Competitive Enterprise Institute

HEALTH CARE
REFORM PROJECT

A NATIONAL SURVEY OF EMERGENCY ROOM PHYSICIANS REGARDING THE FOOD AND DRUG ADMINISTRATION

Prepared by **the polling company™**
for the Competitive Enterprise Institute

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A National Survey Of Emergency Room Physicians Regarding the Food And Drug Administration

Executive Summary

The US Food and Drug Administration is among the most highly regarded agencies of the federal government. But for more than two decades, doctors, patient groups, and public policy experts have argued that FDA's lengthy process for approving new drugs and medical devices often costs lives by denying patients potentially beneficial new treatments. Beginning in the early 1990s, those complaints began to be taken seriously by Congress and the agency. This resulted in a slow progression of legislative and regulatory changes, culminating in passage of the Food and Drug Administration Modernization Act of 1997.

Though the goal of most of these changes was to increase the speed at which beneficial new products reach the market, additional reform is needed. The Modernization Act grants FDA authority to reduce the number of clinical trials needed for approval and to expedite the review of treatments for serious conditions, but does not require it to do so. The Act grants manufacturers broader freedom to disseminate information about "off-label" uses of approved drugs, but does not revoke the agency's often heavy-handed oversight of that practice.

The average length of time it takes the FDA to review New Drug Applications has fallen from roughly 30 months at the beginning of the decade to 17 months today.[1] But that is still three times as long as sanctioned under law,[2] and is in addition to an average of six years of clinical testing.[1] Furthermore, FDA recently implemented a new regulation requiring drug manufacturers to test in children many of the drugs they sell for adults before the drugs can be approved. This is likely to add substantially to development and testing times, keeping new treatments off the market even longer.

The Modernization Act and some of the other recent changes were certainly modest steps in the right direction. However, by leaving the agency too much discretion in resolving issues of concern, they failed to address FDA's innate flaw: By granting FDA sole approval authority, the statutory framework for drug and device regulation gives the agency the power to decide for all patients whether or not the potential benefits of new drugs and devices are worth the risks that those treatments may pose. Such very personal decisions are best left to patients and their doctors.

Today, other critics argue that the FDA's recently expedited reviews have endangered public health by allowing dangerous new drugs onto the market. That position, however, is not supported by many patient groups nor by many practicing physicians. CEI commissioned this poll of emergency room doctors to examine their

[1] Tufts Center for the Study of Drug Development, *Impact Report* (July 1999).
[2] 21 USC 355 (c)(1).

views of the FDA and its review process. ER doctors treat critically ill patients on a daily basis, and they understand the need for groundbreaking new therapies. Consequently, their views of FDA are especially relevant.

This survey indicates that, even today, most emergency room physicians believe that the FDA is too slow in approving new treatments, and that these delays cost lives. Despite recent changes, doctors remain dissatisfied with the slow pace of the FDA approval process, and they support significant change in federal food and drug law. Here are some of the survey's most striking results:

- Nearly two-thirds (64%) of respondents believe that the FDA is too slow in approving new drugs and devices.

- More than half (51%) believe that the additional time it takes to approve new drugs and devices costs lives by forcing patients to go without potentially beneficial treatments. Yet nearly three-quarters (73%) believe that the general public has little or no understanding of this "human cost" of the FDA approval process.

- Four out of five (82%) respondents believe that the FDA should not restrict information about unapproved or "off-label" uses of drugs and devices that have been approved for a different use. And most (77%) believe that FDA's policy of limiting such information makes it harder for them to learn about new uses for approved drugs and devices.

- Perhaps most noteworthy, 69% of the emergency room physicians surveyed said that they favor changing federal law so that unapproved drugs and devices could be made available to physicians as long as they carried a warning about their unapproved status.

This report contains the survey questionnaire and results, a brief analysis of those results, and a side-by-side comparison with the results of three previous CEI polls—one of neurologists released in October 1998, one of cardiologists released in July 1996, and one of oncologists released in August 1995. This side-by-side comparison suggests that negative attitudes toward the FDA are common among medical specialists who are most in need of innovative new therapies, and that those views are consistent over time.

CEI's four polls lend support to proposals that would allow patients to use unapproved drugs and devices under medical supervision and with the clear knowledge that FDA has not certified them. The Access to Medical Treatment Act (H.R. 2635), introduced in the US House of Representatives by Congressman Peter DeFazio in July, offers one approach. Under such an arrangement, the FDA could be as cautious as its politics required, but its overcaution would no longer be as deadly.

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October 26, 1999

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SURVEY INSTRUMENT AND FINAL RESULTS

Conducted by the polling company™ for the Competitive Enterprise Institute

200 Completed Interviews
Margin of Error ±4.9 Percent

1. On balance, do FDA regulations *help* or *prevent* you from using promising new drugs or medical devices in the treatment of your patients? (WAIT FOR RESPONSE, THEN ASK:) would that be *strongly* (INSERT RESPONSE) or just *somewhat* (INSERT RESPONSE)?

53%*	**TOTAL HELP**
19%	STRONGLY HELP
34%	SOMEWHAT HELP
33%	**TOTAL PREVENT**
30%	SOMEWHAT PREVENT
3%	STRONGLY PREVENT
13%	NEITHER (DO NOT READ)
3%	DON'T KNOW / REFUSED (DO NOT READ)

* Note: Numbers may not sum due to rounding.

I will now read *two* statements which people have made about the FDA. After I have read each one, please tell me whether you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with that statement:

2. The FDA is too slow in approving new drugs and medical devices.

64% TOTAL AGREE
23% STRONGLY AGREE
41% SOMEWHAT AGREE

33% TOTAL DISAGREE
27% SOMEWHAT DISAGREE
6% STRONGLY DISAGREE

4% NEITHER (DO NOT READ)
1% DON'T KNOW (DO NOT READ)

3. The additional time it takes for the FDA to approve drugs and medical devices costs lives by forcing people to go without potentially beneficial therapies.

51% TOTAL AGREE
13% STRONGLY AGREE
38% SOMEWHAT AGREE

46% TOTAL DISAGREE
31% SOMEWHAT DISAGREE
15% STRONGLY DISAGREE

3% NEITHER (DO NOT READ)
1% DON'T KNOW (DO NOT READ)

4. In your opinion, to what extent does the general public understand the "human cost" of the FDA approval process: that is, that some people may suffer or die waiting for the FDA to act? Do they . . .

(ROTATE TOP TO BOTTOM AND BOTTOM TO TOP)

22% COMPLETELY / SOMEWHAT UNDERSTAND
1% COMPLETELY UNDERSTAND THE HUMAN COST
21% SOMEWHAT UNDERSTAND THE HUMAN COST

73% LITTLE / NO UNDERSTANDING
39% UNDERSTAND THE HUMAN COST ONLY A LITTLE
34% DON'T UNDERSTAND THE HUMAN COST AT ALL

5% REFUSED / DISAGREED WITH THE STATEMENT (DO NOT READ)
2% DON'T KNOW (DO NOT READ)

5. If a drug or medical device has already been approved for one use by the FDA, should the FDA restrict information about off-label uses: that is, other unapproved uses of that drug or device?

13% YES
82% NO
2% SOMETIMES (DO NOT READ)

4% DON'T KNOW / REFUSED (DO NOT READ)

6. To what extent does this FDA policy of limiting information make it more difficult for *you* to learn about new uses for drugs or devices?

(ROTATE TOP TO BOTTOM AND BOTTOM TO TOP)

77% TOTAL MORE DIFFICULT
20% MUCH MORE DIFFICULT
57% SOMEWHAT MORE DIFFICULT

13% TOTAL LESS DIFFICULT
9% SOMEWHAT LESS DIFFICULT
4% MUCH LESS DIFFICULT

11% DON'T KNOW / REFUSED (DO NOT READ)

7. Would you say the FDA's approval process has hurt your ability to treat your patients with the best possible care frequently, some of the time, at least once, or never?

58% TOTAL AT LEAST ONCE
4% FREQUENTLY
28% SOME OF THE TIME
26% AT LEAST ONCE

42% NEVER

1% REFUSED (DO NOT READ)

8. What would your position be on a proposal to change FDA law so that unapproved drugs or devices could be made available to physicians as long as they carried a warning about their unapproved status? Would you strongly favor, somewhat favor, somewhat oppose, or strongly oppose such a proposal?

69% TOTAL FAVOR
28% STRONGLY FAVOR
41% SOMEWHAT FAVOR

29% TOTAL OPPOSE
18% SOMEWHAT OPPOSE
11% STRONGLY OPPOSE

3% DON'T KNOW / REFUSED (DO NOT READ)

9. Assume for a moment that a system was in place where unapproved drugs or devices were available to you for treating patients. Which of the following would be the *most* important factor in your decision to use such an unapproved drug or device?

(ROTATE AND ACCEPT ONLY ONE RESPONSE)

46% WHETHER PERSUASIVE PUBLISHED RESEARCH EXISTS ABOUT THE DRUG OR DEVICE
24% WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES
24% WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES

7% DON'T KNOW / REFUSED (DO NOT READ)

10. And finally, how many years have you been in practice?

5%	5 YEARS OR LESS
6%	5-8 YEARS
17%	8-12 YEARS
19%	12-15 YEARS
55%	MORE THAN 15 YEARS

11. Are you employed at a teaching hospital?

49%	YES
51%	NO

Thank you for your time . . .

12. Region

43%	NORTHEAST
18%	MIDWEST
16%	PACIFIC
13%	SOUTH
11%	PLAINS / MOUNTAIN WEST

13. Gender (by observation)

88%	MALE
12%	FEMALE

A NATIONAL SURVEY OF EMERGENCY ROOM PHYSICIANS REGARDING THE FOOD AND DRUG ADMINISTRATION

SURVEY ANALYSIS

prepared by the polling company™

Introduction And Methodology

the polling company™ is pleased to release the following results of a national poll of practicing Emergency Room (ER) doctors. The poll was commissioned by the Competitive Enterprise Institute (CEI), and was conducted from August 23-September 17, 1999. Respondents were asked a series of questions regarding their attitudes toward the Food and Drug Administration (FDA), its process for approving new drugs and medical devices and other policies and regulations, and the effect of such measures on the practice of emergency care for patients.

Each survey contained 13 questions and lasted approximately five minutes. A total of 200 interviews were completed with Emergency Room doctors selected and screened from a random sample. The margin of error for this survey is ± 4.9% at the 95% confidence level, meaning that similar results would be obtained in 19 out of 20 cases.

A. Attitudes Toward The FDA

- **On balance, ER physicians tend to think that FDA regulations help them serve their patients, but many report some negative impact of FDA practices on patient care.**

A small majority (53%) of the Emergency Room physicians interviewed thought that FDA regulations on balance *help* them to use promising new drugs or medical devices in the treatment of their patients. One-third (33%) said that FDA rules *prevent* them from doing so. Relatively few held strong opinions on the question, however. Nineteen percent said that FDA regulations "strongly help" while three percent said they "strongly prevent" the use of promising treatments.

ER physicians were somewhat more favorable toward the FDA than were neurologists and neurosurgeons, who were evenly divided between those saying that the FDA helps (46%) and prevents (45%) them from using promising treatments. Yet a majority (58%) of ER doctors claimed that on at least one occasion the FDA's lengthy

approval process has impaired their ability to treat their patients with the best possible care. This majority includes 4% who said that this happens "frequently" and 28% who said that it happens "some of the time."

Compared to previous surveys of other medical specialists, ER doctors were somewhat less likely than either cardiologists (72%) or neurosurgeons and neurologists (64%) to complain that the FDA has prevented them from providing the best possible treatment.

B. New Drug and Device Review Process

- **Many ER doctors were critical of the FDA's lengthy approval process.**

Two-thirds (64%) believed that the FDA is too slow in approving new medical drugs and devices, and half (51%) believed that this delay costs lives. The sentiment that the FDA is too slow in approving new treatments was more strongly held than was the belief that the delay costs patient lives. While a quarter (23%) "strongly" agreed that the approval process is slow, only about one in ten (13%) "strongly" believed that lives were lost as a result.

- **ER doctors said that most people do not understand the human cost of FDA procedures.**

Only a quarter (23%) of the ER doctors surveyed believed that the general public has even a modest understanding of the human cost of the FDA's lengthy approval process, while three-quarters (73%) believed that the public has little or no understanding of this impact. These proportions are virtually identical to those found among both oncologists and neurologists interviewed in previous surveys for CEI.

C. Off-Label Uses

- **Most ER doctors opposed restricting information on off-label uses for FDA-approved drugs and devices.**

If a drug or medical device has already been approved for one use by the FDA, 82% Emergency Room doctors would oppose restricting information about other possible uses. Just 13% would favor restrictions on information about off-label uses.

This finding is consistent with our findings for other branches of medicine, as 79% of neurologists and neurosurgeons, 76% of oncologists, and 67% of cardiologists also opposed this restriction.

- **ER doctors report that FDA restrictions on information make it more difficult to learn about off-label uses.**

Most ER doctors reported that the FDA policy of limiting information about off-label uses makes it either *much* (20%) or *somewhat* (57%) more difficult for them personally to learn about such possible uses. Relatively few (13%) said that the FDA policy makes it less difficult to get information.

A. Access to Unapproved Treatments

- **In addition to their criticisms of the FDA's procedures regarding *approved* drugs, there is broad support among ER doctors for easier access to *unapproved* drugs.**

Seven in ten would either *strongly* (28%) or *somewhat* (41%) favor changing FDA rules so that unapproved drugs or medical devices could be made available to physicians as long as a warning label notes their unapproved status. Three in ten would either *strongly* (11%) or *somewhat* (18%) oppose such a change.

This 69% support among ER doctors for access to unapproved drugs is comparable to the degree of support among neurologists and neurosurgeons (73%) and is somewhat higher than among cardiologists (53%).

- **Published research would be key factor in prescribing unapproved drugs.**

If given the option of using unapproved drugs or devices, a clear plurality (46%) of ER physicians said that the primary factor in their decision would be the existence of persuasive published research about the drug or device. The other half were equally likely (24% each) to say that their decision would be based primarily upon whether the drug or device had recently received approval in other medically-advanced countries or whether it was well-regarded by physician colleagues.

SIDE-BY-SIDE COMPARISON OF FOUR CEI POLLS

In August 1995, the Competitive Enterprise Institute commissioned a survey of oncologists[1] to learn their opinion of the federal Food and Drug Administration's medical device and drug approval process. This was followed, in July 1996, with a survey of cardiologists,[2] and in October 1998, with a survey of neurologists and neurosurgeons.[3] All three groups of medical specialists displayed frustration with the FDA, and validated some of the major complaints about the agency. A majority of each specialty agreed that the FDA was too slow in approving new drugs and devices, and most said that the additional time it takes for the FDA to approve new drugs and devices costs lives by forcing patients to go without potentially beneficial treatments.

A series of statutory and regulatory changes made over the past several years has succeeded in reducing the time it takes FDA to review new drug and device applications. But claims have arisen that the FDA has become too hasty in its approval of new drugs—that its desire to expedite new drug and device applications was leading the agency to make unwise decisions. This latest CEI poll suggests that, despite recent reductions in the length of the FDA reviews, a large majority of Emergency Room physicians believe that the FDA's approval process is still too slow, and that such delays cost lives.

Following is a side-by-side comparison of all four CEI polls.

1. On balance, do FDA regulations *help* or *prevent* you from using promising new drugs or medical devices in the treatment of your patients? Would that be *strongly* or just *somewhat*?

	Emergency Room Physicians	**Neurologists and Neurosurgeons**	**Cardiologists**	**Oncologists**
TOTAL HELP	**53%**	**46%**	**42%**	**44%**
STRONGLY HELP	19%	13%	20%	8%
SOMEWHAT HELP	34%	32%	22%	36%
TOTAL PREVENT	**33%**	**45%**	**46%**	**43%**
SOMEWHAT PREVENT	30%	37%	33%	35%
STRONGLY PREVENT	3%	7%	13%	8%
NEITHER	13%	8%	7%	14%
DON'T KNOW / REFUSED	3%	1%	5%	-

[1] CEI, *A National Survey of Oncologists Regarding the Food and Drug Administration* (160 interviews: margin of error ±5.1 percent) August 1995.
[2] CEI, *A National Survey of Cardiologists Regarding the Food and Drug Administration* (217 interviews: margin of error ±4.8 percent) July 1996.
[3] CEI, *A National Survey of Neurologists and Neurosurgeons Regarding the Food and Drug Administration* (202 interviews: margin of error ±4.9 percent) October 1998.

2. The FDA is too slow in approving new drugs and medical devices.

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL AGREE	**64%**	**67%**	**65%**	**77%**
STRONGLY AGREE	23%	27%	30%	31%
SOMEWHAT AGREE	41%	40%	35%	46%
TOTAL DISAGREE	**33%**	**28%**	**30%**	**20%**
SOMEWHAT DISAGREE	27%	22%	18%	14%
STRONGLY DISAGREE	6%	6%	12%	6%
NEITHER	4%	2%	3%	2%
DON'T KNOW / REFUSED	1%	2%	2%	1%

3. The additional time it takes for the FDA to approve drugs and medical devices costs lives by forcing people to go without potentially beneficial therapies.

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL AGREE	**51%**	**58%**	**57%**	**47%**
STRONGLY AGREE	13%	16%	17%	11%
SOMEWHAT AGREE	38%	42%	40%	36%
TOTAL DISAGREE	**46%**	**38%**	**37%**	**48%**
SOMEWHAT DISAGREE	31%	27%	21%	34%
STRONGLY DISAGREE	15%	10%	16%	14%
NEITHER	3%	3%	5%	4%
DON'T KNOW / REFUSED	1%	1%	2%	1%

4. In your opinion, to what extent does the general public understand the "human cost" of the FDA approval process: that is, that some people may suffer or die waiting for the FDA to act? Do they …

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL UNDERSTAND	**22%**	**26%**	**24%**	**19%**
COMPLETELY UNDERSTAND	1%	2%	4%	1%
SOMEWHAT UNDERSTAND	21%	23%	20%	18%
TOTAL DON'T UNDERSTAND	**73%**	**73%**	**63%**	**74%**
UNDERSTAND ONLY A LITTLE	39%	42%	33%	51%
DON'T UNDERSTAND AT ALL	34%	31%	30%	23%
DON'T KNOW / REFUSED / OR DISAGREED WITH THE STATEMENT	7%	1%	12%	9%

5. If a drug or medical device has already been approved for one use by the FDA, should the FDA restrict information about off-label uses: that is, other unapproved uses of that drug or device?

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
YES	13%	18%	21%	16%
NO	82%	79%	67%	76%
SOMETIMES (VOLUNTEERED)	2%	2%	5%	4%
DON'T KNOW / REFUSED	4%	1%	7%	4%

6. To what extent does this FDA policy of limiting information make it more difficult for *you* to learn about new uses for drugs or devices?

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL MORE DIFFICULT	**77%**	**79%**	**60%**	**60%**
MUCH MORE DIFFICULT	20%	20%	13%	17%
SOMEWHAT MORE DIFFICULT	57%	59%	47%	43%
TOTAL LESS DIFFICULT	**13%**	**10%**	**28%**	**28%**
SOMEWHAT LESS DIFFICULT	9%	6%	14%	22%
MUCH LESS DIFFICULT	4%	4%	14%	6%
NO IMPACT (VOLUNTEERED)	-	-	7%	-
DON'T KNOW / REFUSED	11%	11%	5%	13%

7. Would you say the FDA's approval process has hurt your ability to treat your patients with the best possible care frequently, some of the time, at least once, or never?

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL AT LEAST ONCE	**58%**	**80%**	**71%**	**63%**
FREQUENTLY	4%	4%	7%	11%
SOME OF THE TIME	28%	53%	45%	37%
AT LEAST ONCE	26%	23%	19%	15%
NEVER	42%	18%	28%	36%
REFUSED	1%	1%	1%	1%

8. What would your position be on a proposal to change FDA law so that unapproved drugs or devices could be made available to physicians as long as they carried a warning about their unapproved status? Would you strongly favor, somewhat favor, somewhat oppose, or strongly oppose such a proposal?

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL FAVOR	**69%**	**73%**	**53%**	**61%**
STRONGLY FAVOR	28%	32%	21%	24%
SOMEWHAT FAVOR	41%	41%	31%	37%
TOTAL OPPOSE	**29%**	**26%**	**44%**	**37%**
SOMEWHAT OPPOSE	18%	13%	24%	24%
STRONGLY OPPOSE	11%	12%	20%	13%
DON'T KNOW / REFUSED	3%	1%	3%	2%

9. Assume for a moment that a system was in place where unapproved drugs or devices were available to you for treating patients. Which of the following would be the most important factor in your decision to use such an unapproved drug or device?

	Emergency Room Physicians	Neurologists and Neurosurgeons	Cardiologists	Oncologists
WHETHER PERSUASIVE PUBLISHED RESEARCH EXISTS ABOUT THE DRUG OR DEVICE	46%	63%	47%	59%
WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES	24%	20%	25%	29%
WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES	24%	16%	19%	10%
DON'T KNOW / REFUSED	7%	1%	10%	2%

The Competitive Enterprise Institute

The Competitive Enterprise Institute is a public policy organization committed to advancing the principles of free enterprise and limited government. Founded in 1984 by Fred L. Smith, Jr., CEI promotes classical liberal ideals through analysis, education, coalition-building, advocacy, and litigation. A non-profit, tax exempt organization under Section 501(c)(3) of the Internal Revenue Code, CEI relies entirely on donations from foundations, corporations, and private individuals. Contributions are tax deductible to the extent allowed by law.

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