A National Survey of Oncologists Regarding The Food and Drug Administration

Conducted by the polling company™ for the:

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160 Completed Interviews
Margin of Error ±5.1 at the 95% Confidence Level

1. Over the past five years would you say that your opinion of the FDA on specific issues related to the approval of drugs and medical devices has gotten better, gotten worse or remained the same?

48% GOTTEN BETTER
13% GOTTEN WORSE
39% REMAINED THE SAME

\- DO NOT KNOW (VOLUNTEERED)
\- REFUSED (VOLUNTEERED)

2. On balance, do FDA regulations *help* or *prevent* you from using promising new drugs or medical devices in the treatment of your patients?

43% TOTAL HELP
9% STRONGLY HELP
34% SOMEWHAT HELP

44% TOTAL PREVENT
36% SOMEWHAT PREVENT
8% STRONGLY PREVENT

11% NEITHER (VOLUNTEERED)
1% DON'T KNOW (VOLUNTEERED)
\- REFUSED (VOLUNTEERED)

I am now going to read you a few statements. For each, please tell me if you agree or disagree:

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

61%	**TOTAL AGREE**
18%	STRONGLY AGREE
43%	SOMEWHAT AGREE
37%	**TOTAL DISAGREE**
29%	SOMEWHAT DISAGREE
8%	STRONGLY DISAGREE
1%	NEITHER (VOLUNTEERED)
1%	DON'T KNOW (VOLUNTEERED)
-	REFUSED (VOLUNTEERED)

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

60%	**TOTAL AGREE**
14%	STRONGLY AGREE
46%	SOMEWHAT AGREE
39%	**TOTAL DISAGREE**
28%	SOMEWHAT DISAGREE
11%	STRONGLY DISAGREE
1%	NEITHER (VOLUNTEERED)
-	DON'T KNOW (VOLUNTEERED)
-	REFUSED (VOLUNTEERED)

5. 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 ……

24% TOTAL UNDERSTAND
1% COMPLETELY UNDERSTAND THE HUMAN COST
23% SOMEWHAT UNDERSTAND THE HUMAN COST

70% TOTAL DO NOT UNDERSTAND
41% UNDERSTAND ONLY A LITTLE OF THE HUMAN COST
29% DON'T UNDERSTAND THE HUMAN COST AT ALL

5% REFUSED/ DISAGREED WITH STATEMENT (VOLUNTEERED)
2% DON'T KNOW (VOLUNTEERED)

6. If a medical drug or 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?

58% NO
34% YES

1% SOMETIMES/DEPENDS (VOLUNTEERED)
6% DON'T KNOW (VOLUNTEERED)
1% REFUSED (VOLUNTEERED)

7. 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?

65% TOTAL MORE DIFFICULT
11% MUCH MORE DIFFICULT
54% SOMEWHAT MORE DIFFICULT

26% TOTAL LESS DIFFICULT
12% SOMEWHAT LESS DIFFICULT
14% MUCH LESS DIFFICULT

4% DON'T KNOW (VOLUNTEERED)
4% REFUSED (VOLUNTEERED)

8. 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?

77% AT LEAST ONCE
7% FREQUENTLY
39% SOME OF THE TIME
31% AT LEAST ONCE

21% NEVER

1% DO NOT KNOW (VOLUNTEERED)
1% REFUSED (VOLUNTEERED)

9. 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?

68% TOTAL FAVOR
26% STRONGLY FAVOR
42% SOMEWHAT FAVOR

31% TOTAL OPPOSE
15% SOMEWHAT OPPOSE
16% STRONGLY OPPOSE

1% DON'T KNOW (VOLUNTEERED)
1% REFUSED (VOLUNTEERED)

10. And, 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?

76%	**WHETHER PERSUASIVE PUBLISHED REASEARCH EXISTS ABOUT THE DRUG OR DEVICE**
13%	WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES
8%	WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES
1%	DON'T KNOW (VOLUNTEERED)
2%	REFUSED (VOLUNTEERED)

11. How many years have you been in practice as an oncologist?

11%	5 YEARS OR LESS
9%	5-8 YEARS
17%	8-12 YEARS
15%	12-15 YEARS
48%	MORE THAN 15 YEARS

12. Are you currently employed at a teaching hospital?

54%	**YES**
44%	NO
2%	DON'T KNOW/REFUSED (VOLUNTEERED)

13. GENDER (BY OBSERVATION)

89%	MALE
19%	FEMALE

SIDE-BY-SIDE COMPARISON OF Five CEI POLLS

In 1995 the Competitive Enterprise Institute began to conduct a series of surveys of medical specialists to learn their opinion of the Food and Drug Administration's approval process for new medical drugs and devices. CEI's first poll was of oncologists. This was followed by a survey of cardiologists in 1996, a survey of neurologists and neurosurgeons in 1998, and a survey of emergency room physicians in 1999. CEI is now releasing a new survey of oncologists, the first group that we examined.

All of these groups of medical specialists view FDA as being too slow to approve new therapies, and too restrictive in its control of information concerning off-label uses.

In recent years, FDA has apparently succeeded in reducing the time it needs to review new drug and device applications. But there are claims that FDA has become too hasty in its approvals, and that every drug recall, no matter how rare in relative terms, is evidence of an approval process has gone wrong.

In our view, an insistence on zero drug recalls can easily become an incentive for zero drug approvals. The introduction of new therapies is inherently risky. Nonetheless, as long as mankind faces untreatable illnesses and injuries, those risks pale in comparison to the risks of *not* developing new therapies.

This latest CEI poll suggests that, despite improvements in the FDA review process, this process is still too slow, and that the delays it creates are harmful to human health.

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

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL HELP	**43%**	**53%**	**46%**	**42%**	**44%**
STRONGLY HELP	9%	19%	13%	20%	8%
SOMEWHAT HELP	34%	34%	32%	22%	36%
TOTAL PREVENT	**44%**	**33%**	**45%**	**46%**	**43%**
SOMEWHAT PREVENT	36%	30%	37%	33%	35%
STRONGLY PREVENT	8%	3%	7%	13%	8%
NEITHER	11%	13%	8%	7%	14%
DON'T KNOW / REFUSED	1%	3%	1%	5%	-

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

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL AGREE	**61%**	**64%**	**67%**	**65%**	**77%**
STRONGLY AGREE	18%	23%	27%	30%	31%
SOMEWHAT AGREE	43%	41%	40%	35%	46%
TOTAL DISAGREE	**37%**	**33%**	**28%**	**30%**	**20%**
SOMEWHAT DISAGREE	29%	27%	22%	18%	14%
STRONGLY DISAGREE	8%	6%	6%	12%	6%
NEITHER	1%	4%	2%	3%	2%
DON'T KNOW / REFUSED	1%	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.

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL AGREE	**60%**	**51%**	**58%**	**57%**	**47%**
STRONGLY AGREE	14%	13%	16%	17%	11%
SOMEWHAT AGREE	46%	38%	42%	40%	36%
TOTAL DISAGREE	**39%**	**46%**	**38%**	**37%**	**48%**
SOMEWHAT DISAGREE	28%	31%	27%	21%	34%
STRONGLY DISAGREE	11%	15%	10%	16%	14%
NEITHER	1%	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 …

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL UNDERSTAND	**24%**	**22%**	**26%**	**24%**	**19%**
COMPLETELY UNDERSTAND	1%	1%	2%	4%	1%
SOMEWHAT UNDERSTAND	23%	21%	23%	20%	18%
TOTAL DON'T UNDERSTAND	**70%**	**73%**	**73%**	**63%**	**74%**
UNDERSTAND ONLY A LITTLE	41%	39%	42%	33%	51%
DON'T UNDERSTAND AT ALL	29%	34%	31%	30%	23%
DON'T KNOW / REFUSED / OR DISAGREED WITH THE STATEMENT	7%	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?

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
YES	34%	13%	18%	21%	16%
NO	58%	82%	79%	67%	76%
SOMETIMES (VOLUNTEERED)	1%	2%	2%	5%	4%
DON'T KNOW / REFUSED	7%	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?

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL MORE DIFFICULT	**65%**	**77%**	**79%**	**60%**	**60%**
MUCH MORE DIFFICULT	11%	20%	20%	13%	17%
SOMEWHAT MORE DIFFICULT	54%	57%	59%	47%	43%
TOTAL LESS DIFFICULT	**26%**	**13%**	**10%**	**28%**	**28%**
SOMEWHAT LESS DIFFICULT	12%	9%	6%	14%	22%
MUCH LESS DIFFICULT	14%	4%	4%	14%	6%
NO IMPACT (VOLUNTEERED)	-	-	-	7%	-
DON'T KNOW / REFUSED	8%	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?

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL AT LEAST ONCE	**77%**	**58%**	**80%**	**71%**	**63%**
FREQUENTLY	7%	4%	4%	7%	11%
SOME OF THE TIME	39%	28%	53%	45%	37%
AT LEAST ONCE	31%	26%	23%	19%	15%
NEVER	21%	42%	18%	28%	36%
REFUSED	1%	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?

	Oncologists 2002	Emergency Room Physicians 1999	Neurologists and Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL FAVOR	**68%**	**69%**	**73%**	**53%**	**61%**
STRONGLY FAVOR	26%	28%	32%	21%	24%
SOMEWHAT FAVOR	42%	41%	41%	31%	37%
TOTAL OPPOSE	**31%**	**29%**	**26%**	**44%**	**37%**
SOMEWHAT OPPOSE	15%	18%	13%	24%	24%
STRONGLY OPPOSE	16%	11%	12%	20%	13%
DON'T KNOW / REFUSED	2%	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?

	Oncologists 2002	**Emergency Room Physicians 1999**	**Neurologists and Neurosurgeons 1998**	**Cardiologists 1996**	**Oncologists 1995**
WHETHER PERSUASIVE PUBLISHED RESEARCH EXISTS ABOUT THE DRUG OR DEVICE	76%	46%	63%	47%	59%
WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES	13%	24%	20%	25%	29%
WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES	8%	24%	16%	19%	10%
DON'T KNOW / REFUSED	3%	7%	1%	10%	2%

The Competitive Enterprise Institute

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