TELEFAX TRANSMITTAL SHEET

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DATE: 30 May 1997

TO: Elizabeth Drye

TELEFAX NUMBER: 202-456-7431

COMMENTS: As discussed.

NUMBER OF PAGES, EXCLUDING COVER: 5

DRAFT
3/11/97

DRUG LEGISLATIVE CONCEPTS**

GROUP A

1. CIVIL MONEY PENALTIES. Provide for civil money penalties for any drug-related violation of the Federal Food, Drug, and Cosmetic Act.

2. RECORDS INSPECTION. Revise inspectional authority in section 704 to clarify/broaden the scope of records inspection authority beyond Rx drugs to OTC drugs.

3. RECALLS. Amend FFDCA to require the prompt reporting of voluntary recalls, including the prompt reporting of "market withdrawals," to FDA and to provide authority to recall any drug that poses a significant threat to health and safety.

4. INSPECTION OF TESTING LABORATORIES. Clarify FDA's authority to inspect drug testing laboratories. (Some testing laboratories have taken the position that they are not subject to FDA's inspection authority except in connection with specific product applications.)

5. GENERIC DRUG PROVISIONS. Such as clarification of a number of 1984 Hatch-Waxman provisions, including paper NDAs under 505(b)(2).

GROUP B

1. INFORMATION AVAILABILITY (a) Clarify/broaden FDA's authority to disclose the existence of clinical trials and the results of completed clinical trials (if known), including authority to get assistance from the companies in gathering the information. (b) Clarify FDA's authority to disclose other information in marketing applications under certain circumstances.

2. PEDIATRIC LABELING. Address problem of insufficient information about pediatric uses of drugs.

3. INTERSTATE COMMERCE. Eliminate all interstate commerce elements of the PHS and FDC Acts and provide a Congressional finding that each of the proscribed activities relating to adulterated, misbranded, or unapproved products affects interstate commerce.

** **This list does not include those concepts suggested by PhRMA/BIO that FDA supports.**

4. CLARIFY SEIZURE AUTHORITY. Clarify "intended for export" language of 801(e) and relationship with 304 provision re: export of seized goods to make clear that when goods were not originally intended for export, they cannot be exported after seizure.

5. FORMAL RULEMAKING. Eliminate the formal hearings specified for in 502(n) and 701(e) (as they relate to drugs).

6. LABELING -- INGREDIENT LISTING. Amend 502(e) to require listing of quantity/proportion of active ingredients and the identity of inactive ingredients in drug products.

GROUP C

1. CREATE RISK-BASED TIMEFRAMES FOR DRUG FIRM INSPECTIONS. Low risk products or firms would be inspected less often than high risk products or firms. Eliminate the statutorily imposed two year time frame for all inspections.

2. FDA MARK. Authority to include "FDA mark" in drug labeling. Repeal 301(l), which prohibits a company from stating (in labeling) that its product is FDA approved.

3. INTRAMURAL RESEARCH TRAINING AUTHORITY (IRTA). Amend the PHS Act to allow FDA centers that conduct research to use the intramural research authority to provide fellowships and training to appropriate undergraduate, pre-doctoral, or post-doctoral candidates.

4. ELIMINATE CERTAIN LABELING REQUIREMENTS -- such as "Caution: Federal Law...." (503(b)(4)) and "Warning - May be habit forming" (502(d)).

5. REGISTRATION OF FOREIGN ESTABLISHMENTS. Give FDA authority to require registration and listing of foreign FDA-regulated drug establishments.

6. IOM STUDY -- To find out where time really goes during the drug development process. Requires access to drug company files.

list.db

4/25/97 DRAFT

DEVICE LEGISLATIVE CONCEPTS**

GROUP A

1. REGULATION OF CLASS II DEVICES.

   a. Establish Class II as safety & performance (instead of substantial equivalence/510(k)). Use of consensus standards and design controls to meet essential requirements.

   b. Explicit authority to require FDA-cleared/approved labeling on Class II devices.

2. INFORMATION DISCLOSURE. (a) Clarify/broaden FDA's authority to disclose the existence of clinical trials and the results of completed clinical trials (if known), including authority to get assistance from the companies in gathering the information. (b) Clarify FDA's authority to disclose other information in marketing applications under certain conditions.

GROUP B

1. PERFORMANCE STANDARDS. Specify procedures for adoption and enforcement of national and international standards.

2. DE NOVO CLASSIFICATION OF NEW DEVICES. Streamline process to classify/reclassify "new" postamendment devices.

3. REVIEW TIMES FOR PREAMENDMENT PMA'S. Eliminate mandatory 180-day time frame (or come off market) for decisions on PREAMENDMENT PMA's (replace with 18 month timeframe).

4. PREMARKET APPROVALS (PMAs). Allow data from a PMA to be used 3 years after approval to facilitate reclassification and/or approval of the same kind of device. (Under current law, this data cannot be used. The four of a kind provision in the SMDA has been too difficult to implement.)

** **This list does not include certain other concepts suggested by HIMA/NEMA/NDMA that FDA could support.**

5. DEVICE SAMPLES. Authority to require that the manufacturer of a device involved in an adverse event or recall submit a sample device to FDA (or provide FDA access to a sample) for laboratory analysis. For class II devices, authority to require the submission of a device sample (or access to a device sample) for laboratory testing purposes as part of premarket review.

6. SPECIAL CONTROLS. Clarify the process to designate, enforce (e.g., add adulteration charge to section 501), and adopt (for reclassification purposes) special controls for class II products. (This is to correct an SMDA drafting problem. SMDA changed the definition of class II from performance standards to special controls. It did not describe how to designate the special controls and did not explicitly make failure to comply with them a prohibited act.)

7. INTERSTATE COMMERCE. Eliminate all interstate commerce elements of the FDC Act and provide a Congressional finding that each of the proscribed activities relating to adulterated, misbranded, unapproved products affects interstate commerce.

8 CLARIFY SEIZURE AUTHORITY. Clarify "intended for export" language of 801(e) and relationship with 304 provision re: export of seized goods to make clear that when goods were not originally intended for export, they cannot be exported after seizure.

9. RX VERSUS OTC DEVICES. Statutory provision similar to drugs (Durham-Humphrey provision) that clearly delineates the criteria for OTC use versus use on the prescription or order of a health professional.

10. ELECTRONIC PRODUCT RADIATION CONTROLS.

    a. Revise sections 536(a) and 539(a) to authorize FDA to refuse entry (import) to and prohibit distribution of electronic products that contain a radiation defect and revise section 538(a) to make it a prohibited act for manufacturers, dealers, and distributors to distribute an electronic product that contains a radiation defect. (Currently, the mechanisms to prevent import or marketing apply only to electronic products that are subject to a radiation performance standard and fail to comply with that standard. Examples of defective products that had to be permitted entry or for which there were not adequate ways to prevent marketing include linear accelerators that malfunctioned and emitted excessive radiation and night vision scopes that unintentionally emitted excessive low-energy x-rays.)

    b. Revise section 539(a) to make the electronic product civil money penalties provisions the same as the civil money penalty provisions that apply to all devices (i.e., provide authority to the Secretary, rather than the U.S. District Court, for assessing civil money penalties and make the fee amounts the same).

GROUP C

1. RISK BASED TIMEFRAMES FOR DEVICE FIRM INSPECTIONS. Low risk products or firms would be inspected less often than high risk products or firms. Eliminate the statutorily imposed two-year time frame for all inspections.

2. ADVERSE EVENT REPORTING. Clarify FDA's authority to transfer more responsibility to manufacturers for analysis of adverse event reports.

3. FDA MARK. Authority to include "FDA mark" in device labeling. Repeal section 301(l), which prohibits a company from stating (in labeling) that its product is FDA approved.

4. REGISTRATION OF FOREIGN ESTABLISHMENTS. Give FDA authority to require registration and listing of foreign FDA-regulated device establishments.

5. INTRAMURAL RESEARCH TRAINING AUTHORITY (IRTA). Amend the PHS Act to allow FDA centers that conduct research to use the intramural research authority to provide fellowships and training to appropriate undergraduate, pre-doctoral, or post-doctoral candidates.

6. RECLASSIFICATION. Streamline procedures for reclassification, with particular attention to preamendment class III devices.

FDA Reform — 1/10/97

Carr – one of Dmna's highest priorities.

Principles –

– Unified / speak w/one voice
– Commitment to reform –
 streamlined process / promote p. health
– reach as much common ground as we can –
– build on progress we made last year –
– keep PDUFA separate

Plan

HHS meet w/ industry, consumer groups individually –

Not an attempt to develop Administration bill –

Following this meeting – Sec reach out to a list of principals on Hill – followed by staff meeting –

Dorsle

– More company led, less industry led

Schultz – industry – doesn't seem to be pushing off label

Follow RCBO model – convince public interest groups that this is a good thing to do.

Consumers will have information. Issues

Meetings next week

PHARMA - staff

PEUICS - HIMA staff, (various) outgoing CEO's

- Bliley, Coats have said they're thinking of moving reform and PDUFA together.

- **India Textiles:** On January 6, the panel examining the consistency of a US textile restraint measure on imports of wool shirts from India will issue its final report.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

New Drug Approvals: New drugs are approved faster in the U.S. than in the EU, according to new international data. An examination of 15 new drugs approved by the FDA and the EU shows that the median time for FDA review and marketing approval is 5.8 months, while the median time for authorization for a company to sell those drugs in Europe is 12.2 months. In 11 instances, the drugs were first approved in the U.S., compared to four cases when they were approved first by the EU.

Teen Marijuana and Tobacco Use: On December 19, Secretary Shalala, General McCaffrey, Secretary Riley, and Secretary Pena announced the annual "Monitoring the Future" survey, which shows an increase in marijuana and tobacco use among eighth and tenth graders between 1995 and 1996. Use of these substances leveled off among twelfth graders, according to the report. The survey also showed increases in the use of alcohol by eighth graders.

- **Flu Vaccine:** On December 17, FDA and CDC advised that health care professionals may want to consider reimmunization for some high-risk individuals who received a flu vaccine recalled because of decreased potency in one viral strain. About 5% to 7% of all people who have received the 1996-1997 influenza vaccine received doses with decreased potency. FDA, CDC, and the company have sent notices to health care professionals and state public health departments so they may evaluate whether their patients should be reimmunized.

- **Blood Center:** On December 16, the New York Blood Center (NYBC) and three of its officers agreed in a consent decree with FDA and the DOJ to a series of measures aimed at ensuring the integrity of center's blood and blood-products operations. NYBC has agreed to make a wide range of improvements to ensure compliance with FDA requirements.

- **Welfare Medicaid Provisions:** On December 20, HHS may release new implementing instructions in the State Medicaid Manual interpreting the Medicaid provisions of the new welfare law.

THE WHITE HOUSE
WASHINGTON

Bill Carr —

① POTUS has asked that Report on FDA drug approval times be sent relevant to Members of Congress.

② Status of RPT on pediatric uses; Wed. meeting

③ Radiation rollout

John — Can you pass to Greg at Elena Kagan's request? Thanks

- Elizabeth Drye
6-5573

MDMA

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Elena — Please advise on how you'd like us to respond / who should handle. -Elizabeth

Send to Greg Simon's office. Thanks Elena

FACSIMILE TRANSMISSION INFORMATION

DATE: 1/24/97

TO: ELIZABETH DRYE

COMPANY: DOMESTIC POLICY COUNSEL

FACSIMILE: 202 456-7431

TELEPHONE: 202 456-2216

FROM: JEFFREY J. KIMBELL, Executive Director

TELEPHONE: (202) 496-7150

CLIENT MATTER NAME: MDMA

CLIENT MATTER NUMBER: 165 73 000

OF PAGES INCLUDING COVER: 2

REMARKS:
SCHEDULING REQUEST FOR A GROUP OF APPROX. 100-150 MEDICAL DEVICE MANUFACTURERS.

Transmission completed:_____ By: _____

MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

January 21, 1997

Elizabeth Drye, Chief of Staff
Domestic Policy Counsel
The White House
1600 Pennsylvania Avenue
OEOB Room 213
Washington, D.C. 20502

Via Facsimile: 202 456-7431

Dear Ms. Drye,

Though we have not yet met, I look forward to the future when I have a chance to discuss the current regulatory and financial issues affecting the domestic medical device industry. Support from the Executive branch and in particular from the Vice President will be essential if we are to be successful in modernizing the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA).

In this regard, I would like to offer the Vice President or another member of the cabinet who is equally focused on high technology issues to address 150 members of the National Medical Device Coalition (NMDC) during our Senior Executive Fly-in on February 26-27, 1997. If appropriate, I would suggest that logistically it may be easier for our group to assemble in Room 450 of the Old Executive Office Building in the morning of either day and have our speaker(s) drop by for a brief address. This would provide the Administration and the Vice President a chance to speak directly to the true innovators and entrepreneurs who are fueling the current growth in this economy. The medical device industry is one of the premier high technology industries in the United States.

The fly-in formally begins on February 25 at 6:00 PM for a Legislative Orientation Session at the offices of MDMA, followed by two full days on Capitol Hill visiting with lawmakers. It is my belief that the grassroots support of a fly-in is imperative if we are to be successful in enacting legislation next year. I look forward to your response to this idea and would welcome any of your thoughts, ideas and/or comments to ensure that the Administration gets an opportunity to speak with these companies. I thank you in advance for your attention to our request. I will call you the week of February 27 to discuss this further.

Sincerely,

Jeffrey J. Kimbell, Executive Director
Medical Device Manufacturers Association
Vice President
National Medical Device Coalition (NMDC)

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

15-Jan-1997 10:56am

TO: (See Below)

FROM: Daniel J. Chenok
Office of Mgmt and Budget, OIRA

SUBJECT: CONGRESS MAY NARROW FDA REFORM FOCUS

CONGRESS MAY NARROW FDA REFORM FOCUS
Members of the 105th Congress are expected to renew efforts begun in the last Congress to approve legislation reforming the Food and Drug Administration, but a final bill may be narrower than originally envisioned. Comprehensive reform received bipartisan support in the last Congress, but the legislative session ended while negotiators continued meeting to try and reach agreement on a final bill. Among other things, negotiators were working to reach agreement on establishing a system under which third-party organizations would be certified to do product reviews and on revising FDA's policy on dissemination of information about off-label use of drugs and devices.
To achieve agreement among Congress, industry, and the Clinton administration on FDA reform, negotiators may choose to ``carve out'' or jettison provisions addressing issues that cannot be resolved easily. While this approach would ensure consensus earlier, Rep. Jim Greenwood (R-Pa) said he would prefer that negotiations continue until difficult issues are resolved. On the other hand, further delay on FDA legislation could subject the issue to 1998 campaign pressures, he said.
Greenwood was appointed by House Commerce Committee Chairman Thomas J. Bliley Jr. (R-Va) to head a House Commerce Republican task force that developed reform bills in the 105th Congress (HR 3199, 3200, 3201) targeting three product areas regulated by FDA--drugs and biologics, foods, and medical devices.
A carve-out approach to negotiating agreement on reform could affect the reauthorization of the Prescription Drug User Fee Act passed by Congress in 1992. According to an FDA expert, supporters of particular reform provisions could make FDA's acceptance of these provisions the basis for reauthorizing user fee legislation.
This tactic could prove fatal to an FDA reform bill, however. A Hill source predicted that adding reform-related provisions to a reauthorization bill would sink the bill--an unpleasant scenario for both FDA and regulated industry. Industry groups want the user fee system to continue, but are seeking to change the performance goals FDA must meet. The agency, meanwhile, needs the revenues from the user fees to support speedy drug reviews and approvals.
Considering the amount of work done by reform proponents in 1996, members of Congress and administration officials should be able to reach agreement

since they have identified the areas over which each disagree, Greenwood told BNA. He believes less effort will be needed to hammer out agreement on the remaining issues and leaving these difficult provisions unaddressed would be a mistake.

Deadline Looms On Reauthorization

Both industry and FDA want the user fee act reauthorized, sources said. Under the drug user fee act, FDA accepted mandatory goals for completing drug reviews in exchange for revenues to hire additional staff to do the work within the statutory timeframe. On FDA's part, if Congress fails to reauthorize the legislation, the agency will have to eliminate approximately 600 employees whose salaries are paid for through user fees.

In a Dec. 10, 1996, speech at the Food and Drug Law Institute's annual meeting, Kessler told reporters that, based on the success of the user fee act, everyone recognized the need for reauthorization, but urged that reform and reauthorization be kept as separate issues.

Although pharmaceutical companies have most at stake in the reauthorization discussions, now that improvements have been realized in c( )leting drug reviews more quickly, the industry wants to raise the bar and create a mechanism for reducing overall drug development times. According to Carl Feldbaum, president of the Biotechnology Industry Organization, FDA and industry groups currently are discussing the terms for reauthorizing the user f act, such as treating biological products on an equal footing with chemically derived drugs.

However, levying user fees to support medical device reviews still are opposed by industry groups. According to Jeffrey J. Kimbell, executive director of the Medical Device Manufacturers Association, legislation reforming FDA's device review process is a primary goal for his association in 1997. He also believes the 105th Congress may take an incremental approach to FDA reform rather than moving a comprehensive bill. For example, an independent medical device reform bill could be attached to another piece of legislation, Kimbell said.

Reform Talks Continue

In a Dec. 9 speech at an American Enterprise Institute conference, Bliley promised to complete the work begun in the 104th Congress toward effectively streamlining agency procedures. Negotiations begun last summer will resume, he said. Health and Human Services Secretary Donna E. Shalala contacted him prior to the November elections, expressing an interest in continuing the talks.

The Commerce Committee already has a full legislative agenda for 1997, which could affect the timing on FDA reform activity. Besides jurisdiction over Medicare and Medicaid, the committee is facing a statutory deadline on an FDA-related issue, namely a decision on reauthorizing the Prescription Drug User Fee Act by September 1997.

Greenwood told BNA Dec. 16 that, while he had not spoken to Bliley about the reform issue since the election, he believes that the three FDA reform bills introduced during the last Congress would be the basis for future legislation. He expects these will be reintroduced pending the conclusion of discussions among FDA, industry groups, members of Congress, and the Clinton administration.

Based on Bliley's comments, the House Commerce Committee, spearheaded by the Health and Environment Subcommittee, will see activity on FDA reform. On the Senate side, the picture is less clear. There is a new chairman at the helm of the Senate Labor and Human Resources Committee, which has jurisdiction over FDA. Incoming Chairman Jim Jeffords (R-Vt) has reorganized the committee, establishing a public health and safety subcommittee to be headed by Sen.

William Frist (R-Tenn). Jeffords has announced that FDA matters will be handled at the full committee level, but what issues will be considered and what priority these will hold is not known.

Effect Of Kessler's Resignation

Notwithstanding possible action on either a comprehensive or pared down FDA reform bill, there is considerable speculation about what effect, if any, the impending departure of FDA Commissioner David A. Kessler will have on prospects for FDA reform.

When he announced his resignation in November 1996, Kessler said he would stay until a replacement is selected.

According to some observers, members of Congress will wait to see who Clinton nominates before pursuing further legislative efforts to reform FDA. The president is expected to select a reform-minded candidate acceptable to congressional Republicans, industry groups said. Another source suggested that the Department of Health and Human Services wants FDA reform ``off its plate,'' which could influence the selection of a new commissioner.

The choice will not be easy, however, given competing viewpoints about the qualifications for an acceptable successor. For example, Sidney Wolfe, director of Public Citizen's Health Research Group, told BNA that the Clinton administration must find a candidate acceptable to both industry and consumer groups. If consumer groups are unhappy, some of the positive feedback the administration has gotten for its pro-consumer stance will evaporate, he suggested.

``Let's get on with it,'' Jim Benson, senior vice president, product technology and regulatory affairs for the Health Industry Manufacturers Association, said. In his view, the worse-case scenario for advocates of both administrative and legislative reform would be Kessler as a lame-duck commissioner.

Tobacco Regulation

In any event, the candidate-commissioner will be subject to intense scrutiny and members of Congress will want answers about the nominee's attitudes on controversial issues, including abortion and tobacco. Kessler has been criticized for devoting time and resources to developing a case for regulating tobacco at the expense of products traditionally regulated by the agency.

FDA's final rule, published in August 1996 exerting jurisdiction over the sales and marketing of cigarettes and smokeless tobacco products as drug delivery devices aims to reduce the appeal and access these products have for children and teenagers under 18. The move, applauded by consumer and antismoking groups, is being challenged in court by tobacco industry, advertising, and retail and vending sales groups. The parties have filed briefs in the U.S. District Court for the middle district of North Carolina, where a judge is expected to make a decision on the suit by March 1997 (Coyne Beahm Inc. v. U.S. Food and Drug Administration, DC MNC, No. 2:95CV00591; 1/6/97).

This controversy may not affect congressional efforts to approve FDA reform legislation, however. The regulation has taken on a life of its own and the matter will be decided in court over the next six to 24 months, the FDA expert said. Moreover, Commerce Chairman Bliley, an opponent of the regulation, does not believe Congress should make any move until the courts have ruled on the issue, the expert said.

For antismoking groups, the focus will be on making sure Congress does not attempt to derail the implementation of the regulation, according to Matthew L. Myers, executive vice president of the National Center for

Tobacco-Free Kids. He commended Kessler's hard work in making tobacco a serious issue and bringing about a significant policy change within the federal government.
Although his organization's priority is making sure implementation takes place, Myers believes that, even if the rule is overturned, the effort has been important. For the first time, there has been national debate about what choices should be made on the issue of underage smoking, he said.
-- By Ellen McCleskey

Distribution:

TO: Jonathan D. Winer
TO: John F. Morrall III
TO: Donald R. Arbuckle
TO: Sally Katzen
TO: Elizabeth E. Drye

CC: Michael A. Fitzpatrick

Elizabeth —
Can you tell
JRH/HHS to do this?
Thanks —
BR

- **India Textiles:** On January 6, the panel examining the consistency of a US textile restraint measure on imports of wool shirts from India will issue its final report.

con - Ports title

B Reed

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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- **Welfare Medicaid Provisions:** On December 20, HHS may release new implementing instructions in the State Medicaid Manual interpreting the Medicaid provisions of the new welfare law.

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IMPORTANT NOTICE
TELECOPY/FACSIMILE COVER LETTER

TO: Elizabeth Drye

DATE: 05/20/97

FROM: Nancy Granese
Governmental Affairs Advisor

TIME: 12:07 PM

TOTAL NO. OF PAGES, INCLUDING COVER: 5

MESSAGE:

FOR INTERNAL PURPOSES ONLY

TELECOPY/FAX NUMBER: 202 456-5573

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HEALTH CLAIMS

BACKGROUND

As mandated by the 1990 Nutrition Labeling and Education Act, FDA regulates health claims that are permitted to appear on food labels. Currently the agency allows claims for ten different diet/disease relationships, including: calcium and osteoporosis, fat and cancer, saturated fat and cholesterol and coronary heart disease (CHD), fiber-containing grain products, fruits and vegetables and cancer, fruits, vegetables and grain products that contain fiber and the risk of CHD, sodium and hypertension. In 1996, the FDA finalized health claims regulations on the relationship between folic acid and neural tube defects.

PROBLEM

Health claims can be approved for use only by FDA, and FDA maintains that it lacks the statutory authority to defer approval authority to other agencies. However, other federal agencies with public health responsibilities, such as the National Cancer Institute, have unsurpassed expertise in this area. For example, in 1992, the Centers for Disease Control (CDC) published findings regarding the relationship between intake of folic acid and a reduction in neural tube defects, but FDA did not issue final health claims regulations addressing the proven relationship until 1996 because they did not initially agree with CDC.

SOLUTION

FDA should permit use of health claims about diet/disease relationships that have been determined by authoritative federal agencies responsible for public health protection and/or nutrition research. This would ensure a more expedited use of appropriate claims in a time of limited resources.

FOOD ADDITIVE APPROVAL PROCESS

BACKGROUND

Consumers in the United States enjoy the world's most varied, wholesome and affordable food supply. Innovations in food processing and technology and in food packaging technology, enable food companies to develop and offer consumers increased food choices, including foods that have fewer calories, less fat, or more fiber, as well as enhanced convenience. Since 1958, new food ingredients that qualify as "food additives" have been required to have FDA approval before marketing. Food additives include both those ingredients added directly to food to achieve a physical or technical function, such as sugar or fat substitutes (so-called "direct" food additives and those substances that are used in food packaging or other food contact situations which may become part of the food through contact with it (so-called "indirect" food additives). Approximately 75 percent of the food additive petitions submitted to FDA are for indirect food additives.

PROBLEM

Although the FDA is required by law to review a food additive petition and to take action on it within 180 days, few, if any, food additive petitions are acted upon in that time period. The typical time period is 4-6 years, if any action is taken at all.

SOLUTION

Reforming the FDA food ingredient review processes does not mean eliminating FDA review or lowering the standards that help to provide consumers with a safe and wholesome food supply. For direct human food and color additives, a new system of "third party review" should be established with strict time periods, allowing FDA to continue to be actively involved in the petition process while directing the agency to accept the recommendation of the third party or demonstrate why such a recommendation is not justified. The petitioner would agree to provide the funds for the third party efforts in the review.

DELANEY REFORM

BACKGROUND

The Delaney clause was first added to the federal Food, Drug and Cosmetic Act (FD&C Act) in 1958 as a House floor amendment to legislation to require pre-market approval of new food ingredients. The clause was controversial from the start -- the Department of Health, Education and Welfare and the FDA both opposed its inclusion. The clause was adopted because Congress believed that few food ingredients ("additives") would be found to induce cancer in man or animals and because there was no scientifically sound basis upon which to assess the risk to humans of substances that had been found to induce cancer in animals. Thus the clause was adopted to apply to food additives (1958), color additives (1960) and residues of animal drugs (1968).

In 1994, dietary supplements were exempted from the Delaney clause as part of "The Dietary Supplemental Health and Education Act, PL103-417. In 1996, as part of PL104-170, "The Food Quality Protection Act," pesticide residues that concentrate in processed foods were exempted from the Delaney clause. Both had initially been defined as food additives under the clause.

PROBLEM

The Delaney clause, while increasingly discredited and rejected in other areas, still exists for all other food additives, color additives and residues of animal drugs. The clause for these substances flatly prohibits the use of any substance to which it applies if that substance is "found to induce cancer when ingested by man or animal, or is found after tests that are appropriate for the evaluation of the safety of food additives to induce cancer in man or animal." The premise on which the "zero-risk" Delaney clause rests, which might have been valid nearly three decades ago, is not valid now.

SOLUTION

There is general scientific agreement that the rest of Delaney should be changed to a "negligible" or "insignificant" risk standard, conforming with the safety standard that exists in the FD&C act for other substances. In fact, the Presidential Commission on Risk Assessment and Risk Management recently recommended that the Delaney clause be changed to a "reasonable certainty of no harm" standard. This would provide substantial improvement to the current process, which wastes scientific resources on inappropriate or insubstantial risks.

NATIONAL UNIFORMITY

BACKGROUND

Government regulation of the food supply has been a recognized function in all civilized societies since the beginning of recorded history. When the United States was founded, people relied on food produced in their immediate surrounding area and thus food regulation appropriately was undertaken by state, county and city governments. It became apparent by the late 1800s, however, that a federal food law was needed to cover the entire nation. Following the enactment of the 1906 Federal Food and Drugs Act, there has been no explicit requirement for national uniformity, although many individual laws, such as the Nutrition Labeling and Education Act of 1990, include specific preemption provisions.

PROBLEM

FDA's programs constitute a comprehensive federal scheme of strict safety standards for food, drugs, cosmetics and medical devices. Laws that deviate from FDA standards undermine consumer confidence in the safety of nationally-distributed products regulated by the agency. When faced with a flood of trivial warnings that can result from such laws, consumers grow confused and will ignore all information. Permitting consumer confusion conflicts with FDA's mission to promote public health. Such individual state laws often cause unwarranted costs to companies and interfere with interstate commerce.

SOLUTION

Amend the Federal Food, Drug and Cosmetic Act to establish national uniformity for foods and other FDA-regulated products with regard to safety standards and warning labels.

Clinton Presidential Records
Digital Records Marker

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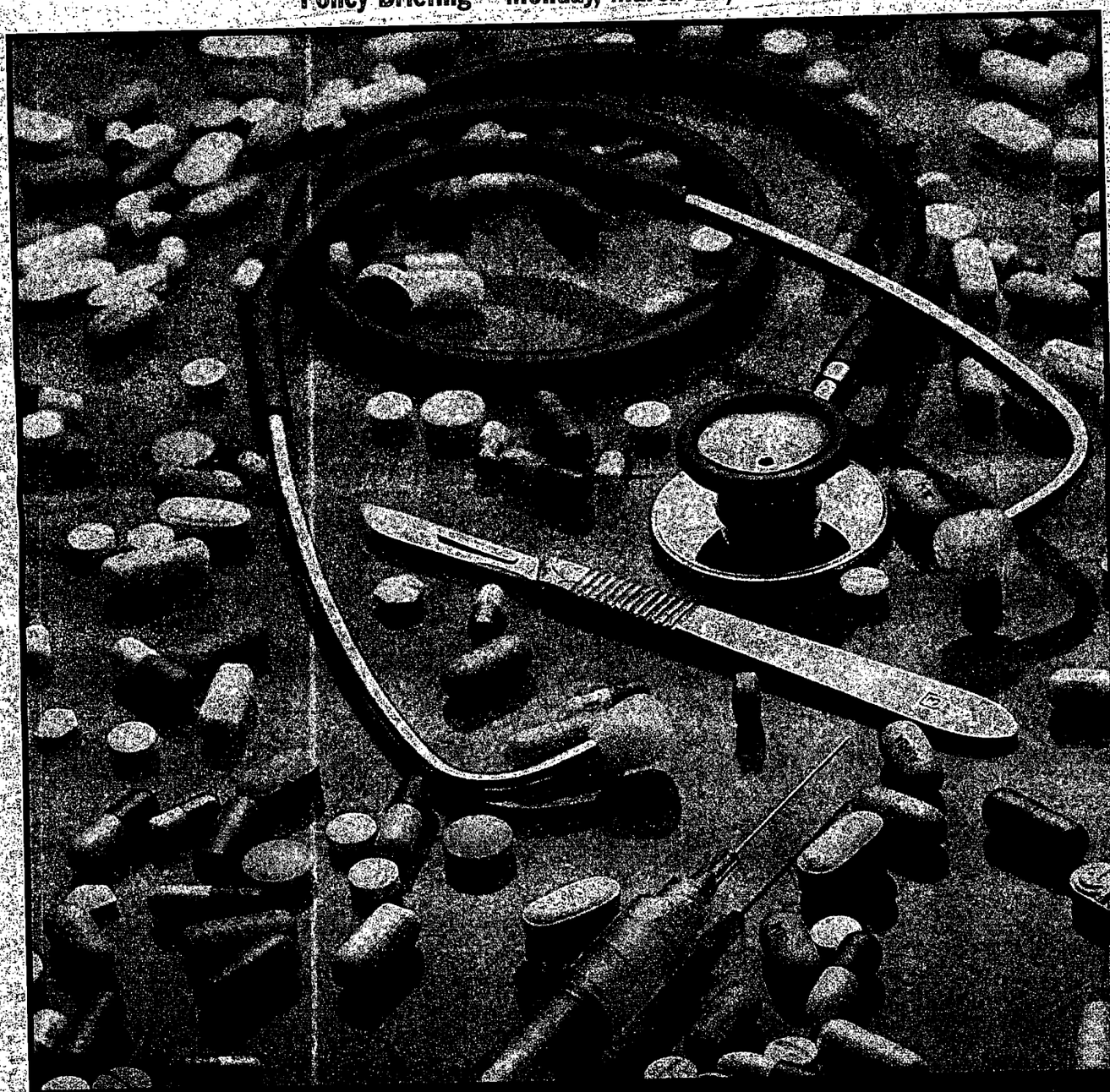
ROLL CALL

FDA Reform

Policy Briefing • Monday, March 17, 1997



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Inside

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

February 3, 1997

Ned Crabb
Letters to the Editor
Wall Street Journal
200 Liberty Street
New York, NY 10281

VIA FACSIMILE, 212-416-2658

To the Editor:

Robert Goldberg's commentary in your edition of January 16th totally distorted the record of three regulatory issues before the Food and Drug Administration and ignored the easily obtainable facts about each case.

The commentary's assertions about inconsistent handling of two drugs for Lou Gehrig's disease are simply wrong. The first drug, Riluzole, was approved on the basis of two well-controlled studies -- not one, as the article claims. The second drug, myotrophin, was also tested in two trials but the positive results of one trial were put in doubt by the negative results of the other. So the FDA required an additional study, which scientific logic and common sense dictates.

The piece also misstates the reason for FDA's 1992 moratorium on the use of silicone gel-filled breast implants and misrepresents the composition of the advisory committee FDA convened to discuss this product. FDA asked the committee to evaluate newly available information on the manufacturing and quality assurance for breast implants. The panel was also asked to consider new reports of breast implant patients who were experiencing autoimmune disorders.

Contrary to the article's assertions, the panel included two expert rheumatologists, and the record shows that the group heard -- and considered -- all views and then-current information before making its recommendation.

Finally, the article alleges that political considerations influenced FDA's decisions concerning Summit Technology Inc.'s excimer lasers. Here, too, there are serious inaccuracies. FDA has moved against the importation of all used excimer laser devices that are considered unapproved products -- including Summit's products -- whose capacity goes beyond similar devices approved in the United States. Further, despite the article's assertions, a credit card reader had no bearing on FDA's decision.

This commentary made the bald -- and incorrect -- assertion that political considerations drive the agency's decisions. Although FDA's decisions often have important economic consequences, the fundamental strength of those decisions comes from their being based on science and medicine -- not, as Mr. Goldberg incorrectly implies, on pressure from any interested parties.

Sincerely yours,

Mary Pendergast

Mary K. Pendergast
Deputy Commissioner/
Senior Advisor to the Commissioner

1/16/97
Bennett Reed
Is this a problem a) user fee b) Kessler going? Smart

EK

The Ethical Mess at the FDA

By Robert Goldberg

This year Congress has the best chance in 30 years to reform the Food and Drug Administration. The departure of Commissioner David Kessler gives the Senate some control over who will be the agency's new leader. And the agency's power to raise hundreds of millions of dollars by charging drug companies for the review of drug applications expires this year unless Congress renews the Prescription Drug User Fee Act. Congress should delay any action until the FDA addresses what appears to be a disturbing legacy of Dr. Kessler's years as commissioner: an agency that is more politicized and open to political influence than at any time in its history. Before approving a new commissioner, Congress must deal with an FDA that is nearly in ethical ruins.

Under Dr. Kessler, the FDA formed an iron triangle of influence between its defenders in Congress and companies seeking special treatment from the agency. In the most egregious case, Summit Technology Inc., a Massachusetts-based manufacturer of devices used in laser eye surgery, collected nearly $500,000 in campaign contributions for Sen. Edward Kennedy (D., Mass.), who later pressured the FDA to approve Summit's application for its laser surgery device.

In a sworn statement in federal court in Santa Ana, Calif., James Fallon, a former Summit salesman turned whistle-blower, contends that former Summit chairman David Muller was "discussing a potential payment in excess of $1 million to Sen. Kennedy's re-election campaign in order to accelerate FDA approval. . . . Mr. Muller met at Sen. Kennedy's townhouse in Washington on a Saturday to discuss the details of this potential action." But don't take Mr. Fallon's word for it. Federal Election Commission records show that Summit, which was not a profitable company, along with its senior executives, kicked in $500,000 to Sen. Kennedy in 1994 and 1995.

Thanks to the FDA, Summit got its money's worth. During this time, the FDA was aware that Summit may have been violating federal law by pre-selling an unapproved device. The company was marketing a holmium laser—already approved by the FDA—with the promise that it would add—for free—its excimer laser once it too was approved. While holmium lasers normally sell for $40,000, Summit's was being sold for more than $400,000 because of the promised FDA approval of the excimer laser. Summit issued written statements to its sales force not to promote or sell the excimer, but salesmen also were told that Summit needed the money to stay alive until the FDA approved the device.

An FDA memo dated Jan. 1, 1995, provided to this writer, shows how the FDA went about doing helping Summit and Sen. Kennedy. "Summit has apparently complained a lot in the past to Ted Kennedy regarding the lack of timeliness in FDA's responses to issue regarding [Summit's application for approval]," the memo states. It then goes on to state that the FDA will not seek criminal charges against Summit, and to assert that Summit will eventually get approval. This decision blessed Summit's practice of charging $400,000 for a device that was really worth only $40,000. In effect, the FDA gave Summit a windfall worth millions of dollars.

The FDA also benefited Summit by banning the use of any other excimer laser made by Summit that didn't have a credit-card reader that collects a royalty for the company. The FDA has even gone after doctors who had purchased Summit-made excimer lasers overseas, minus the credit-card counter; the agency threatened to seize their lasers. Since each procedure with the excimer laser costs $250, this requirement is potentially worth billions to Summit.

When asked about all this, Sen. Kennedy's spokesman merely said he supported Summit as a good deed for Massachusetts workers. In a prepared statement, Summit denied wrongdoing and labeled "completely unfair" allegations that the company used political influence to win FDA approval.

David Kessler

Unfortunately this isn't the only instance where FDA has put political considerations first. Earlier this year, when pressure for FDA reform was building, Dr. Kessler told both the House and Senate that the FDA can approve a drug for life-threatening or serious conditions based on a single well-controlled trial and still ensure a drug's safety and efficacy. Soon after this statement, the FDA approved the first drug to treat (but not reverse) Lou Gehrig's disease using data from one study.

Months later, as the chances for FDA reform began to wane, Dr. Kessler changed course. He testified that "data can be considered reliable only if, when an experiment is run for the second time, it produces the same finding and observations that it produced the first time." So when another company with a drug for Lou Gehrig's disease, called myotrophin, showed the FDA data from one study demonstrating that it slowed down the progression of the illness, the FDA told the company it needed two studies or the drug wouldn't get approved. Never mind the needs of patients suffering from this dread disease. The political heat was off, the agency no doubt figured, so why move faster?

Another, better known instance of the FDA playing politics with public health occurred in the breast implant controversy. When concerns about the "dangers" of silicone-gel breast implants were being raised, an FDA advisory committee concluded the implants should stay on the market while additional data were collected.

But Dr. Kessler was under political pressure to ban implants. Talk shows were awash with women blaming their implants for a variety of health problems. Plaintiff's lawyers and the misinformed press turned up the heat. So the commissioner convened another panel to make the "scientific" results fit the political realities. This time the panel was filled with people who had no expertise in autoimmune disorders. In addition, women against a ban were not allowed to testify. Though the experts still couldn't find any evidence of a relationship between implants and autoimmune disease, the panel recommended a ban. Armed with that FDA edict, trial attorneys whipped up a panic, amassed 400,000 women in a class action suit against implant manufacturers, and bankrupted Dow Corning.

It will be up to Congress to clean up this mess. Dr. Kessler enlarged and institutionalized the role money and politics play in public health issues. As a result, the FDA is no longer a neutral, science-based consumer agency. Congress can and should expect better.

Mr. Goldberg is an adjunct scholar at the American Enterprise Institute.

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