Perspectives
on current developments

The FTC and Children's Advertising

On April 27, the Federal Trade Commission presented in the *Federal Register* a number of alternative proposals for restricting television advertising directed at children. Rulemaking proceedings had been recommended by the FTC staff in a 346-page report prepared in response to two separate petitions—one from Action for Children's Television, which sought a ban on televised candy advertising aimed at children, and the other from the Center for Science in the Public Interest, which sought a ban on such advertising of high-sugar snacks.

The FTC staff argues that the present advertising aimed at young children is unfair and deceptive within the meaning of Section 5 of the Federal Trade Commission Act (which directs the FTC to prevent "unfair methods of competition"). The staff recommends that the commission consider three actions: (1) ban all television advertising aimed at young children (under the age of eight), (2) ban television advertising of the products most likely to cause tooth decay when the advertising is aimed at older children (eight to twelve years of age) and (3) require that television advertising of other sugared products aimed at older children be offset by messages on nutrition and dental care paid for by the advertisers of the sugared products.

Along with these staff recommendations, the commissioners proposed for consideration four less severe restrictions. These would require advertisers to (1) include affirmative disclosures in advertisements for products most likely to cause tooth decay; (2) air separate ads containing affirmative disclosures and nutritional information, funded by advertisers of high-sugar products; (3) limit the use of certain advertising techniques or messages for either high-sugar products or for all products aimed at very young children; and (4) limit the number and frequency of high-sugar product ads aimed at all children, and of all ads aimed at very young children.

Several commissioners have expressed concern over a number of unresolved legal, economic, health, and social issues. As for the legal issues, there is, first, the question whether injury to children because of the advertising would be serious enough to merit a ban under the current interpretation of the First Amendment. The FTC staff argues that the effects of advertising highly sugared foods to children parallel the effects of cigarette advertising (which the commission banned in 1964) in that, while one advertisement might not be injurious enough to be banned, the cumulative effect of many advertisements does merit the ban. However, in the rule against cigarette advertising, the commission itself stated that cigarette advertising differed from advertisements for candy and rich foods because cigarettes, unlike candy, are harmful even when consumed in small amounts.

The staff also argues that advertising considered fair when aimed at adults can be unfair when aimed at children—unfair since it can induce children to take health risks that they are unable to evaluate properly. The staff notes that the Supreme Court has in the past accepted a very broad definition of unfairness where children are involved, because of children's naiveté and vulnerability. On the other hand, the Supreme Court recently ruled, in *Carey* v. *Population Services International* (1977), that commercial speech enjoys some protection under the First Amendment, even when minors are involved. At issue here is whether that protection is sufficient to prevent the proposed advertising restrictions.

A more pragmatic problem involves the difficulty of targeting an advertising ban to specific age groups of children. For example, young children rarely, if ever, constitute a majority

of the audience for any television program. As a result, a ban imposed on ads intended for this group could be interpreted so that either it would apply only to a trivial amount of advertising or it would have the effect of prohibiting advertising also directed to a majority of viewers—older children—in order to protect what would generally be a small minority of the viewing audience.

As for economic issues, one consequence of a ban or strict limitation on the number and frequency of television advertisements directed to young children would be a decline in revenue for children's television programming. Unless the networks were given economic incentives to maintain programs that could no longer attract their previous advertisers, the resulting loss to viewers might more than offset the benefits from the absence of advertising during the programs.

One health issue suggested by the proposals arises from the fact that the sugar content of a food is only one of several factors that contribute to tooth decay. The relative percentage of sugar in a food product may be less important as a cause of tooth decay than the frequency or circumstances of consumption (with a meal or as a snack, with or without liquids, and so on). If this is the case, focusing on percentages of sugar content may be misleading.

There is also the broader, social question of how children's television advertising affects parent-child relationships. According to the FTC staff, the advertising turns children into persistent naggers, undermines parental authority, and encourages confrontations between parents and children. But a study done for the National Science Foundation has found that children's requests for products, in addition to being a source of conflict, can be an opportunity for parents to teach their children about good eating habits.

Related to this controversy is a fundamental question: who should be responsible for protecting children from any harmful effects of television advertising—parents, broadcasters, or the government? The FTC staff, in arguing for government's responsibility, states that many parents object to children's advertising but are reluctant to take the "drastic" step of turning off the television set. Advertisers argue that if parents really believed there was anything seriously wrong with the advertising they would not permit their children to watch it. And the National Association of Broadcasters claims that the proposed rule is unnecessary since the existing NAB television code is a "viable mechanism" for setting and maintaining standards for advertisements.

Issues in the CFTC's Sunset Review

In 1974 Congress created the Commodity Futures Trading Commission and gave it exclusive jurisdiction over the regulation of all trading in "futures" and commodity "options." Before that time the Department of Agriculture regulated agricultural futures, while the Securities and Exchange Commission and the states sometimes asserted jurisdiction over trading in non-agricultural futures and in certain kinds of options.

Simply put, "futures" are contracts to buy or sell a commodity for a set price at a specific time in the future. A farmer, for example, might insure against the possibility that the price of wheat will fall by contracting now to sell at a specific price later on. "Options," on the other hand, are contracts that give the purchaser the right—but not the obligation—to buy ("call") or sell ("put") a commodity at a specific price up to a particular date in the future. The holder of an option to buy, for example, will usually decide to exercise the option if the market price of the commodity rises above the price specified in the option at any time prior to the expiration date.

The principal reason why Congress gave the CFTC exclusive jurisdiction over the regulation of futures and commodity options was to avoid the uncertainties and other costs arising from contradictory and duplicative regulation and from diffused jurisdiction. Another reason was the SEC's reluctance to allow futures trading in unconventional commodities (meaning, primarily, financial instruments). In 1972, the Federal Home Loan Bank Board had sought SEC approval to establish a futures market in home mortgages. After a cool reception from the SEC, the board supported the creation of the CFTC and its being given exclusive jurisdiction over the trading of mortgage futures, in-

cluding futures on Government National Mortgage Association (GNMA) securities. Under CFTC authority, the trading of GNMA futures began on the Chicago Board of Trade in October 1975 (over the objections of the SEC).

Recently, the CFTC's exclusive jurisdiction has been the subject of much debate, focussed by the current congressional "sunset" review of the agency. This review, the first of its kind for any federal regulatory agency, is taking place under the provisions of the Commodity Exchange Act (as amended) and is designed to determine whether the commission's funding should be continued past "sunset date"—September 30, 1978. In a February 7, 1978, memo responding to General Accounting Office inquiries about commodity regulation, the SEC requested that Congress transfer the regulation of financial futures to the SEC and said it was willing to absorb all of the CFTC's responsibilities if need be. Shortly thereafter, the Treasury Department, concerned about the impact of futures trading on the issuance and subsequent trading of the underlying U.S. government securities, requested joint jurisdiction with the CFTC over futures markets in those securities. Finally, several states have asked Congress to amend the CFTC's statute so as to give state securities commissioners some role in regulating commodity transactions.

The CFTC's position on the issue of exclusive jurisdiction is that it regulates a unique "form of trading," regardless of the object being traded (agricultural commodities, Treasury bills, or whatever). While government agencies that regulate the market in the actual commodity or that "produce" the commodity (as in the case of government securities) may be concerned about trading in futures and options, it is more efficient—in the CFTC's view—to have that trading regulated by a single agency. In addition, exclusive jurisdiction does not and should not preclude consultation and cooperation with other agencies. Consistent with this view, the CFTC argues that the role of the states be limited to policing fraud.

Closely related to the issue of exclusive jurisdiction is the issue of where the power should be lodged—in an independent regulatory agency or in the executive branch. The Office of Management and Budget recommends sub-cabinet status within the executive branch, much like that possessed by the Environmental Protection Agency. One part of the futures industry advocates returning the regulation of futures to the Department of Agriculture, where it rested before the creation of the CFTC. However, this just revives the old question that contributed to the creation of the CFTC: are the objectives of agricultural futures regulation compatible with programs designed to influence the levels of agricultural prices? A similar difficulty exists on the question whether the Treasury Department should oversee futures and options trading in government securities.

Much of the futures industry is in favor of continuing the independent and exclusive status of the CFTC, at least until more experience can be gained. The General Accounting Office also took this position in a February 22 statement to Congress, but reversed itself on the jurisdictional question in a report of April 5 when it supported transferring some authority (including the authority to regulate trading in futures contracts on stocks and corporate bonds) to the SEC. Nonetheless, in view of the rapid growth of futures markets that has accompanied the CFTC's stewardship of this industry and the agency's relatively short history, gaining more experience under the present regulatory regime is arguably the most prudent course of action.

Protecting the Environments of Other Nations

Should our concern for the environment end at our shores or should it extend beyond them? And if the latter, to what extent should we regulate U.S. commerce in an attempt to preserve the environment outside of the United States? These are among the major questions at issue in a proposal by the Council on Environmental Quality to require federal agencies to state publicly the environmental impact of their overseas activities.

Under the CEQ's proposal, agencies would have to provide conventional environmental impact statements (EISs) for intended actions having a significant environmental impact on (1) the United States and its trust territories, (2) the "global commons" outside the jurisdiction of any nation (oceans, for example) and (3) Antarctica. Where an action might affect

the environment of one or more foreign nations, the agency would be obliged to prepare a new foreign environmental statement (FES) which, under certain conditions, need not be as thorough in scope and detail as the more common EIS. FESs would be required, for example, with applications for an export license for Tris-treated children's sleepwear, now banned in the United States, and for a construction loan by the Export-Import Bank for a proposed petrochemical plant that could cause pollution across national borders.

The new proposal is based on CEQ's view that the National Environmental Policy Act (which CEQ administers) does not limit the geographical region to which its provisions apply. Section 102 (2)(c), on which the current requirement for EISs is based, states:

> The Congress . . . directs that to the fullest extent possible . . . all agencies of the Federal government shall . . . include in . . . major Federal actions significantly affecting the quality of the human environment, a detailed statement . . . on the environmental impact of the proposed action. . . .

A legal memorandum released to agency heads in late 1976 by then CEQ Chairman Russell W. Peterson quoted statements from members of Congress, congressional hearings, and court cases in support of his conclusion that Congress intended the act to cover environmental impact beyond U.S. borders.

Until last summer, CEQ was able to do no more than issue guidelines, and some agencies complied. For example, the Agency for International Development prepared an EIS for its worldwide pesticide program, and the National Oceanic and Atmospheric Administration prepared one for its hurricane-seeding program. Other agencies, however, did not respond so well. To deal with this inconsistency and other problems, President Carter issued an executive order on May 24, 1977, requiring CEQ to establish uniform regulations on the preparation of all EISs by the federal government.

CEQ responded to this directive by unveiling on January 6, 1978, a draft regulation that would apply the requirement for EISs to overseas activities. The draft was supported by the Environmental Protection Agency, the National Oceanic and Atmospheric Administration, and the Agency for International Development, but was strongly opposed by the Departments of State, Treasury, Commerce, and Defense, as well as the Export-Import Bank and the Nuclear Regulatory Commission (now part of the Department of Energy). Opponents did not question the goal of limiting environmental degradation, but feared the requirement for FESs might unduly restrain the implementation of government programs abroad. They argued that these programs should be governed by overall foreign policy rather than by a strict interpretation of the National Environmental Policy Act. Also, some worried that vital commercial and national security secrets would become public, while others objected that the regulations might embarrass foreign governments and interfere with their sovereignty.

Reacting to the furor, CEQ has since emphasized that the "unusual and exceptional circumstances" involved in federal agency activities abroad are reflected in the proposed regulation. The council points out that agency procedures for FESs would take into account such special factors as diplomatic considerations, availability of information, commercial confidentiality, and the extent of the agency's role in the proposed activity. CEQ Chairman Charles Warren stresses that the FES requirement would not impose U.S. environmental standards on other countries, but would merely clarify the environmental effects of actions taken by U.S. agencies.

U.S. commercial activity, however, could be affected, although apparently no one in government, including the CEQ, now knows to what extent. Exports may be a case in point. Excluding military sales and economic grants-in-aid, the Commerce Department estimates that the total volume of U.S. exports last year was nearly $120 billion. Consider the U.S. nuclear reactor industry, which estimates potential export business at $25 billion over the next five years. Late in 1975, the United States Export-Import Bank approved $644 million in loans and loan guarantees—the largest financing package in its history—to the government of the Philippines to help purchase a $1.1 billion nuclear reactor from the Westinghouse Electric Corporation. If future financing packages are of similar size, the bank might find itself writing FESs on loans for roughly $13 billion for nuclear reactor exports alone over the next five years. While CEQ claims that relatively few FESs would be required and that less

than ten federal agencies would be writing them, it should be noted that more than 1,100 federal EISs are now being prepared each year, mainly by seventeen agencies. So, many government officials remain skeptical, with one Department of Commerce official seeing "acres of paperwork ahead and nothing but delays."

Many members of Congress and congressional staff aides have also voiced concern. Whether bills will be proposed to modify the FES requirement will depend on the final form the regulation takes. But there would appear to be little hurry: Although CEQ asked federal agencies to submit written comments on its draft as soon as possible, only a few had been received as of the end of April. Written comments are normally taken into account before a proposed regulation is published in the *Federal Register.*

Aqua Slide 'N' Dive: The CPSC and the Court

The provisions of the Consumer Product Safety Act of 1972 embody many unusual, frequently criticized concepts of administrative law and procedure. One of these requires the Consumer Product Safety Commission to base its mandatory safety standards on "substantial evidence" rather than on the more conventional rule that agency regulations not be "arbitrary or capricious." Another provision directs the commission to consider the costs to consumers when deciding whether a product presents an "unreasonable" risk of injury and whether a mandatory safety requirement is "reasonably necessary" to reduce that risk.

In its March 3 decision in *Aqua Slide 'N' Dive* v. *Consumer Product Safety Commission,* the U.S. Court of Appeals for the Fifth Circuit overturned a CPSC product safety standard for swimming pool slides. The standard in question would have required manufacturers (1) to put labels on new slides warning swimmers against the risks of improper use and (2) to equip the slides with ladder chains or other suitable barriers to discourage children from using the taller slides intended for installation near deep water. The court ruled that the CPSC did not have "substantial evidence" for concluding that these requirements were "reasonably necessary."

The court accepted the CPSC's finding that the potential injuries from improper slide use —paralysis and drowning—are severe, while noting, however, that the paralysis risk is remote. Conceding that these risks might nonetheless be a sufficient basis for CPSC regulation, the court then looked into the evidence that the challenged regulations would reduce these risks. On this issue, it found against the commission, faulting it for not testing the efficacy of its requirement: the labels might be ignored and—in combination with other provisions of the standard—might encourage installation of slides near deeper water, thus increasing the risk of drownings. The court also reviewed the available injury information and suggested that the standard would not have averted previous known accidents. Finally it rejected the claim that expert judgment—the CPSC had relied on this rather than on "substantial evidence"—justified the commission's prediction that the labels would benefit swimmers by modifying their behavior.

Aqua Slide 'N' Dive also faulted commission estimates of the regulation's costs to consumers. Under the court's reading of the Consumer Product Safety Act, the consumer costs that the CPSC must consider are "increases in price, decreased availability of a product, and reductions in product usefulness." While not disagreeing with the commission's estimate that the immediate regulatory costs (of affixing labels and installing ladder chains) would be nominal, the court found that the agency had dealt inadequately with the "costs" of sales that would be lost if potential slide customers reacted strongly to the warnings placed on the labels. This type of regulatory "cost" (that is, lost sales resulting from providing consumers with information about product risks) is relevant, the court said, because the act requires consideration of "decreased availability of a product." Here the court's interpretation is doubtful, since consumer welfare is generally believed to be enhanced rather than impaired when purchasing decisions are based on material and truthful information about products. The court's treatment of this question is muddied, however, by its skepticism that the information would be material (the court implied that swimmers, if not potential slide purchasers, might ignore it) and truthful (the court implied that it might be misinterpreted).

The court also rejected the ladder chain requirement, holding that the CPSC lacked substantial evidence that it would deter children from using tall slides placed in shallow water.

Although *Aqua Slide 'N' Dive* leaves unanswered many questions about the commission's authority, it gives important meaning to the "substantial evidence" and "reasonableness" requirements of the CPSC law. In particular, the court stressed the desirability (if not the necessity) of actually testing the effects of proposed standards on consumer behavior before the standards are promulgated.

Revamping the Civil Service

In keeping with a campaign commitment, President Carter proposes sweeping changes in some of the most troublesome areas of the civil service system. Carrying out the reforms will take both executive action and new legislation.

Acting under existing reorganization authority, the President would replace the Civil Service Commission with three new agencies: an Office of Personnel Management, a Merit Systems Protection Board, and a Federal Labor Relations Authority. The Office of Personnel Management would be in charge of staffing, personnel investigations, and executive development throughout the federal government. It would report to the President much in the manner that the Office of Management and Budget now does, and could delegate certain of its functions to the heads of federal agencies. The Merit Systems Protection Board would hear and decide appeals and complaints of federal employees and job applicants. The board's special counsel could investigate and prosecute alleged political abuses and merit system violations. The Federal Labor Relations Authority would oversee federal labor-management relations and investigate alleged unfair labor practices within federal agencies and departments.

As for the needed legislation, the proposed Civil Service Reform Act of 1978 (S. 2640 and H.R. 11280) would represent a truly radical departure from existing civil service practice. One of its most controversial provisions would eliminate the preference in hiring now given

"This could be trouble—get those desks into a circle. . . !"

to veterans. This preference has been alleged to produce discrimination against women since most veterans are men.

Another controversial provision would change pay procedures for almost all government managers. The current practice of linking salary levels and automatic pay increases to service time for "middle-management" grades (GS-13 to GS-15) would be eliminated. Instead, these managers would receive merit pay increases based on performance and given at the discretion of supervisors (within the ranges permitted for each grade). Federal managers at the GS-16 level and above would be grouped into a Senior Executive Service. These senior executives could earn bonuses based on performance, but would be subject to the risk of being removed for nonperformance.

There are, it should be said, some identifiable problems with the civil service that President Carter's proposal does not address. For example, it would do little to speed up the hiring process which, because of the number of steps required, often takes up to six months. Moreover, the current system relies heavily on written descriptions of applicant qualifications for screening purposes. The screening process used selects potential interviewees from the civil service "pool" by matching the written qualifications of applicants with a generalized description of the particular job opening. But if either the written qualifications or the job descriptions are too broadly defined, many who appear for interviews will not possess the specific skills needed by the requesting agency.

Nevertheless, the President's proposal goes a long way toward coming to grips with the need to make the federal civil service more efficient and more responsive. Partially because it represents such a strong break with tradition, the proposed legislation has run into opposition from representatives of government workers and from those concerned about "politicizing" the federal bureaucracy.

Blood and the Visible Hand

Traditionally the collection and distribution of human blood in this country have been regulated, and now are becoming even more so—mainly because of the implementation of the Department of Health, Education, and Welfare's National Blood Policy. This policy seeks four principal, relatively uncontroversial goals: (a) an adequate blood supply, (b) the highest standards of blood transfusion therapy, (c) accessibility based on "need" rather than economic status, and (d) efficient collection, processing, and utilization. But the major operational goal of the policy—to improve blood quality by relying solely on volunteer donors—has many critics.

HEW established its National Blood Policy in 1973 following the discovery that, *on average,* blood obtained from volunteer donors (usually from higher socioeconomic classes) presented a lower risk of post-transfusion hepatitis than blood obtained from paid donors (at the extreme, derelicts frequenting blood collection shops located in rundown neighborhoods). Even the most sophisticated testing procedures eliminate only about half of the hepatitis-infected blood. Thus the chances of getting the disease—and dying from it—are approximately three times as great, on average, if paid blood is used in a transfusion than if the blood used is from volunteer donors. (Paid blood now accounts for approximately 7 percent of the national blood supply.)

In November 1975, the Food and Drug Administration (part of HEW) proposed that containers of whole blood and red blood cells be labeled (1) to indicate whether the contents came from volunteer donors or paid donors and, (2) in the case of paid-donor blood, to warn of the higher risk of hepatitis. Because the initial notice failed to define a "paid donor," a subsequent notice (February 1976) requested suggestions for definitions. A third notice (February 1977) and a final notice (January 1978) extended the regulation to all blood components intended for transfusion, including cryoprecipated antihemophilic factor, platelet concentrate, and single-donor plasma. However, after numerous blood banks (one being the Mayo Clinic's) demonstrated that their paid blood was safer than volunteer blood, the FDA withdrew the requirement for the hepatitis warning. Now all that is required is that the blood units be labeled "paid" or "volunteer."

The FDA's labeling regulations, as well as the National Blood Policy goal of eliminating paid blood, have drawn criticisms from the General Accounting Office, the Council on Wage and Price Stability, many blood bankers,

and some economists. While conceding that the elimination of paid blood would increase the average quality of the blood supply, many have argued that there would also be higher recruitment costs, lessened competition within blood banking, and possible shortages of blood (especially during such periods of short supply as summers and holiday seasons). Many argue also that the reason blood quality is not as high as it should be is that hospitals, blood banks, and physicians are usually exempt from the implied warranty provisions applying to other commodities. Since the exemption reduces their incentive to use high quality blood (from any source), the solution, it is argued, is to make these groups liable for suit if they fail to make a reasonable effort to secure high-quality blood.

A recent action by the Board of Directors of the American Blood Commission—a group encouraged and partially subsidized by HEW to aid it in implementing the National Blood Policy—underscores the need to address the blood quality issue in a careful, analytical manner. Last December the ABC board voted to adopt a policy of eliminating the fee charged to patients who were not part of a blood assurance program or could not get friends or relatives to "replace" the blood they had used. This decision, if not modified by the commission's membership, could lead to the elimination not only of the "nonreplacement fee," but also of all the blood assurance or insurance programs in which individuals periodically donate a unit of blood in order to "insure" themselves and members of their families against paying the nonreplacement fee should they need blood transfusions in the future. The result might be significant shortages since blood collected under these incentive programs currently accounts for approximately 40 percent of the national blood supply.

During the past four years, there has been a clearly discernible trend toward replacing economic incentives with social incentives and altruism as motivating factors in procuring whole blood and red blood cells. And this trend may continue to generate new regulatory proposals. The next target, according to some observers, will be to replace economic incentives in the plasma fractionation sector of the market, which is now entirely commercial. Unless altruism incentives prove to be sufficient, there could be serious complications for those throughout the world who depend on the U.S. plasma fractionation industry for important medical products.

Revising the Drug Law—A Case of Give and Take?

Present law requires not only that a new drug be proven safe before it can be sold, but also (since 1962) that it be proven to work. This situation has been offered as a major reason this country lags behind others in the development and availability of new drugs. Specifically, critics attribute much of the lag to the Food and Drug Administration's focus on a drug's premarketing performance, a focus that stems, they claim, from the fact that the agency has nearly absolute control over a drug's fate before approving it for market but little control thereafter. Once a drug comes to market, physicians can legally prescribe it for uses for which it has not been approved by the FDA, and the FDA's authority to remove the drug from the market is limited, even when unanticipated side-effects appear. Consequently, some say, the FDA takes an extremely cautious approach in approving a new drug.

Dissatisfaction with the FDA's approach has been mounting. In March, Senator Edward Kennedy (Democrat, Massachusetts), along with Senators Jacob Javits (Republican, New York), Gaylord Nelson (Democrat, Wisconsin), Harrison Williams (Democrat, New Jersey), and Thomas Eagleton (Democrat, Missouri), introduced the proposed Drug Regulation Reform Act of 1978 (S. 2755). In the House, Congressman Paul Rogers (Democrat, Florida) introduced an identical bill (H.R. 11611). These bills, which were developed in consultation with the Department of Health, Education, and Welfare and FDA staff, are supported by the Carter administration.

S. 2755 is innovative and controversial. One section would relax existing drug regulation by permitting the FDA to give provisional approval to new drugs even when safety and efficacy testing was not complete. The intent is to allow earlier marketing of drugs that the FDA determines to be highly promising compared to alternative therapies. Another section would

tighten regulation by authorizing the FDA to require post-marketing surveillance of clinical tests conducted after a drug had been marketed and by making it easier for the FDA to suspend the sale of drugs. A third section would attempt to make the drug approval process more open, through public hearings and through the release of laboratory and clinical test data on the drug (data now considered to be "trade secrets").

While many in the drug industry think the existing law needs revising, they view S. 2755 with considerable alarm. Their fear is that it would expand the FDA's authority, make regulation more burdensome, and further reduce incentives for developing new drugs. A major concern with the proposed legislation is how it would be implemented. If the FDA (specifically, in this instance, its medical examiners) did not make good use of its new power to expedite the approval process but fully exercised its new authority over approved drugs, the result would be just one more layer of costly regulation.

Another concern is that the release of laboratory and clinical test data ("trade secrets") might allow foreign companies to get a head start in marketing new drugs abroad without having had to do the research and development themselves. Domestic producers argue that if this should occur, U.S. companies would lose part of their foreign markets for new drugs and, as a result, would have less incentive to invest in research and development.

An alternative approach, the proposed Medical Freedom of Choice Act (H.R. 54), is offered by Representative Steven Symms (Republican, Idaho) and approximately 130 cosponsors. That bill would simply revoke the FDA's authority to require the testing of drugs for efficacy, thus limiting the agency's role to ensuring only that drugs were safe. Supporters of this proposal maintain that fewer restrictions on the marketing of new drugs would lead to safer and more effective drugs for both physicians and consumers. Unsafe drugs would not be allowed on the market, and market competition would eliminate those drugs that were less effective. On the other hand, FDA Commissioner Donald Kennedy argues that, if the efficacy requirement were repealed, some unscrupulous firms would market useless drugs.

Bermuda II: A Footnote

Bermuda II, the air services agreement between the United States and the United Kingdom signed in July 1977, requires the airlines of the two countries to take into consideration the interests of their competitors "so as not to affect unduly that airline's or those airlines' services. . . ." This obligation on an airline to pull its punches in competing on U.S.-U.K. routes was criticized by John Barnum in "Carter Administration Stumbles at Bermuda," January/February issue of *Regulation*. In that article, Barnum questioned the propriety of bilateral provisions that are inconsistent with U.S. antitrust laws, particularly in light of the lack of statutory authority to execute bilateral air transport agreements in the first place.

Recent developments indicate that our international aviation negotiators have recognized—and may even have solved—the problem.

In the protocol to the air transport agreement between the United States and the Netherlands negotiated and signed in March 1978, the requirement that *airlines* not compete aggressively was deleted. Instead, the United States agreed with the Dutch that the two *governments* "shall take into consideration the interests of the other Contracting Party in its designated airlines so as not to affect unduly the opportunity for the airlines of each Party to offer the services covered by the Agreement and this Protocol." Similarly, the amendment to Bermuda II pertaining to charter air service, signed a week later, requires each *government* to "take into consideration the interests of the airlines of the other." Moreover, since this language is not expressly limited to charter air service, it could be treated as an amendment to, or at least as superseding, the more anticompetitive language in Article II of the original Bermuda II agreement.

These changes appear to reflect a recognition that it is one thing for friendly governments to agree to treat the other country's airlines fairly, but that it is undesirable—and may be a violation of U.S. antitrust laws—for our government to impose by executive agreement constraints on the competitiveness of airlines short of predatory practices or unfair competition.