Letters

We welcome letters from readers, particularly commentaries that reflect upon or take issue with material we have published. The writer's name, affiliation, address, and telephone number should be included. Because of space limitations, letters are subject to abridgment.

Synthetic Fuels

TO THE EDITOR:

The article by my colleagues Paul Joskow and Robert Pindyck, "Synthetic Fuels—Should the Government Subsidize Nonconventional Energy Supplies?" (your September/October issue), is a lucid presentation that supports the decontrol of prices of conventional energy supplies. However, it implicitly assumes that this action will satisfactorily resolve the energy shortage that will face the United States and its allies for at least the rest of this century. The Carter administration supports phased decontrol of domestic oil prices to stimulate supply and moderate demand. But we do not believe that decontrol alone can adequately reduce dependence on foreign oil. Decontrol must be accompanied by increased emphasis on energy conservation (still the quickest and most cost-effective means to reduce oil imports), on coal conversion, and on synthetic fuel production.

Professors Joskow and Pindyck do not place the administration's proposed synthetic fuel program in the proper context of our overall import-reduction program, which is motivated both by expected economic benefits and by security considerations. Nor do they provide an accurate report on our proposed Energy Security Corporation. Finally, their article reflects one-dimensional economic thinking by not recognizing the practical and technical requirements for developing a synthetic fuels industry.

The President's proposal for the Energy Security Corporation, contrary to this article, (1) does not call for direct subsidy (except in special and limited circumstances for GO/CO plant construction) but rather stresses price and purchase guarantees in a manner similar but not identical to the "second best" policy mentioned by the authors, (2) permits decision making under conditions as close as possible to those in the private sector in order to avoid the danger of government management, and (3) has a more limited scope (only synfuels, not solar or wind), size ($88 billion at the maximum, not $100 billion), and duration than is suggested.

The reasons for undertaking such an effort now are also not adequately treated. A demonstrated capacity to produce synthetic fuels may provide an important backstop to OPEC price increases and at a level below the effective cost of the marginal barrel of imported oil. A reduction of 2 or 3 million barrels per day of imports will significantly influence the OPEC price. We believe such import reduction will dampen OPEC prices and thus should be pursued through a synthetic fuels program as well as other measures such as coal conversion and, most importantly, conservation. Also, the authors rather uncritically accept the cost of the alternative they appear to prefer—continued dependence on imported oil and, along with that, massive uncertainty about future price and the availability of supplies. Finally, the authors do not recognize the importance of time. The central purpose of the administration's program is to bring about the commercial production of synthetic fuels sooner than would be likely without government support: the private sector cannot be expected to make investments that protect the nation in a manner that goes beyond the corporate balance sheet.

Perhaps the most serious flaw in this article is its lack of appreciation for the technology requirements of synthetic fuel production. Joskow and Pindyck claim that fundamental technological advances are not required (wrong), that the cost of synfuels will be twice that of conventional fuels (maybe true when the article was written, but not anymore), that government subsidies for industrialization and commercialization of alternative energy technologies are not justified (wrong for solar and nuclear, as well as for synthetic fuels), and that "most new energy technologies that are candidates for huge subsidies are well understood" (wrong).

The synfuels program and other energy development efforts supported by the President amount to an insurance program that would give the United States the needed supply options—that would encourage development of alternative energy supply technologies by sharing both the cost and the risk in the development and initial commercial deployment. A large part of the funds in the recommended programs may not actually be spent because they will be used to back up various price or loan guarantees. The fact remains, however, that major incentive programs are an appropriate response to our energy problems.

John M. Deutch,
Under Secretary,
Department of Energy

TO THE EDITOR:

Professors Joskow and Pindyck mention that the synthetic fuels program would involve tax incentives, loan guarantees, as well as financial assistance to demonstration plants, and they offer arguments against all of these forms of incentives or "subsidies." Yet, they do not note that the rest of the energy industry is highly subsidized, or deal with the full range of the incentives that the federal government offers the industry.

At Battelle's Pacific Northwest Division, an ongoing program has examined federal incentives to all forms of energy production. We have found that, during the years 1950–1976, the federal government spent some $117 billion to stimulate conventional energy industries. These expenditures provided incentives of seven types, three of which Joskow and Pindyck argue against for synfuels. Our seven are: (1) disbursements (straight subsidies), (2) services (provision of roads and waterways, demonstration plants, R&D and commercialization programs), (3) reorganization (the creation or prohibition of organizations), (4) exhortation (voluntary action programs, publicity, and jawboning), (5) market activities (en-

ergy purchases or sales loan guarantees), (6) taxation, and (7) requirements (such as price controls). In 1978 the federal government allocated $13.719 billion to these types of incentives for the energy industry. . . .

These research results have several implications for Joskow and Pindyck's arguments. In an ideal world, in which markets operate without the infusion of outside incentives, the elimination of price controls might be sufficient to stimulate energy production and conservation. However, given past market imperfections, decontrol is not sufficient to guarantee adequate production and conservation. Some form of the market activity incentive is needed. Our data suggest that government proposals to promote conservation or to buy some quantity of new fuel produced could be accommodated within the range of present energy policies.

In addition, an argument based on historical equity can be made for granting other forms of incentives to alternative means of production and conservation. Lacking such incentives, new forms of energy production may never be able to compete on an equal basis, and the nation will lack the range of fuel sources that it needs. Currently, services—such as the financing of demonstration plants—are the second most costly governmental energy incentive. In the absence of subsidies, the development of alternative energy forms would be severely handicapped.

In sum, the magnitude of current and past incentive programs implies that there are immense economic costs in a transition to an incentive-free regime. The authors' preferred strategy of price decontrol deals with only part of existing incentives and would leave synfuels at a disadvantage. To go further and eliminate all energy incentives would greatly disrupt energy production. . . .

Paul Sommers, Alfred Marcus, and Roland J. Cole,
Battelle Memorial Institute

TO THE EDITOR:

. . . The structure and purpose of the Synthetic Fuel Corporation are, in the main, consistent with the concerns addressed by Paul Joskow and Robert Pindyck. However, there are substantive differences.

The actions of the Carter administration and the Congress have been directed, for the most part, toward the so-called first-best policy of energy price decontrol. The administration's gradual decontrol plan will free domestic crude oil prices by October 1981, while the National Gas Policy Act of 1978 will decontrol domestic natural gas prices by 1985. Domestic energy prices will be determined by the marginal source of supply, which will continue to be imported energy.

The choice is not between higher taxes or higher energy prices, since energy prices will continue to be externally determined. The issue concerns alternative ways of loosening our dependence on foreign sources of oil—a dependence which continues to fuel price rises.

By suggesting that the nation's first-best energy policy is price decontrol, the article subscribes to the belief that energy supply is highly elastic—that adequate additional supplies will become available, in a timely fashion, as prices rise. The evidence strongly suggests, however, that the additional cost of conventional domestic supplies exceeds the additional benefits of such supplies. For example, the "windfall profits tax" is projected to net in excess of $200 billion over the next ten years. If the oil companies were allowed to retain these revenues, production is projected to increase by, at most, 1 to 2 million barrels/day. Thus, the additional cost of such production is $100,000 to $200,000 per barrel stream day—a very large expense for such minimal additional production.

In its first and most expensive phase, the Energy Security Corporation is limited to a maximum potential liability of $20 billion, with a goal of 0.5 million barrels/day—equivalent to $40,000 per barrel stream day. Since the assumption underlying this proposal is that energy prices will rise so that some projects become successful, the actual outlays will probably be even less. In that case, synfuel production would appear to be economic and private industry could be expected to invest in it.

The issue is one of *timing*. Are perceptions of a highly uncertain future likely to lead to adequate energy supplies when they are needed? America's future energy prospects can be described in blunt and sobering terms: domestic conventional oil production is likely soon to start a rather steep decline, relatively independent of price, for geological and physical reasons. Conservation, currently our highest priority, probably cannot restrain demand growth enough to match the decline in supply without a very large increase in prices and resulting serious economic costs. All of this means that oil imports must expand at the same time that Middle East instabilities and production cutbacks by OPEC producers are likely to make that expansion impossible. The very great cost of serious shortages and abruptly forced transitions away from oil argue for undertaking measures, *now*, to bring on unconventional supplies as quickly as possible—more quickly than would private industry alone, facing as it does the conflicting signals of rising prices and inhibiting uncertainties.

In short, in the nation's interest, I cannot agree that it is "better to purchase oil and gas at home and abroad at world market prices than to subsidize nonconventional oil."

. . . Joskow and Pindyck correctly conclude that second-best policies are required for the synthetic fuel industry. The corporation is so structured. The major financial assistance mechanisms are in fact price and purchase guarantees. However, it is not clear that government programs to speed introduction of nonconventional fuels are more costly than available alternatives. High prices and lost income from shortages induced by too-slow industry action on nonconventional fuels are the great costs that current policy seeks to avoid.

John D. Dingell,
Chairman, Subcommittee on Energy and Power

PAUL JOSKOW responds:

The letters from John Deutch and Congressman Dingell indicate that we have come a long way toward achieving the policies that Robert Pindyck and I emphasize in our article. Both Congress and the Carter administration seem to have become convinced that the decontrol of energy prices is an essential component of a rational energy policy. The marginal social cost of imported oil to the U.S. economy is *at least* the monetary cost of these imports and, to give consumers and producers the proper incentives, all domestic energy prices must be allowed to rise to at least this level. We should recall, however, that not too long ago there was vigorous opposition to oil price decontrol in Congress and a subsidized synthetic fuels program was viewed by many as a substitute for

(Continues on page 59)

(Continued from page 3)
decontrol, rather than as a complement. Whether the new commitment to oil price decontrol will survive the current inflationary environment or a change in administration, only time will tell.

It is also gratifying to see that the long discussions in Congress over the synthetic fuels proposal have led to a more sober assessment of the size, duration, and structure that such a program should have. The plan has been cut back in size and duration and serious efforts have been made to structure the incentives in such a way that "industry's dogs" will not become the "government's pets." However, I remain skeptical about the ability of the Energy Security Corporation to achieve these objectives in practice. I fear that political considerations will inevitably influence how and where funds are spent, that programs which begin to look bad will stay on the budget for too long, and that more promising programs will suffer if they do not get the government's sanction as being sufficiently "promising." Once large financial commitments are made to a few large projects in a few congressional districts, I suspect that there will be considerable difficulty in turning them off. This has been our experience with the breeder reactor demonstration program and it has been the experience in other countries that have made large government financial commitments to particular technologies (for example, gas-cooled reactors in Britain and France, as well as the SST).

The Drug Lag

TO THE EDITOR:

In 1977, concerned over an apparent decline in productivity and technological innovation in the pharmaceutical industry, I directed the Government Accounting Office to study the so-called drug lag in the United States. I sought answers to three fundamental questions: (1) Has the American consumer become a second-class patient? (2) Do therapeutically significant drugs generally become available abroad sooner than in the United States? If so, why? (3) To what extent is the U.S. government responsible?

The preliminary conclusions of the GAO study were presented to the House Subcommittee on Science, Research, and Technology, on which I serve, during hearings last June. At that time we also had the opportunity to hear testimony from Dr. William Wardell, from then FDA Commissioner Donald Kennedy and from several representatives of the medical, scientific, and academic communities.

The evidence presented convinced me that a drug lag does, in fact, exist and that it is highly significant. Because of it, U.S. doctors have been limited to a smaller armamentarium of safe and effective drugs from which to draw in treating their patients.

The substantial delays—seven to ten years—and exorbitant cost—up to $50 million—of getting a single new drug approved for marketing in this country have produced few cost benefits to the American consumer in terms of safer or more effective drugs. Some Americans have paid a high price—including unnecessary suffering and death—for the unavailability of some of the most advanced drug therapies, frequently the most cost-effective method of health care.

The question is: why has the United States, once the world's leader in therapeutic drug innovation, fallen behind in the development and introduction of needed new drug products? As Dr. Wardell points out, we have been losing the fruits of R&D by small firms and individual scientists or chemists because they can no longer bear the economic costs and regulatory burdens of innovation. Our patent system, designed to spur technology, has been rendered ineffective by regulations that frequently preclude a reasonable rate of return on research investment. We have created an environment that penalizes drug innovation and stifles productivity. Ironically, the loser is the American health-care consumer.

Regrettably, there are no easy solutions. One possibility would be for the Congress to enact legislation to reform existing drug statutes. If, however, as Dr. Wardell points out, the problem is not with the 1962 drug amendments, but rather in the "mind set" of FDA reviewers, no amount of legislative tinkering will do any good. Reportedly, the FDA has begun to take certain administrative actions that, it maintains, will take care of the drug lag problem—whose existence it denies. Particularly worthy proposals include a reduction of FDA's regulation of earliest stages of clinical investigation of new drugs, an expanded role for expert advisory committees, a greater acceptance of foreign test data in new drug-approval decisions, and a system of postmarketing surveillance that reduces the time it takes to get a new drug approved.

In each instance, I believe the experience of European countries can be instructive. In the United Kingdom, for example, there is little regulatory involvement in early clinical studies at no cost to the safety or rights of patients. In addition, many European systems appear to have benefited from the widespread use of expert advisory committees. It is in such forums that the totality of scientific evidence, including data available from other countries, can be objectively weighed and evaluated. One advantage of such systems is that drug-approval decisions are made by experts whose determinations are likely to be widely accepted. Another is that civil servants are protected from undue outside influence or criticism.

Finally, in countries where postmarketing surveillance systems exist, regulatory agencies appear to have greater confidence in approving new drug products because they know that follow-on investigations will be made to detect unforeseen drug reactions or toxicities.

James H. Scheuer,
House of Representatives

TO THE EDITOR:

In responding to Dr. Wardell's essay, I wish to emphasize that the United States has evolved a rigorous process and standards for substantiating the safety and effectiveness of new drugs, and the system is well regarded at home and abroad. But I know of no one who thinks that it cannot be further improved. Indeed, we have been making, and intend to continue making, every effort to improve the system. We have, for example:

—established a priority tracking system to facilitate the review of important new drugs;

—developed and published clinical guidelines (which will be revised on a regular basis) to aid manufacturers in the design and performance of drug studies;

—established procedures for referring important drug questions to advisory committees and for reviewing progress with sponsors to ensure swift resolution of issues and steady progress in drug investigations; and

—undertaken a complete revision of our investigational and new drug-approval regulations; this re-

vision, involving the publication of a concept paper and opportunities for public comment and discussion, should expedite the review process, reduce paperwork, and achieve simpler reporting requirements.

I believe we are making genuine progress toward achieving the kind of drug-approval system that continued progress in drug development requires and protection of the public health demands.

Jere E. Goyan,
Commissioner on Food and Drugs, FDA

TO THE EDITOR:

William Wardell is to be congratulated for his factual article on the adverse effects of the FDA's overregulation (see "Rx: More Regulation or Better Therapies?" September/October). As a clinical investigator of new antihypertensive agents during the most repressive ten years of the FDA, I can personally testify to the frustrations clinical investigators experienced during that time. In an entire decade, not a single antihypertensive drug was approved in the United States, while propranolol, bethanidine, and debrisoquine were tested and made available in Europe. I and other American researchers tested the latter two agents, which were refused acceptance by the FDA. Propranolol was not even evaluated for hypertension in the United States until years later because the manufacturer decided that it could not at that time gain FDA approval. This drug, recognized today as one of the most valuable antihypertensives, was finally approved in the United States almost ten years later than in Great Britain.

How could such a negative and retrogressive policy have lasted for so long? First, and perhaps most important, was the climate of public opinion. It was a time of reaction to the thalidomide disaster—a time of irrational fear of all new drugs. The media reinforced the public hysteria by underplaying the beneficial effects of drugs and overemphasizing their adverse effects. Second, reviewing officers in the cardiovascular drug division of FDA, having received their medical training in an era when the drug treatment of hypertension was frowned upon, had a strong bias against the use of antihypertensive agents in general. Third, because of the climate of public opinion, the reviewing officers knew that no credit would accrue to them for recognizing the therapeutic value of an important new drug and that, in fact, approval exposed them to the risk of not having foreseen rare, previously undetected toxicity that might appear at a future date. On the other hand, delaying approval of a drug on the off chance that toxicity might appear later could lead to great rewards, as it had in the case of thalidomide. Reviewing officers had everything to gain and nothing to lose by procrastination, despite the potential detriment to the public who were denied new drugs that could have an important beneficial health effect.

Equally important and not so generally realized was the negative impact these policies had on research and development programs of pharmaceutical companies. During this ten-year period, the development of new antihypertensive agents fell off markedly in this country, but not in Europe.

Fortunately, the competence and attitude of the cardiovascular drug division has improved considerably in recent years—in large measure because of efforts of the new division chief. Also important has been the establishment of a Cardiovascular Drug Review Committee composed of outside experts who are competent to make knowledgeable and balanced judgments.

But still further improvements are needed to overcome the harmful effects of the past. The present cost of bringing a new drug to market is too high. Overly restrictive requirements regarding the amount and type of evidence needed for demonstrating the efficacy and toxicity of a new drug should be pruned to reduce unessential and expensive data collection.

Finally, as Dr. Wardell pointed out, the extremely expensive and time-consuming premarketing Phase III clinical testing has provided little useful information that was not known at the end of Phase II evaluation. The substitution of a well-designed and carefully conducted program of postmarketing surveillance will greatly reduce the cost of new drug development and will be more effective in detecting toxicity.

Edward D. Freis, M.D.,
Veterans Administration

WILLIAM WARDELL responds:

Representative Scheuer and Dr. Freis give valuable accounts of the size of the problems in drug regulation and of some solutions. Commissioner Goyan describes some of the major efforts the FDA is making to meet the challenges.

I would like to make the following observations:

(1) There remains the fundamental and growing problem of the way the FDA interprets the standards of scientific evidence needed to prove a drug's efficacy. Over the years, the agency's guidelines and operating practices have tended to complicate unnecessarily and depart from the straightforward and desirable standards of the 1962 law on efficacy. This situation must be addressed specifically.

(2) Improved postmarketing surveillance is clearly desirable, and the system the FDA uses has improved greatly even in the past year or two. But these improvements can only solve the drug-development bottleneck if there is a conscious decision to use postmarketing surveillance as a *substitute* for some or all of the present Phase III premarketing studies. The danger is that postmarketing surveillance will simply be added on to the present requirements, thus raising the barriers even higher.

(3) The FDA's increased use of outside, expert advisory committees has been one of the most encouraging developments of the past decade. But the conflict-of-interest rules that the FDA has to work under are keeping many of the nation's best experts from serving on these committees. This waste of talent could be prevented by a more realistic interpretation (for example, by the Justice Department) of how these rules apply to the FDA's case.

(4) The FDA is currently rewriting the IND/NDA regulations in an effort "to improve the efficiency of the agency's review and approval processes and to refine its policies in reviewing and processing INDs and NDAs, and communicating with sponsors and applicants on them." The intention is praiseworthy, and the agency has gone about this massive project in an impressive manner.

However, early signs are that two key aims of this rewrite—improving efficiency overall and decreasing the FDA's involvement in the earliest phase of the development process—may not be achieved, given the present directions of the project. Some, indeed, think that the opposite of these aims will be the result. It is vitally important that this reassessment of the regulations should fulfill its promise.