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FDA Accepts DCT Board's Criteria For Approval Of New Drugs, Explains Plan For Early Action

The Food & Drug Administration has accepted, with only a few reservations, the recommendations made a year ago by the Board of Scientific Counselors of NCI's Div. of Cancer Treatment, on criteria for approval of new anticancer agents. FDA Commissioner Frank Young appeared at this week's meeting of the Board to discuss those recommendations and to explain the agency's proposal for approving after phase 2

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In Brief

Basic Science Center Funding Plan Clarified; Janice Feldman Leaves As Chief of NIH Nursing

CLARIFICATION of how the proposal for funding basic science cancer centers would work: That portion of NCI's budget for centers which is awarded as core grants to the basic science centers (currently about $20 million) would be moved into a new category, still in the cancer center support grant mechanism. The basic centers would compete for those funds among themselves and not against the clinical or comprehensive centers. The amount earmarked for basic centers would get the same percentage increase each year which is experienced by the research project grant pool (mostly, RO1s and PO1s), but they would not be funded out of the RPG pool. The clinical and comprehensive centers, which usually don't score as well in peer review as the basic science centers, would be assured their portion of the core grant budget ($70 million now), would be reserved for them. . . . **ELI GLATSTEIN**, chief of the Radiation Oncology Branch in NCI's Div. of Cancer Treatment, is acting director of the Clinical Oncology Program, vacated when Samuel Broder moved up. Glatstein "does not want the job on a permanent basis," DCT Director Bruce Chabner said. Former DCT Deputy Director Gregory Curt is the leading candidate. . . . **JANICE FELDMAN**, chief of nursing at the NIH Clinical Center, has resigned to accept the position as head of nursing at New Rochelle, NY. . . . **WADIE ELAIMY**, long time executive with the Mountain States Tumor Institute in Idaho and former NCI cancer control staff member, has been named executive director of the Louisiana Cancer Consortium in New Orleans. The consortium includes the LSU Medical Schools in New Orleans and Shreveport, the Tulane Medical School and School of Public Health, the state Dept. of Health and the Ochsner Cancer Center.

FDA Says Board's Approval Criteria "Compatible With Current Practice"

(Continued from page 1)
studies drugs for treatment of life threatening diseases, including cancer and AIDS.

The Board sent its recommendations to FDA last March, spelling out its suggested criteria. Development of those recommendations had been spurred by repeated conflicts between FDA and NCI over what the latter charged were inappropriate and unrealistic demands which it contended delayed or stopped entirely approval of potentially useful agents (**The Cancer Letter**, June 17, 1988).

No response from FDA was heard until Carl Peck, director of FDA's Center for Drug Evaluation & Research, appeared at the Board's meeting last June. Peck said then that FDA agreed with much of what was in the Board's paper, but had some reservations. DCT Director Bruce Chabner and Robert Wittes, then director of DCT's Cancer Therapy Evaluation Program, were highly critical of Peck's response. They were not pleased that Peck presented only a brief general response to the recommendations; their displeasure increased over the summer and fall as another meeting of the Board came and went still without further response.

The response finally came this week, when Young presented point by point agreement with nearly every position taken by the Board. FDA had reservations on only two points, and those were apparently minor.

FDA, in fact, took the position that the Board's recommendations were for the most part what it had been doing anyway. Robert Temple, director of FDA's Office of Drug Evaluation, wrote to Peck in a memo summarizing the agency's response:

"The (Board's) document was perceived by its authors as recommending a significant departure from FDA's past practices, specifically with respect to our accepting as a basis for approval favorable effects on end points other than survival, but it does not seem so great a departure to me; rather it seems to me to describe our current practices, perhaps with a few exceptions. This could reflect some internal evolution on our part, over the last five-six years, so that we really do not take some positions as strongly as we once did; it could also reflect some misimpressions of what our positions really have been. It is also possible that the few areas that I will describe below as needing further discussion will prove to represent major differences of view, although I doubt this. In any event, we are pleased to find the (Board's) recommendations and our current practices not far apart."

The recommendations included five assumptions, five acceptable endpoints, and seven examples. Summaries of those and FDA's response:

Assumptions

*Safety and efficacy are appropriate requirements. "We concur in full."

*Neither safety nor efficacy is an absolute concept. The approval process must consider underlying prognosis. "We concur in full."

*Randomized trials generally are preferred; refractory disease may need different methods. "We agree."

*Premarket experience should be sufficient to characterize long and short term benefit and toxicity. "We agree."

*Relative effectiveness is often medically important; it must be addressed in premarketing only when a claim is for a population for which effective standard therapy exists. "We agree, but this may be an area of ambiguity (as noted with example #4).

Acceptable endpoints

*Survival. "We agree."

*Time to treatment failure. "We agree, particularly in the adjuvant setting."

*Complete response rate. "We concur fully."

*Response rate. "We probably agree, but there is a need for clarification. We agree with examples 1-3."

*Disease related symptoms and/or quality of life. "We agree in full."

Illustrative examples

1. Hypothetical antiestrogen. "We probably agree."

2. Drug with 20% response rate in kidney

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cancer. "We agree."

3. Hypothetical cystotoxic with activity in Hodgkin's. "We agree."

4. Analog A (less toxicity). "We generally agree, but think premarket comparison is needed where the parent is known to be effective, especially life prolonging."

5. Analog B (noncross resistant). "We agree."

6. Drug with 30% response rate in kidney cancer. "We agree."

7. Drug with 30% response rate in kidney cancer, with complications. "We agree."

Young spent most of his time at the Board meeting discussing FDA's proposal for approving new drug applications (which permits marketing as a prescription drug) after phase 2 studies under certain circumstances and for life threatening diseases only.

When FDA announced last year it was considering such a policy, Chabner was skeptical. After the meeting this week, he was more hopeful.

"I was gratified for the response to the Board's recommendations," he told **The Cancer Letter**. "Some of the tension has been diffused. The key to implementation of the (phase 2 approval) policy is, are they really prepared to act after phase 2? The carboplatin experience is one where they are still looking for phase 3 survival results. I think it should be approved for both first and second line treatment (of ovarian cancer. The FDA Oncologic Drugs Advisory Committee has recommended approval as second line therapy, but voted against approval as first line until survival data are in)."

Chabner feels that ODAC's failure to ask for first line approval reflects the makeup of the committee as one lacking "activists." He asked Young if he would consider consulting him and/or the DCT Board on appointments to ODAC. He also suggested that a member of his Board could sit as an ad hoc member on ODAC, and that former Board members be appointed to the committee.

"We'll seduce talent wherever we can get it," Young said.

"I have one outrageous suggestion," Chabner said. "One thing that riles people the most regarding an FDA decision is when a drug is referred to the wrong committee. That could be defused by giving NCI a chance to express its opinion on which committee should review it."

"That's not outrageous," Young said. "Some of us have felt the same way about NIH review committees. Ninety percent of my grants (when he was applying for grants as a geneticist) were approved. When I had one turned down, did I think it had been reviewed by an inappropriate committee? That thought crossed my mind."

Young said he would accept a system for peer review of adverse FDA decisions. Also, "I would be delighted if NIH would accept my suggestion (made years ago) for a peer review of peer review."

The plan for approval after phase 2 studies depends heavily on discussions between FDA and the sponsors, and NCI when appropriate, during or immediately after phase 1 studies, Young emphasized. At that time, the parameters of phase 2 studies and desired endpoints could determined. If the desired endpoints are achieved, the agent could be considered for approval at that time, rather than go into phase 3 studies.

Young said that cooperation and close collaboration with sponsors and NCI in the design of phase 2 trials are vital to the success of the plan.

Chabner, seeking a specific example, asked, "If we have response rates, once we know it is active, can we allow approval and more wider use at the end of phase 2?"

"That's our goal," Young answered. "If we can key that in up front, and go with well designed trials. I can't say we'll do that every time. We will need to see the data in each case. And the commissioner does see that data."

NCI Director Samuel Broder greeted Young by expressing "my admiration for and gratitude to the fine men and women who work at FDA. They receive little pay and even less gratitude for their professionalism and career commitment. We may have differences from time to time, but as in any meaningful friendship, an expression of honest disagreement is a sign of strength, not weakness in the relationship."

Broder noted "a cultural drift" involving the word "experimental." The term "may routinely be applied to therapies which offer patients their only realistic chance for survival. . . More recently, in an era of fiscal restraints, the word "experimental" becomes a code supporting the denial of therapies for which no insurance budget exists. The term may become an unintentional rationing device for a new therapy thereby restricting access to a limited number of patients. In so far as it is under our control, we need to ensure that new treat-

ments are made available to all segments of society in such a way that active but experimental therapies do not become the exclusive province of a privileged few."

Young agreed, and noted that insurers are increasingly saying, "unless a drug is approved by FDA, there will be no payment. Fifty percent of drugs in medical practice now are off label. That will mean efficacy supplements (submitted by sponsors for addiltional indications) will take on an entirely new life."

NCI To Fund 29 Percent Of Grants In FY 1990; Negotiations Necessary

NCI anticipates funding 29 percent of research project grants in fiscal 1990, or 3,085 grants, 18 fewer than those funded in the current year.

Of the grants funded, 822 will be competitive, and priority scores probably will be close to 150.

Although research project grants, including grants for AIDS research, received an increase of nearly $44 million in President Reagan's farewell budget, negotiations resulting in 10 percent reductions in budgets approved by review committees will be necessary for competing grants. Noncompeting grants will require 4 percent reductions.

Percentiles for RO1s will be about the same as in 1989, about 20 percent.

President Bush's budget amendments, presented to Congress last week, did not include any changes in funding for NCI.

The proposed budget for NCI is $1.646 billion, an increase of $74.5 million over the fiscal 1989 level, or 4.7 percent. However, the budget proposed consolidating AIDS money for all institutes with the office of the assistant secretary for health (**The Cancer Letter**, Jan. 13). In the past, Congress has rejected the move.

Of the increase, AIDS research received $28 million, while cancer got $46 million.

NCI received 32 additional full time equivalency positions, or FTEs, for AIDS activity in fiscal 1990, but lost 28 FTEs for cancer. The result was an overall increase of four FTEs.

NCI Director Samuel Broder, speaking to the National Cancer Advisory Board last week, noted that since fiscal 1984, NCI has lost 400 FTEs, a 20 percent reduction. During the same period, 148 FTEs for AIDS have been added.

The ceiling on the number of FTEs "has an impact on what kinds of activities we can do, and what kinds of programs we can administer," Broder said.

Broder gave the NCAB an outline of the tight budget and an update on how the current year's budget is shaping up.

Five months into fiscal 1989, little has changed, Broder said. NCI received an overall increase of $103 million, or 7 percent over 1988. Of the increase, $70 million is for cancer and $33 million is for AIDS research.

NCI estimates funding a total of 3,103 research project for the current year, about 80 more than were funded in 1988. The number of competing awarded funded fell by 250.

NCI is now developing a funding plan for the cancer centers program. "I think we can realistically expect there will be a phase out of several existing grants, and negotiations on remaining awards," Broder said.

Another area affected by tight budgets for the past few years is the National Research Service Awards program. The program is slated to receive a $1 million increase in the fiscal 1990 budget, but NCI stands to lose about 100 training slots for fiscal 1989, Broder said.

Congress has raised the stipend level of pre and postdoctorate fellows for fiscal 1989, but added no money to fund them. Predoctoral increases would range from $6,500 to $8,500 and the average increase for postdoctoral fellows would be about 10 percent.

This would require a loss of about 150 training slots, but NIH is proposing several possible actions to mitigate the loss. Among options under discussion are a freeze in tuition at the 1988 level and a slight reduction in the number of noncompeting institutional awards in order to fund additonal competing slots, which might come out to about 100 for NCI.

NIH also is requesting authority to redirect grant into the training grant area. For NCI, this would be about a $1.6 million proposed redirection from research project grants into training. For NCI, all of those actions would result in maintaining--at a higher stipend--about 1,383 trainees rather than 1,293 currently shown in the budget. This still represents a decrease of 73 positions.

Board Chairman David Korn said he was concerned about the loss of research training positions. "It's a national problem," he said.

Armand Hammer, chairman of the President's Cancer Panel, missed the NCAB meeting due to the flu, but asked board member William Longmire to read remarks he had prepared.

"The (President's Cancer) Panel is very concerned that recent budget increases for cancer research and training have not been sufficient even to sustain existing activities," Hammer wrote. "We must attack these problems head on."

Hammer said he hopes to present the Panel's report on the cancer centers program to Bush and his advisors in person. "At that time, I also hope to draw their attention to the bypass budget prepared by NCI, which, to my mind, makes a most compelling case for increased support for the National Cancer Program," Hammer said.

"Additionally, I plan to bring the report and the bypass budget to the attention of Congress. Since the Cancer Act gives NCI the special authority to prepare such a budget, I feel it should be brought to the attention of as many people as possible."

Hammer continued: "We are in danger of losing the momentum that has been built up with so much effort over the past several years. We are in danger of not being able to take advantage of the opportunities now before us. We are in danger of condemning many more thousands of Americans to the ravages of cancer."

Hammer said his effort to raise money for cancer research, called "Stop Cancer," has received $12.5 million to date. He said he hopes within a few months to secure matching funds from Congress, raising the total to $25 million. "Despite any criticism I may be subject to for the effort, I intend to pursue the campaign with all my energy and commitment," he said.

The Board also decided to try to bring the bypass budget to Bush's attention by sending a letter to the President. The letter, dated Feb. 7, described the work of NCI over the past several years, and the current funding difficulties.

"Although the Reagan Administration actively supported biomedical research and NCI, when the resources targeted for AIDS research are separated out, it becomes evident that the cancer program has experienced much more modest growth than might initially seem apparent," the Board wrote.

"While increasing resources have been allocated to NIH, including NCI, for basic science research, NCI has received only modest increases for other important research programs such as cancer treatment and prevention clinical trials....

"The bypass budget, not subject to change within (HHS), is intended to provide a realistic, but comprehensive, projection of the resources that could be wisely and productively spent to exploit scientific opportunities in the many different areas of cancer research and control....

"We believe that the bypass budget is an excellent blueprint, accurately describing the scientific activities necessary to exploit opportunities, maintain an aggressive cancer program and help accomplish our national goal to control cancer.

"In developing your budget program, we urge you to consider the accomplishments of the past nearly two decades and the solid basis they provide for the plans of the National Cancer Program as they are described in the 1990 bypass budget."

In his remarks to the NCAB, Broder noted that while half of the NCI budget supports investigator initiated research, other activities are important. He listed three such areas and promised that "they will remain high priority activities in the future."

<> The Cancer Centers Program. "We need to make sure we maintain excellence in both our basic centers and in our clinical/comprehensive centers," Broder said. "We need to ensure independence and diversity. But at the same time wee need to ensure that the centers program will remain a vital force for implementing certain national priorities. For example, I do not think we can undertake the surpassingly important task of rectifying excess cancer deaths in blacks without the participation of our centers program."

<> The Clinical Cooperative Group Program. "In an era of limited resources, it is important to keep in mind the enormous importance of this program to the overall mission of the institute." Broder said he was "proud" that CCOP was a model for a new mechanism set up by NIAID to support what is called the AIDS Therapy Evaluation Units.

<> Biotechnology industry relationships. "We have good working relationships with industry. We help train and maintain a crucial labor pool of new scientists. We transfer important technology to the private sector. It is my belief that we will continue to serve as a major force for technology transfer." Broder gave the example of NCI's supercomputer as a national resource for designing new drugs.

"Newer supercomputer technology will allow novel approaches to problems that are so complex that a scientist might not even attempt to solve them," Broder said.

DCPC Board Objects To NCI's Method Of Cutting Awards; Unique To NIH

NCI's method of cutting the budgets of RO1 and PO1 grants has drawn some protest from the Board of Scientific Counselors of the Div. of Cancer Prevention & Control.

Board member Mary-Claire King raised the issue at the last DCPC Board meeting.

King gave an example the way the budget cutting method works:

Suppose the recommended funding for a grant is $200,000 per year for five years. Because of the tight NCI budget, a 10 percent annual cut is taken. In the first year, the cut leaves an investigator with $180,000 per year for five years.

However, NCI's method makes cuts each year over the life of the grant. So if the 10 percent cut is taken every year for five years, the investigator is left with $118,000 in the fifth year--a 41 percent cut.

NCI does not actually take such large cuts, but the usual method is to take a 10 percent cut the first year, and then 2 percent cuts each year for four years. That results in a 17 percent cut for a five year grant. No other NIH institute uses this approach.

"I am concerned because there is no fixed limit on what cuts per year can be," King said. "As long as NCI takes cuts over the life of a plan, every time they take those cuts, we can be easily wiped out if NCI were under pressure in any one year or a couple of years in a row to make big cuts.

"What can the Board do to make a request that any one grant only be cut once?" King asked.

Board member Edward Bresnick said he supported King's concern. Because universities mandate salary increases for personnel, the cuts usually can only come out of the investigator's supply budget, he said.

"The main thing you are doing here is penalizing the person you least want to penalize, the person who was productive enough to get the five year grant," Bresnick said.

"The person who gets a three year grant can go back in year four. And I'm even more sorry for people who get a seven year grant," he said. "There must be a different way of doing business."

Bresnick and King suggested that any cuts be made "at the front end" of the grant, which would give investigators the ability to plan on the amount of money they will receive.

"There is a dilemma," DCPC Director Peter Greenwald said. "It is an issue of maintaining good grants and good investigators versus the level of funding."

NCI's budget for investigator initiated research--about $700 million--has increased slightly each year, but the number of "grant opportunities" has increased rapidly, Greenwald said.

He said the NCI Executive Committee "does look at these policies every year and goes over them with the National Cancer Advisory Board."

Greenwald said he would bring up the board's concern with the Executive Committee.

Public Participation Hearings Lead To Recommendations By NCAB

The National Cancer Advisory Board has developed recommendations to reduce cancer mortality by the Year 2000, NCI's stated goal, as the result of hearings held around the country during the past year and a half.

The report, "Public Participation Hearings: A Report to the Nation," is based on hearings held in Los Angeles, Atlanta, Dallas, Miami and Philadelphia. About 200 individuals gave testimony at the hearings.

Following are the report's recommendations:

<> Intensify the pressure and activity to eliminate smoking and tobacco use, creating a tobacco free society by the Year 2000.

To accomplish this, the NCAB recommends that Congress should reclassify tobacco as a drug subject to regulation by FDA. Smoking should be banned on all airline flights, public transportation, the workplace, schools and all public areas.

The movie, television and theater industries should eliminate on screen smoking. Smokeless tobacco should be subject to strictures similar to those imposed on cigarettes and should be the focus of preventive efforts by athletic groups, including major league baseball and football organizations.

Doctors should recommend that patients stop using tobacco and offer referrals and materials to assist them. Americans should support the efforts of the American Cancer Society, the American Heart Assn. and the American Lung Assn. to make the high school class of 2000 and all subsequent classes smoke free. The efforts of the Surgeon General and the American Medical Assn. also should be supported.

<> Increase the accessibility and affordability of appropriate cancer screening

and detection procedures, particularly for breast cancer, cervical cancer and colorectal cancer.

Mammography must be readily available to all women over age 40. Concerned citizen groups, voluntary cancer organizations, medical societies and cancer centers must press at the state level for laws requiring insurance coverage of mammography screening for women. To date, 12 states have passed such laws.

There should be pricing restraints to assure maximum use of the procedure. Private insurance companies should require that providers hold prices under $50, the screening cap set by Congress last year.

Employers should subsidize or finance through health insurance programs, low cost fully reimbursable mammography screening for employees.

Physicians should recommend that women over 40 get routine mammography screening. High quality screening should be more convenient and physically accessible. NCAB endorses mobile mammography units and recommends their use.

All women who are or who have been sexually active or have reached age 18 should have an annual Pap test and pelvic exam. After a woman has had three or more consecutive normal exams, the Pap test may be performed less frequently at her physician's discretion.

Tests for colorectal cancer must be included in periodic health examinations, particularly for anyone over age 50. NCAB recommends that physicians should provide a rectal exam as part of a routine physical. After age 50, annual fecal occult blood tests should be done, and a sigmoidoscopy performed every three to five years.

The usefulness of rectal exams, fecal occult blood testing and sigmoidoscopy in detecting colorectal cancer must be more aggressively communicated to patients who are at risk by physicians, health care providers and the media.

<> Improve the accessibility of cancer information, prevention and early detection techniques to special population groups for whom a combination of economic disadvantage and cultural factors impede access to the health care system. Such population groups include the poor, older Americans, blacks, Hispanics, Asian Americans and Native Americans.

NCAB recommends that voluntary organizations, community cancer centers and public health authorities open new avenues of dialogue through available institutions and media for communicating with special audiences. Social agencies should assist special populations in maximum effective use of existing public and private third party payment benefits for appropriate cancer screening procedures.

Political figures, celebrities and members of the medical profession with special influence among these populations should devote some of their time to promote positive messages about cancer prevention and early detection.

<> Expand active involvement of the private sector, specifically the employer, in cancer control through on site programs and incentives.

All employers should review carefully the health plans they offer to assure that the benefits of adequate coverage of cancer screening of all employees are fully realized.

All employees should receive health benefit cost incentives linked to their participation in cancer control activities and adoption of lifestyle changes, such as not smoking, that reduce cancer risk.

Employers should give strong emphasis to cancer prevention messages and activities, such as smoking bans and cessation programs, mobile or on site screening programs, or cafeterias with healthful, high fiber and low fat foods.

Employers whose products and services can be used for cancer prevention and early detection should seek new ways to associate their business interests with cancer communications and prevention programs.

In concert with their employers, nurses and physicians who work in industrial or business settings should plan cancer detection and prevention activities at the worksite.

<> Broaden the role of the mass media, professional and civic organizations and voluntary health organizations in cancer control, especially through greater education and information dissemination.

Outstanding local cancer communication initiatives need greater peer recognition and replication in communities nationally. Local or grass roots level programming and stories are most useful to disseminate information.

The American Cancer Society should be encouraged in its new initiative to address the needs of lower socioeconomic populations, while maintaining its excellent coverage of the general population with cancer prevention and

early detection messages and programs.

NCI should intensify its initiatives to reach special populations and the general public, as should voluntary agencies and the cancer communities.

Specific efforts must be made to encourage more nonhealth related voluntary and civic groups to endorse and sponsor cancer control projects.

Experts in cancer prevention and control and cancer survivors for whom early detection made a critical difference must receive special communication training and encouragement to discuss cancer prevention with the public.

Local and national media efforts to communicate messages about cancer prevention and early detection, through news coverage, community relations, celebrity spokesmen and public service advertising, must increase.

NCI and cancer centers responsible for operating the Cancer Information Service and 1/800/4-CANCER hotline must promote this service frequently and aggressively.

<> Encourage the active participation of the schools in cancer prevention and early detection.

NCAB recommends that the combination of motivational programs such as the "Smoke Free Class of 200" and curricular innovations such as "Know Your Body" merit the widest possible adoption in local elementary schools. Such efforts also should be designed for secondary schools and colleges. Specific curriculum content about healthful dietary practices and school cafeteria management practices regarding the fat and fiber content of school lunches must take into better account the nutritional guidelines of the major cancer organizations, including NCI, the American Cancer Society and the National Heart, Lung and Blood Institute and the Surgeon General.

Schools should not provide any smoking areas or areas for the use of smokeless tobacco.

<> Enhance the involvement of state and local government in cancer prevention and screening, and appropriate control of environmental risk factors.

State governments should take advantage of the models being provided by such states as New Jersey, Texas and Florida to assist in the federal effort to combat cancer. City and county governments must make major contributions to cancer prevention and screening by understanding the dimensions of the cancer problem in their areas and by mounting special control programs to meet the

Bills To Prohibit Smoking In Aircraft, Federal Buildings, Introduced In House

Democrats in Congress have introduced new antismoking legislation, including bills further restricting smoking on airline flights, ending expense deductions for tobacco advertising and increasing excise taxes on cigarettes and smokeless tobacco.

HR 160, by Rep. Richard Durbin (D-IL). Makes permanent the prohibition against smoking on scheduled flights of two hours or less in duration.

HR 561, by Rep. Robert Torricelli (D-NJ). Prohibits smoking on all domestic commercial aircraft flights. HR 598, by Rep. James Oberstar (D-MN), does the same.

HR 817, by Rep. James Scheuer (D-NY). Make permanent the prohibition against smoking on domestic flights of two hours or less and would extend this prohibition to all flights.

HR 818, by Scheuer. Restricts smoking to designated areas in all federal government buildings or building sections.

HR 412, by Rep. Weiss. Disallows tax deductions for advertising or promotion expenses for sales of tobacco products unless the taxpayer pays for a certain amount of advertising on the health effects of smoking.

House Resolution 34, by Weiss, expressing the sense of the House that the federal government should encourage both electronic and print media to air or print more antismoking advertisements as a public service.

HR 665, by Rep. Chester Atkins (D-MA). Requires that grants provided under the Drug Free Schools & Communities Act of 1986 be used to provide education relating to the use of tobacco products, and to prohibit the sale of cigarettes to minors.

HR 293, by Rep. Joe Moakley (D-MA). Directs the secretary of HHS to promulgate fire safety standards for cigarettes. S17, by Sen. Alan Cranston (D-CA), does the same.

HR 673, by Rep. Frederick Boucher (D-VA). Implementae recommendations of the Interagency Committee and the Technical Study Group on cigarette and cigar Fire Safety.

HR 154, by Rep. Brian Donnelly (D-MA), would increase the federal excise tax on smokeless tobacco.

HR 230, by Rep. Andrew Jacobs (D-IN), would increase to 32 cents per pack the federal excise tax on cigarettes and provide that the revenues shall be deposited in the Federal Hospital Insurance Trust Fund.