A NATIONAL SURVEY OF NEUROLOGISTS AND NEUROSURGEONS REGARDING THE FOOD AND DRUG ADMINISTRATION

SURVEY ANALYSIS

prepared by **the polling company™**

I. Introduction And Methodology

the polling company™ is pleased to release the following results of a national poll of practicing neurologists and neurosurgeons. The poll was commissioned by the Competitive Enterprise Institute, and was conducted from August 24 to September 15, 1998. 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, other FDA policies and regulations, and the effect of such measures on the practice of neurology and the care of patients.

Each survey contained 13 questions and lasted approximately five minutes. A total of 202 interviews were completed, with neurologists and neurosurgeons selected and screened from a random sample. The margin of error for this survey is $\pm$ 4.9% at the 95% confidence level, meaning that similar results would be obtained in 19 out of 20 cases.

II. Attitudes Toward The FDA

- **67% of the neurologists and neurosurgeons surveyed believe that the FDA takes too much time to approve new drugs and medical devices, and 58% agree that such delays cost lives.**

The breakdown for both questions is markedly similar to our survey of cardiologists in 1996. In that particular poll, 65% of cardiologists agreed that the FDA was too slow in approving new drugs and medical devices while 57% agreed that the delays cost lives.

- **The substantial human cost is widely unknown to the public, according to the neurosurgeons and neurologists.**

73% of them stated that the general public has little or no understanding of the tradeoffs involved in the lengthy approval process. Only 23% claimed that the public had

some understanding, and a mere 2% claimed that the public understands it "completely." This is remarkably consistent with our 1995 finding that 74% of oncologists believe that the public is largely unaware of the human toll of FDA's lethargic pace.

- **The FDA's approval process has impaired most neurologists' and neurosurgeons' ability to provide their patients with the highest standard of care. A majority (57%) claim that it has hurt their ability to provide the best possible medical care at least some of the time.**

A staggering 80% claim that the approval process, on at least one occasion, prevented them from treating their patients with the best possible care. This is consistent with our earlier findings; 71% of cardiologists also agreed that the FDA's approval process has negatively affected their ability to provide their patients with the best possible medical care on at least once occasion.

- **One practice of the FDA that has been singled out for criticism is the restriction of information about off-label uses for already-approved drugs. 79% of neurologists and neurosurgeons oppose such restrictions.**

These figures are consistent with our findings for other branches of medicine, as 67% of cardiologists and 76% of oncologists opposed the restriction of such information.

- **Neurologists and neurosurgeons complain that such a policy makes it more difficult for them to learn about new uses for drugs and devices. 79% claimed that this policy made it more difficult, while a mere 10% found it helpful.**

It should be noted, however, that the overall sentiment was only moderately intense; 20% of all respondents found that the restriction of information made it "much more difficult," while 59% claimed that it was "somewhat more difficult."

III. Receptivity Toward An Alternative Approval Process

- **Not only is the FDA's treatment of *approved* drugs under question, many neurologists and neurosurgeons also criticize the agency's approach to *unapproved* drugs and devices. 73% support proposals to make unapproved drugs available to physicians as long as their unapproved status is noted on a warning label.**

This level of support is even higher than in the previous polls, where majorities of cardiologists (53%) and oncologists (61%) also supported this concept. It is beyond the scope of this project as to whether the higher level of support in this study is due to circumstances inherent to neurology, or to changes over time in the mindset of the medical community generally.

- **63% of the neurologists and neurosurgeons surveyed consider the presence of persuasive, published research to be the primary factor in whether or not they would prescribe unapproved drugs or medical devices if given the opportunity.**

Under such expanded access, changes in medical practices will not occur in a dangerous, haphazard fashion. Sound medical research will remain the guiding force behind a physician's decision to prescribe a certain drug or treatment—but the research need not necessarily be directed by government in all cases.

Such a figure is supplemented by the 59% of oncologists in our 1995 study who cited existing research as the most persuasive factor in their decision to use an unapproved drug or device.

20% of the neurosurgeons and neurologists surveyed would prefer to follow the lead of other nations, while 16% would rely upon how highly the treatment was esteemed in the medical community. These figures are very consistent with the findings for the cardiologists. In that survey, 25% opted for the "approval in other nation" approach while 19% supported the "well-regarded by colleague" factor. Oncologists, however, give comparatively greater credence to the actions of other countries; 29% of them would be persuaded by other nations' approval, whereas a mere 10% would be convinced by the approval of their peers to try unapproved, experimental treatments.

II. Conclusion

Most neurosurgeons and neurologists are concerned about the FDA approval process for drugs and medical devices. Despite some recent reductions in the average length of new product review times, a majority of respondents believe that the FDA takes too long to review new drugs and devices, and that this delay costs lives.

An overwhelming majority of them agree with the notion that federal food and drug law should be changed so that unapproved drugs or devices could be made available to physicians (provided they carry a warning label about their unapproved status). In doing so, they join cardiologists and oncologists who have voiced approval for the same proposal in past surveys.

Despite concerns that such a policy shift would endanger the lives of patients, the physicians who would prescribe such newly allowed drugs or devices agree that their ability to provide the best possible care for their patients would be enhanced by giving them this extra degree of freedom.

Prepared for the Competitive Enterprise Institute by Kellyanne Fitzpatrick and Jason Booms of **the polling company™**, *September 17, 1998.*

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SURVEY INSTRUMENT AND FINAL RESULTS

202 Completed Interviews
Conducted by the polling company™ for
the Competitive Enterprise Institute

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)?

46%*	**TOTAL HELP**
13%	STRONGLY HELP
32%	SOMEWHAT HELP
45%	**TOTAL PREVENT**
37%	SOMEWHAT PREVENT
7%	STRONGLY PREVENT
8%	NEITHER (DO NOT READ)
1%	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.

67% TOTAL AGREE
27% STRONGLY AGREE
40% SOMEWHAT AGREE

28% TOTAL DISAGREE
22% SOMEWHAT DISAGREE
6% STRONGLY DISAGREE

2% NEITHER (DO NOT READ)
2% 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.

58% TOTAL AGREE
16% STRONGLY AGREE
42% SOMEWHAT AGREE

38% TOTAL DISAGREE
27% SOMEWHAT DISAGREE
10% 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)

26% COMPLETELY / SOMEWHAT UNDERSTAND
2% COMPLETELY UNDERSTAND THE HUMAN COST
23% SOMEWHAT UNDERSTAND THE HUMAN COST

73% LITTLE / NO UNDERSTANDING
42% UNDERSTAND THE HUMAN COST ONLY A LITTLE
31% DON'T UNDERSTAND THE HUMAN COST AT ALL

1% REFUSED / DISAGREED WITH THE STATEMENT (DO NOT READ)
0% 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?

18% YES
79% NO
2% SOMETIMES (DO NOT READ)

1% DON'T KNOW (DO NOT READ)
0% 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)

79% TOTAL MORE DIFFICULT
20% MUCH MORE DIFFICULT
59% SOMEWHAT MORE DIFFICULT

10% TOTAL LESS DIFFICULT
6% SOMEWHAT LESS DIFFICULT
4% MUCH LESS DIFFICULT

9% DON'T KNOW (DO NOT READ)
2% 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?

80% TOTAL AT LEAST ONCE
4% FREQUENTLY
53% SOME OF THE TIME
23% AT LEAST ONCE

18% 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?

73% TOTAL FAVOR
32% STRONGLY FAVOR
41% SOMEWHAT FAVOR

26% TOTAL OPPOSE
13% SOMEWHAT OPPOSE
12% STRONGLY OPPOSE

1% 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)

63% WHETHER PERSUASIVE PUBLISHED RESEARCH EXISTS ABOUT THE DRUG OR DEVICE
20% WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES
16% WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES

1% DON'T KNOW / REFUSED (DO NOT READ)

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

14% 5 YEARS OR LESS
11% 5-8 YEARS
13% 8-12 YEARS
17% 12-15 YEARS
44% MORE THAN 15 YEARS

Thank you for your time . . .

11. Region

40% SOUTH
25% NORTHEAST
18% MIDWEST
17% WEST / MOUNTAINS

12. Gender (by observation)

89% MALE
11% FEMALE

13. Specialty

84% NEUROLOGIST
16% NEUROSURGEON

SIDE-BY-SIDE COMPARISON OF THREE 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] Both 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 FDA was too slow in approving new drugs and devices, and 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.

Following enactment of the Food and Drug Administration Modernization Act of 1997, claims arose that the FDA had 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 some recent reductions in the length of the FDA reviews, a large majority of neurologists and neurosurgeons still believe that the FDA's approval process is too slow, and that such delays cost lives.

Following is a side-by-side comparison of all three 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*?

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

[1] CEI, *A National Survey of Oncologists Regarding the Food and Drug Administration* (August 1995) 160 Interviews: Margin of Error ±5.1 Percent.

[2] CEI, *A National Survey of Cardiologists Regarding the Food and Drug Administration* (July 1996) 217 Interviews: Margin of Error ±4.8 Percent.

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

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL AGREE	**67%**	**65%**	**77%**
STRONGLY AGREE	27%	30%	31%
SOMEWHAT AGREE	40%	35%	46%
TOTAL DISAGREE	**28%**	**30%**	**20%**
SOMEWHAT DISAGREE	22%	18%	14%
STRONGLY DISAGREE	6%	12%	6%
NEITHER	2%	3%	2%
DON'T KNOW / REFUSED	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.

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL AGREE	**58%**	**57%**	**47%**
STRONGLY AGREE	16%	17%	11%
SOMEWHAT AGREE	42%	40%	36%
TOTAL DISAGREE	**38%**	**37%**	**48%**
SOMEWHAT DISAGREE	27%	21%	34%
STRONGLY DISAGREE	10%	16%	14%
NEITHER	3%	5%	4%
DON'T KNOW / REFUSED	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 …

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL UNDERSTAND	**26%**	**24%**	**19%**
STRONGLY UNDERSTAND	2%	4%	1%
SOMEWHAT UNDERSTAND	23%	20%	18%
TOTAL DON'T UNDERSTAND	**73%**	**63%**	**74%**
UNDERSTAND ONLY A LITTLE	42%	33%	51%
DON'T UNDERSTAND AT ALL	31%	30%	23%
DON'T KNOW / REFUSED / OR DISAGREED WITH STATEMENT	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?

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
YES	18%	21%	16%
NO	79%	67%	76%
SOMETIMES (VOLUNTEERED)	2%	5%	4%
DON'T KNOW	1%	5%	1%
REFUSED	0%	2%	3%

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?

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL MORE DIFFICULT	**79%**	**60%**	**60%**
MUCH MORE DIFFICULT	20%	13%	17%
SOMEWHAT MORE DIFFICULT	59%	47%	43%
TOTAL LESS DIFFICULT	**10%**	**28%**	**28%**
SOMEWHAT LESS DIFFICULT	6%	14%	22%
MUCH LESS DIFFICULT	4%	14%	6%
NO IMPACT (VOLUNTEERED)	-	7%	-
DON'T KNOW	9%	4%	8%
REFUSED	2%	1%	5%

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?

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

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
TOTAL FAVOR	**73%**	**53%**	**61%**
STRONGLY FAVOR	32%	21%	24%
SOMEWHAT FAVOR	41%	31%	37%
TOTAL OPPOSE	**26%**	**44%**	**37%**
SOMEWHAT OPPOSE	13%	24%	24%
STRONGLY OPPOSE	12%	20%	13%
DON'T KNOW / REFUSED	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?

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

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

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
FIVE YEARS OR LESS	14%	7%	14%
FIVE TO EIGHT YEARS	11%	7%	14%
EIGHT TO TWELVE YEARS	13%	14%	14%
TWELVE TO FIFTEEN YEARS	17%	17%	11%
MORE THAN FIFTEEN YEARS	44%	56%	47%

11. Gender

	Neurologists and Neurosurgeons	Cardiologists	Oncologists
MALE	89%	94%	89%
FEMALE	11%	6%	11%