. I want them to focus on what sort of public-private partnerships we can develop to meet this goal. And I want them to report back to me with their findings within 90 days.

Finally, let me add that all these new investments are paid for line-by-line, dime-by-dime in the balanced budget I will officially send to Congress next month.

With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children. Together, with steps like these, we will see to it that our people find a land of new promise in the 21st century.

Thanks for listening.

NOTE TO DAVID SHIPLEY --

FROM: Elizabeth Drye

SUBJECT: Radio Address

Attached are fact sheet, directive, and my edits to your previous food safety radio address. Bruce has not had time to review. I suggest you do a first redraft and then we'll share with him in the a.m. Have a nice flight.

11/1/96 FINAL

PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS TO THE NATION
NOVEMBER 2, 1996

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

I believe this is a positive and hopeful time...an age of enormous possibility...a chance for us to build a country and a world that is stronger and safer and full of more possibility than any that existed before.

The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. ^{State and 6 other western states this fall.} Several children, some as young as 2, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria. ^{reached supermarket shelves}

still checking facts [Several children, some as young as 2, were hospitalized, and one died] I imagine just about every parent in America remembers what E Coli can do. ^{Four years ago [this week]} In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

Keep or drop and add A below Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, ^{the recent} and the swift and efficient action of the Food and Drug Administration, we stopped ~~this week's outbreak~~ of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. The Centers for Disease Control and Prevention notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get its juice off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. ~~Now, of the 5 children who were hospitalized in Seattle, all are recovering.~~

This quick response is part of our larger effort to protect the health and safety of all our people. ~~Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us.~~ We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90 years. I signed into law legislation to keep harmful pesticides off our fruits and vegetables --

meat and poultry
Next week these ^{meat and poultry} rules begin to take effect -- plants must have in place new sanitation procedures and all slaughter plants must begin testing for E. Coli.

and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of food safety we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the CDC sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of "disease detectives" to investigate and control food-borne disease outbreaks...to give health experts state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will do everything in our power to make sure that the world's most bountiful food supply is also the safest.

By protecting the public health, by bringing our people together around our basic values of opportunity, responsibility, and community, we will surely make this an age of possibility for all Americans.

Thanks for listening.

pesticides -- and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken ~~our~~ most basic safeguards for clean air, clean water, and clean food.

Today, we add to the solid foundation of health security we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the Centers for Disease Control sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will ~~double~~ ^{increase} the number of these sites from 5 to ~~10~~ ^{in 5 states}. ~~This national~~ system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

~~Second~~ ^W, we will use state-of-the-art technology ^{at the Sentinel sites and in other states} to keep our food safe. We will increase the number of expert disease detectives to investigate and control food-borne disease outbreaks. We will give these experts the technology to use sophisticated new DNA fingerprinting methods to trace infectious agents to their source, and create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use advanced communications networks to speed outbreak information from these centers to hospitals and public health agencies all across the country.

~~Third~~ ^{Second}, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within ~~60~~ ⁹⁰ days with additional measures to further improve the safety of our food.

~~With this new early-warning system to track food-borne illness,~~ ^{these investments} we are saying, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children.

Thanks for listening.

and will link them together with other state health agencies, to create a national early warning system. The new

working with consumers, producers, industry states and the public -- to suggest new ways to improve food safety, and to explore 2 public-private partnerships.

Third, ~~I will~~ ^{my 1998 budget} asks Congress for \$42 million in additional funds to pay for the early-warning system →

additional seafood safety inspectors, and further research and education.

(A)

~~We can never eliminate all~~

But we can and must do better. My Administration has already put in place new laws that use the best science to protect our food.

MEMORANDUM TO: Bruce Reed
Jack Quinn
T.J. Glauthier
Nancy Ann Min
Sally Katzen

Received 11-1-96

6:12 p.m.

FROM: Elizabeth Drye, 456-5573

SUBJECT: Draft Presidential Directive on Food Safety

FOR YOUR IMMEDIATE REVIEW

----- DRAFT 10/31/96 -----

Memorandum on Improving the Safety of the Nation's Food Supply

November 2, 1996

Memorandum for the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency.

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better in our efforts to eliminate disease caused by microorganisms and other contaminants. Americans still suffer thousands of food-related deaths and millions of food-related illnesses.

The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to treatment. Americans consume record levels of imported food, some of which moves across the globe overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention, research, and education.

My Administration has already taken a number of steps to improve food safety. We modernized the meat, poultry, and seafood safety systems. I signed into law new legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. Earlier today I announced a new national early warning system for foodborne illness. The system will allow us to respond more quickly to disease outbreaks and to better prevent them in the future. But we need to do more.

I hereby direct that you report back to me within 60 days and recommend additional measures to improve the safety of our food. Your recommendations should include ways to improve surveillance, inspections, research, education and coordination among local, state, and federal health authorities. In particular, I direct you to consider ways to: increase the number of experts investigating food-borne disease outbreaks; give health experts state-of-the-art technology to trace infectious agents to their source; and use advanced communications networks to speed outbreak information to health authorities across the country.

THE WHITE HOUSE

WASHINGTON

December 3, 1996

MEMORANDUM TO LEON PANETTA
DON BAER

FROM: Elizabeth Drye, DPC

SUBJECT: Possible Food Safety Radio Address or Event

Bruce Reed asked that I forward to you a copy of the food safety radio address and Presidential directive we prepared last month (attached). The address announces a new early warning system for food-borne illness, and directs USDA, HHS, and EPA to recommend additional food safety improvements.

We previously worked out the language and policy in the address with Secretary Shalala's staff. However, Secretary Shalala does not want to go forward with the radio address announcement at this time. She instead wants to announce a broader food safety initiative in the State of the Union Address (she just sent OMB an amendment to her 1998 budget request asking for an additional \$96 million for the initiative). The early warning system we would announce in the address is a small part of her FY98 request and requires a commitment of FY97 funds. We would have to firm up funding commitments from USDA, FDA, CDC, and OMB before making an announcement.

Attachments