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REGULATORY RELIEF OR POWER GRAB: SHOULD CONGRESS EXPAND FDA'S ENFORCEMENT AUTHORITY?

INTRODUCTION

Legislation now in Congress would add another layer of regulation and significantly expand the enforcement authority of the Food and Drug Administration (FDA), the federal agency that approves drugs for safety and effectiveness. This legislation would slow down the pace of approvals, increase consumer costs, and add reams of unnecessary paperwork. Yet it would provide little or no benefit to Americans. Meanwhile the Bush Administration, through the Council on Competitiveness, has been taking administrative action to attempt to streamline the regulatory process and speed up approval of new drugs to treat such deadly diseases as AIDS, cancer, and cystic fibrosis.

The FDA is a division of the Public Health Service, itself an agency of the U.S. Department of Health and Human Services (HHS). It is the largest consumer protection agency in the world, with regulatory authority over food, drugs, cosmetics, and medical devices. In fact, the FDA's vast authority covers approximately one-third of all items consumed in the United States. Some 25 cents out of every dollar spent in America is spent on products regulated by the FDA.

The FDA is also a law enforcement agency. It is responsible for enforcing the federal Food, Drug, and Cosmetic Act, and several other statutes regarding foods, drugs, and medical devices. These include the Biologics Act, the Safe Medical Devices Act of 1990, the Fair Packaging and Labeling Act, and parts of many other statutes.[1] One of the FDA's key responsibilities is certifying prescription drugs as safe and effective.

1 Peter Barton Hutt and Richard A. Merrill, *Food and Drug Law* (Westbury, New York: The Foundation Press, 1991), Appendix B.

This April, Vice President Dan Quayle and HHS Secretary Louis Sullivan announced reforms in the FDA regulatory process to speed up the availability of new drugs, especially to patients who are desperately ill. The reforms were generated by the President's Council on Competitiveness, chaired by Quayle, and are part of the Administration's strategy to ease burdensome regulation. The FDA reforms include "accelerated approval" of new "breakthrough drugs" for patients with life-threatening diseases, such as cancer, Alzheimer's disease, and cystic fibrosis. Under the new rules, for instance, AIDS patients have the freedom to use experimental drugs outside of the normal process of controlled clinical studies used to test a drug's safety and effectiveness. The Bush Administration also has ordered the FDA to rely upon outside experts, under contract, to review applications for new drug approvals. It has ordered the agency to use scientific data validating the safety of drugs from Japan and member nations of the European Community as a basis for drug approval in the United States. According to HHS Secretary Sullivan, these initiatives are designed to save lives, cut the time required to bring new drugs into the market, and enhance the competitiveness of American pharmaceutical companies while retaining "rigorous" FDA oversight.[2] While these reforms are well intentioned, they must be administered by the FDA bureaucracy, and therefore their impact is likely to be limited.

While the Bush Administration is going ahead with regulatory relief, Congress is considering the "Food, Drug, Cosmetic and Device Enforcement Amendments of 1991" (H.R. 3642).[3] This would give the FDA sweeping new regulatory powers. The legislation is sponsored by Representative Henry Waxman, the California Democrat, and cosponsored by John Dingell, the Michigan Democrat and Chairman of the powerful House Committee on Energy and Commerce.

Some of the powers the bill confers on the agency are to: administratively recall products with no court hearing; seize or embargo products if an officer or employee of the FDA believes that a product is in violation of the Act, with no requirement that the violation be safety related, and no requirement of proof; subpoena company records, including trade secrets and names of individuals in medical files; and levy large fines. The Bush Administration is opposed to the bill in its current form, but still might agree to some form of the legislation. If some version of this bill becomes law, costs of prescription drugs would rise and consumer health might well suffer.

While the proposed increased enforcement authority will add to manufacturers' costs, there is no reason to believe that the agency's enhanced powers will have any beneficial effect in improving health. For example, the FDA recently raised concerns about the safety of silicone breast implants. But the FDA already has sufficient administrative discretion to essentially ban breast implants under current law without any new powers. Indeed, in the wake of the breast implant episode, FDA is increasing regulation of all medical devices, and is able to do so under current law.[4] Thus, even if breast implants are determined to be unsafe, current law provides adequate remedies.

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2 *HHS News*, April 9, 1992.

3 A word regarding notation. A bill with the same title and with only slight modifications was previously considered as H.R. 2597. Much of the published analysis of the bill refers to "H.R. 2597." For consistency, I will generally use H.R. 3642 in discussing this bill. Whenever a direct quotation refers to "H.R. 2597," I will refer to [H.R. 3642].

There is no good case for the strengthened FDA enforcement powers included in H.R.3642. Among the reasons:

- ✘ **The FDA already has substantial enforcement authority.** The agency has a wide variety of powerful legal tools at its disposal, including injunctions against food and drug firms, and recalls and seizures of food and drug products. It also has powerful criminal sanctions. And since the FDA regulates virtually all aspects of many food and drug firms' business, it can use these powers to influence a firm's commercial activities.

- ✘ **There is no evidence that current FDA enforcement policies are harming consumers through ill-considered approvals or lax enforcement of the law.** Supporters of the bill have not presented convincing evidence that consumers are harmed by lax enforcement. Advocates of stronger enforcement authority focus on narrow bureaucratic justifications for the proposed statute, such as consistency of enforcement powers across all products the agency regulates.

- ✘ **Congress already is concerned that FDA is not using its current regulatory authority in a responsible fashion.** For example, Congressman Dingell, a strong supporter and co-sponsor of H.R. 3642, has also recently criticized the FDA for abuse of the powers it already possesses. The FDA is threatening to close Barr Laboratories, a maker of generic drugs, which was the "whistleblower" regarding misconduct at the FDA. Chairman Dingell is obviously aware that the agency already has awesome power and that an abuse of that power is a real danger.[5]

- ✘ **Provisions of proposed legislation could be harmful to consumers.** H.R.3642, for example, increases FDA's powers to issue subpoenas, demand record-keeping and inspections, issue recalls and embargoes, and levy fines. All of these powers would lead to increased costs of doing business for firms regulated by the FDA, which would be passed on to consumers. But even more important, the threat of FDA intervention and the increased risk of loss of trade-secret protection would discourage firms from developing and marketing new products, denying these to American consumers who could be helped by them.

While strengthening FDA's enforcement authority may be unnecessary, Congress should support genuine reforms that benefit consumers, such as the Bush Administration's initiative to assure more rapid drug approval procedures, allowing new drugs to become available much more quickly to Americans who can benefit from them. Taking swift action to approve a drug may mean that some drugs will reach the market that pose some risks to patients. But painstaking certification procedures also

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4 Philip J. Hilts, "U.S. Cracks Down on Health Devices Made Before 1976," *The New York Times*, February 24, 1992, p. 1; Bruce Ingersoll, "Changes Vowed for Reviewing Medical Devices," *The Wall Street Journal*, March 26, 1992, p. A3.

5 Milt Freudenheim, "FDA Moves to Shut Drug Maker Queried," *The New York Times*, November 7, 1991, p. C6.

may pose risks, because a drug that may cure a patient's illness is held back until every conceivable risk or side-effect is checked out. Wisely, the Bush Administration realizes that these risks should be weighed against potential consumer benefits. Abundant statistical analysis, moreover, indicates that traditionally the FDA has placed much more weight on the risk of action than of inaction. By streamlining drug approval, rather than making the process more lengthy and cumbersome, consumers will benefit.

The FDA now spends about one-half of its resources on enforcement.[6] But the health of Americans has been suffering from delays in the approval of new drugs, not from the inadequate inspection of foods and drugs. For example, 204 new drugs were introduced in the U.S. from 1977 to 1987; of these, 114 were first available in Great Britain, and had been available for an average of five years. Only 41 drugs approved in Britain during this period were available in the U.S. first, and then only for an average of two-and-a-half years, not five.[7] The health of Americans will be improved by shifting FDA resources to drug approval procedures, thus speeding up the approval of new drugs. Instead of focussing on greater enforcement authority, Congress also can amend the laws to make it even easier for the FDA to spend more on drug approvals.[8] Rather than simply adding another layer of regulations, Congress could re-evaluate current FDA authorities and clarify FDA's authority to protect commerce.

According to one source, "FDA lacks the resources to implement all of the missions delegated to it by Congress."[9] The agency openly admits that it does not enforce "economic" provisions of its statute.[10] In effect, FDA already chooses to enforce some laws but not others, and to enforce some laws more stringently than others. In the meantime, it clearly has the power to shift resources to drug approval from enforcement if it so desires. Such a shift would greatly benefit the public health.

Congress appears to be going in another direction. By giving the FDA greater regulatory power, proponents of H.R. 3642 would encourage the agency to spend more resources on enforcement and therefore less on drug approval. Thus, the incentives in this bill would move the agency further away from efficiency, and would inadvertently lead to greater health risks.

Congressional supporters of increased FDA enforcement powers seem mainly concerned with bureaucratic consistency and avoiding bad publicity for the agency if it fails to stop the marketing of a product which carries minor risks—even if that product could bring benefits to millions. In fact, consistency could as easily be obtained by

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6 Alan L. Hoeting, "The FDA's Philosophy of Enforcement," *Food Drug Cosmetic Law Journal*, Vol. 46, No. 2 (1991), p. 269.

7 Sam Kazman, "Deadly Overcaution: FDA's Drug Approval Process," *Journal of Regulation and Social Costs*, Vol. 1, No. 1 (September 1990), p. 40.

8 The argument is as follows: As of now, no consumer is harmed from inadequate inspection but many consumers are harmed from delays in drug approval. If the amount spent on inspection is marginally reduced, some harm might begin to occur, but for small shifts this harm would be small. On the other hand, shifting resources towards faster drug approval would definitely provide large benefits to consumers. Resources should be incrementally moved from enforcement to approval until, at the margin, benefits to consumers from each activity are equal.

9 Hutt and Merrill, *Food and Drug Law*, pp. 1240.

10 Hutt and Merrill, *Food and Drug Law*, p. 1056.

streamlining the regulatory powers associated with some products as by making the overview of less-regulated products more stringent. In any case, bureaucratic consistency is a weak reed on which to hang a major policy revision, particularly one which will impose substantial costs and seems unlikely to provide any benefits other than bureaucratic consistency.

THE FDA'S MASSIVE REGULATORY AUTHORITY

Proponents of increased FDA enforcement authority argue that the agency now has insufficient regulatory authority. Yet nothing is further from the truth. The agency has enormous regulatory authority. According to Alan L. Hoeting, the Director of the FDA's Office of Enforcement, the FDA already has at its disposal 26 possible enforcement tools.[11] The agency can, for instance:

- ✔ **Inspect pharmaceutical factories without warrant;**
- ✔ **Seize batches of a product if the batch is adulterated or mislabeled;**
- ✔ **Carry out multiple seizures, effectively eliminating a product (or a company) from the market;**
- ✔ **Avoid paying compensation if perishable products are ruined pursuant to a seizure, even if the seizure turns out to be groundless.**

Indeed, says Hoeting, the agency is "vulnerable to criticisms of untimely action" because it "has many internal discussions on the selection of the proper regulatory tool."[12] Thus the FDA, paradoxically, may be too slow in some instances in taking action, precisely because it already has so many enforcement tools that it cannot easily decide which to use. Such an agency does not need additional regulatory powers.

The agency can also inspect all food handling establishments. FDA agents, for instance, can enter these businesses without notice and spend as much time as they wish monitoring compliance with the Food and Drug Act.[13] In 1990, the FDA conducted approximately 20,000 such inspections and analyzed about 29,500 samples. On a typical day, about 6,000 import entries into the U.S. are subject to review, and an average of 100 entries, worth in total an average of $4,500,000, are detained.[14]

The FDA in addition has the authority to send warning letters to companies. If these firms fail to convince FDA that its assessment of the firm's products is incorrect, or fail to comply with its directives, these companies may be subject to criminal prosecution.[15] The FDA is clearly quite prepared to use this power.[16] In fact, over 10 percent

11 Hoeting, *op. cit.*, p. 269.

12 *Ibid.* Apparently representatives of at least four types of offices (field office, Center, General Counsel, Enforcement) must decide on which of the 26 available tools to use in a given instance.

13 Statement of Peter Barton Hutt on behalf of the Grocery Manufacturers of America, Inc., regarding [H.R. 3642], June 27, 1991, p. 5.

14 Hoeting, p. 268.

of cases referred by the FDA to the Department of Justice have been criminal.[17] In most cases the FDA alleges crimes in addition to violations of the Food, Drug and Cosmetic Act. These include false statements, mail and wire fraud, obstruction of justice, and conspiracy.[18] Under the 1984 Sentencing Reform Act, which since 1987 has set sentencing guidelines for federal judges, the size of a fine the FDA can levy has greatly increased.[19] Fines are now some multiple of the actual harm caused by the offense, and can in principle be open-ended. It is now more likely that officers of a firm who run afoul of the FDA will serve time in prison.[20]

The FDA has perhaps the most sweeping powers of any regulatory agency to impose criminal penalties on American citizens. Americans can even be made subject to criminal sanctions without having known of or participated in the conduct deemed illegal by the FDA.[21] According to Peter Barton Hutt, a former General Counsel of the FDA, "It is easier for FDA to convict a food company or its officials of a violation of the FD&C [the Food, Drug and Cosmetic] Act than it is for the Drug Enforcement Agency to convict a cocaine dealer of a violation of the Controlled Substances Act."[22]

The FDA's Informal Powers

Beyond its formal, legal authority, the FDA has substantial informal coercive powers. One major power is simply publicity. Official press releases containing negative information can discourage consumers and impose tremendous costs on a firm. While the financial impact of a FDA press statement can be devastating, the FDA makes clear it will use the power of the press when it feels that this is appropriate.[23]

Publicity alone is a powerful tool. Adverse publicity can result in substantial loss of reputation for a firm accused of making an unsafe product. Johnson and Johnson, for example, lost an estimated $1 billion in the value of its reputation from the Tylenol poisonings, even though the company was in no way culpable.[24]

There are similar losses from government-mandated recalls. Studies examining safety-related product recalls show that for products recalled by the FDA and the Consumer Product Safety Commission (CPSC), there is a substantial impact on the stock value of the firms involved, even though many of the risks that trigger the recalls are

15 Hutt statement, pp. 8-9.
16 Steven M. Kowal, "Defending Food and Drug Criminal Cases in a New Era of Criminal Enforcement," *Food Drug Cosmetic Law Journal*, Vol. 46, No. 2, pp. 273-309.
17 Kowal, p. 274.
18 Kowal, p. 276.
19 Kowal, pp. 304-308.
20 Kowal, p. 273.
21 Kowal, at 291.
22 Hutt statement, pp. 7-8.
23 Hoeting, p. 270.
24 Mark Mitchell, "The Impact of External Parties on Brand-Name Capital: The 1982 Tylenol Poisonings and Subsequent Cases," *Economic Inquiry*, Vol. 27 (October 1989), pp. 601-618.

quite small.[25] There are of course direct costs of recalls, but the loss in firm value caused by FDA-mandated recalls is much greater than this direct cost, and larger than any potential product liability exposure as well. The additional loss in firm value is the loss in the value of the reputation of the firm. For both FDA and CPSC recalls, the average loss in value as a result of a recall is about 6 percent of the value of the firm, as measured by stock value.[26] Thus, adverse FDA publicity can impose substantial costs on firms.

Beyond recalls, any publicized concern relating to safety can inflict large costs on a firm. Charges of product tampering, for example, can seriously damage a firm's reputation, even though there may be no realistic way in which a firm could have prevented the tampering, and even if the potential risk due to tampering is minuscule.[27] News stories on product-liability suits, which indicate safety problems with products, can also lead to significant losses in the value of a firm.[28] And if the FDA should indicate that it is concerned with the safety of some product, this can have a similar impact on the firm.

The FDA can informally affect the food and drug producers in other ways, sometimes to the detriment of consumers. For example, a 1988 study indicated the beneficial effects of aspirin in preventing heart attacks. This study found that the risk for male physicians over fifty was reduced by almost 50 percent.[29] Some manufacturers of aspirin understandably began advertising the results of the research. One producer even began selling aspirin in a "one-a-day" package, presumably for this use. But the FDA in July 1989 told manufacturers that they must not advertise the benefits of aspirin in reducing the chances of a heart attack.

The FDA had the power to do this in part because aspirin is not labeled as a preventative for heart attacks, so any advertising of this property would be contrary to the previously approved label, a practice which the FDA has the power to forbid. Apparently Frank Young, Commissioner of the FDA during the Reagan Administration, believed that consumers should obtain this information only from physicians. Manufacturers of aspirin were unwilling to contest the issue with the FDA because of the agency's general power.[30] This decision was an administrative ruling by the FDA: there were no hearings and no litigation. The FDA simply used its informal powers, and the threat of further actions was enough to block the efforts of firms to publicize the aspirin study's findings.

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25 Sam Peltzman and Gregg Jarrell "The Impact of Product Recalls on the Wealth of Sellers," *Journal of Political Economy*, Vol. 93 (June 1985), pp. 512-536; Paul H. Rubin, R. Dennis Murphy, and Gregg Jarrell, "Risky Products, Risky Stocks," *Regulation*, No.1 (19880, pp. 35-39.

26 Peltzman and Jarrell; Rubin et al.

27 Mitchell, *op. cit.*

28 W. Kip Viscusi and Joni Hersch, "The Market Response to Product Safety Litigation," *Journal of Regulatory Economics*, Vol. 2 (1990), pp. 215-230.

29 Steering Committee of the Physician's Health Study Research Group, "Preliminary Report: Findings From the Aspirin Component of the Ongoing Physician's Health Study, *New England Journal of Medicine*, Vol. 318, No. 4 (January 28, 1988), pp. 262-264.

30 This meeting and the rationale behind the FDA's decision are discussed in Charles C. Mann and Mark L. Plummer, *The Aspirin Wars* New York: Alfred A. Knopf, 1991), pp. 3-10.

With this arsenal of legal enforcement devices, the FDA already has an enormous impact on the behavior of firms. It is hard to see what case there could be for increasing the enforcement authority of the agency.

THE LOST GOAL OF CONSUMER BENEFIT

If FDA enforcement regulations without question benefitted consumers, then even draconian regulatory power might in principle be justified. But this is not the case. The FDA is an inefficient regulator, and in many instances actually causes harm to consumers rather than helping them. One example, of course, has been FDA's notorious delays in approving new drugs. The FDA has also denied consumers valuable information about drugs and about the health properties of foods.

New Drug Approvals

There is always risk associated with introducing a new drug. This presents the FDA with a problem. It can approve the drug swiftly, or it can withhold approval, pending further testing and information. Either decision might be erroneous.[31] If the agency approves a drug which later turns out to be harmful, officials will be attacked for their lack of thoroughness. On the other hand, if the agency demands exhaustive evidence that a drug is safe and effective, some Americans might suffer or die while FDA is gathering and evaluating information about the drug.

In fact, the FDA has been sufficiently cautious that there are no examples of major disasters from excessively lenient approval of a new drug. Thalidomide is the classic example of a harmful drug which was approved for sale—but never in the U.S. The laws on the books in 1960 were sufficiently stringent so that this drug was never sold here. What is surprising is that as a result of the thalidomide episode, U.S. laws were strengthened and a proof of efficacy was required for new drugs to be sold in the U.S., even though thalidomide was never sold in America and even though the problem with thalidomide was safety, not efficacy. In any case, a thalidomide-like event would be the worst possible occurrence if the FDA were to err and be too lax in drug approval. Sam Peltzman, the first scholar to point out the problems of drug approval, has indicated, based on the thalidomide episode, that the strongest possible argument in favor of the FDA's current powers would be that it could prevent "...something like 10,000 deaths or serious disabilities and an economic loss of something like $300 million perhaps once per decade...."[32]

Note that this statement was made in 1973. Since that time, there has never been a major problem with too-easy drug approval anywhere in the world, even though the U.S. has much more stringent standards than any other country. In twenty years there has nowhere been a thalidomide-like episode, so it is clear that Peltzman was overly

31 There will always be such uncertainty; it is never possible to have enough information to be absolutely certain about the costs and benefits of a drug. Indeed, one potential costly error is to delay approval while seeking new information because some will suffer and even die while awaiting new information.

32 Sam Peltzman, "Statement Before the Subcommittee on Monopoly of the Senate Small Business Committee," 1973, quoted in Hutt and Merrill, *Food and Drug Law*, p. 582.

pessimistic in estimating the potential harm from reduced enforcement. If traditional FDA policies have had any beneficial impact, it has been smaller than Peltzman predicted in his worst-case estimate.

Against this hypothetical loss must be counted the real and measurable costs of the injuries which FDA-delayed drug approvals have caused. A major example is the class of drugs known as beta-blockers, which are aimed at reducing heart attack risks. These drugs were unavailable in the U.S. from 1967 to 1976 as a result of FDA policies. It is estimated that this delay cost 10,000 lives per year, or a total of 100,000 needless deaths.[33] This is but one example of a real cost of FDA delay in drug approval, and for this one drug alone, costs are greater than any possible estimate of the benefits of reduced harm from prematurely approved drugs.

The public interest is best served if the FDA strikes a reasonable balance between these risks. Traditionally, the agency has not balanced these risks. In practice, it has placed a much greater weight on the risk of approving a drug which will ultimately be harmful than on denying approval of a beneficial drug.[34] The result has been that far more Americans have died from a lack of drugs to treat their disease than would have died from drug reactions if the FDA had approved drugs more easily.

It is not surprising that the FDA has erred on the side of excessive caution. Public outrage is swift when the FDA is deemed to be responsible for allowing a dangerous drug to reach the market. By contrast, consumers suffering from a disease which would be treatable if some new drug were approved often are unaware that FDA delays are the cause of their suffering. Congress has behaved in a similar way. Officials at the FDA have rarely been accused at congressional hearings of excessive delays in approving new drugs. But officials have on many occasions been accused of wrongly approving drugs which subsequently turned out to be harmful.[35]

When potential beneficiaries of drugs have identified themselves in advance, the situation changed radically. For example, AIDS sufferers could identify themselves, and thus knew that the FDA failed to approve a new drug which would prolong their lives. Therefore it has not been surprising that the FDA made special efforts to rapidly approve AIDS drugs. Because victims of AIDS were articulate and were able to organize themselves into a powerful lobbying group, the FDA accelerated approval of drugs to

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33 Kazman, *op. cit.*

34 The original research demonstrating this point was by Sam Peltzman, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," *Journal of Political Economy*, Vol. 81 (September 1973), pp. 1049-1091. A summary of the literature appears in William S. Comanor, "The Political Economy of the Pharmaceutical Industry," *Journal of Economic Literature*, Vol. 24 (1986), pp. 1178-1217. For a recent discussion, see Kazman, *op. cit.* The issue is also discussed in Hutt and Merrill, *Food and Drug Law*, pp. 580-583.

35 According to a former Commissioner of Foods and Drugs: "In all of our history, we are unable to find one instance where a Congressional hearing investigated the failure of FDA to approve a new drug. The occasions on which hearings have been held to criticize approval of a new drug have been so frequent in the past ten years that we have not even attempted to count them." Statement of Alexander M. Schmidt in Senate Hearings, 1974, quoted in Hutt and Merrill, *Food and Drug Law*, p. 1318.

fight this disease, and relaxed normal standards for proofs of safety and efficacy.[36]

The Bush Administration's recent regulatory initiatives would speed up the approval of "breakthrough" drugs for Americans suffering from deadly diseases such as cancer. The Administration action could save lives and improve the health of millions of Americans. But, although such reforms are desirable, the bureaucrats at the FDA are opposed [37] and likely will do all they can to sabotage them.

The Administration's reforms would, among other things:

- ✗ **Accelerate approvals.** In approving new "breakthrough" drugs for patients with life-threatening or serious illness, such as cancer or Alzheimer's disease the FDA will use "surrogate endpoints," a technical term meaning to rely upon earlier indicators of improved health, such as changes in blood cholesterol, rather than more comprehensive testing and analysis as a condition for expeditious approval. In the meantime, FDA may require additional and more comprehensive testing of the drug for its effectiveness after expedited approval, plus provisions for quick withdrawal of the drug if the FDA conditions are not met.

- ✗ **Adopt parallel track rules for use.** Under new FDA guidelines, "investigational" drugs, or drugs not yet finally approved by FDA for safety and effectiveness, can be made more readily available to AIDS patients. The idea is to allow AIDS patients to use such experimental drugs even if these patients are not participating in the "ongoing controlled clinical studies" required by FDA. Sponsors of experimental drugs can submit alternative testing proposals to the FDA or the Public Health Service to test drugs' safety and effectiveness. Through these alternative programs, more patients can receive promising therapies more quickly. While this "parallel track" regulatory reform is directed toward speeding up drug availability for AIDS patients, the Bush Administration is also considering this approach for other serious diseases such as cancer.

- ✗ **Use overseas safety data.** Safety data for drugs developed from animal testing in European countries and Japan can be used in the United States. FDA will establish standards for expediting the use of such foreign studies in the drug approval process. By using this data, drug sponsors will not be required to repeat animal studies and thus will reduce the time for drug development by as much as six months, according to FDA authorities.

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36 This is discussed in Hutt and Merrill, *Food and Drug Law*, pp. 552-566.

37 For example, 81 percent of FDA officials "disagreed" or "strongly disagreed" with proposals to privatize new drug application reviews. See Sidney M. Wolfe, "FDA Physicians Oppose White House Plan Which Will Endanger Millions of Americans By Weakening the Drug Approval Process," Public Citizen Health Research Group, Washington, December 19, 1991.

✗ **Use outside experts.** The FDA is also beginning to contract with qualified outside experts, seeking competitive bids to review applications for new drugs. This measure is designed to reduce the backlog of applications for new drugs, particularly anti-infective, anti-inflammatory, and analgesic drugs. While FDA will supervise contractors and retain final authority on drug approval, contacting out is also expected to expedite the drug approval process.

Consumer Information

The FDA also harms consumers by denying them useful information. For example, it sharply limits advertising by manufacturers of prescription drugs.[38] In most cases, advertising to consumers is burdened by requiring companies to include what the FDA terms a brief summary of side effects and contraindications.[39] This brief summary, however, typically is a full page of small print. This requirement increases the cost of print advertisements and makes television advertising of prescription drugs virtually impossible. Advertising could better convey vital health information if it were less heavily restricted. Moreover, increased advertising is likely to lead to price reductions for drugs.[40] Since prescription drugs cannot be purchased without the help of an informed intermediary—a physician—there is less chance for deception and confusion in this market than in almost any other. Nonetheless, the FDA continues to restrict advertising of the beneficial effects of prescription drugs. The FDA ban on advertising the benefits of aspirin in preventing heart attacks is one example.

More recently, the FDA has begun to restrict excessively advertising of pharmaceuticals even to physicians.[41] Many drugs are approved and labeled for one use, but turn out to be useful for other conditions. This is particularly true of drugs useful for cancer treatment. A common pattern is for a drug to be approved for one cancer's treatment and then tested for additional forms of cancer. If the tests are successful, an article is published in a medical journal. The manufacturer of the product will then publicize

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38 Paul H. Rubin, "The FDA's Prescription for Consumer Ignorance," *Journal of Regulation and Social Costs*, November 1991, pp. 5-25; Alison Masson and Paul H. Rubin, "Matching Prescription Drugs and Consumers," *The New England Journal of Medicine*, August 22, 1985, p. 513; Alison Masson, "Direct To Consumer Advertising," in Robert N. Mayer, ed., *Enhancing Consumer Choice*, American Council on Consumer Interests, Columbia, Missouri, 1991 (in press); Paul H. Rubin, "Economics of Prescription Drug Advertising," *Journal of Research In Pharmaceutical Economics*, Vol. 3, No. 4 (1991), pp. 29-40.

39 A "contraindication" is a condition which makes use of some drug undesirable. For example, some pharmaceuticals should not be taken by a pregnant woman, so that for these products, pregnancy is a contraindication.

40 Lee Benham, "The Effect of Advertising on the Price of Eyeglasses," *Journal of Law and Economics*, Vol. 15 (1972), p. 337; Robert Steiner, "Does Advertising Lower Consumer Prices?," *Journal of Marketing*, Vol. 37 (1973), p. 19; Howard Marvel, "The Economics of Information and Retail Gasoline Price Behavior," *Journal of Political Economy*, Vol. 84 (October 1976), p. 1033; John Kwoka, "Advertising and the Price and Quality of Optometric Services," *American Economic Review*, Vol. 74 (1984), p. 211; Deborah Haas-Wilson, "The Effect of Commercial Practice Restrictions: The Case of Optometry," *Journal of Law and Economics*, Vol. 29 (April 1986), p. 165; Paul Farris and Mark Albion, "The Impact of Advertising on the Price of Consumer Products," *Journal of Marketing*, Vol. 44 (Summer 1980), p. 17; Mark Albion and Paul W. Farris, *The Advertising Controversy: Evidence on the Economic Effects of Advertising* (Boston: Auburn House, 1981).

41 John E. Calfee, "The FDA: Moving Toward a Black Market in Information," *The American Enterprise*, March/April 1992, pp. 34-41.

this new use by sending copies of the medical journal article to interested physicians and by sponsoring seminars and symposia where physicians can learn of the drug's new use. The FDA is now stopping companies from publicizing results showing that drugs are useful in unapproved applications.

Even if a drug is approved for one use, it must additionally be approved for any new uses if these uses are to be put on the drug label; physicians, however, are free to prescribe an approved drug for any purpose, even if the purpose is not mentioned on the label. Approval for additional uses can take longer than the original approval, since new supplemental approvals have lower priority than original approvals.[42] Moreover, since these drugs already are on the market when a supplemental approval is requested, future patent life is shorter, and new approvals are less valuable to a manufacturer. The new FDA policy limiting promotion of drugs for unapproved uses, therefore, often will mean that drugs will not be used for these purposes, and the result will again be reduced health of consumers.

The FDA similarly places restrictions on advertising the health benefits of foods. Again, this policy harms consumers.[43] Such advertising would be beneficial. For example, advertising of higher fiber content in cereals has been shown to have caused greatly increased level of fiber.[44] This kind of advertising is generally against FDA policy, and was allowed only because the Federal Trade Commission (FTC) intervened and suggested that the FDA allow the advertising. By excessively restricting such advertising, the FDA denies valuable health information to consumers.

Dr. David Kessler, the Commissioner of the FDA, appointed in 1991 by President Bush, seems to be even more restrictive than his predecessors in his attitude to such advertising.[45] While no evidence of any harmful health effect of current advertising and promotion policies has been shown, Kessler nevertheless is increasing the staff devoted to enforcing regulations limiting advertising. These resources could better be devoted to ensuring the success of the Administration's effort to secure more rapid drug approval.

While the Administration's political leadership, including Vice President Quayle and Secretary Sullivan, are committed to cutting red tape and streamlining FDA's regulatory processes to make it easier for companies to develop and market life-saving drugs, within the FDA bureaucracy the institutional philosophy is quite different.

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42 Hutt and Merrill, *Food and Drug Law*, p. 535.

43 Richard M. Cooper, Richard L. Frank and Michael J. O'Flaherty, "History of Health Claims Regulations," *Food Drug Cosmetic Law Journal*, Vol. 45, No. 6 (1990), pp. 655-691. Note that this finding of excessive regulation was before Dr. Kessler began his current crusade to increase such regulation.

44 Pauline M. Ippolito and Alan D. Mathios, "Information, Advertising and Health Choices: A Study of the Cereal Market," *The Rand Journal of Economics* Vol. 21, No. 3 (Autumn 1990), pp. 459-480.

45 See remarks by Dr. David Kessler at the 20th Anniversary Conference, Center for Science in the Public Interest, Washington, D.C., June 6, 1991.

The institutional regulatory spirit at FDA has perhaps best been expressed by Kenneth Feather, head of the Drug Surveillance Branch of the FDA, and a regulator of advertising for prescription drugs:

> The old way is over. We used to say that if a company made certain changes, then we would probably not take any action. Now, we won't. Now, even if they make the changes, they might end up in court. We want to say to these companies that you don't know when or how we'll strike. We want to eliminate predictability.[46]

FDA staff, in short, favor adding to the financial risk firms face in introducing new drugs by adding a stiff dose of regulatory uncertainty and arbitrary retribution for actions that anger FDA bureaucrats. The result: Fewer therapeutic drugs and less information about them for Americans. Reversing the agency's current institutional biases in favor of excessive regulation is a genuine management challenge for the Bush Administration.

H.R. 3642: A PRESCRIPTION FOR MORE POWER[47]

Although the FDA already has more than adequate enforcement powers, some members of Congress want to increase the agency's enforcement authority. H.R.3642, the Food, Drug, Cosmetic and Device Enforcement Amendments of 1991, is the leading measure to do this. The bill does this in two basic ways.

First, it gives the FDA authority to take many actions administratively, without obtaining judicial review. Although the FDA can now undertake some actions without any judicial review, for others a court order is needed. H.R. 3642 would expand the number of regulatory activities for which a review is not needed. This gives agency employees even wider discretion than they now have.[48]

In most cases, firms voluntarily comply with FDA requests. But the FDA itself is tempered in what it asks of firms because it realizes that a firm does have the option of going to court and seeking judicial review if it believes that an order is unreasonable, or that the terms of an order are excessively onerous. Under the proposed legislation, the FDA would no longer be subject to the discipline of a potential court review, and the result would be increased bureaucratic arbitrariness. As indicated earlier, for example, FDA officials are now attempting to put Barr Laboratories out of business because this firm has been a whistleblower with respect to FDA misconduct in approving generic drugs. If H.R. 3642 were now law, the FDA could admin-

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46 Quoted in *The Washington Times*, September 12, 1991.

47 The exact terms of the bill are apparently changing as various amendments and redraftings occur. I am relying on the October 7, 1991 "Section-By-Section Analysis"; on the comments of various parties from the July 17, 1991 Hearings; and on the October 24, 1991 draft of H.R. 3642. (There are slight changes from 2597 to 3642.) In general, I attempt to discuss the broad nature of the provisions, rather than the particular details, so that these comments will apply even if the bill is modified further.

48 See the Testimony of Edward Dunkelberger, General Counsel for the National Food Processors Association, on [H.R. 3642], July 17, 1991.

istratively eliminate this company by, for example, indiscriminately seizing or recalling products of the company.

Second, the bill would impose new costs on manufacturers, which would increase prices to the consumer. The bill would lead to such increased regulation and costs primarily because of changes in the law affecting recalls, subpoenas, and new civil penalties.

More Costly Recalls. H.R. 3642 would strengthen the FDA's power to order recalls. Today most recalls technically are voluntary. But few if any firms resist FDA recall requests. If a firm does resist, the agency has various tools for enforcing recalls; it can seek an injunction from a court against a firm, or permission from a court to order a seizure. Criminal prosecution is also possible. The FDA also can publicize the refusal of a firm to recall its products. Such publicity can be very damaging financially to a firm. In 1989, for example, there were 2,183 recalls by the FDA,[49] so the agency is apparently not now hampered in its ability to convince firms to undertake recalls which it feels are justified. In 1937, even before the advent of modern communications technology, a recall of a truly toxic drug, elixir sulfanilamide, which caused 100 deaths, accounted for 99.2 percent of the product.[50] So there is no reason to believe that any product which truly presents a hazard would be a problem with respect to a recall.

Although firms generally comply with FDA recall requests, there is still room for negotiation. For example, firms may negotiate over the "depth" of the recall, the level of product distribution to which a recall will apply. Recalls may be at the consumer level, the retail level, or the wholesale level.[51] Empirical evidence indicates that recalls at the consumer level are generally ineffective,[52] but these recalls impose substantial losses in reputation capital.[53] Thus, a firm might rationally suggest a recall only at the wholesale or wholesale and retail level if the danger from the product is not substantial. Today, the FDA would be likely to comply with this request because the firm could threaten litigation if the FDA went farther. But if H.R. 3642 were passed into law the FDA could simply order a recall at the consumer level, even if this were unlikely to provide any additional benefits.

Greater Subpoena and Records Inspection Powers. Current law allows the FDA to inspect "'records, files, papers, processes, controls, and facilities' except for 'financial data, sales data other than shipment data, pricing data, personnel data... and research data' for prescription drugs and restricted devices."[54] The bill would

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49 Hutt and Merrill, *Food and Drug Law*, p. 1205.

50 Hutt and Merrill, *Food and Drug Law*, p. 1178.

51 Hutt and Merrill, *Food and Drug Law*, p. 1185.

52 R. Dennis Murphy and Paul H. Rubin, "Determinants of Recall Success Rates," *Journal of Products Liability* Vol. 11 (1988), pp. 17-28, show that for recalls ordered by the Consumer Product Safety Commission, for products in the hands of consumers, only about 7 percent are returned even if the recall occurs immediately after sale. Since FDA products are more perishable than CPSC products, one would expect the return rate to be even lower.

53 Rubin, Jarrell and Murphy; Peltzman and Jarrell.

54 Hutt and Merrill, *Food and Drug Law*, p. 1111.

grant subpoena powers to the FDA for all documents, including those classes of documents not now subject to examination.

The FDA can already examine records related to health or safety, and it can examine all products directly. This is adequate to detect any safety concerns with the product. Economic data, such as sales data, are not needed for determining the safety of a product, and is valuable competitive information. In this area then, current law strikes a balance between safety requirements and competitive protection. The subpoena authority in H.R. 3642 would destroy that balance and place competitively valuable materials at risk.[55]

The bill also authorizes the taking of photographs during plant inspections. Under current law, inspectors generally have the right to take photographs, and will sometimes obtain court orders for this purpose.[56] Thus, the bill will have a relatively small effect on this practice. Nonetheless, it will make it somewhat easier for inspectors to take photographs, and in some cases could lead to additional photographs. Photographs are particularly likely to show trade secrets, because competitors can learn about secret manufacturing processes and techniques from such photographs. Currently, if a photograph would be particularly harmful to a firm for competitive reasons and if it is of relatively little value to the FDA, the inspector might choose not to take the photo. Under the new law, he is much more likely to ignore the firm's requests for secrecy.

Giving the FDA greater access to business records increases the risk that a firm's confidential business data or commercial secrets will be revealed to its competitors. While the FDA no doubt would attempt to protect such documents, there is no guarantee that it could do so successfully. Corporate attorney Marvin Frank complains that "While the majority of the (record) requests are benign, every time the FDA takes a piece of information from company files, it should be assumed that the documents will eventually be available to competitors and adversaries."[57]

Document requests also can be quite costly for a firm, simply in the time it takes to comply. One heavy cost is the internal corporate review necessary before the release of a document. As Frank explains, "No document of this type should be provided without prior review by a company's own attorney."[58] The FDA is aware of the costs of document requests, and Alan Hoeting of FDA's Office of Enforcement admits that "some of the congressional requests for information [Congress' equivalent of a document subpoena] may best be described as onerous."[59]

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55 The bill attempts to protect such information by requiring that the Commissioner himself must make a finding about information regarding trade secrets and names of individual research subjects, and forbidding the Commissioner from delegating this authority. In practice, this will simply mean that the Commissioner will be required to sign such orders, not a particularly onerous restriction.

56 Hutt and Merrill, *Food and Drug Law*, p. 1117.

57 Marvin R. Frank, Assistant General Counsel, Assistant Secretary, Pfizer, Inc. "FDA Inspections: A Practical Corporate Response," *Food Drug Cosmetic Law Journal*, Vol. 46, No. 1 (January 1991), p. 73. Note that this analysis was prepared in connection with existing FDA authority; it was not written with H.R. 3642 in mind.

58 Frank, p. 76.

59 Hoeting, p. 268.

Another legitimate concern of firms is that greater FDA power to obtain internal documents can mean unfair accusations of corporate malfeasance. Low-level company employees may write innocent statements which do not in any way reflect the company position, or which may be based on misinformation. Nonetheless, if quoted out of context, such statements may cause the company great embarrassment. Example: A safety issue may be raised in writing but answered orally; in such a case, a subpoena would show only the written question. The lack of a written answer might imply that a reasonable employee concern had been ignored or covered up. That, in turn, could be used against the company in regulatory proceedings or in litigation. Example: In the breast implant matter, it appears that certain memos written by salesmen have been interpreted as indicating that the company had safety concerns with the product, even though the memos were not written by technical experts. A law making such memos easily accessible to the FDA would lead to additional litigation and would ultimately lead companies to greatly restrict the information employees were allowed to put in writing.

If additional classes of documents are made subject to subpoena or inspection, one rational corporate response would be simply to create fewer documents. For example, according to court interpretations, any contaminant found in a food is a violation of the Food, Drug and Cosmetic Act.[60] If a company conducts thorough quality control, and its records indicate some contamination, the firm has technically created a record of a law violation. This means that the firms with the best quality control records run the greatest risk of self-incrimination. Thus, one counterproductive incentive created under H.R. 3642 would be for companies to reduce their quality control record keeping.[61] From the standpoint of protecting the public, this outcome clearly is absurd.

Civil Penalties. H.R. 3642 gives the FDA power to levy civil penalties of up to $5,000,000. Under current law, there are only a small number of instances in which the agency can levy civil penalties, and amounts are limited.[62] This bill would greatly expand this authority.

The Congressional Staff Analysis of [H.R. 3642] notes that "...it is expected that in its prosecutorial discretion the FDA would not impose civil penalties for insignificant or minor violations, just as today it does not pursue criminal penalties for such types of violations of the Act."[63] It is unusual, however, for a prosecutorial body to be given authority to assess fines of up to $5,000,000 with no limits except its own "prosecutorial discretion." Moreover, the agency would be more likely to use this discretion in criminal cases, where it knows that it must be able to prove allegations

60 Statement of Jerome J. Kozak, Vice President, International Dairy Foods Association, regarding [H.R. 3642], July 17, 1991, p. 5.

61 It might appear that this could be prohibited by requiring the company to retain such records. However, it is difficult to see how all companies which now undertake quality control inspections could be ordered to continue, and difficult to see how companies could be ordered to keep "high quality" records. Moreover, there is no such requirement in H.R. 3642.

62 Discussed in Hutt and Merrill, *Food and Drug Law*, pp. 1171-1175.

63 Section-By-Section Analysis of Substitute Amendment to H.R. 2597, October 7, 1991, p. 7.

"beyond a reasonable doubt," than in civil proceedings, where it is more likely to win because of the lower standard of proof—a "preponderance of the evidence"—required in civil actions. It also appears that FDA Commissioner Kessler views his job as enforcing the law independently of any measure of costs or benefits. He is conspicuously not using, or is misusing, prosecutorial discretion in his enforcement of advertising restrictions in cases where no consumer harm has been demonstrated or even alleged, as discussed previously.

But even if the FDA does not misuse its civil penalty authority, firms will be wary of this power and will react accordingly if the bill becomes law. Because penalties will be possible for even minor technical violations of the law, companies will greatly increase the amount they spend to avoid such violations. The results will be higher costs and higher prices to consumers. The threat of seeking civil penalties will also serve as a weapon to force individuals—who can be fined up to $250,000—and firms to accede to other FDA requests, even if these are unjustified.

THE WEAK CASE FOR STRONGER FDA ENFORCEMENT

The FDA's job is to protect the health and safety of Americans. To make the case that the FDA should have increased enforcement powers to discharge its responsibility, it is logically necessary for proponents to show that current FDA powers are insufficient. Advocates must link laxity or weakness in FDA enforcement to reduced health and higher risks for consumers. And if such a link can indeed be shown, they must show that the proposed enforcement strategy would correct these problems and lead to improved health among consumers.

But advocates of H.R. 3642 have forged neither link: They have not shown that the FDA's current powers are insufficient to protect the health of Americans, nor have they shown that the bill will improve the health status of Americans. Most of the arguments advanced for increasing FDA enforcement authority center instead on the alleged virtues of bureaucratic consistency.

The bill was introduced by Representative Henry Waxman, who is Chairman of the House Subcommittee on Health and the Environment. In his opening statement introducing the bill, Congressman Waxman nowhere mentions health. His main argument is that "...the [existing] statute is inconsistent," adding that "Other comparable agencies also have these authorities."[64] Representative John Dingell, who is a cosponsor of the bill, seems to agree: "As matters now stand, the Agency is operating under enforcement tools and procedures enacted 50 years ago. Its regulatory authority differs from one product category to the next."[65] Neither of these arguments, however, indicate any national health problems stemming from current FDA enforcement.

64 Opening Statement of Representative Henry A. Waxman, at the Hearing on H. R. 2597, The Food, Drug, Cosmetic and Device Enforcement Amendments of 1991, July 17, 1991.

65 Statement by Representative John Dingell on H.R. 2597, July 17, 1991, p.2.

The staff of the House Subcommittee on Health and the Environment, in an analysis supporting an earlier version of the bill, refers at one point to health, pointing out that "...between 6.5 million and 33 million people become sick from microbiological contamination of food, 9,000 of whom die."[66] These data were derived from a U.S. Department of Agriculture study.[67] However, the analysis on which this study is based,[68] and discussions with the author, indicate that the analysis applies to contamination from foods which are subject to Department of Agriculture but not FDA inspection. This would not be changed by the bill. Thus, the original congressional staff analysis does not provide any evidence for adverse health outcomes due to current FDA enforcement efforts. It does not even claim that the proposed legislation would affect the illnesses that it asserts occur from microbiological contamination.

The only other reference to health is on page 8 of the congressional staff analysis in connection with recalls, which states:

> Ordinarily, where the FDA discovers a serious defect with respect to one of the products it regulates, the responsible company voluntarily recalls the product. Unfortunately, there have been a significant number of instances where the responsible company has refused to cooperate, which has led to serious risks to the public health.

No data are given, so it is impossible to determine how significant this problem is, if it indeed exists. In today's world of product-liability litigation, it is unlikely that many companies would resist recalls if the relevant products truly represented safety risks. Moreover, if a firm does resist, the FDA has the power to seize the product, enjoin its sale, or institute criminal prosecution.

The other justifications in this document are remarkably bureaucratic, rather than substantive. For example, the staff report states, "The main thrust of [H.R. 3642] is to give the FDA the same enforcement tools for all the products that it regulates" and "Although the FDA does not currently have subpoena authority...there are more than 200 federal statutes giving subpoena authority to other federal agencies."[69]

Another source of support for H.R. 3642 is the *Final Report of the Advisory Committee on the Food and Drug Administration,* which spent some time studying the FDA. This committee, appointed by HHS Secretary Louis Sullivan, refers in its final report to problems with generic drug approval, and with bribes accepted by some FDA employees for rapid approval of certain generic drugs.[70] It does not, however, refer to any adverse health outcomes from the alleged deficiencies in the generic drug approval or inspection process. It is not at all clear from the final report that the relevant generic drugs themselves were inferior or caused adverse health outcomes, although some of

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66 Section-By-Section Analysis of Substitute Amendment to H.R.2597, October 7, 1991.

67 Tanya Roberts and Eileen van Ravenswaay, "The Economics of Safeguarding the U.S. Food Supply," United States Department of Agriculture, Economic Research Service, *Agriculture Information Bulletin* No. 566, July 1989.

68 Tanya Roberts, "Human Illness Costs of Foodborne Bacteria," *American Journal of Agricultural Economics*, Vol. 71, No. 2 (May 1989), pp. 468-474.

69 Section-By-Section Analysis, p. 2.

70 Final Report, pp. 25 and 30-31.

the data used in their approval apparently were fraudulent. While bribery of FDA employees is and should be a genuine concern, H.R. 3642's combination of greater FDA authority to levy fines and increased discretion for FDA employees could exacerbate this problem.

The authors of the final report do not provide any basis for the argument that the FDA's current enforcement powers are inadequate. In fact, the report actually bolsters the arguments of the critics of increased FDA powers, who maintain that the agency has more than enough authority, but is not using it carefully or rationally. Notes the report, it is "...difficult to speak confidently about the extent to which FDA's current enforcement efforts are adequate in magnitude or appropriately targeted."[71] This is a disturbing conclusion about the powers of a major regulatory agency whose decisions affect 25 percent of all expenditures in the U.S. economy. Yet despite the absence of evidence of effectiveness, the final report argues that "The Agency should be armed with the same tools for all the products that it regulates."[72] So the public gets another bureaucratic plea for bureaucratic consistency.

RECOMMENDATIONS

Since the FDA has tended consistently to err on the side of withholding approval of new drugs rather than making them available to patients, and since the agency's sweeping powers in many instances have counterproductive results, the best way to enhance the health of Americans would be to streamline the FDA's regulatory process, not add to its powers. The Bush Administration has greatly advanced this goal by issuing new regulatory guidelines designed to speed up drug approval.

Beyond the Bush Administration's reforms, the FDA's service to consumers could be further enhanced. Four reforms in particular would improve consumer health. Of these, the first two could be implemented relatively easily; the last two would require major legislative changes, although they would provide substantial benefits.

Reform #1: Shift resources from enforcement to drug approval.

While the Bush Administration initiatives rightly emphasize expeditious drug approval, this shift would give budgetary substance to the Administration's reforms. Good intentions and good policy should be backed up with staff and dollar shifts.

Reform #2: Base current and future FDA enforcement efforts on likely health impact.

The FDA should attempt to measure the health impact of its policies and to allocate its resources so as to maximize the health benefits of its actions. As mentioned above, one major study of the FDA found that it is difficult to tell if the agency now appropriately allocates its enforcement resources. To do so, it should use quantitative

71 Final Report, p. 26.
72 Final Report, p. 29.

measures and economic analysis, such as cost-benefit or risk-benefit analysis, on a much more formal basis than it does today.

Reform #3: Repeal the efficacy requirement for prescription drug approval.

Before 1962, drugs were approved on the basis of safety. But in that year, the law was amended to require proof of efficacy as well as safety. The result: Fewer new drugs are approved; approvals involve long delays and drugs often are approved for use in other countries long before they are available in the U.S. This can mean thousands of Americans die unnecessarily because new drugs are unavailable. For example, as already discussed, as many as 100,000 Americans needlessly may have died of heart disease as a result of the ten-year delay in approving beta-blockers for use in the U.S.[73] The Bush Administration's regulatory change, which would allow the use of safety data from animal testing in other countries, is a step in the right direction. Repealing the efficacy requirement altogether would be a more decisive step.

Reform #4: Change FDA approval to certification.

Physicians should be allowed to prescribe unapproved drugs as long as the drugs clearly indicate that they are not approved. In this way, the costs of the excessive delay in drug approval could be reduced and the drugs made available to Americans who face severe health problems without them. The FDA could serve a useful function by testing and certifying new drugs, but those physicians (and their patients) who prefer to be able to use newer drugs could satisfy that preference. Short of this, drugs which have been approved in another major country could be sold in the U.S. with the caveat they are not yet FDA approved.

CONCLUSION

Some federal policy makers in the Congress want to invest the FDA with greater authority. They want the FDA to have more power to seize and recall products, to subpoena company records, including trade secrets, and to levy huge fines on companies. In many cases, these policy makers want the FDA to have these powers without judicial review or oversight.

But the FDA already has immense power, sufficient to accomplish almost all of its goals. If the FDA can convince a judge that its proposed action is meritorious and deals with a genuine safety concern, it can force companies to comply. It can back up its demands with powerful criminal sanctions, even for violations committed unknowingly, and it can cost a firm its reputation by indicating in public that it has compromised safety.

Supporters of legislation to expand FDA's enforcement authority have made no credible case that such increased authority will lead to increased public health. Most of the arguments for the bill are bureaucratic, not substantive; they refer to "consistency" in

73 Discussed in Kazman, *op. cit.*, pp. 42-43.

regulatory powers across products, not to health outcomes. If consistency is a goal, it can just as easily be achieved by weakening the FDA's regulatory powers. Congress could examine instances where FDA has abused its regulatory authority or acted with excessive zeal at the expense of innocent companies.

The only demonstrated harm to safety associated with the FDA is the harm it has caused by excessively delaying the approval of new drugs. The Bush Administration's reforms of the FDA drug approval process would enable the agency to more rapidly approve drugs. The health of Americans would be improved if these Administration reforms were effected, and if FDA resources were shifted away from enforcement and used to speed up drug approval. H.R. 3642, by giving additional enforcement power to the FDA, would likely result in more resources being devoted to enforcement, and would therefore exacerbate the health problems caused by the FDA through preventing Americans from purchasing useful and beneficial therapies.

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