DRUG AND MEDICAL DEVICE WORKING GROUP
SUMMARY OF OPTIONS PRESENTED

DRUGS

Problem: FDA's longstanding regulations governing the marketing of new drugs place burdens on the industry that are unnecessary for the protection of the public health. For biological drugs the requirements have been especially strict.

Regulatory Approach: Streamline/reduce burden; tailor requirements to the risk involved.

Proposals	Alternatives
1) Waive pre-market approval for all manufacturing changes in new drugs that introduce no or negligible risk;	Waive FDA pre-approval of all manufacturing changes.
2) Permit manufacturers to demonstrate capability to make biotech drugs without building a new plant;	Waive entirely the requirement to demonstrate capability to manufacture a new drug before FDA approval.
3) Permit biotech drug companies to place their name on the drug produced by a subcontractor; and	
4) Eliminate special requirements for insulin and antibiotics and allow existing private standard setting body to establish testing and quality standards, similar to those required for other drugs.	Eliminate quality and testing standards entirely for insulin and antibiotics.

GENERIC DRUGS

Problem: Once the brand name drug patent has expired, generic drug manufacturers must go through the time consuming, costly, and burdensome process of purchasing the brand name drug, analyzing it, determining how to make it, and submitting an application to the FDA demonstrating that it has "guessed right" in how to make the generic version.

Regulatory Approach: Streamlining application process.

Proposal

1) Publicly release information about the manufacturing of brand name drugs before the patent expires and alleviate the need for the generic company, through reverse engineering, to attempt to determine how the brand name drug was made.

Alternatives

Review generic drugs more rapidly, thus speeding their marketing approval;

Have a two pronged approach, maintaining the current 1st approved generic, while ultimately making the patent available for more exact copies.

MEDICAL DEVICES

Problem: The medical device industry believes that the FDA's regulatory actions for medical devices have delayed the introduction of devices into the marketplace and have negatively impacted the U.S. device industry's international competitiveness. Industry concerns include (1) FDA reviews of pre-market approval applications and pre-market notification actions (requests to market a device on the ground that it is substantially equivalent to another device that is already on the market) take too much time and delay a devices entry into the marketplace; (2) FDA approval of requests to export unapproved devices in unnecessary and delays exports; (3) the device classification process in unduly burdensome because it requires classification procedures even for low risk devices; and (4) FDA has a list of firms that fail to observe good manufacturing practice (GMP) requirements when manufacturing their devices and firms are unable to determine whether they are on the list or precisely what corrective actions they should take in order to regain FDA approval to manufacture devices.

Regulatory approach: Performance standards; privatization; streamlining/reducing regulatory burden by tailoring regulation to risk; place greater reliance on industry certifications for exports; exempt certain low risk devices from pre-market approval.

Proposals	Alternatives
1) Initiate a pilot study for 3rd party review of certain device applications by private organizations;	Relying on private organizations certified by FDA. Options include: a) adopting European system or b) privately contracting out for review of all device applications; Phase-in 3rd party private sector review bodies to conduct pre-market approvals and inspections starting with lower risk devices.
2) Waive FDA review of export requests for devices that are approved for investigational use in the United States;	Permitting self-certification of exports to countries where the exported product is already approved. Could also increase penalties for export of unsafe devices to address concerns of "dumping."
3) Exempt over 140 device categories from pre-market review;	Exempting more device categories.

MEDICAL DEVICES CONTINUED

Proposals

4) No longer utilize the list of manufacturers who have good manufacturing practice (GMP) problems as a means to delay review process of a product unrelated to the product that had the GMP problem; and

5) Request authorization for device user fees; these fees would be dedicated to increasing FDA resources for receiving. device application and pre-market notifications.

CROSS - CUTTING
(Categorical Exemptions from requirements of National Environmental Policy Act)

Problem: The National Environmental Policy Act (NEPA) requires all Federal agencies to assess the environmental impacts of their actions. Before a drug, biologic, food additive, or animal drug is approved for marketing, FDA currently requires the company manufacturing the product to conduct an environmental assessment (EA). Hundreds of EAs are done each year, at a cost of $40,000–$150,000 per EA. FDA almost always finds no significant impact; thus the EAs are not believed necessary in the context of these product approvals.

Regulatory Approach: Administratively exclude product approvals from EA requirements; reduce burden.

Proposal

1) In consultation with the Council on Environmental Quality, the FDA would reclassify product approvals with de minimis environmental review requirements. For example, it is known that human excretion of a drug's residues into the environment through public sewers poses no environmental impact.

Alternatives

Have FDA staff do the EAs thus relieving the burden on regulated industry.

CROSS-CUTTING
(FDA Submission, Tracking, and Communication of Information)

Problem: FDA receives hundreds of application for approvals of new products each year, particularly from drug and biologic firms. These applications frequently comprise thousands of pages of detailed scientific information. The enormous documents require substantial space for storage, pose difficulty in retrieving information, and waste valuable time in forcing FDA medical staff to carry out analyses of findings in the data. There is a need to permit companies to submit applications electronically and communicate questions and answers with FDA electronically; and to utilize electronic tracking and analysis in reviewing the data.

Regulatory Approach: Modernize, utilize latest technology.

Proposal

1) Embark on a program to expand and standardize the use of information systems in support of a product review process. This would include developing a system for electronic receipt, processing, tracking and archiving of all documents; provide the capability to analyze and sort complex data rapidly; and enhance communication between industry and the FDA. System would begin with drug regulation, expand later to medical devices, food additive, and other products.

Alternatives

Retain current system;

Allow computerization to occur at its own pace;

Impose a strict FDA requirement to use computerized applications in a specified manner.

CROSS-CUTTING
(Harmonization of Standards)

Problem: Various countries have differing requirements for approval of new drugs, biologics, medical devices, food additives and animal drugs. This results in multiple test on animals and drugs and different applications for marketing approval. There is substantial need to harmonize standards where ever possible while retaining basic safety precautions.

Regulatory Approach: Common international standards.

Proposal

1) Work jointly with other countries, particularly NAFTA partners, the European Community, and Japan to harmonize testing and product development standards with those of the U.S. Alternatives

Alternatives

Adopt certain foreign standards already in place such as the CE mark accepted by the European Community or standards in countries that have comparable levels of health and safety.

Establish reciprocity of product approvals with certain foreign countries.

ADDITIONAL OPTIONS FOR DISCUSSION

DRUGS AND BIOLOGICS

1) The following options can be considered for relatively low risk subcategories of drug approval applications (e.g. applications for new uses of currently marketed drugs):

   - FDA contracting out to private organizations the review of new drug applications.
   - Allow drug manufacturers to gain pre-market approval through "certification" that their drugs are safe and effective from a third-party standards setting organization; manufacturer pays for the certification.
   - Allow drug manufacturers to "self-certify" that their drugs are safe and effective, market the drugs without FDA approval, then rely on FDA to find unsafe drugs and remove them from the market.

2) Further relaxing the "efficacy standard" for breakthrough drug approval; i.e., requiring less evidence of a drug's effectiveness than currently.

3) Increased access to experimental drugs, via a dual system. Drug company could 1) go through the current FDA approval process to test drugs in humans, or 2) allow use of experimental drugs with a warning to physicians and patients that the drugs have not yet been approved by the FDA when the risks are either low or the potential benefits outweigh the risks.

4) Reduce regulation of "off-label" uses for drugs; FDA would approve a drug for its first indication, additional indications could be promoted by manufacturers in advance of FDA approval. Manufacturers would still be subject to the requirements that the labeling cannot be false or misleading, thus the full disclosure that the indication is not approved would be required.

5) Revoke the biologics portion of the Public Health Service Act, thereby regulating biotech drugs and vaccines as traditional drugs, eliminating requirement for establishment licensing.

MEDICAL DEVICES

1) Legislation protecting biomaterial suppliers to medical manufacturers with liability protection if the device harms a patient.

2) Post market reporting and surveillance should be streamlined to focus on devices posing significant harm.

CROSSCUTTING

1) Reciprocity of approvals of drugs, biologics, devices and food additives with foreign countries, i.e., when another industrialized country with review programs and comparable rigor approves a product, approval would be automatic in this country.

2) Unrestricted export of unapproved drugs, biologics, and devices to countries that have already given the products their approval.

3) Creating one government wide "inspection service" under which most government inspections would be carried out (e.g., a firm would get a visit from one inspector, who would inspect for food/drug, environmental, worker safety, and other violations).

AGENDA

REINVENTING HEALTH, DRUG, AND MEDICAL DEVICE REGULATION

February 21, 1995

I. Overview

II. Health Care Presentation -- Health Care Financing Administration, Bruce Vladeck

A. Summary of Primary Regulatory Reform Concepts Utilized for Review

B. Specific Application of Regulatory Reform Principals:

- Physician Attestation
- Health and Safety Standards for Medicare Providers
- Clinical Laboratories Improvement Amendments (CLIA)
- Additional Options for Consideration

III. Drug and Device Presentation -- Food and Drug Administration, David Kessler

A. Summary of Primary Regulatory Reform Concepts Utilized for Review

B. Specific Application of Regulatory Reform Principals:

- Name Brand Drugs and Biotechs
- Generic Drugs
- Medical Devices
- Cross-Cutting Issues
- Additional Options for Consideration

HEALTH INDUSTRY WORKING GROUP
SUMMARY OF OPTIONS PRESENTED

I. Physician Attestation

Problem. Currently, a physician must sign an "attestation form" (certifying the accuracy of all diagnoses and procedures) for each Medicare patient discharged from a hospital. Obtaining the physician's signature is burdensome for hospitals and physicians, and cause billing delays that hurt hospital cash flow.

New Regulatory Approach. Streamline paperwork.

Proposal. Eliminate the requirement for the form entirely and instead hold hospitals responsible for the accuracy of diagnoses and procedures.

II. Health and Safety Standards for Medicare Providers

Problem. Hospitals, home health agencies, hospices, and end-stage renal disease facilities must meet health and safety standards to participate in the Medicare program. Currently, these regulations consist of procedural and administrative requirements rather than "outcome" measures that evaluate actual patient care.

New Regulatory Approach. Performance standards.

Proposals

- Eliminate unnecessary process requirements and instead develop outcome-based performance standards and increase consistency of requirements across providers.
- Tailor oversight and survey frequency of home health agencies to performance.

Alternatives

- Extend use of flexible survey cycle for nursing homes.
- Completely eliminate surveys for providers with good records.

III. Clinical Laboratories Improvement Amendments (CLIA)

Problem. CLIA is unnecessarily burdensome (especially for small and physician office laboratories), and laboratories fear sanctions for failure of proficiency testing.

New Regulatory Approach. Reduce oversight for certain test systems; establish performance standards; use information and education rather than sanctions.

Proposals

- Waive the routine two year survey of users of "black box" technology.

  Alternatives

  - Do not create new testing category.
  - Seek legislation to waive "black box" technology.

- Clarify and expand waiver criteria and streamline the waiver process. Waive all tests approved by FDA for home use.

  Alternatives

  - Exempt all tests performed in physician office laboratories from CLIA requirements.
  - Repeal CLIA.

- Use performance standards and require less frequent on-site inspections of excellent performers. Approve private accrediting organizations for deemed status. Exempt labs from CLIA requirements when the State has requirements equal to or more stringent than CLIA.

  Alternatives

  - Repeal quality assurance and personnel requirements (except in cytology laboratories), and rely on proficiency testing and outcomes as the bases for quality control.
  - Allow HCFA to waive these requirements for labs that perform well.

- Clarify regulations so that proficiency testing failures are used for education and as an outcome indicator in laboratory quality. Sanctions are imposed only for repeated failures or immediate jeopardy.

  Alternative. No longer require proficiency testing.

SUMMARY OF OTHER ALTERNATIVES

I. **Competition in Medicare**. There are various proposals being discussed that are described as efforts to increase choice and competition in Medicare. The Administration is currently considering proposals (as part of health reform discussions) to offer beneficiaries greater choice among managed care plans. The Administration has opposed proposals to create a voucher system under which private insurers bid for Medicare patients.

II. **Physician Review Organizations (PROs).** Proposals have been made: (1) to set Medicare standards for hospital quality and utilization review and allow hospitals to contract for review either through PROs or other third parties; and (2) to eliminate the PRO program entirely.

III. **Ownership and Referral**. Proposals have been made to replace the current ban on self-referral (i.e., referral by physician to facilities in which they have an ownership interest) with restrictions on over-utilization.

IV. **Reimbursement Mechanisms**. Proposals have been made to change arbitrary and inefficient payment and coverage rules.

V. **Paperwork Reduction in Federal Programs**. Proposals have been made to have the Office of Personnel Management announce that their carriers accept the HCFA 1500 (which is required by Medicare and used by the Department of Defense and the Department of Veterans Affairs) and to standardize the instructions for filing the form across all of the Federal agencies that use it.

HEALTH INDUSTRY WORKING GROUP RECOMMENDATIONS

I. PHYSICIAN ATTESTATION

PROBLEM: Currently, a physician must sign an "attestation form" for each Medicare patient discharged from a hospital. The form is used to certify the accuracy of all diagnoses and procedures; without an attestation form, the hospital cannot bill Medicare. Obtaining the physician's signature is burdensome for hospitals and physicians, and resulting billing delays hurt hospital cash flow.

REGULATORY APPROACH: Streamline paperwork.

PROPOSED SOLUTION: Eliminate the requirement for the form entirely and instead hold hospitals responsible for accuracy of the diagnoses and procedures. Hospitals are better equipped to combat fraud and abuse given improvements in record keeping and coding capabilities. (This change can be implemented by regulation.)

PROS:

- Reduces paperwork burden and "hassle" on physicians and hospitals.
- Can be implemented quickly, with an immediate impact on providers.
- Implements recommendation by the Medicare Technical Advisory Group which is comprised of hospitals, intermediaries and trade associations.
- Decreases administrative costs for hospitals.
- The attestation requirement appears unnecessary. There has never been a prosecution in the 11 years of operation of the prospective payment system for hospitals.

CONS:

- Although the hospital will be responsible for accuracy of the diagnoses and procedures, this may create the impression that the Health Care Financing Administration (HCFA) is relaxing its controls on fraud.
- Despite coding/DRG complexities, physicians are viewed as most knowledgeable on care given to hospitalized patients. This may create the impression that administrators rather than doctors control patient care.

Revised 2/16/95

REGULATORY IMPACT:

- **11 million forms will be eliminated.**
- **Almost 200,000 hours of physician time will be saved.**
- **Hospitals will have improved cash flow and reduced labor costs.**

II. HEALTH AND SAFETY STANDARDS FOR MEDICARE PROVIDERS

PROBLEM:

- Hospitals, Home Health Agencies (HHAs), hospices, and End-Stage Renal Disease (ESRD) facilities must meet health and safety requirements to participate in the Medicare program. These requirements measure "process" (i.e., procedural and administrative requirements as proxies for quality health care) rather than "outcome" (i.e., evaluations of actual patient care) and continuous quality improvement.

- Regulatory requirements vary by type of facility and provider even when the services provided in each facility are the same, creating inequities and inappropriate incentives.

- Very little information is available for consumers on the quality of care at a given facility. Information about quality can help consumers make health care choices.

- By law, HHAs must be surveyed yearly--even though historical data show that this frequency is excessive for many HHAs and does not improve care.

REGULATORY APPROACH: Performance standards; tailor oversight and survey frequency to performance.

PROPOSED SOLUTIONS:

A. Eliminate unnecessary process requirements and instead:

- develop outcome-based performance standards;

- collect and analyze patient care data needed for continuous quality improvement and performance evaluation;

- increase consistency of requirements across providers; and,

- ask the customer to provide input on what the outcome measures should be, and to evaluate the services they received.

(These changes can be implemented by regulation.)

PROS:

- Eliminating unnecessary process requirements for compliance will reduce compliance and survey burdens and make it possible to focus on actual patient care.
- Educating the consumer will produce a strong, non-regulatory force to improve quality of care.
- Powerful data will be available to regulators and providers.

CONS:

- Eliminating unnecessary process requirements may be viewed by patient advocates as an elimination of patient safeguards.
- Developing patient care data requirements could be viewed as an additional burden for some providers because they do not currently report this data to HCFA.

REGULATORY IMPACT:

- Produces savings because providers are free to achieve high quality outcomes in the most cost-effective manner. (Note: Outcome measures focus on results whereas process regulations require providers to follow certain procedures. To the extent we can evaluate quality by looking at results, we can discontinue the use of required procedures).

B. Seek an amendment to Section 1891(c)(2)(A) of the Social Security Act to allow flexible survey schedule for HHAs.

PROS:

- Reduces burden on good providers (on-site inspections involve extensive provider staff participation).
- Enables survey agencies to target scarce on-site survey resources to problem providers.
- Reviews problem providers more thoroughly, which will improve care or get them out of the program.
- Provides a positive incentive to furnish good care continuously.

CONS:

- Some out-of-compliance HHAs may fall through the cracks under a flexible system.

REGULATORY IMPACT: Approximately $8.8 million in savings to the Federal Government.

ALTERNATIVES NOT RECOMMENDED:

(1) Seek flexible survey cycle for nursing homes.

(2) Eliminate surveys altogether for providers with good records.

WHY NOT RECOMMENDED:

(1) Current nursing home survey cycle allows some discretion (i.e., allows a maximum of 15 months between surveys for a given home while requiring a 12 month average for each State). Greater flexibility would be inappropriate due to the vulnerability of the nursing home population, generally low level of professional supervision, and historical problems with the quality of nursing home care.

(2) Quality of care at an institution can go from good to bad virtually overnight as a result of change of ownership, high turnover of non-professional staff, loss of key professional staff, reduction in census/client base, changes in patient mix (e.g., influx of patients who need hi-tech care), etc. Flexibility in surveying all providers reduces costs while keeping all providers alert to the possibility of inspection.

III. CLIA

The Clinical Laboratories Improvement Amendments (CLIA) of 1988 established baseline quality standards that ensure the accuracy, reliability and timeliness of laboratory testing. These requirements are based on the complexity of the test performed in the laboratory, rather than where the test is performed. Compliance with the standards is determined through on-site inspection.

PROBLEM: CLIA is unnecessarily burdensome (especially for small and physician office laboratories), and laboratories fear sanctions for failure of proficiency testing.

REGULATORY APPROACH:

- Reduce oversight for certain test systems.
- Establish performance standards.
- Use information and education as a substitute for sanctions.

PROPOSED SOLUTIONS:

A. Waive the routine 2-year survey of users of "black box" technology, conducting surveys only if there are indications of problems or complaints, and to validate a 5% sample. Develop and implement criteria for accurate and precise "black box" technology that will be followed to determine if the technology qualifies for waiver of the routine 2-year survey. Black box technology refers to simple and easy to use test systems that have demonstrated accuracy and precision through scientific studies. (These changes can be implemented by regulation.)

PROS:

- Creates incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise technological testing systems.
- Reduces paperwork and costs for providers, especially for physician office laboratories, as well as costs of program management.

CONS:

- Less oversight and monitoring of quality in physician office laboratories.

REGULATORY IMPACT: The dollar magnitude of savings cannot be predicted.

ALTERNATIVES NOT RECOMMENDED:

(1) Do not create new testing category to recognize "black box" technology.

(2) Seek legislation to waive all requirements for "black box" technology.

WHY NOT RECOMMENDED:

(1) Limits incentives to develop new technology and does nothing to reduce burden.

(2) Our approach achieves a similar end administratively without requiring a statutory change.

B. Clarify and expand the waiver criteria and streamline the waiver process so that more tests can be waived from CLIA requirements. In addition, waive all tests approved by FDA for home use; i.e., tests that do not require trained personnel. (These changes can be implemented by regulation.)

PROS:

- Decreases burden, especially for physician office laboratories because of less regulatory oversight.
- Increases access to greater variety of tests. Physician office laboratories may expand the range of tests they perform without an increase in costs/burden.
- Creates incentives for manufacturers to develop more test systems that meet the clarified waiver criteria and criteria for approval for home use.

CONS:

- Removes quality protections for a greater number of tests.
- Major groups of laboratory professional scientists such as the American Society of Clinical Laboratory Scientists and the College of American Pathology may protest this reduction in requirements.

REGULATORY IMPACT:

- Eliminates inspection fees for many of the 60,000 physician office and other small laboratories that perform only tests from the expanded waiver category.
- Many additional laboratories will face lower inspection fees because, while they will continue to perform non-waived tests, many more tests will fall into the expanded waiver category.
- Minimizes regulatory requirements.

ALTERNATIVES NOT RECOMMENDED:

(1) Exempt all tests performed in physician office laboratories from CLIA requirements.

(2) Amend statutory "risk" language to allow consideration of net benefits and costs.

(3) Repeal CLIA.

WHY NOT RECOMMENDED:

(1) Complex tests, if incorrectly performed, can cause irreparable harm to a patient. Data from inspections indicate that a significant percentage of tests critical to the diagnosis and treatment of patients are not accurately performed.

(2) A proposed waiver rule has already been developed that delineates a set of criteria to objectively define what constitutes a test that will have negligible risk of an erroneous result, thus allowing for waiver from CLIA standards. Once these criteria are finalized and disseminated, manufacturers and others will have a clear understanding of negligible risk. Manufacturers will have incentive to produce high quality tests that are accurate and precise and have only a negligible risk of error.

(3) Due to serious problems (e.g., incorrectly read Pap smears), public concern has demanded oversight of laboratory testing in the U.S. HCFA inspections have since confirmed the existence of quality problems.

C. Use performance standards and require less frequent on-site inspections (surveys) of excellent performers. Approve private accrediting organizations for deemed status when their accreditation standards are as stringent as CLIA.

Exempt labs from CLIA requirements when the State where they are located has requirements equal to or more stringent than CLIA's. (These changes can be implemented by regulation.)

PROS:

- Reduces inspection burdens.
- Rewards good performers with fewer inspections. This is a positive incentive to improve performance.
- Educational emphasis on the inspection process has generated a positive response from the laboratory community.
- Approving organizations for deemed status offers laboratories oversight by peers.
- Approving States for CLIA exemption allows expanded role for States with strong licensure programs.

CONS:

- Without frequent inspections of all laboratories quality may decline.

REGULATORY IMPACT:

- Less oversight.
- Lower burden for laboratories.
- Lower user fees needed to offset the costs of the inspections.
- Deemed status allows for privatization; State exempt status allows for State role.

ALTERNATIVES NOT RECOMMENDED:

(1) Repeal quality control, quality assurance, personnel requirements (except in cytology laboratories), while relying on proficiency testing and outcomes as the basis for quality control.

(2) Amend the statute to allow for waiver of quality control, quality assurance and personnel qualification requirements to allow HCFA to waive such requirements for high performing laboratories.

WHY NOT RECOMMENDED:

(1) Elimination of quality and personnel requirements will have an adverse impact on the accuracy of laboratory tests and their use for patient diagnosis and treatment. It is important to note that:

- Inspection data indicate that significant numbers of laboratory tests are not accurately performed; good quality control and quality assurance practices are not being followed by many laboratories.
- Proficiency testing results reveal that the failure rates for previously unregulated labs are double that of previously regulated labs.
- Deficiency rates in physician office laboratories are two to three times that of previously regulated labs.

(2) Adherence to quality and personnel requirements is what defines sound laboratory practices in high performing laboratories. If these requirements are waived there would be no standards available to evaluate the laboratory in the event their performance deteriorated. Further, proficiency testing alone is unreliable as the sole indicator of laboratory performance.

D. Use proficiency testing (PT) "failures" for education and as an outcome indicator in laboratory quality. (PT is testing samples of known values to assess the accuracy of a laboratory's results). Sanctions (i.e., loss of Medicare payment or loss of approval to do testing) are imposed only in cases of immediate jeopardy or when the laboratory has refused to correct the problem or has had repeated failures on proficiency testing. (This change can be implemented by regulation.)

PROS:

- Less intrusive than traditional regulation and oversight.
- Reduces anxiety in the physician office laboratory community while maintaining opportunity for self-assessment and improving performance.
- Allows use of proficiency testing as an outcome measure to monitor laboratory performance and provide laboratories with feedback on test quality.

CONS:

- Difficult to prevent egregious disregard for quality testing.
- Physicians do not think that this action by itself reduces burden sufficiently.

REGULATORY IMPACT: Minimizes the fear of sanctions in 60,000 non-waived labs.

ALTERNATIVES NOT RECOMMENDED: No longer require proficiency testing.

WHY NOT RECOMMENDED: Proficiency testing is a valuable outcome indicator and educational tool.

Health Industry Working Group -- Other Alternatives for Regulatory Reform

1. **Competition in Medicare.** The Administration is considering proposals (as part of health reform discussions) that would offer beneficiaries greater choice among managed care plans. Competition among organized delivery systems has the potential to promote greater efficiency and increase consumer choice.

   As we broaden managed care options for Medicare beneficiaries, we must:

   - Be aware of the practical limitations of a rapid expansion of managed care; the movement to managed care cannot outpace the capacity of managed care plans to serve large numbers of new enrollees, particularly those with the expensive and special health needs of the Medicare program.

   - Improve payment methods to managed care plans. Currently, Medicare pays 5.7 percent more for every enrollee in managed care rather than fee-for-service. Efforts are underway to improve the current payment methodology by adding health status adjusters.

   - Continue to assure quality and preserve beneficiary choice. Increasing managed care options for Medicare beneficiaries will succeed only if beneficiaries recognize the benefit of the coordination of care and case management that high quality managed care plans can provide.

   Alternative: Proposals are being discussed to create a voucher system under which private insurers bid for Medicare patients. The Administration has opposed these voucher proposals.

   Concerns: Any discussion of voucher proposals should be informed by some facts about Medicare beneficiaries.

   - Currently, the major areas of growth for the Medicare population are older seniors age 85 and older, women, and persons with disabilities.

   - Second, there is an inverse relationship between income and health status and per capita Medicare expenditures.

   - Third, per capita health care spending for aged beneficiaries is four times the average for the under 65 population.

   Because problems of risk selection and premium and marketing discrimination in the private insurance market have not been addressed adequately, a voucher system

could put the most vulnerable beneficiaries at risk, and could effectively eliminate real plan choice for many older persons. Any broad structural changes to Medicare will be seen by beneficiaries, providers and advocates as an attempt to cut, or even destroy, the program.

2. **Physician Review Organizations.** Physician Review Organizations (PROs) work with local communities and hospitals to assess variations in processes, quality and outcomes of care. Because there is a substantial emerging market in private utilization review, continuing government intervention may be unnecessary.

   Alternatives: (1) Set Medicare standards for hospital quality and utilization review and allow hospitals to contract for review either through PROs or other third parties; or (2) eliminate the PRO program entirely.

   Concerns: Medicare has a responsibility to ensure that its beneficiaries receive high quality care. The newly structured PRO program has the potential to improve quality, and hospitals and physicians support the new program.

3. **Ownership and Referral.** Current law prohibits physicians from referring patients to health care facilities in which they have an ownership interest. The prohibition is intended to address over-utilization rather than self-referral; therefore, restrictions and penalties should be structured to address excessive referral more directly. In addition, the current prohibition is arbitrary because it does not apply to vertically integrated facilities (e.g., labs or x-ray facilities that are part of a clinic).

   Alternative: (1) Replace the ban on self-referral with restrictions on over-utilization (i.e., referring patients too often to any facility); and (2) impose heavy penalties on physicians who refer patients excessively to facilities in which they have an ownership interest.

   Concerns: Studies by the Government Accounting Office, the Office of the Inspector General and non-government groups have concluded that physicians who have financial relationships with health facilities tend to refer their patients to those entities more frequently than other physicians. These studies suggest that self-referral is an effective proxy for the over-utilization of services. It may be difficult to measure and prove over-utilization in the absence of the ban on self-referral.

4. **Reimbursement Mechanisms.** Reimbursement and coverage rules under Medicare are often arbitrary and inefficient. For example, some services may be reimbursed if performed in one type of facility but not in another. In other cases, a provider may be forced to give higher cost care because a lower cost alternative is not reimbursable, or may be unable to use a new treatment or technology because it is not yet covered by Medicare.

Some examples are: (1) Medicare requires a 3-day hospitalization before it will reimburse for care in a skilled nursing facility; (2) telemedicine is reimbursed at the same rate as a face-to-face encounter, even though telemedicine is a less intensive interaction that can produce savings; and (3) reimbursement rates vary for identical care performed in inpatient and outpatient facilities.

Alternatives: (1) Identify inappropriate constraints and reform Medicare coverage and payment rules that prevent physicians and hospitals from providing lower cost care; and (2) reimburse for experimental drugs and devices administered in clinical trials for diseases for which there are no adequate proven therapies.

Concerns: The Health Care Financing Administration (HCFA) is conducting demonstration projects to explore alternatives to current reimbursement programs, including reimbursement for telemedicine and prospective payment for outpatient care, skilled nursing and home care. However, constraints on reimbursement and coverage control utilization and costs. Expanding reimbursement and coverage will increase the volume of services provided and may therefore increase total costs for both beneficiaries and the Federal government.

5. **Paperwork Reduction in Federal Programs.** Although many Federal programs require the use of the HCFA 1500, use of the form is not required by the Federal Employees Health Benefit Plan (FEHBP). In addition, instructions for the form vary across programs.

Alternative: Ask the Office of Personnel Management (OPM) to require participating carriers to announce to providers that they accept the HCFA 1500 for claims filed under FEHBP. Ask HCFA, the Department of Defense, the Department of Veterans Affairs and FEHBP to develop a single set of instructions for filling out the HCFA 1500 in order to streamline further the claim filing process.

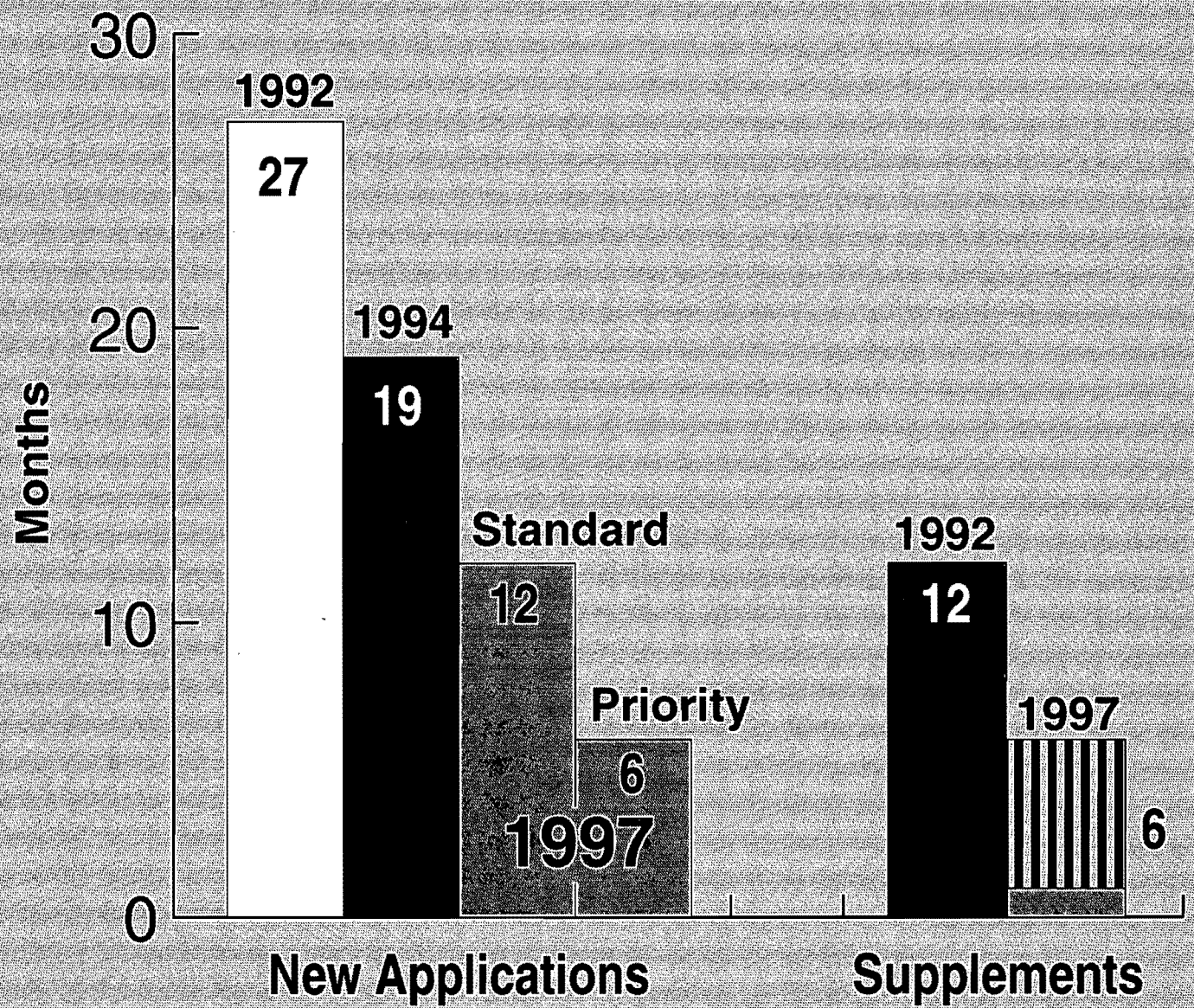
Concerns: This will reduce paperwork for providers and consumers, but may be an added burden on insurers who do not yet use the form. OPM is concerned that insurance carriers, particularly HMOs or fee-for-service plans with preferred provider arrangements, have established data systems suited to their individual informational needs. These carriers would be required to create new data systems to process FEHBP claims (although most of these carriers already serve Medicare patients and therefore already process the HCFA 1500).

Drugs

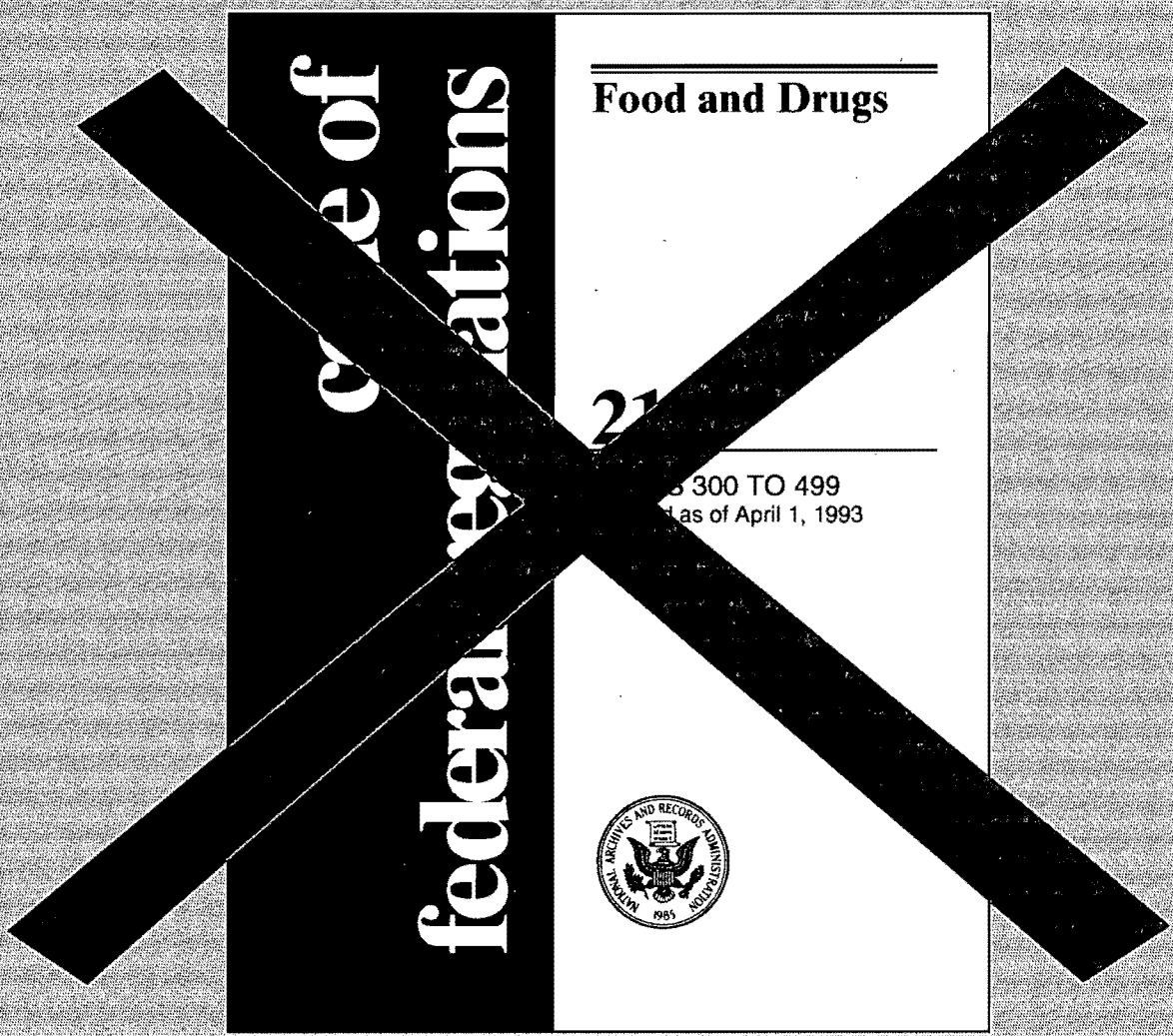
STREAMLINING/REDUCING REGULATORY BURDEN

- Waive premarket approval for certain manufacturing changes for biotech drugs
- Allow use of a pilot facility during development for biotech drugs
- Relax restrictions on use of subcontractors for biotech drugs
- Waive premarket approval for certain manufacturing changes for traditional drugs
- Eliminate batch by batch certification of insulin
- Substitute modern quality control procedures for outdated, prescriptive requirements for antibiotics and insulin
- GENERIC DRUGS: Replace current convoluted reverse engineering approach to generic drugs with simple recipe approach

Drug Review Times



Antibiotic and Insulin Standards/Certificates



Eliminate 700 Pages

Medical Devices

STREAMLINING/REDUCING REGULATORY BURDEN

- Exempt an additional 140 device types from premarket review
- Waive FDA review of exports of experimental devices when approved for testing in the U.S.
- Eliminate presumption that all manufacturing practice violations are related to pending applications

PRIVATIZATION

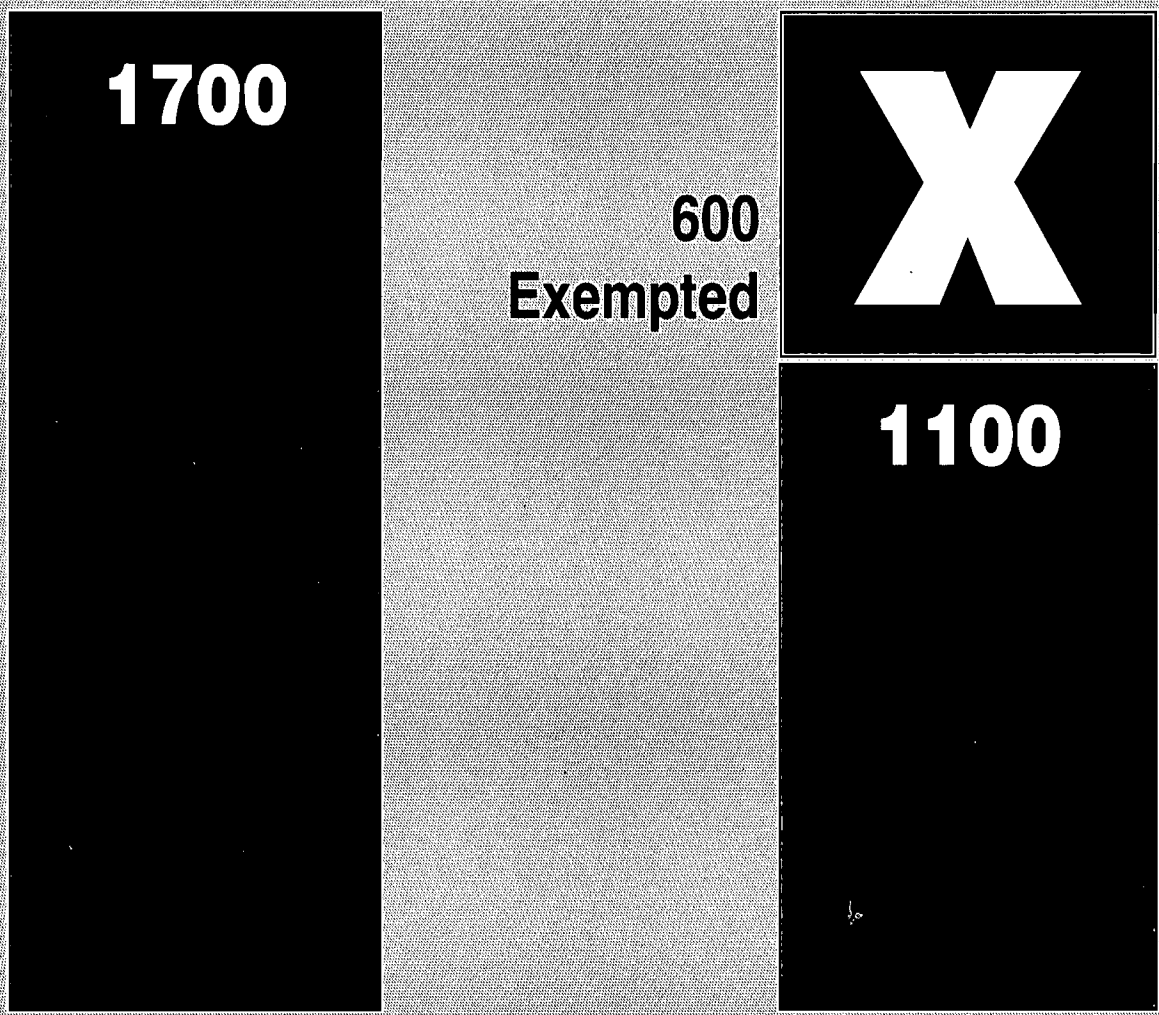
- Pilot program for review of certain device applications

MANAGEMENT STANDARDS

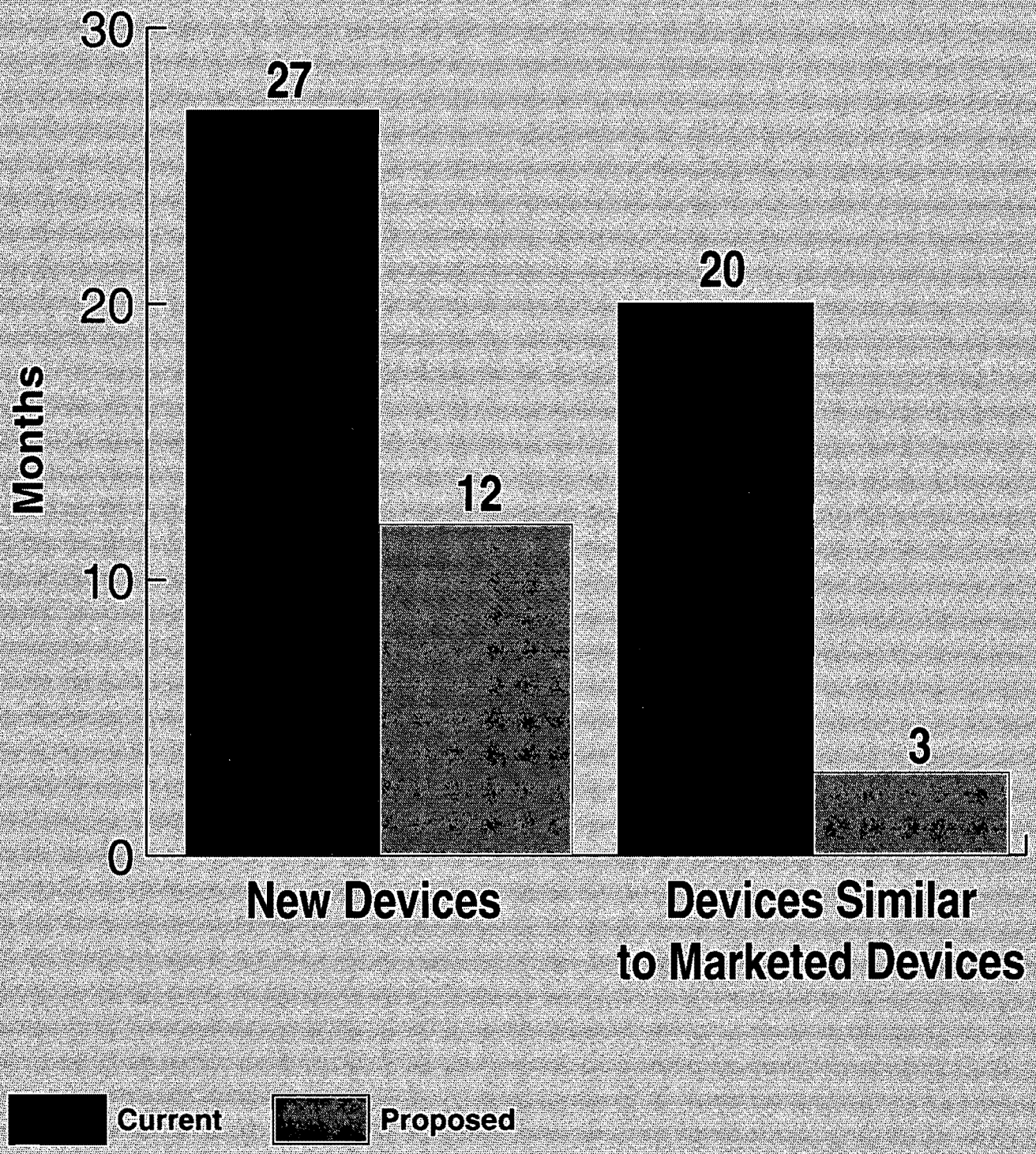
- Reduce application review times to 90-360 days through industry-FDA user fee program

Device Premarket Reviews

Categories Being Reviewed



Device Review Times



Cross Cutting

INFORMATION TECHNOLOGIES

- Paperless automated drug application review system
- Automate administrative systems
- Automate import review system

ENVIRONMENTAL ASSESSMENTS

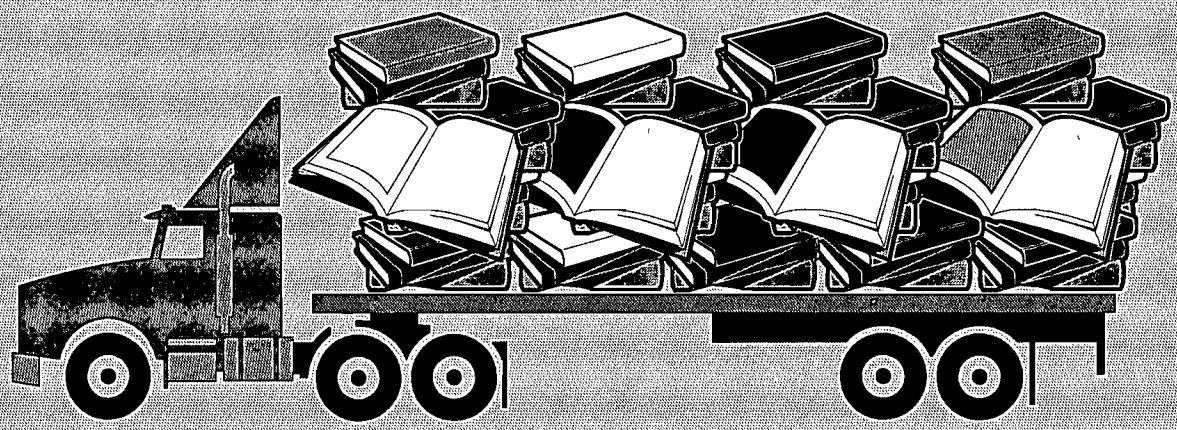
- Exempt individual drug applications from environmental impact assessments

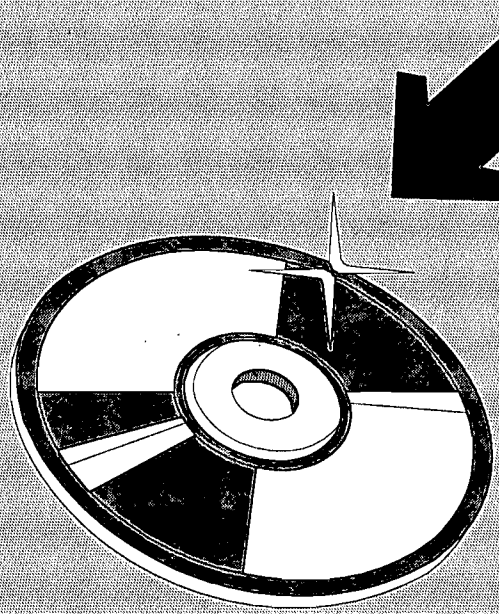
HARMONIZATION

- Expand international harmonization on testing requirements

Information Technology

100,000 Pages





CD Rom

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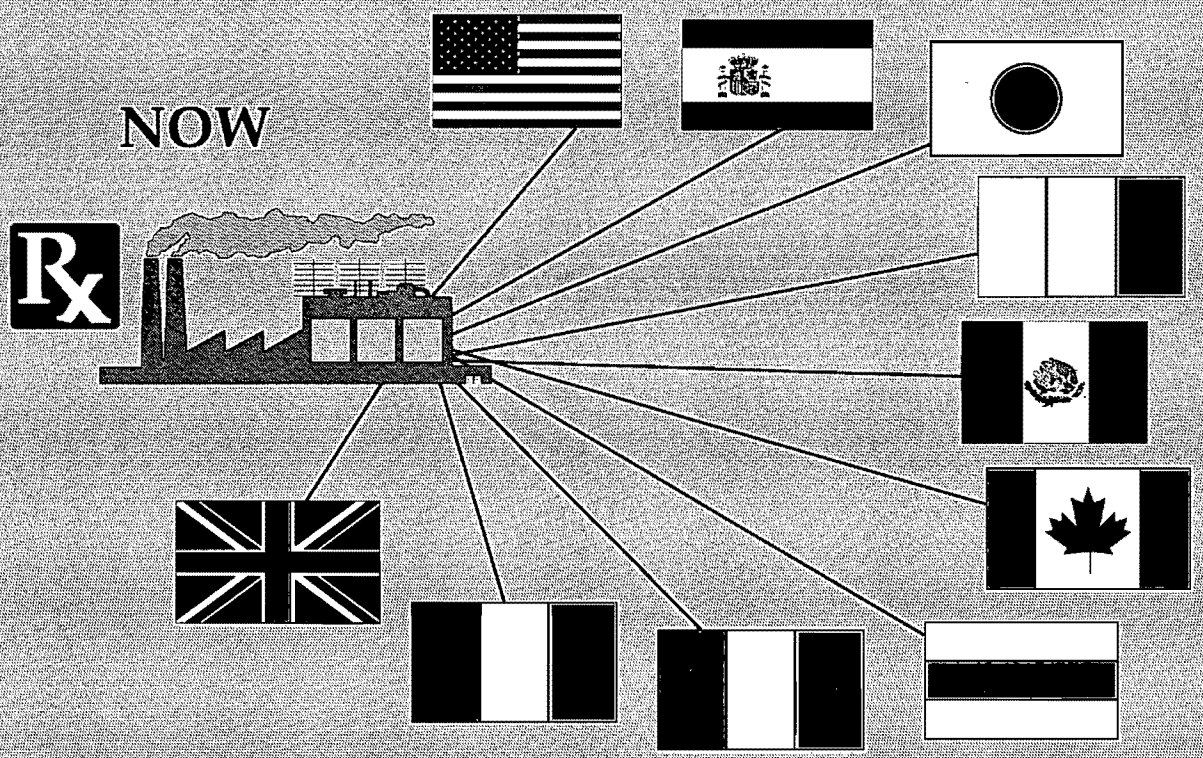
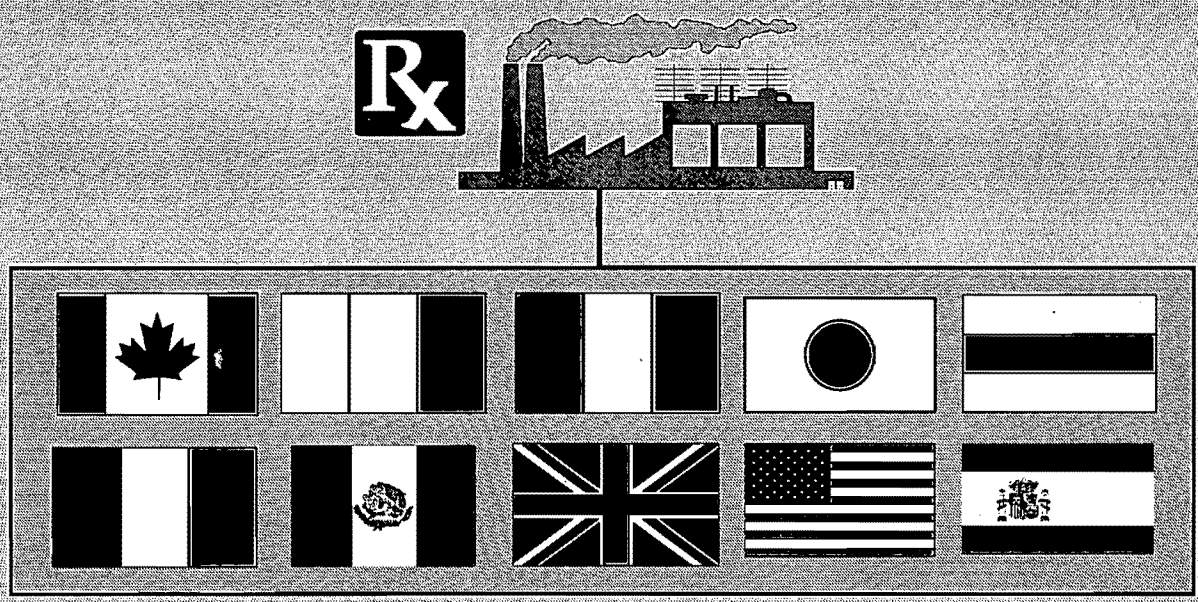
Industry Savings of $50 Million

International Harmonization



PROPOSED



DRUG AND MEDICAL DEVICE WORKING GROUP
SUMMARY OF OPTIONS PRESENTED

DRUGS

Problem: FDA's longstanding regulations governing the marketing of new drugs place burdens on the industry that are unnecessary for the protection of the public health. For biological drugs the requirements have been especially strict

New Regulatory Approach: Streamline/reduce burden; tailor requirements to the risk involved.

Proposals

1) Waive pre-market approval for all manufacturing changes in new drugs that introduce no or negligible risk;

2) Permit manufacturers to make biotech drugs without building a new plant;

3) Permit biotech drug companies to place their name on the drug produced by a subcontractor; and

4) Eliminate special requirements for insulin and antibiotics and allow existing private standard setting body to establish testing and quality standards.

Alternatives

1) Waive FDA pre-approval of all manufacturing changes;

2) Waive entirely the requirement to demonstrate capability to manufacture a new drug before FDA approval;

3) Eliminate quality and testing standards entirely for insulin and antibiotics.

GENERIC DRUGS

Problem: Once the brand name drug patent has expired, generic drug manufacturers must go through the time consuming, costly, and burdensome process of purchasing the brand name drug, analyzing it, determining how to make it, and submitting an application to the FDA demonstrating that it has "guessed right" in how to make the generic version.

Regulatory Approach: Exemption from current application process; privatization of standard setting process.

Proposal

1) Publicly release information about the manufacturing of brand name drugs at the time the patent expires and alleviate the need for the generic company, through reverse engineering, to attempt to determine how the brand name drug was made.

Alternatives

1) Review generic drugs more rapidly, thus speeding their marketing approval;

2) Have a two pronged approach, maintaining the current 1st approved generic, while ultimately making the patent available for more exact copies.

MEDICAL DEVICES

Problem: The FDA has not been adequately responsive to the medical device industry. Concerns that the Agencies regulatory actions for medical devices have delayed the introduction of devices into the marketplace and have negatively impacted the U.S. device industry's international competitiveness. Industry concerns include (1) FDA reviews of pre-market approval applications and pre-market notification actions (requests to market a device on the ground that it is substantially equivalent to another device that is already on the market) take too much time and delay a devices entry into the marketplace; (2) FDA approval of requests to export unapproved devices in unnecessary and delays exports; (3) the device classification process in unduly burdensome because it requires classification procedures even for low risk devices; and (4) FDA has a list of firms that fail to observe good manufacturing practice (GMP) requirements when manufacturing their devices and firms are unable to determine whether they are on the list or precisely what corrective actions they should take in order to regain FDA approval to manufacture devices.

Regulatory approach: Performance standards; privatization; streamlining/reducing regulatory burden by tailoring regulation to risk; place greater reliance on industry certifications for exports; exempt certain low risk devices from pre-market approval.

Proposals

1) Initiate a pilot study for 3rd party review of certain device applications by private organizations;

2) Waive FDA review of export requests for devices that are approved for investigational use in the United States;

3) Exempt over 140 device categories from pre-market review;

4) Process a manufacturers pending applications that are unrelated to the manufacturer's GMP problems while making the GMP failure list available to industry; and

5) Request authorization for device user fees; these fees would be dedicated to increasing FDA resources for receiving. device application and pre-market notifications.

Alternatives

1) Relying on private organizations, certified by FDA, for review of all device applications;

2) Phase-in 3rd party private sector review bodies to conduct pre-market approvals and inspections starting with lower risk devices;

3) Permitting self-certification of exports to countries where the exported product is already approved. Could also increase penalties for export of unsafe devices to address concerns of "dumping"; and

4) Exempting more device categories.

CROSS - CUTTING
(Categorical Exemptions from requirements of National Environmental Policy Act)

Problem: The National Environmental Policy Act (NEPA) requires all Federal agencies to assess the environmental impacts of their actions. Before a drug, biologic, food additive, or animal drug is approved for marketing, FDA currently requires the company manufacturing the product to conduct an environmental assessment (EA). Hundreds of EAs are done each year, at a cost of $40,000–$150,000 per EA. FDA almost always finds no significant impact; thus the EAs are not believed necessary in the context of these product approvals.

Regulatory Approach: Administratively exclude product approvals from EA requirements; reduce burden.

Proposal

In consultation with the Council on Environmental Quality, the FDA would reclassify product approvals with de minimis environmental review requirements. For example, it is known that human excretion of a drug's residues into the environment through public sewers poses no environmental impact.

Alternatives

Have FDA staff do the EAs thus relieving the burden on regulated industry.

CROSS-CUTTING
(Harmonization of Standards)

Problem: Various countries have differing requirements for approval of new drugs, biologics, medical devices, food additives and animal drugs. This results in multiple test on animals and drugs and different applications for marketing approval. There is substantial need to harmonize standards where ever possible while retaining basic safety precautions.

Regulatory Approach: Common international standards.

Proposal

1) Work jointly with other countries, particularly NAFTA partners, the European Community, and Japan to harmonize testing and product development standards with those of the U.S. Alternatives

Alternatives

1) Adopt certain foreign standards already in place such as the CE mark accepted by the European Community or standards in countries that have comparable levels of health and safety.

2) Establish reciprocity of product approvals with certain foreign countries.

CROSS-CUTTING
(FDA Submission, Tracking, and Communication of Information)

Problem: FDA receives hundreds of application for approvals of new products each year, particularly from drug and biologic firms. These applications frequently comprise thousands of pages of detailed scientific information. The enormous documents require substantial space for storage, pose difficulty in retrieving information, and waste valuable time in forcing FDA medical staff to carry out analyses of findings in the data. There is a need to permit companies to submit applications electronically and communicate questions and answers with FDA electronically; and to utilize electronic tracking and analysis in reviewing the data.

Regulatory Approach: Modernize, utilize latest technology.

Proposal

1) Embark on a program to expand and standardize the use of information systems in support of a product review process. This would include developing a system for electronic receipt, processing, tracking and archiving of all documents; provide the capability to analyze and sort complex data rapidly; and enhance communication between industry and the FDA. System would begin with drug regulation, expand later to medical devices, food additive, and other products.

Alternatives

1) Retain current system;

2) Allow computerization to occur at its own pace;

3) Impose a strict FDA requirement to use computerized applications in a specified manner.

OTHER PROPOSALS FOR REFORMING FDA

DRUGS AND BIOLOGICS

1) The following options can be considered for certain subcategories of drug approval applications:

   - FDA contracting out to private organizations the review of new drug applications.
   - Allow drug manufacturers to gain pre-market approval through "certification" that their drugs are safe and effective from a third-party standards setting organization; manufacturer pays for the certification.
   - Allow drug manufacturers to "self-certify" that their drugs are safe and effective, market the drugs without FDA approval, then rely on FDA to find unsafe drugs and remove them from the market.

2) Relaxing the "efficiency standard" for drug approval; i.e., requiring less evidence of a drug's effectiveness than currently.

3) Increased access to experimental drugs, via a dual system. Drug company could 1) go through the current FDA approval process to test drugs in humans, or 2) allow use of experimental drugs with a warning to physicians and patients that the drugs have not yet been approved by the FDA when the risks are either low or the potential benefits outweigh the risks.

4) Reduce regulation of "off-label" usus for drugs; FDA would approve a drug for its first indication, additional indications could be promoted by manufacturers in advance of FDA approval. Manufacturers would still be subject to the requirements that the labeling cannot be false or misleading, thus the full disclosure that the indication is not approved would be required.

5) Revoke the biologics portion of the Public Health Service Act, thereby regulating biotech drugs and vaccines as traditional drugs, eliminating requirement for establishment licensing.

MEDICAL DEVICES

1) Exempt more devices from FDA review, based on the assumption that they are low risk.

2) Adopt the European or Japanese system for reviewing changes in devices already marketed, i.e., allow companies to get "certification" from private organizations that their devices modifications are safe, then present those certifications to the FDA as proof of safety (without any FDA review). FDA would then monitor the devices on the market for safety.

3) Accept European CE mark in lieu of FDA approval.

4) Contract out reviews of new medical devices with private organizations.

5) Legislation protecting biomaterial suppliers to medical manufacturers with liability protection if the device harms a patient.

6) Post market reporting and surveillance should be streamlined to focus on devices posing significant harm.

CROSSCUTTING

1) Reciprocity of approvals of drugs, biologics, devices and food additives with foreign countries, i.e., when another industrialized country with review programs and comparable rigor approves a product, approval would be automatic in this country.

2) Unrestricted export of unapproved drugs, biologics, and devices to countries that have already given the products their approval.

3) Creating one government wide "inspection service" under which most government inspections would be carried out (e.g., a firm would get a visit from one inspector, who would inspect for food/drug, environmental, worker safety, and other violations).

FOOD AND DRUG ADMINISTRATION

(Reforms in Regulation of Drugs and Devices)

The Food and Drug Administration is the component of the Department of Health and Human Services charged with ensuring that foods are safe and wholesome; human and veterinary drugs, vaccines, and medical devices are safe and effective; cosmetics and electronic products that emit radiation are safe; and that regulated products are accurately labeled. In carrying out those responsibilities, FDA regulates over $1 trillion worth of products, which account for 25 cents of every dollar spent annually by American consumers.

Drugs must be approved by FDA prior to marketing. New chemical discoveries ("new drugs") are subjected to animal, then human testing, and the resulting data submitted to FDA scientists for review via a New Drug Application. The total time for industry testing and FDA review takes 7-10 years. Changes in a drug, such as substituting a different ingredient, are also approved by FDA via a "supplement" to the original application for approval. A similar process is followed for "biologics"--which include vaccines and drugs made from biotechnology. Generic versions of brand name drugs can be approved by FDA after the brand name drug's patent has expired, although the generic drug manufacturer must "reverse engineer" the drug by analyzing the brand name's content and making a reasonably accurate "guess" as to its formula--which FDA approves via an Abbreviated New Drug Application.

Medical devices are approved for marketing in two ways, as required by legislation enacted in 1976. Totally new devices must be subjected to testing to demonstrate safety and effectiveness, with the resulting data submitted to FDA via a Premarket Approval Application. Devices "substantially equivalent" to ones already marketed are reviewed by FDA via a Premarket Notification, in which the manufacturer informs the FDA of changes it has made in the device and why those changes can be safely made--such as changing an implanted heart valve from metal to plastic.

In considering candiates for regulatory reform, FDA has considered the concerns expressed by the drug and device industries, which are focused on expediting product reviews and eliminating unnecessary requirements. While these reforms would eliminate a number of burdensome direct cost elements, the major savings to these industries would result from the economic value of the time saved in bringing new products to market. Overall, the drug/biotech industry could realize almost $400 million a year and the medical device industry about $100 million a year in such time-cost savings. Savings to the FDA would be around 50 FTEs after the first year, and perhaps in the hundreds by the year 2000.

DRUGS

The Problem: FDA's longstanding regulations governing the marketing of new drugs place burdens on the industry that are unnecessary to protection of the public health. For biological drugs, originally produced from living organisms, the requirements have been especially strict and biotechnology products fall under these requirements. Specifically:

1) All manufacturing changes in biologic (biotech) products need FDA preapproval, even if they are relatively minor;

2) Manufacturers of biotech drugs must often build a production facility long before marketing approval;

3) Biotech drug manufacturers are inhibited from using subcontractors by requirements limiting manufacturer name on the drug; and

4) FDA issues "monographs" dealing with production and testing of antibiotics and insulin.

New Regulatory Approach: Streamline/reduce burden, tailor requirements to the risk involved.

Proposed Solution: Expedite market access for new drugs by fitting requirements to risk. As technology has advanced, extremely tight regulatory controls over drug manufacturing have become unnecessary. Products can now be safely made with reduced regulation, i.e.,

1) Waive premarket approval for all manufacturing changes in new drugs that introduce no or negligible risk;

2) Permit manufacturers to demonstrate capability to properly make biotech drugs without building a new plant (i.e., but establishing a small "pilot" production line);

3) Permit biotech drug companies to subcontract product production by allowing them to place their name on the drug produced by the subcontractor; and

4) Eliminate special requirements for insulin and antibiotics and allow an existing private standard setting body to establish testing and quality standards.

Pros and Cons:

Pro: - Relieves industry resources;

- Saves government resources; and

- Provides public faster access to products.

Con: - Slight risk that supposedly "minor" change could turn out to be important.

Alternatives Not Recommended (and Why):

1) Waive FDA preapproval of all manufacturing changes (Many manufacturing changes affect a product's active ingredients and can be significant to health).

2) Waive entirely the requirement to demonstrate capability to manufacturer a new drug before FDA approval (Experience has demonstrated that some firms cannot properly manufacture a new drug at the beginning and need some initial FDA oversight).

3) Eliminate quality and testing standards entirely for insulin and antibiotics (Antibiotics and insulin can pose significant health risks if improperly produced).

Regulatory Impact:

1) Amendments to requirements for manufacturing changes would reduce by 50% instances whereby manufacturers of biotech drugs must wait for FDA approval, and by 10% instances whereby other drug manufacturers must wait. Will reduce FDA workload by 12-1400 applications as well as staff years assigned to those functions. Average processing times would be reduced from an average of 6-12 months to an overall time of 0-30 days;

2) Eliminating need for early construction of new manufacturing facility could result in savings of up to 250 million dollars to the biotechnology drug industry according to our private sector study; and

3) Amending antibiotic and insulin requirements would eliminate 700 pages of the Code of Federal Regulations; certification and other fees of approximately $2 million per year by industry would be removed; FDA would save up to 3 FTEs.

GENERIC DRUGS

(Exemption of Generic Drugs from Premarket Approval Requirements)

The Problem: Generic drugs manufacturers must apply to FDA for permission to market generic versions of brand name drugs (once the patent has expired). Because data on the makeup of the brand name drug is unavailable to the generic drug manufacturer, that company must purchase the brand name drug, analyze it, determine how to make it, and submit an application to the FDA demonstrating that it has "guessed right" in how to make the generic version. Thus, generic manufacturers each year must go through that process almost 4,000 times, even though the resulting drug is merely a close copy of the brand name version.

New Regulatory Approach: Exemption from current application process; privatization of standard setting process.

Proposed Solution: Change the requirements for FDA preapproval of generic drug applications. Publicly release information about the manufacturing of brand name drugs at the time the patent expires. The application submitted to FDA would be far simpler, thus alleviating the need for the generic company, through reverse engineering, to attempt to determine how the brand name drug was made.

Pros and Cons:

Pro:

- Greatly streamlines generic drug marketing process, without compromising safety;
- Generic drugs produced under this system will have less variability, thus improving patient care; and
- Generic drug industry likely to support such a change.

Con:

- Brand name drug industry likely to oppose, based on resistance to FDA releasing drug content data.

Alternatives Not Recommended (and Why):

1) Review generic drugs more rapidly, thus speeding their marketing approval (insufficient FDA resources, does not address question of variability between generic and brand name drugs--e.g., a generic drug may dissolve differently than the brand name drug or otherwise be slightly "different," because the generic drug

manufacturer must "guess" how the brand name drug is made.)

2) Have a two-prong approach, maintaining the current 1st approved generic, while ultimately making the patent available for more exact copies.

Regulatory Impact:

- Eliminates some Federal preapproval;
- Speeds market access for generic drugs;
- Enhances consistency among generics when appropriate;
- Saves government FTEs;
- Saves industry resources;

MEDICAL DEVICES

The Problem: The medical device industry claims that the Food and Drug Administration's (FDA's) regulatory actions for medical devices have delayed the introduction of devices into the marketplace and have negatively impacted the U.S. device industry's international competitiveness. Industry concerns about FDA's device responsibilities include: (1) FDA reviews of premarket approval applications (PMA's) and premarket notification actions (requests to market a device on the ground that it is substantially equivalent to another device that is already on the market) under section 510(k) of the Federal Food, Drug, and Cosmetic Act take too much time and delay a device's entry into the marketplace; (2) FDA approval of requests to export unapproved devices is unnecessary and delays exports; (3) the device classification process is unduly burdensome because it requires classification procedures even for low risk devices; and (4) FDA has a list of firms that fail to observe good manufacturing practice (GMP) requirements when manufacturing their devices and firms are unable to determine whether they are on the list or precisely what corrective actions they should take in order to regain FDA approval to manufacture devices.

New Regulatory Approach: Performance standards; privatization; streamlining/reducing regulatory burden by tailoring regulation to risk; place greater reliance on industry certifications for exports; exempt certain low risk devices from premarket approval.

Proposed Solution: Expedite market access and export of devices by fitting requirements to risk and working with the industry by:

1. Initiating a pilot study for 3rd party review of certain device applications by private organizations;

2. Waiving FDA review of export requests for devices that are approved for investigational use in the United States;

3. Exempting over 140 device categories from premarket review;

4. Processing a manufacturer's pending applications that are unrelated to the manufacturer's GMP problems while making the GMP failure list available to industry; and

5. Requesting authorization for device user fees; these fees would be dedicated to increasing FDA resources for reviewing device applications and premarket notifications [This proposal is in the President's 1996 budget].

Pros and Cons:

Pro:
- Addresses major concerns of the device industry;
- Increases the Agency's efficiency in regulating devices;
- Once the review process is streamlined, user fees will ensure adequate resources for efficient review; and
- Provides therapies to patients more quickly both in the United States and abroad.
- Provides industry more information to determine what corrective actions are necessary to comply with GMP's;
- Pilot study of external review would provide important information on whether third party review should be adopted for certain devices;
- U.S. industries could compete more effectively in foreign markets;

Cons:
- User fees for review would add FTEs (albeit paid by industry);
- Previous industry support for user fees shifting toward privatization;
- Slight risk that exported devices and exempted devices may cause harm or present more risk than anticipated;
- Recognition of potential problems may be delayed in exempted devices.

Alternatives Not Recommended (And Why):

1. Relying on private organizations, certified by FDA, for review of device applications (could result in marketing of unsafe devices and reduce public confidence in device products) [Pilot program will address this alternative.];
2. Phase-in third party private sector review bodies to conduct premarket approvals and inspections starting with lower risk devices. (Need experience with pilot program to determine appropriateness of expanded third party review);

3. Permitting self-certification of exports to countries where the exported product is already approved. Could also increase penalties for export of unsafe devices to address concerns of "dumping"; and

4. Exempting more device categories (many devices require some agency review to determine what controls are appropriate for the use of the device).

Regulatory Impact:

- Approval times for new devices cut from 27 months to 6 months for 1st decision, 12 months of Agency time for final approval;

- Changes in existing devices cut from 7 months to 3 months;

CROSS-CUTTING

(Categorical Exemptions from Requirements of National Environmental Policy Act)

The Problem: The National Environmental Policy Act (NEPA) requires all Federal agencies to assess the environmental impact of their actions. Before a drug, biologic, food additive, or animal drug is approved for marketing, FDA currently requires the company manufacturing the product to conduct an environmental assessment (EA). Hundreds of EAs are done each year, at a cost of $40,000-150,000 per EA. FDA almost always finds no significant impact; thus the EAs are not believed necessary in the context of these product approvals.

Regulatory Approach: Administratively exclude product approvals from EA requirements; reduce burden.

Proposed Solution: In consultation with the Council on Environmental Quality, the FDA would reclassify product approvals with de minimis environmental effects as actions that normally are not subject to environmental review requirements. For example, it is known that human excretion of a drug's residues into the environment through public sewers poses no environmental impact.

Pros and Cons:

Pro:
- Eliminates requirements that have little real impact on the environment; and
- Saves resources to focus on those actions that do have environmental impacts.

Con:
- None apparent.

Alternatives Not Recommended (and Why): Have FDA staff do the EIAs, thus relieving the burden on regulated industry (insufficient resources, inadequate data to conduct assessments).

Regulatory Impact:

- Reduces burden on industry by saving $10+ million in annual costs to carry out EAs;
- Saves government resources expended on reviewing these EAs.

CROSS-CUTTING
(FDA Submission, Tracking, and Communication of Information)

The Problem: FDA receives hundreds of applications for approvals of new products each year, particularly from drug and biologics firms. Those applications frequently comprise thousands of pages of detailed scientific information. The enormous documents require substantial space for storage, pose difficulty in retrieving information, and waste valuable time in forcing FDA medical staff to carry out analyses of findings in the data. There is a need to permit companies to submit applications electronically and to communicate questions and answers with FDA electronically; and for FDA to utilize electronic tracking and analysis in reviewing the data.

New Regulatory Approach: Modernize, utilize latest technology

Proposed Solution: Embark on a program to expand and standardize the use of information systems in support of the product review process. This would include developing a system for the electronic receipt, processing, tracking and archiving of all documents; provide the capability to analyze and sort complex data rapidly; and enhance communications between industry and FDA. System would begin with drug regulation, expand later to medical devices, food additive, and other products.

Pros and Cons:

Pro: - Prepares FDA-industry relations for 21st century.

Con: - Some, although modest, initial costs for transition.

Alternatives Not Recommended (and Why):

1) Retain current system (outmoded, inefficient)

2) Allow computerization to occur at its own pace (substantial inertia, need for leadership)

3) Impose a strict FDA <u>requirement</u> to use computerized applications in a specified manner (could be viewed as burdensome)

Regulatory Impact: It is estimated that increased use of information technology con reduce drug development time considerably. Annual savings to the industry could be approximately $50 million.

CROSS-CUTTING

(Harmonization of Standards)

The Problem: Various countries have differing requirements for approval of new drugs, biologics, medical devices, food additives, and animal drugs. This results in multiple tests on animals and drugs and different applications for marketing approval. There is a substantial need to harmonize standards wherever possible while retaining basic safety protections.

New Regulatory Approach: Common international standards

Proposed Solution: Work jointly with other countries, particularly NAFTA partners, the European Community, and Japan to harmonize testing and product development standards with those of the U.S. Work has already begun on drug development and should be continued in that area and expanded to other areas of FDA regulation.

Pros and Cons:

Pro: - Improves U.S. position internationally; and

- Encourages trade among nations.

Con: - Some initial FDA costs to seek/reach agreements with foreign governments.

Alternatives Not Recommended (and Why):

1) Adopt certain foreign standards already in place such as the CE mark accepted by the European Community or standards in countries that have comparable levels of health and safety standards.

2) Establish reciprocity of product approvals with certain foreign countries (many countries have insufficient protections, U.S. citizens would oppose accepting decisions made by some, if not all, foreign nations)

Regulatory Impact:

- Improved quality/safety of imported goods;

- Enhanced exports of U.S. goods;

- Burden reduction for industry; and
- Savings to FDA in regulatory costs.

OTHER PROPOSALS FOR REFORMING FDA

DRUGS & BIOLOGICS

The following options can all be considered for certain subcategories of drug approval applications:

FDA contracting out to private organizations the review of new drug applications.

Allow drug manufacturers to gain premarket approval through "certification" that their drugs are safe and effective from a third-party standards setting organization; manufacturer pays for the certification.

Allow drug manufacturers to "self-certify" that their drugs are safe and effective, market the drugs without FDA approval, then rely on FDA to find unsafe drugs and remove them from the market.

Relaxing the "efficacy standard" for drug approval, i.e., requiring less evidence of a drug's effectiveness than currently.

Unrestricted access to experimental drugs, via a dual system. Drug company could 1) go through the current FDA approval process to test drugs in humans, or 2) allow use of experimental drugs with a warning to physicians and patients that the drugs have not yet been approved by FDA when the risks are either low or the potential benefits outweigh the risks.

Reduce regulation of "off-label" uses for drugs; FDA would approve a drug for its first indication, additional indications could be promoted by manufacturers in advance of FDA approval. Manufacturers would still be subject to the requirements that the labeling cannot be false or misleading, thus the full disclosure that the indication is not approved would be required.

Revoke the biologics portion of the Public Health Service Act, thereby regulating biotech drugs and vaccines as traditional drugs, and eliminating requirement for establishment licensing.

MEDICAL DEVICES

Exempt more devices from FDA review, based on assumption that they are low-risk

Adopt the European system for reviewing changes in devices already marketed, i.e., allow companies to get "certification" from a private organization that their devices' modifications are safe, then present those certifications to the FDA as proof of safety (without any FDA review). FDA would then monitor the devices on the market for safety.

Contract out reviews of new medical devices with private organizations.

Legislation protecting biomaterial suppliers to medical manufacturers with liability protection if the device harms a patient.

Accept European CE mark in lieu of FDA approval.

Post market reporting and surveillance should be streamlined to focus on devices posing significant harm.

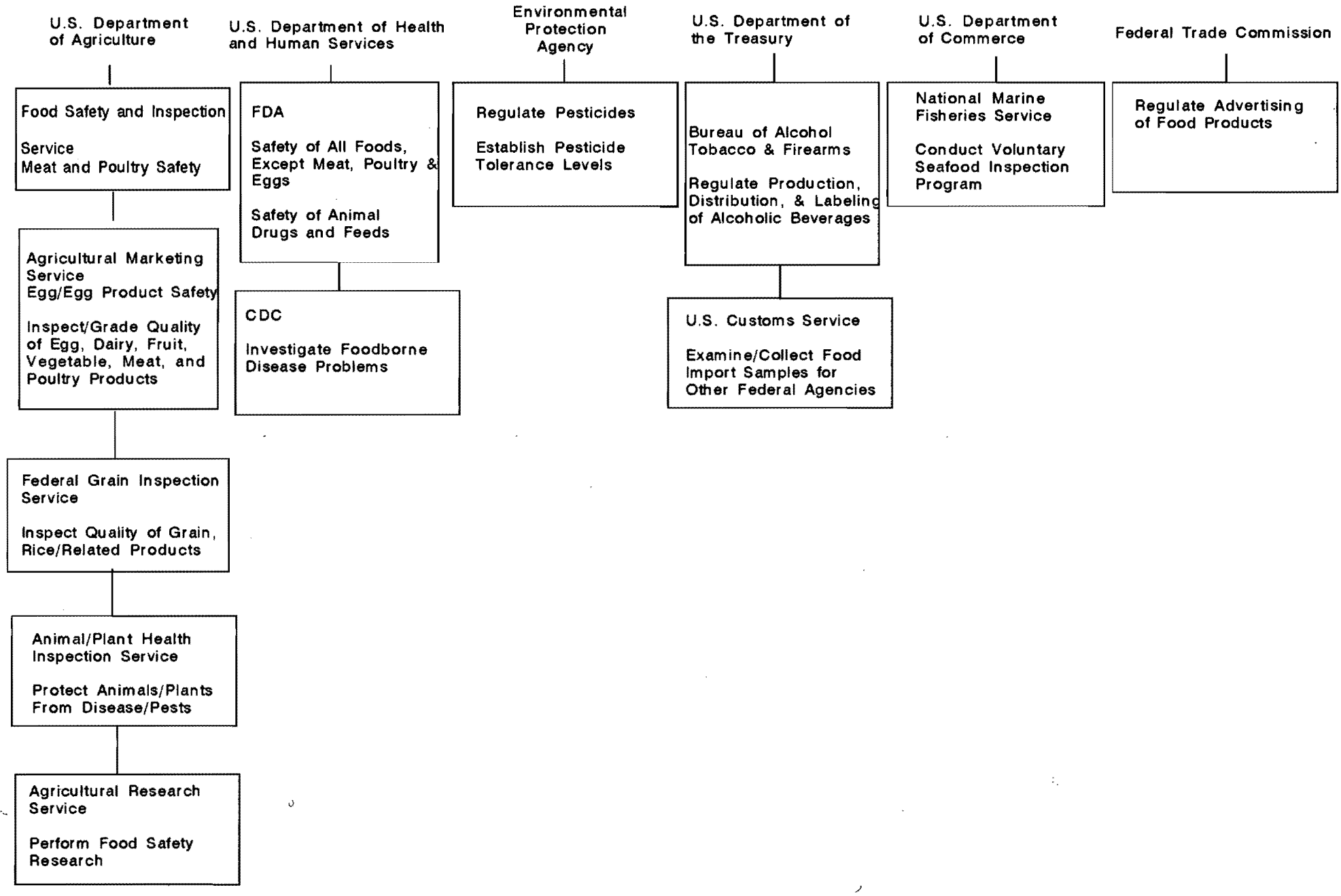
CROSSCUTTING

Reciprocity of approvals of drugs, biologics, devices and food additives with foreign countries, i.e., when another industrialized country with review programs and comparable rigor approves a product, approval would be automatic in this country.

Unrestricted export of unapproved drugs, biologicals, and devices to countries that have already given the products their approval.

Creating one government-wide "inspection service" under which most government inspections would be carried out (e.g., a firm would get a visit from one inspector, who would inspect for food/drug, environmental, worker safety, and other violations).

FEDERAL FOOD SAFETY AND QUALITY RESPONSIBILITIES



USDA Presentation to Follow

FDA Presentation

FOODS

PRIVATIZATION

- Pilot program for private laboratory analysis of imported foods

STREAMLINING/REDUCING REGULATORY BURDEN

- Replace FDA GRAS food additive review with notification only

PERFORMANCE STANDARDS

- HACCP

FOOD AND DRUG ADMINISTRATION

(FOODS)

FDA regulates foods primarily under a postmarket surveillance system, in which FDA inspectors conduct random inspections of about 50,000 food processing establishments. However, because resources today allow only about 5,000 inspections annually, the agency has been criticized for inadequate coverage of the food supply, and those critics attribute continuing foodborne illnesses costing hundreds of millions of dollars per year to those insufficient inspection levels. In 1994, FDA announced plans to change from these random inspections alone to an international standard of quality control known as HACCP (Hazard Analysis Critical Control Points). Under HACCP, food firms and FDA agree upon a "plan" in which food hazards are identified in each facility and prevented through necessary controls (e.g., cooking foods to high enough temperature). Imports of foods are also subject to FDA inspection and, when possible, to sampling and analysis for such contaminants as pesticides, heavy metals, and pathogens.

Food additives are regulated in two ways. Those that have a long history of safe use can be deemed "Generally Recognized As Safe" (GRAS); their manufacturer can self-determine that an additive is safe and market the additive without FDA prior approval. However, manufacturers often seek FDA's concurrence in that determination by submitting a GRAS Affirmation Petition to FDA, which FDA reviews to "affirm" that the substance is indeed generally recognized as safe. Truly new food additives with no past history of use must be approved by FDA prior to marketing, through a Food Additive Petition.

FDA ensures that foods are accurately and completely labeled for their ingredient and nutritional content. Food advertising is regulated by the Federal Trade Commission.

The agency also regulates standards of identity for foods, which define what a given good product is, its name and the ingredients which must be used, or may be used. Standards of identity were authorized by Congress in 1938 to protect consumers from economically adulterated products, and have since been supported by the food industry as a way of protecting manufacturers from disreputable competitors. There are some 300 standards in force covering a wide array of foods and classes of foods, such as cheeses, flour, cereal, and jellies.

FOODS

(Use of Performance Standards in Connection with Food Inspections)

The Problem: The U.S. food industry perceives an inconsistency in the Federal government's regulation of different segments of the market. The prevalence of certain foodborne illnesses has created the perception that the U.S. food supply is unsafe. FDA's food program has been unable to keep pace with the increasing workload, resulting in fewer inspections of food manufacturers each year. FDA's inspection processes rely on "catching" problems during infrequent inspections, rather than relying more heavily on food manufacturers to ensure that they are safely producing food. [USDA regulates meat and poultry, FDA the rest of the food supply.]

New Regulatory Approach: Performance standards for industry; improved Federal/State/industry cooperation.

Proposed Solution: Implement a system in which the industry identifies and prevents food contamination during processing and handling, known as HACCP (Hazard Analysis Critical Control Points). Under this system, each food producer identifies the likely areas in which food could become contaminated during processing and puts in place procedures to protect it from such contamination (e.g., free from microbial or chemical contamination, proper cooking and refrigeration temperatures). Regular records of process monitoring are kept and available to FDA inspectors when they visit the plant. Thus, a continuous monitoring of the food's safety is ensured with only infrequent visits by FDA inspectors. Regulations applying HACCP to seafood are scheduled for 1995, to be followed by other segments of the food industry.

Pros and Cons:

Pro:

- Industry-chosen plan, not dictated by govt.
- Risk-based program
- Demonstrated effectiveness of concept in U.S., evidence of success in other countries
- Adopts international standard for food safety
- Has much industry support
- Enhances public health without increase in Federal resources

Con: - Could take years to fully implement

- Some startup costs

- Could be viewed as increased Federal regulation, as new HACCP rules would need to be promulgated.

Alternatives Not Recommended (and Why):

1) Continue current inspection system (inefficient, unreliable, inadequate resources);

2) Discontinue all Federal oversight of food manufacturing (a basic Federal responsibility dating to 1906).

Regulatory Impact: Moves toward consistent, government-wide approach to food inspection. Will improve the industry's international competitiveness and lower costs associated with foodborne illness, product recalls, and waste from destroying contaminated food.

FOODS

(Privatization of Lab Analysis for Food Imports)

The Problem: Imported foods are not being adequately inspected and analyzed to ensure safety. Although FDA oversees the importation each year of about 1.5 million entries of imported foods, the Agency has the resources to inspect and analyze only about 2% of those entries, resulting in public skepticism about the safety of imported foods (as well as FDA's inability to identify and stop all imports that may be unfit for sale in this country). Also, the agency often must detain many import entries pending laboratory analysis, resulting in costs and delays for the importer.

New Regulatory Approach: Privatization of laboratory analysis; harmonization of international standards.

Proposed Solution: Expand pilot program to allow importers to elect to have a private laboratory sample and analyze an incoming food and notify FDA if it passes whatever test is necessary (e.g., for an unapproved pesticide or for decomposition). The laboratory would be paid by the importer and would be accredited by FDA as capable of making such analyses. The resulting certification would be accepted by FDA as evidence that the food was fit for entry into the U.S. FDA would audit the laboratories to ensure integrity of their sampling and analysis processes.

Also, Memoranda of Understanding (MOUs) would be arranged with other developed countries, under which their standards of food safety would be accepted as equivalent to U.S. standards, thus requiring less attention by FDA inspectors of food entries when they arrive in the U.S.

Pros and Cons:

Pro:
- Addresses one of FDA's greatest vulnerabilities in protecting food;
- Allows importers to gain easier market entry, for a fee;
- Affords increased safety to the U.S. food supply.

Con:
- Need to establish quality lab network free of conflict of interest;
- MOUs require time, resources to establish.

Alternatives Not Recommended (and Why):

1) Increase FDA import inspection (will require many additional FDA inspectors to make major impact)

2) Allow firms to self-certify as to product quality (some products/firms/countries need Federal oversight to ensure safety, compliance with U.S. laws

Regulatory Impact:

- Saves government resources and FTEs;

- Expedites market access for imported goods by reducing inspection/sampling time;

- Provides better protection to the consumer.

FOODS

(Exemption of Certain Food Additives from Preapproval-Type Requirements)

The Problem: The industry perceives that FDA's preapproval of new food additives unnecessarily delays entry onto the market of useful new foods. New chemical ingredients added to foods are "food additives" under the law, such as new sweeteners, and must be preapproved by FDA. However, many new food ingredients, such as new cooking oils, are not food additives under the law and need not be preapproved by FDA. Although food firms can market such new ingredients by independently determining that they are "Generally Recognized As Safe," firms often ask FDA to "affirm" that they are GRAS (thus gaining Federal agreement that the ingredient will be safe if widely marketed). FDA often takes 6-10 years to carry out those "GRAS Affirmations."

New Regulatory Approach: Streamline/reduce burdens by tailoring requirements to risk.

Proposed Solution: Change current "approval" system to a notification only. Food firms wishing to gain GRAS Affirmation from FDA would submit a notification only, which FDA would review for problems within 30-60 days. After that period, the company could market the new food ingredient with the understanding that an FDA review had been obtained. They would not have to await a thorough and time-consuming review.

Pros and Cons:

Pro:
- Allows foods to be marketed expeditiously with minimal government review; and
- FDA can check notification to ensure proper attention to safety questions.

Con:
- Could be postured as overly rapid review that could miss a problem with a food ingredient that should not be marketed.

Alternatives Not Recommended (and Why):

1) Faster premarket approval by FDA scientists (insufficient resources, would not improve safety)

2) Go all the way and eliminate notification to FDA entirely (Removes check to ensure that firm has asked the right questions in ensuring that the ingredient is GRAS)

Regulatory Impact:

- Reduces 6-10 year full-blown scientific review time to a 30-60 day review (of a notification only);

- Savings to food firms would range from thousands to hundreds of thousands of dollars each year;

- Savings to FDA of 4-5 FTEs.

OTHER PROPOSALS FOR REFORMING FDA'S FOOD PROGRAM

Make HACCP voluntary (or target to foods with greatest risk).

Merge FDA and USDA's Food Safety Inspection Service within the Department of Agriculture (such a merger was recommended by RIGO I, but within HHS)

Eliminate food standards, which are Federal "recipes" for foods that comprise almost 300 pages in the Code of Federal Regulations.