

THE PRICE WE PAY: The Efficacy Requirement for New Drugs Under the Food, Drug and Cosmetic Act

Corey B. Rubenstein

I. INTRODUCTION

The newly sworn Republican-controlled Congress has, as one of its primary objectives, the downsizing of government. Speaker Newt Gingrich has specifically targeted the federal Food and Drug Administration (FDA) for the conservative wrath.¹ The political climate that led to the change in power in Congress is partly based on the nation's anti-regulatory demeanor – the belief, whether correct or mistaken, that the regulators have run riot, that there is too much power in the hands of a few appointed bureaucrats. The FDA draws specific attention because of the palpable effects of its rulings in the lives of all citizens. Specifically, the requirements for the pre-market approval of new drugs have been criticized for being too cumbersome.² This paper will attempt to draw a compromise between the observed problem of overregulation in that area and the still important policies underlying the federal Food, Drug, and Cosmetic Act (FDCA). It will call for the elimination of the efficacy requirement for new drug applications (NDA) as a way to reduce the costs of developing new drugs, while maintaining the safety requirement in order to ensure the public health.

NDAs are covered by section 505 of the FDCA.³ The provisions

¹Howard Kurtz, *The Jaded Crusader*, The Washington Post, December 15, 1994, at D1. Gingrich was quoted as saying that the FDA is the number one job killer in America.

²Michael Kinsley, *The FDA: Too Cautious, Not Too Bold*, Washington Post, August 10, 1989, at A25.

³21 U.S.C. § 355 (1988).

of that section prohibit the introduction into interstate commerce of new drugs unless approved by the FDA.⁴ Approval may be refused by the Secretary if the applicant fails to show the drug's safety or fails to submit substantial evidence of the drug's efficacy. Such evidence, however, can only be garnered by animal and clinical testing.⁵ The NDA itself generally consists of two to fifteen volumes of summary material of such testing and may be accompanied by as many as 200,000 pages of raw data.⁶ In 1980, the clinical testing stage of development could last between seven and thirteen years and cost up to fifty million dollars, while the average time for the approval of an NDA was almost three years.⁷ It is difficult to determine exactly what percentage of this can be traced to the efficacy requirement as opposed to the safety requirement. Nonetheless, it remains clear that the efficacy requirement alone is a substantial factor.⁸

The FDCA as originally enacted in 1938 required only that a drug be shown to be safe before being approved for commercial use. This original NDA process was enacted in response to the elixir sulfanilamide disaster, a tragedy in which hundreds died from ingesting a drug whose liquid base was poisonous.⁹ The Act required an applicant to submit the NDA accompanied by the safety information, but allowed for automatic approval if the FDA failed

⁴Section 201(p) defines new drugs, *inter alia*, as [any drug... the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and

⁵The clinical testing is allowed by an exemption in the statute falling under section 505(i), known as the investigational new drug (IND) exemption.

⁶House Comm. on Science and Technology, 96th Cong., 2nd Sess., Report on The Food and Drug Administrations's Process for Approving New Drugs (Comm. Print 1980).

⁷A more recent estimate cited in 53 Fed. Reg. 41,517 is that it takes an average of eight years from animal testing to FDA approval.

⁸*See infra* section III-A.

⁹Richard.I. Nelson, *Regulation of Investigational New Drugs: Giant Step for the Sick and Dying?*, 77 Georgetown L.J. 463, 468 (1988).

experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof... 21 U.S.C. § 321(p) (1988). to act within sixty days.¹⁰ In 1962, however, Congress passed the Drug Amendments in response to another tragedy, the thalidomide tragedy that occurred in European countries.¹¹ The Drug Amendments did away with the system of automatic approval, but are better known for adding the efficacy requirement to the NDA process.¹² What is sticking, though, is that this addition is really unrelated to the thalidomide disaster, for that disaster was a result of an unsafe rather than an ineffective drug. The impetus for these amendments, as well as that for the original act, was a concern over safety. Efficacy was never a primary concern. Through regulation the FDA has, in recent years, loosened the NDA requirements in certain circumstances, generally for patients with life-threatening diseases. This trend began in 1977 when the FDA initiated an informal policy called compassionate INDs— allowing terminal patients to procure IND drugs on an *ad hoc* basis,¹³ and culminated with the promulgation of a regulation regarding treatment (as opposed to clinical) use of INDs in 1987.¹⁴ In 1990, the FDA specifically addressed the problem of NDA inflexibility as it applied to AIDS when the FDA announced a parallel track policy allowing for treatment use of AIDS INDs.¹⁵ Through these policies, the FDA has addressed the important though narrow

¹⁰ *Id.* at 469.

¹¹ Thalidomide, a tranquilizer prescribed to pregnant women to alleviate morning sickness, caused birth defects in thousands of babies. *Id.*

¹² *Id.* at 470. The amendments also instituted the [ND system.

¹³ *Id.* at 471.

¹⁴ 21 C.F.R. § 312.34 (1987).

¹⁵ 55 Fed. Reg. 20856 (1990). The policy requires that the patient have no therapeutic alternative

problem of the so-called drug lag as it applies to terminal diseases. The policies have the effect of allowing any terminal patient to obtain INDs prior to FDA approval, and cannot participate in controlled clinical trials.

Therefore, one can argue that the efficacy requirement has already been eliminated for such patients insofar as an experimental drug is still pending NDA approval.

This paper, however, argues that we should go much further than the FDA has in its recent liberalization of the NDA process. We should eliminate efficacy as an independent requirement for *all* new drugs, whatever the seriousness of the targeted condition or the status of the NDA.¹⁶ Where a drug is found safe, the government should stay out of the decision of an individual and his doctor to proceed with its use. Three arguments support this proposal:

First, there are limited resources for the development of new drugs and unnecessary regulations increase the cost of development, reducing the number of beneficial drugs developed. Second, the notion of drug efficacy is one that a marketplace can handle more efficiently than a too cautious government agency. Third, patients' privacy interests in choosing a method of treatment should be respected. To put this proposal in a contemporary context I will analyze how the NDA process works for two recent examples of questionably efficacious drugs: the AIDS panacea, AL-721, and the hair-growth application, minoxidil.

¹⁶This does not mean that efficacy would be completely irrelevant, for the FDA might still consider it as a part of the safety determination. For instance, a drug which is not completely safe may still be approved if it is very effective in treating a serious disease. Conversely, a completely safe drug could not be denied approval because of its questionable efficacy.

II. PREVIOUS ATTEMPTS AT JUDICIAL LIMITATION

Before addressing the specific arguments for eliminating the efficacy requirement, I will summarize the relevant case law. The courts have generally been unwilling to remove or limit the efficacy requirement as a matter of either statutory or constitutional interpretation. The most celebrated case, *United States v. Rutherford*, involved the unapproved cancer drug

Laetrile.¹⁷ The plaintiff class there argued that the 1962 amendments should not be read to apply to terminal patients. Since they would die without Laetrile anyhow, they contended, the protective policies behind the amendments were not applicable. The Supreme Court disagreed, holding that the FDCA allowed the FDA to require a showing of efficacy as well as safety for all drugs, including those intended to treat terminally-ill patients.¹⁸ The amendments gave the discretion to the FDA, not to the patients, to decide whether to insist on a showing of efficacy.¹⁹ In essence, the Court accepted the FDA's argument that people may need to be protected from themselves.

The *Rutherford* decision was based completely on statutory grounds. The constitutional validity of the efficacy requirement as applied to terminal or non-terminal patients has never been squarely tested in the Supreme Court.²⁰ However, in *People v. Pnuvera* the California Supreme Court held that the constitutional right to privacy did not encompass the right of terminal cancer

¹⁷442 U.S. 544 (1979).

¹⁸*Id.* at 552.

¹⁹*Id.* at 553-554.

²⁰Though on remand, the 10th Circuit rejected the constitutional grounds, thus refusing to extend the constitutional right to *refuse* medical treatment. 616 F.2d 455 (1980).

patients to obtain Laetrile.²¹ It is fairly clear, therefore, that neither the Constitution nor the FDCA forbids the application of the efficacy requirement to drugs intended to treat terminal diseases. It follows from these decisions that *all* drugs may be validly subjected to the efficacy requirement. Thus, it appears that the only available route to the requirement's elimination is through legislative or regulatory action.

III. THE EFFICACY REQUIREMENT SHOULD BE ABANDONED

The simple reason for doing away with the efficacy requirement is that its costs outweigh its benefits. Michael Kinsley articulated the costs of the NDA process:²² First, people die or suffer while possibly beneficial drugs await FDA approval. Second, pharmaceutical companies never develop hypothetically beneficial drugs because the process is too costly. Third, actually beneficial drugs may never be approved because the FDA's standards are too high, i.e., the FDA is too cautious. I will not specifically address Kinsley's first cost in this paper, because I believe it has largely been reduced by the treatment (INT) and parallel track IND policies instituted by the FDA.²³ I will argue, however, that the other two costs relating to drug development and the cost of the diminished privacy rights of patients outweigh the benefits associated with the efficacy requirement. Those benefits are (1) minimizing the expenditure of money spent on ineffective drugs, and (2) minimizing the medical costs of foregoing proven treatments for ineffective ones.

A. The NDA Process is Too Costly

²¹591 P.2d 919 (1979).

²²Kinslev, *supra* note 2.

²³*See supra* notes 13-15 and accompanying text.

As described above, the NDA process is a very lengthy and costly one.²⁴ Drug manufacturers, however, have limited resources to invest in experimental drugs. Therefore, one would ordinarily expect that the cheaper the approval process, the more drugs would be developed. And the more drugs developed, the more beneficial drugs developed. To complete this syllogism, a decrease in the cost of the process would lead to more beneficial drugs. One way of reducing costs is to eliminate the efficacy requirement.²⁵ However, doing so would also eliminate its benefits. But I argue that such benefits are largely illusory. The truth is that the market would be likely to display a drug's ineffectiveness in a timely fashion without the help of the FDA. Competitors as well as academics and medical journalists would point out and criticize the anemic evidence of a drug's efficacy. Armed with such knowledge, patients would shy away from using such a drug, and, anyhow, their physicians would be unlikely to prescribe such drug's use. Therefore, since the safety of a new drug is ensured by normal FDA standards, efficacy should be irrelevant.

Nonetheless, proponents of the efficacy requirement might argue that the incremental cost of investigating efficacy once safety has been investigated is actually minimal. That argument contends that safety and efficacy can be determined simultaneously with little additional cost, and, therefore, the possible benefits of the efficacy requirement should be preserved by retaining that requirement. Such a claim would be wrong, however. Safety determina-

²⁴See *supra* notes 6-7 and accompanying text.

²⁵Another way is to eliminate the safety requirement. That, however, is a harder argument to make, for the offsetting benefits of the safety requirement are more easily observed than the benefits of the efficacy requirement.

tions are made in the first and second phases of clinical testing, while efficacy determinations are made partly in the second and mostly in the third phases of testing.²⁶ Furthermore, the number of subjects in the third phase can be hundreds of times greater than the number studied in the first phase and tens of times greater than those in the second phase.²⁷ Therefore, it is clear that the efficacy requirement, as an independent standard, forces drug manufacturers to incur substantial and unnecessary extra costs.

B. The FDA is Too Cautious

There is something of a phenomenon of bureaucratic conservatism in public agencies charged with protecting the health of Americans. Milton Friedman explained this phenomenon as it applies to the FDA.²⁸ He argued that a risk averse FDA official would rather make the mistake of refusing approval of a what is actually a safe and effective drug that would have saved lives, than approving what turns out to be an unsafe or ineffective drug that results in death or serious injury. Therefore, the FDA enters the NDA process with a bias against approval. It is a combination of this risk aversion and the unfettered discretion of the FDA that may exact a high cost in terms of human lives. Though such an observation may not be a good argument for doing away with the system completely, it does suggest that FDA discretion should be reduced where possible. Since this paper displays that the marginal benefits of the efficacy requirement, if any, are small, it follows that we should reduce the FDA's discretion by eliminating that requirement.

²⁶Nelson, *supra* note 9, at 470-471.

²⁷*Id.*

²⁸Milton Friedman, *Frustrating Drug Advancement*, Newsweek, January 8, 1973, at 49.

A further problem with the existing discretion the FDA has under the efficacy requirement is that efficacy is too difficult to prove by substantial evidence.²⁹ A determination of efficacy for certain drugs may not be available until the drug has achieved widespread general usage, long after Phase III studies are completed.³⁰ Furthermore, where experts have attempted to determine efficacy at the clinical stage, they have been surprisingly unable to accurately assess false-positive and false-negative findings.³¹ The main problem, though, is that the FDA is institutionally incompetent to determine efficacy. The agency has no controlling principles on which to base such decisions, and, in any case, it has no expertise to apply those principles. Therefore, we should let the medical profession and the market deal with the question of efficacy. For even without the FDA's supervision, there is no reason to fear that ineffective drugs will prosper since competitors are free to question efficacy and doctors are obligated to do the same.

C. The Individual's Privacy Interests Outweigh those of the Government

Probably the most important reason for doing away with the efficacy requirement is that it interferes with the right of a patient to control his own course of treatment. Although such a right is not embedded in the Con-

²⁹Section 505(d) defines substantial evidence as evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is

³⁰Margaret Salmon Rivas, *The California Aids Initiative and the Food and Drug Administration*:

³¹Katherine M. Atikian, *Nasty Medicine*, 27 Loy. L.A. L.R. 1513, 1532-1533 (June 1994).

stitution,³² it is an interest that we should respect where possible. If a drug is proven safe, non-addictive, and non-impairing, then the represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

Working at Odds with Each Other?, 46 Food Drug Cosm. L.J. 107, 117 (January 1991). government has no significant countervailing interest in preventing its use. The only possible interests the government could claim are *parens patriae*, protection against fraud, and control of national health care expenditures. The first interest goes to the question of whether an individual can assess for himself, with the counsel of a doctor, the costs and benefits of proceeding with an unproven treatment. Where an individual is informed about the unproven traits of a drug versus the proven, though less than ideal, alternative treatments, the decision of which road to choose is best left to him. For that reason, a patient may decide to undergo an experimental surgical procedure without government intrusion, and the surgeon's only restrictions on going forward with such an operation are malpractice liability and peer review. As to the government's interest in protecting patients from fraud, I have already argued that the market and the medical profession are better able than a public agency to guard against false claims of efficacy.³³ Further, the physician's duty to give informed consent ensures that his patients will be apprised of the relative merits of competing drugs or of the unproven efficacy of a prescribed drug.

³²See *supra* section II. Though, in a strong dissent in *Privitera*, Judge Byrd argued that each individual [cancer] patient has the right to obtain the substance [laetrile] from a licensed physician who feels it appropriate to prescribe it to him, as long as the substance is safe. 591 P.2d 919, 927 (1979).

³³See also *infra* section VI.

Proponents of the efficacy requirement may nonetheless argue that the requirement is necessary in an insurance-funded health care system such as ours. In such a system patients will not internalize the costs of using experimental drugs; therefore, the argument goes, we need the efficacy requirement to limit health care expenditures to those treatments that are medically necessary and effective. Such an argument ignores two important facts, however. First, insurance policies are not required to cover experimental treatments in general, and, for example, Medicaid does not.³⁴ Second, doctors still have to prescribe the drug. It is this second fact that will act as the greatest barrier to the potentially wasteful expenditure of money on drugs of unproven efficacy, for physicians will not be apt to prescribe experimental drugs except in unusual circumstances. Anyhow, the ability of third-party payors to remove such drugs from their coverage ensures that expenditures will be limited.

IV. AIDS AND THE EGG-YOLK PANACEA

The well-publicized furor over the experimental and unapproved AIDS drug AL-72 1 displays why we should eliminate the efficacy requirement. A.L-72 1 is an egg-yolk derivative which was sold as a food supplement by Ethigen, a small Los Angeles company, to people with AIDS.³⁵ Advocates of AL-721 claimed that the substance retards the ability of the AIDS virus to infect cells.³⁶ Though the substance is harmless, it has never been shown to have any

³⁴Angela R. Holder, *Funding Innovative Medical Treatment*, 57 Albany Law Review 795, 803 (1994).

³⁵Elizabeth Sanger, *Anti-AIDS Substance May Go on Sale Soon*, *Newsday*, April 19, 1988, at 43. AL-72 I is not subject to NDA approval because the FDA has considered it to be a food supplement rather than a drug.

³⁶Lee Ann Dean, *Acquired Immune Deficiency Syndrome, Viatical Settlement, and the Health Care Crisis*, 25 Rutgers L.J. 117, 125 n. 36 (1993).

effect on the AIDS virus and has been discredited by most experts.³⁷ For the purpose of this discussion, I will assume that AL-721 should be subjected to NDA approval despite its status as a food supplement.

For a disease such as AIDS, the only hope for a cure is a shot in the dark. However, the heavy costs imposed by the efficacy requirement on pharmaceutical companies makes it unlikely that such companies will go ahead with any testing of a questionable candidate drug, although such a drug may have otherwise turned out to be the one. Therefore, the efficacy requirement has a direct effect on limiting the number of experimental AIDS drugs that may go through all phases of clinical testing. For example, say AL-721 is being presently developed and tested. Chances are it would be abandoned in an early phase of clinical testing by the manufacturer because of equivocal results. Thus, money would be saved (for we really know that the drug would turn out to be ineffective here). Such a result would be merely fortuitous, however, because the decision to cancel testing would not have been based solely on the merits of the results. Rather, the decision would have been artificially influenced by the extra costs required to show efficacy by substantial evidence. If one accepts the market theory, then such a decision, though correct in the result, can be considered fallacious in the process.

Ethigen also would be likely to abandon AL-721 at an early phase of testing because of the high standards of the efficacy requirement and the FDA's overcautiousness. Knowing beforehand of the substantial evidence re-

³⁷Gina Kolata, *Strange Saga of AL 721*, San Francisco Chronicle, June 27, 1988, at AS.

quirement and the wide discretion of the FDA, Ethigen would be hesitant to expend resources on the drug without some early hard proof of efficacy. Again, that would be the correct result here, though it shows how the process is flawed in general. And even if Ethigen were to allow AL-721 to go through the complete NDA process, the NDA's eventual denial would represent a substantial waste of money that could have been spent on developing another candidate drug for AIDS treatment.

Finally, the efficacy requirement makes no sense as applied to AL-721 because it is an unnecessary interference with the privacy interests of people with AIDS. As discussed above, the use of truly ineffective drugs will most likely wane in time as such information is disseminated.³⁸ In any case, terminal patients, such as people with AIDS, should not be denied the hope of a miracle cure as long as the drug is safe and the patients are not deceived about the actual chances that the drug will lead to recovery. It cannot be claimed here that the government is protecting these people from themselves, for they will die one way or another. Therefore, the government has no countervailing interests to the assumed privacy interests of the individual.

V. HAIR GROWTH FROM HEART MEDICATION

The Upjohn Co. discovered in 1984 that its blood pressure medicine called minoxidil might aid in curing or preventing baldness.³⁹ The FDA approved the substance, called Rogaine, as a prescription scalp application, though

³⁸ *See supra* section III-A. For example, by 1990 most advocates for the use of experimental AIDS drugs had shied away from supporting the use of AL-721. Elaine Herscher, *Book Review*, San Francisco Chronicle, October 28, 1990, at 5.

³⁹ Mary Granfield, *At a Glance the Bald Truth About Minoxidil*, Money Magazine, April 1989, at 87.

it was revealed that Rogaine could only work for men with hair thinning on top and, by the best estimate, for only 39% of those men.⁴⁰ The drug has been found harmless if not very effective at curing baldness.⁴¹

1987, at 1,5,5.

The efficacy requirement places a high cost on the balding as it does on the AIDS-stricken. The disease or disfunction is largely irrelevant. If there is any difference, though, the argument should be even stronger for a drug like Rogaine whose intended effect is merely cosmetic. Why should the FDA be concerned in any way with an individual's decision to spend his own money on a treatment with no medical downside as long as he is informed by the manufacturer or his doctor of the low rate of success?⁴² Baldness is not a trivial problem to many people, though objectively less serious than other medical conditions. In requiring a manufacturer to show efficacy by substantial evidence, the cure for baldness, if one exists, may be passed over just as the cure for AIDS may have already been dismissed as ineffective. Further, the extra expense to prove the effectiveness of Rogaine might have been better spent on research for another baldness medication or, perhaps, an AIDS drug. Once again, drug companies have limited resources and money spent on documenting efficacy studies for the benefit of the FDA is inevitably taken from another

⁴⁰John Langone, *Gone Today, Hair Tomorrow*, Time, August 29, 1988, at 78. Though according to an FDA advisory panel member, only 15% of men would grow enough hair to make a visible difference, and a year's supply could cost \$600. *Hair-Raising News*, Time, March 30, 1987, at 62.

⁴¹John Sansing, *Minoxidil Falls Short as Miracle Baldness Cure*, Los Angeles Times, August 10,

⁴²Since Rogaine is likely to retain its prescription status there is no real worry that misinformation by Upjohn would not be rectified by physician consultation. *Panel Advises FDA Not to OK Over-the-Counter Rogaine Sales*, Star Tribune, July 28, 1994, at SA.

endeavor.

In the case of Rogaine, the conservatism of the FDA did not lead to a refusal to approve the drug for prescription use. Nonetheless, that agency's overcautiousness and the inordinately high standard it has for new drug approval contribute to the problems discussed above. The cost of testing and documenting the drug's efficacy was artificially heightened relative to what the marketplace would have required. In effect, Upjohn was forced to test the substance on about 5,000 subjects to determine efficacy where a much smaller number might have been sufficient, and an even smaller number necessary to determine safety.⁴³ The result of such conservatism is that either a possibly effective drug will be precluded from the marketplace, or it will be allowed entry only after an unnecessary premium is attached to it.

Even if Rogaine were shown to be completely ineffective, the government should not interfere with an individual's physician-informed decision to use the substance. This privacy argument is strongest for cosmetic drugs, such as Rogaine, because there is no worry that the patient may be hurt by foregoing a more effective alternative (though I have argued above that such a worry also does not justify government intrusion). Again, the market and the medical profession will enlighten patients about false cures, especially for breakthrough medications that are likely to be widely publicized. And the ability of government and private insurers to remove such drugs from coverage and force patients to pay for them out-of-pocket means that such drugs' purchases will

⁴³Sansing, *supra* note 41.

not be improvident. Furthermore, the FDA is not competent to decide whether Rogaine is effective. Would a 5% success rate justify use? Would a 1% rate do it? Does it matter that the medication must be used for life to preserve any growth?⁴⁴ Should the high cost of its use play a part in assessing efficacy? Since the drug is safe, these are questions that should be answered privately and personally. They are not questions best left to experts or bureaucrats. q

VI. IN THE CASE OF MARKET FAILURE

The previous analysis is dependent on the existence of a well-functioning market. Such a market cannot always be counted on, though. Drug patents create monopolies and the medical profession cannot oversee the introduction of every substance. Further, physicians may be misinformed and patients ignorant. The lack of regulation under such circumstances may lead to the triumph of actually ineffective drugs, at least for a time. If drug companies could predict such market failures, then they might be tempted to make a quick buck by falsely stating their drugs' efficacy. One might argue from this that the efficacy requirement is an integral and necessary part of new drug approval.

For six reasons, however, the possibility of such a market failure does not mean that ineffective drugs would prosper. First, even without an efficacy requirement the FDA has a very strong weapon to battle what it thinks are ineffective drugs. That weapon is publicity. For instance, when Upjohn issued an overly optimistic report of Rogaine's effectiveness in 1986, the FDA countered with a press release questioning the report's validity.⁴⁵ The FDA's

⁴⁴Langone, *supra* note 40.

⁴⁵Sansing, *supra* note 41.

action caused a drop in the value of Upjohn's stock and, presumably, helped to correct the market failure⁴⁶ Second, the FDA can attack companies for false claims of efficacy on a drug's labeling.⁴⁷ Such an attack may include the issuance of an injunction,⁴⁸ the imposition of criminal penalties,⁴⁹ and the seizure of the misbranded drugs.⁵⁰ The existence of such sanctions should deter companies from making false representations despite a market failure.

Third, the Federal Trade Commission can sue under section 53(a) of the Federal Trade Commission Act to enjoin advertisements relating to false claims of drug efficacy.⁵¹ Fourth, private parties can sue drug manufacturers under section 43(a) of the Lanham Act for damages caused by false representations made in the labeling or commercial advertising of such drugs.⁵² Fifth, state and federal criminal fraud prohibitions should deter companies from knowingly or recklessly overstating the efficacy of drugs. Finally, the argument for the elimination of the efficacy requirement does not preclude the enactment of other measures designed to protect the public from ineffective drugs, as long as such measures do not require a pre-market showing of efficacy. For instance, Congress could require that questionably efficacious drugs declare that uncertainty on their labels, with the failure to do so constituting misbranding. Congress could also enact new and harsher penalties for misbranding. Anyhow, an elimination of pre-market efficacy approval, even in the face of a market failure, does not

⁴⁶*Id.*

⁴⁷Section 502(a) of the FDCA deems a drug misbranded [i]f its labeling is false or misleading in any particular. 21 U.S.C. § 352(a) (1988).

⁴⁸21 U.S.C. § 332 (1988).

⁴⁹21 U.S.C. § 333 (1988).

⁵⁰21 U.S.C. § 334 (1988).

⁵¹18 U.S.C. § 53(a) (1988).

⁵²15 U.S.C. § 1125(a) (1988).

leave drug companies free to make unsubstantiated claims of efficacy.

VII. CONCLUSION

The costs imposed by overregulation are not just felt in the treasury or in the gross national product numbers. They are discernable in the lives of the sick and dying, of the suffering, and even of the balding. When such costs can be diminished without an offsetting diminution in benefits, we should act accordingly. In eliminating the efficacy requirement for new drug approval we would achieve such a net gain. The market, the prescription drug requirements, and the post-approval requirements of the FDCA already ensure that only effective drugs will prosper. The use of limited resources to document efficacy studies for the benefit of the FDA is thus a waste. Such resources could otherwise be conserved for testing as many drug candidates as possible. One could argue that there would be an even greater net benefit if the safety requirement were to be eliminated as well as the efficacy requirement. Such an argument may have merit, because the market principles that apply to efficacy would be enhanced by tort principles – though an unsafe drug may exact such a high cost on patients that such safeguards would not be sufficient. Either way, the case against the efficacy requirement is clear, and that is as good a place as any to begin the downsizing of government.