The purpose of this essay is to examine the political economy of drug innovation and apply it to an evaluation of the Food and Drug Administration. Particular emphasis is placed on an overlooked problem—that of the efficient management of innovational resources. This essay applies an analysis developed in a more general context in my recently published paper "The Nature and Function of the Patent System" to the problems of drug technology.

The traditional political economy of innovation has started with the fact that an innovation can be copied. Copying will keep the innovator from capturing the full social value of his innovation. As a result, investment in search for innovation will be less than the anticipated value of innovations, the resulting underinvestment will be a social loss.

At this point the analysis has followed two lines.

One line suggests the use of tax revenues to subsidize the process of investment in innovation. This subsidy will increase the amount of investment in innovation in the direction of the socially optimum amount. Since the ability of an innovator to capture the returns from an innovation is less, the more basic and fundamental it is, the analysis suggests that the proportion of tax subsidy should be higher the more basic the research being undertaken. Doubtless this analysis has something to do with the generally high level of support for government subsidy of research, particularly (at least among intellectuals) of basic research. For government subsidy to improve the situation, however, it must be managed with sufficient skill so that the returns are positive. Government subsidy will raise the cost of specialized inputs to the research process (because total end demand for these inputs will rise) and thus reduce the amount of non-subsidized research that would otherwise occur. If the return from the government subsidy is not sufficiently positive to
offset this loss, it will not improve the situation. If the government is a poor manager of its subsidy because of an inability to separate promising from unpromising projects, to allocate funds in proportion to the promise of projects, or to obtain the appropriate match of project and personnel, the tax subsidy will not result in a social gain.

The second line that has been followed in analysis of the political economy of innovation is the possible use of a rights system to overcome the problem of underinvestment. The patent system, which evolved long before the systematic analysis of these problems was undertaken, has been considered to be such a system. An inventor is entitled to a patent on his invention, and the invention gives him the right, for a limited time, to keep others from using his invention. The patent solution will not be completely effective because some gains from an invention will fall outside the reach of patent claims. For instance a patent on a particular compound which reveals therapeutic properties of the compound may suggest to others the possibility that related compounds have those properties, but those related compounds will not fall within the patent claim. The tendency of the patent, however, will be to increase the return to innovation and overcome the underinvestment problem.

A patent introduces other problems. During the life of the patent its owner will charge the monopoly price for the product subject to the patent. If the critical assumption is made—and it has usually been made in the literature—that other firms could acquire and use this information without cost, then the existence of the patent generates a social loss. Persons who would purchase and use the product if its price were lower, and who could be provided the product at no additional cost to anyone, are denied the product. In the case of drugs, it has been common for observers to comment on the high price margins over manufacturing costs enjoyed by some patented drugs and to bemoan the loss that the high prices cause.

Ideas from the theoretical literature have found their way into the political debate about drugs. Provisions designed to introduce compulsory licensing were a dominant feature of the early Kefauver proposals, and his hearings focused on the high profit margin of some patented drugs. The thalidomide episode carried the drug legislation off in another direction toward a focus on safety. The government has the power to confer a compulsory drug license upon itself under the existing statutes and has from time to time made use of this power. And there has been much support for government subsidy for medical research, on condition that the fruits of the research are not subject to exclusive appropriation.

Analysis of institutions shaping innovation in the drug industry in the United States is greatly complicated by the role of the Food and Drug Administration. Whether or not to market a new drug product, and indeed, whether or not to begin human testing on a new drug product, is a decision made not by the firm making the investment in the innovation but by the Food and Drug Administration. There is some reason to think that at least since the early 1960's the FDA has been more cautious than the firms, free of regulation, would have been—although the striking rise in judicial product liability standards would have had effects in the same direction as the FDA regulation. What is clearer is that the FDA, driven by the logic of its own regulatory needs, has imposed upon the process of research and marketing a set of general procedures and standards applicable to all new drugs, which are probably not optimum in the case of many particular drugs. The flexibility that a firm would otherwise have to adapt its own procedures has been lost. Most importantly, the ability of the firm to control the timing of its research and marketing has been handed over to the FDA, where the operation of regulatory resource constraints and uniform procedures causes delays unrelated to drug specific cost benefit relationships.

Yoram Barzel's essay "The Optimal Timing of Innovation" persuaded me that the problems of innovation are more complicated than simply equating the marginal investment in innovation
with the marginal social return. It is important
to consider not only the relationship between
inputs and outputs, but also the process by
which resources are brought to bear on possi-
bilities for innovation. This focus suggests con-
clusions strikingly at odds with the traditional
analysis and puts forward another set of prob-
lems which should be confronted by those who
would reform the controlling institutions.

In his essay, Barzel pointed out that the
exploitation of technological information has
much in common with fisheries, public roads,
and oil and water pools—they are all resources
not subject to the exclusive control of an owner.
Under a rule of first appropriation, there will
be inefficiently rapid depletion of the resource.

It has long been a conventional point of
welfare economics that a rule which bases
ownership upon first use creates an incentive
for use of the resource at a rate faster than
that which optimizes the social value of the
resource. This is because each competitor in
the race for ownership will have an incentive
to accelerate the time of his use in order to
be first, and this process will continue until the
costs of being first are equal to the value of
being first. Thus if a fisherman owns a fish only
if he catches it, he has an incentive to catch it
before his neighbor. Even though this will re-
result in fishing (or hunting—another common
example) at a rate that depletes the stock, no
one in the process has an incentive to stop.
Similarly, if the right to drive on the public
road is conferred in order of arrival, everyone
will have an incentive to hurry out onto the
road, even though this causes a traffic jam, until
the time that traffic slows to the point that the
value of being on the road is equal to the gain
from using it. This is so even though the traffic
then moves at a rate which reduces the capacity
of the road to carry traffic. And in the case of
oil, a rule that gives ownership to the first owner
to pump the oil out gives each owner of land
over the pool an incentive to pump as fast as he
can, even if the effect is to reduce the total
amount of oil that can be extracted and to sup-
ply the oil to the market in a time pattern that
reduces its total social value.

Because, unlike fish, bears, roads and oil,
technological information is not something that
can be physically appropriated, the analogy is
not immediately obvious. The fact that I take
"some information" does not mean that you
can't have it too. The fact that I have read
Barzel's article does not mean that you can't
read it too, and even if we both read it—and
indeed if we both read it with inefficient haste
—the article will still be there. Or in the drug
area, the fact that one firm is exploring the
therapeutic properties of compound X does not
mean that another company cannot explore
those properties, and it certainly does not mean
that if both explore them, the properties, what-
ever they are, will be used up.

Barzel's point, and the point of the analogy,
is more subtle. There are two resources in-
volved in fishing, driving, and pumping oil.
One is the fish, et cetera. The other is the re-
sources used to acquire the fish, et cetera. An
appropriation system causes those resources to
be used at an inefficiently rapid rate. Thus in
the case of a fishery, the problem is not only
that the fish are depleted at an inefficient rate.
The fishing boats are also used inefficiently.
Since ownership is based upon speed, there is
an overuse of resources which produce speed.
The number of boats will be inefficiently high in
relation to the number of fish. For instance, if
30 boats would be the socially efficient way to
exploit a fishing ground, a rule of appropriation
may produce a fleet of 60.

In the area of innovation, the key loss of an
appropriation rule is the inefficient deployment
of the resources used to locate and develop an
innovation. For instance in the drug area, if
several firms were competing to be the first to
prove that a chemical entity has a therapeutic
effect, under a rule that the first to demonstrate
the effect was entitled to market the drug, the
following things would happen. Each firm
would emphasize speed in its work, even
though the most efficient way might be to
proceed more slowly. Each firm would have to
limit its commitment by the estimate of the
value of the product less its estimate of the
chance that some other firm will be first. And
each firm will have to duplicate work of others
since there are no exclusive rights in the infor-
mation until the effect has been demonstrated. Firms would tend to crowd their resources on possibilities they considered close and to duplicate each other’s work. Because there would be inefficient allocation of the resources both over time and the set of innovation possibilities, the output from the resources used for drug research would be less than it otherwise could be.

This analysis can be used to argue against a patent system because a patent system is a first appropriation system. Its basic rule is that the patent on the invention goes to the first inventor. However, such an argument turns on confusion about the meaning of the term invention. In common usage the term invention has a meaning quite different from its meaning in patent law. When we speak of an inventor’s invention in everyday speech, we are thinking of the commercial product that the inventor made possible: Alexander Graham Bell’s telephone, Edison’s light bulb, Land’s polarizer, and so on. But something can be patented long before it has any commercial feasibility at all. For instance, patents issue on chemical entities based not upon a demonstration that they are wonder drugs, but upon a demonstration that they have some possible therapeutic effects. After the patent is applied for, the patent owner can search for the information about the therapeutic significance of the entity. Since he has the exclusive right to market the drug, he is the only one with an incentive to find the effect. The patent will eliminate the race to be first. Thus patents can and do issue on the basis of “first results,” and the issuance of the patent (and for the most part the application) can stop the race to be first.

Because trade secrecy—whether based upon legal recognition of trade secret doctrines or upon the natural ability of the possessor of information to control its dissemination—is the principal alternative institutional arrangement to the patent system, I was led in “The Nature and Function of the Patent System” to compare the systems in some detail. I identified six ways in which a patent system is superior to a trade secrecy system. One—the ability of the owner of a patent to control the allocation of resources to its development without the misincentives caused by competitive appropriation—has already been developed at length here. Two others are of particular importance.

One is the transaction effect which has long been a commonplace of the applied legal literature but has not been noted in the theoretical literature. To quote from “The Nature and Function of the Patent System”:

A patent system lowers the cost for the owner of technological information of contracting with other firms possessing complementary information and resources. A firm that has a design for a new product or process needs to be able to obtain financing, knowledge about or use of complementary technology, specialized supplies, and access to markets. Unless the firm already possesses the needed inputs, it must enter into contracts. The practical difficulties of entering into contracts concerning trade secrets are spelled out in the applied legal literature. Disclosure of the secret imperils its value, yet the outsider cannot negotiate until he knows what the secret is. Disclosure under an obligation of confidence strengthens the discloser’s legal position but may prove costly to the receiver, who must accept the obligation before he knows the secret. The patent creates a defined set of legal rights known to both parties at the outset of negotiations. And although the patent will seldom disclose the real value of the patent, the owner can disclose such information protected by the scope of the legal monopoly. Indeed, most know-how or trade-secret licensing takes place within the framework of patent rights, the agreement involving both a license of the patent and an undertaking to disclose how to apply the technology efficiently. This reduced transaction cost increases the efficiency with which inventions can be developed. A second advantage of a patent system is that it allows firms to space themselves across the set of innovation possibilities in a more efficient manner. A striking problem with trade secrecy

3. 20 J. Law & Econ. 277-8.
is that during the period of the secrecy other firms have an incentive to invest in the search for the very information that is already known. This duplicate search is economically wasteful if the patent system provides a way that the information already known can be transmitted to other firms. It does. To quote:

A patent system enables firms to signal each other, thus reducing the amount of duplicative investment in innovation. Once a patent has been issued, other firms can learn of the innovative work of the patent holder and redirect their work so as not to duplicate work already done. Indeed, the patent gives its owner an affirmative incentive to seek out firms and inform them of the new technology, even before issuance, if the most efficient and hence patent-value-optimizing way to exploit the invention is to license it. Under a regime of trade secrecy, the competitive firm might never learn of a competitor’s processes and would not learn of the technology incorporated in a new product until it was marketed. During this period, the investments made in a search for technology already invented by others is wasted. This private incentive to disseminate information about the invention should be distinguished from the reward for disclosure theory traditionally discussed. That theory assumes that the disclosure effect of the patent system comes from the disclosure on the public record.4

To illustrate in the context of drug technology, suppose that a firm is considering the possibility that a compound will act as an anti-histamine. It runs a series of tests on animals and finds that the compound causes a serious undesirable side effect. It drops the project. When another company considers the possibility of pursuing the same project, it will not know of the negative results obtained by the first company and will be led to repeat the same tests to obtain the same information. However, if there was a patent issued on the compound, then the second company would know to explore with the owner of the patent the status of work on the compound before it began work itself. This would save the resources involved in a repeat of the same tests.

Conversely, if the first company obtains positive results and does not have a patent, it will not want to publicize the existence of its work. But if it has a patent, it will want to publicize the fact of positive results disseminated in order to increase the value of its patent rights. This information will then become available to others and they can avoid duplicating the work.

What, then, do these points have to suggest for the problems of evaluating the role of the Food and Drug Administration in drug technology development?

They highlight the fact that the FDA has become a regulator of the research process. How it carries out that task is an important part of evaluating the regulation. The statute does not formally do this. It is modelled on the assumption that firms control their research and the FDA approves or disapproves. But given the multistage regulatory process that has evolved, and given the existence of regulatory queues, the FDA is in fact influencing the time flow of projects and this is an important matter. The statute and regulations do not address this problem, although doubtless in a world of sometimes practical men there are ways that a firm can inform the FDA of its sense of the priorities and the FDA can readjust timing and resources. But these are awkward, costly, and sub rosa processes.

The regulatory problem is particularly difficult because in the process of research and development resource allocation should be constantly reiterative—each new piece of information alters the desired portfolio. These adjustments are hard enough for firms to manage, but when the readjustments must also be taken through the regulatory process, the difficulty becomes staggering. Can you imagine a firm that has just told the FDA that the processing of drug X should be expedited because it is enormously promising for the treatment of an important disease, later trying to persuade the

4. 20 J. Law & Econ. 278.
FDA that in light of information which became available a month later, some other drug is really what is now urgent? Research is an exploration of the unknown, yet the regulatory process requires firms to appear consistent in the positions they take.

These problems are greatly aggravated by the Administration's reform bill. The bill proposes to substantially increase the degree of control that the FDA can exercise over the research process. It is a logical response to much of the criticism of the existing regulatory scheme. But since that criticism has not considered the problem of regulating the research process, it could not take these problems into account. One of the important criticisms of the regulatory scheme that has been made is that it confronts the FDA with an all or nothing choice. Either a drug is approved for general marketing subject only to the constraints of the label limitations, or it is not approved for marketing. And once it is approved for marketing, the formal regulatory review of safety and efficacy ends—at the very time when the commercial sales, much higher in volume than experimental use and production could ever be—are generating much more information of potential regulatory value. Since the FDA has an all or nothing choice, it tends to be very cautious before it says yes. The suggested solution—and a solution adopted in the administration bill—is to give the FDA a much greater range of choices, making possible stages of controlled release with a wide range of cautionary monitoring and information feedback procedures.

To deal with one of the anomalies generated by the present regulation, the bill also contains a provision empowering the FDA to order a firm to do research. The anomaly is the fact that a drug now released for use under labelling for one condition, may come to be used for another condition. At this point the firm that sells the drug has strong incentives to ignore the second use. If it recognizes the use, it will be open to the charge that it is violating the act by encouraging the use of the drug for a condition not permitted. It has little incentive to undertake the research necessary to expand the labelling since an expansion in labelling will not expand the market—the drug is already being used for that condition. Or even if the existing illicit use is limited, the potential market may still be too small to justify the regulatory expense. The solution of the bill is to empower the FDA to order firms to do the research. Exactly how one orders a firm to do research in a meaningful way is an interesting problem—doubtless the drafters have in mind a combination of threat and grant. But when the FDA exercises this power, it will be explicitly ordering the research priorities of the firm. How is it to acquire the information necessary to do this?

The cumulative effect of these provisions would be to greatly increase the scope of FDA involvement in the allocation of resources to research, and thus to make even more important concerns about the efficient management of research resources in evaluating the regulation. From this perspective, the advantage of the present system is that it at least limits the form and number of potential FDA interventions and probably makes the FDA responses, although inflexible, more mechanical and predictable.

There are various ways that might be explored to ameliorate the problem of the firm-FDA interface in research. Firms could be permitted to exchange queue positions, to purchase regulatory speed with money, or with chits. Such a system would have to be flexible enough to permit firms to change their designations over time as they obtained new information. Some explicit recognition of the difficulty of the problem would itself make it easier for the agency to face it and attempt to fashion procedures to deal with it. The prospects for any solution, however, are very dim because the whole problem of procedures for the allocation of regulatory resources among items on the regulatory agenda is one that has defied satisfactory resolution. The complex, multifaceted nature of the problem has caused agencies and critics all too often to simply ignore it. I would not be surprised if full study of the problem

5. S. 2755, 95th Congress.
would lead to the conclusion that the agency should be held to a first come, first served principle with the right given to firms to exchange places in the queue with side payments permitted.

The basic problem is: who is to manage the process of research. The present statute adopts a simple minded model—the firms research and the FDA checks. The agency has limited and inflexible powers. The critics have then pointed out that the FDA manages poorly, because it really doesn’t have the range of flexible powers the management job requires. The response is to give the FDA the powers the management job requires. But no attention is paid to the question as to how the FDA acquires the personnel skills and information base necessary to exercise these powers well. It is quite possible that the FDA as flexible manager will be considerably more wasteful than the combination of firm as manager and FDA as arbitrary check. If one thinks that the prospects for improvements in drug technology are significant, and the resources for making those improvements scarce, their wasteful management is an important problem.