Issue Analysis

A National Survey of Orthopedic Surgeons Regarding the Food and Drug Administration and the Availability of New Therapies

Conducted by **the polling company, inc.**

January 30, 2007

A National Survey of Orthopedic Surgeons Regarding the Food and Drug Administration and the Availability of New Therapies

Summary

In recent years there has been mounting criticism of the U.S. Food and Drug Administration's approval process for new medical drugs and devices. Critics have claimed that newly-discovered risks for several therapies demonstrate that FDA's current process is inadequate.

But there is another side to this story. Any attempt to make FDA's approval process more stringent will add to its length and expense, making the development of new therapies even more difficult. In the view of many analysts, impeding the availability of new therapies creates a far greater risk to public health than that posed by the handful of drugs and devices that may have been erroneously approved.

This new survey demonstrates that a large majority of orthopedic surgeons believe that the current FDA approval process is already too slow. If that approval process becomes even more drawn out, this situation will worsen.

This is the sixth survey of medical specialists that CEI has conducted. Our first, of oncologists in 1995, demonstrated a high level of dissatisfaction with FDA's performance. The results of our subsequent surveys have been consistent with these findings. Among the highlights of the new survey are the following:

- over three-quarters, 76%, believe FDA's approval process is too slow;
- 60% believe FDA hinders their use of new therapies;
- 73% believe FDA approval delays hurt patients;
- 70% favor changing the law to give physicians access to unapproved therapies if they carry a warning about their unapproved status;
- 80% favor having Vioxx available again.

Vioxx was included in the survey even though its withdrawal in 2004 was voluntary. The drug's continued absence from the market, despite an FDA panel's recommendation that it be returned, illustrates how needed therapies can be blocked not only by FDA regulations but by liability concerns as well.

While this new survey is consistent with our previous polls, in some respects it represents an exceptionally negative view of FDA. The percentage of those viewing FDA as too slow, 76%, is the highest since our 1995 oncologist poll. The 60% who view FDA as hindering their use of new therapies is the highest recorded in any of our surveys. The same is true of the 58% who report that FDA has hindered their treatment of patients on more than one occasion.

All new therapies carry risks, and sometimes those risks cannot be discovered until after clinical testing. If we set a goal of zero unexpected risks, then the only way to meet that goal is through zero new therapies. As the results of this latest survey indicate, from a public health standpoint that could well be the riskiest approach of all.

Sam Kazman, General Counsel
Competitive Enterprise Institute
January 2007

A National Survey of Orthopedic Surgeons
Regarding the Food and Drug Administration
and the Availability of New Therapies

Analysis of Findings

Introduction & Methodology

the polling company™, inc. is pleased to present to the **Competitive Enterprise Institute (CEI)** the results and analysis of a recent online survey of 175 orthopedic surgeons nationwide regarding the Food and Drug Administration's approval process for new drugs and medical devices.

This web-based survey was fielded continuously from December 28, 2006 through January 3, 2007. Respondents, randomly selected from a list of orthopedic surgeons, were invited to participate in this study via an e-mail containing a URL link to access the survey instrument. As is standard when conducting research among highly-specialized professionals, including doctors, participants were offered a $50 incentive for their time.

The original survey instrument contained 15 questions, including four demographic inquiries. Ten of the eleven substantive inquiries were based on questions asked in previous surveys conducted by **the polling company™, inc.** for **CEI** of oncologists (2002 and 1995), emergency room physicians (1999), neurologists/ neurosurgeons (1998), and cardiologists (1996). The eleventh question dealt with a relatively new issue—the withdrawal of Vioxx from the market. All questions were approved by an authorized representative of **CEI** prior to data collection.

The margin of error for the survey is $\pm$ 7.4% at a 95% confidence interval, meaning that the data obtained would not differ by any more than 7.4 percentage points in either direction had the entire population U.S. orthopedic surgeons been surveyed. Margins of error for subgroups are higher.

Background Information: Orthopedic Surgeons

Orthopedic surgery deals with the repairing of the musculoskeletal system. In 2006 the *American Academy of Orthopedic Surgeons* estimated there were over 21,000 board certified orthopedic surgeons in the United States. The need for orthopedic surgery is expected to grow exponentially as the large, aging Baby Boomer population requires more hip and joint replacements. The vast majority (81%) of orthopedic surgeons operate private practices, and on average, perform 32 procedures per month.[1]

[1] "Orthopedic Practice in the US 2005-2006" (June 2006), published by the American Academy of Orthopedic Surgeons.

Key Survey Findings

Orthopedic Surgeons More Concerned By Slow FDA Approval for New Drugs and Devices than Other Doctors Surveyed in the Past.
All six of the CEI medical polls have shown a high level of concern over the slow pace of FDA's approval process for new medical drugs and devices. In all of these surveys, majorities of 60 percent or more have agreed that FDA is too slow in approving new therapies. Similarly, on the question of whether FDA helps or hinders these physicians' use of new therapies, past polls have shown a relatively even split, indicating a surprising level of professional discomfort concerning a public health agency, especially one with FDA's repute.

This new Orthopedic Surgeons Poll, however, is exceptionally high in the level of discontent that it demonstrates. Seventy six percent viewed FDA as too slow—the highest percentage since CEI's 1995 Oncologist Poll. Moreover, 60% viewed FDA as hindering their use of new therapies—by far the highest level recorded in any of the CEI polls.

Patients Suffer Because of FDA's Slow Pace.
All doctors, as part of the Hippocratic Oath, pledge to "first, do no harm." According to these orthopedic surgeons, FDA apparently is not bound by the same promise. Its slow approval process for new drugs and devices has a direct negative impact on patients. **Furthermore, this harm is more than hypothetical, as more than three-quarters of respondents indicated they personally had been hindered at least once in treating a patient due to FDA's approval process.**

In all of the CEI polls, a majority of doctors responded that FDA had hurt their ability to treat patients on at least one occasion. *However, the new Orthopedic Surgeons Poll has the second highest percentage in this category of all the CEI polls (78%, compared to 80% in CEI's 1998 Neurologists and Neurosurgeons Poll). Moreover, the new poll has the highest percentage of doctors who experienced this difficulty on more than one occasion (58%).*

The Newest Orthopedic Surgeons —Perhaps Not Yet Resigned to FDA's Pace —Are Most Dissatisfied With its Inefficiency.
Throughout the survey, orthopedic surgeons who had been in practice eight years or less consistently stood out as most critical of FDA's approval process and the most apt to believe that such delays are costly to patients and their ability to treat them.

These new physicians may be more informed about newer therapies due to their more recent graduation from medical school, and possibly less accustomed to practicing medicine in the face of FDA's obstacles.

Analysis of Findings

Orthopedic Surgeons Unequivocally View FDA's Approval Process as Sluggish; Very Few See Improvement Over Past Five Years
A full three-quarters (75%) of surgeons interviewed deemed FDA "**too slow in approving new drugs and medical devices.**"

- **The level of agreement regarding FDA's unhurried pace was markedly higher among these orthopedic surgeons than among previous specialists surveyed.** While over a decade ago, in 1995, oncologists revealed a similar level of concern (77% agreed FDA was "too slow"), by 2002, just 61% of oncologists felt the same way. Similarly, 64% of emergency room physicians (1999), 67% of neurologists

and neurosurgeons (1998) and 65% of cardiologists (1996) believed FDA's approval process needed a shot of speed.

- ✧ Orthopedic surgeons who had been practicing for 12 years or less were more likely than those in their field longer to agree that FDA's approval process was "too slow."

When asked how their opinion of the U.S. Food and Drug Administration's approval process for new drugs and medical devices had changed over the past five years, a majority (51%) of orthopedic surgeons surveyed stated that their views had "remained the same." However, among those who noted a shift, surgeons saying their opinion of the process had "gotten worse" were double those reporting it had "gotten better" (30%-14%).

- ✧ Almost seven-in-ten (69%) orthopedic surgeons whose views of FDA's approval process had *improved* over the past five years still viewed the agency as "too slow." Of those who previously indicated that their opinion of FDA had *remained the same*, 71% said the agency was too slow. Thus, the stable nature of these physicians' opinion of FDA is hardly an endorsement of its performance.

- ✧ Those newer to the practice (in it for less than eight years) were more likely than their more senior colleagues to report a worsening opinion of FDA.

Majority of Orthopedic Surgeons Say that FDA's Foot-Dragging Has a Direct Negative Impact on Patients. The unnecessarily long time that FDA takes to approve new drugs and medical devices certainly frustrates these orthopedic surgeons —in part because it has a real effect on their ability to care for patients.

In fact, 60% of survey respondents revealed that, on balance, the regulations imposed by FDA *hindered* them in using "promising new drugs and medical devices" to treat patients. This is nearly twice the 31% who felt the regulations *helped* them.

- ✧ These orthopedic surgeons offered a much sharper rebuke of FDA than did physician groups studied previously. When asked a similar question[2], most past respondents were fairly evenly divided between "help" and "prevent":

	Prevent	*Help*
Cardiologists (1996)	46%	42%
Neurologists/ Neurosurgeons (1998)	45%	46%
Oncologists (2002)	44%	43%
Oncologists (1995)	43%	44%
ER Physicians (1999)	33%	53%

Additionally, orthopedic surgeons drew a direct nexus between FDA's delayed approval process and patient harm. In fact, **73% of orthopedic surgeons asserted that the "additional time it takes for FDA to approve new drugs and medical devices hurts patients by forcing them to go without potentially beneficial therapies"**—triple the number who disagreed (25%).

[2] Previous question: "On balance, do FDA regulations *help* or *prevent* you from using promising new drugs or medical devices in the treatment of your patients?"

- Orthopedic surgeons near the start of their careers (practicing less than 8 years) were more likely than their longer-serving counterparts to agree that FDA's drug approval process hurts patients.

- Again, orthopedic surgeons were in broader agreement about the negative impact of FDA's slow pace than were their counterparts polled in the past. The question in previous polls was phrased a bit differently (asking whether FDA delay "costs lives" rather than "hurts patients"), but the sentiment expressed was similar[3].

What's more, the perception of patient harm was based on the real world experience of these surgeons, 78% of whom indicated that the slow nature of FDA's approval process had specifically hindered their own ability to treat patients "*at least once*." This is more than five-times the 14% who claimed that FDA had *never* adversely affected their care of patients. More than half characterized the problem as one that affects them at least "some of the time."

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?

78%	**TOTAL HURT ABILITY TO TREAT PATIENTS (NET)**
4%	FREQUENTLY
54%	SOME OF THE TIME
20%	AT LEAST ONCE
14%	**NEVER**
7%	DO NOT KNOW

- Surgeons who had been practicing for 8 years or less were more apt than those operating longer to report experiencing difficulty due to FDA's slow drug approval process.

- Difficulty treating patients due to FDA was reported at similar frequencies by orthopedic surgeons (78%), neurologists and neurosurgeons (80%), oncologists (77% in 2002), and cardiologists (71%).

Most Orthopedic Surgeons Believe the Public is in the Dark Regarding the Harm Wrought by FDA's Sluggish Pace.

While these surgeons believe that FDA's slow process for approving new drugs and medical devices hurts patients, they view those same patients as unaware of this problem.

Nearly eight-in-ten (78%) respondents said the general public understands the "human cost" of the process "just a little bit" (38%) or "not at all" (40%). By comparison, just 20% credited the public as "somewhat" familiar with the toll —that is, "that some people may suffer or die waiting for the FDA to act" —and less than one-half of one percent felt that everyday people "completely" understood the stakes.

- Orthopedic surgeons and doctors surveyed in past studies felt similarly with respect to the level of appreciation the public had for the human cost of FDA's approval process. Strong majorities of all agreed that the average American knew little or nothing about the human toll of the FDA process.[4]

[3] Percentage agreeing with statement: 60% of oncologists in 2002 and 47% in 1995, 58% of neurologists/ neurosurgeons, 57% of cardiologists, and 51% of ER doctors.

[4] Percentage agreeing public understood only "a little" or "not at all": 74% of oncologists in 1995 and 70% in 2002, 73% of ER doctors and neurologists/neurosurgeons, and 63% of cardiologists.

Orthopedic Surgeons Call for Easier Access to Information About "Off-Label" Uses for Drugs and Devices.
Respondents were unsure about the extent to which FDA should restrict information about "off-label" uses for approved drugs —meaning, other, unapproved uses of a drug or medical device that has passed muster for treatment of at least one condition or ailment.

When asked, only 12% definitively answered "yes" —that FDA should keep a lid on this information, while 39% called for increased openness. The remaining 49% were noncommittal, suggesting that they would favor details about off-label uses for certain drugs but not for others. Despite this somewhat mixed result**, it is clear that most orthopedic surgeons favor at least some loosening of current FDA regulations that keep doctors uninformed about alternative, off-label uses for approved therapies.**

- ✧ Orthopedic surgeons in the Northeastern and Western regions of the country were especially critical of FDA's restrictions on information.

- ✧ Those in practice for 12 or fewer years were more apt to call for a more open flow of information than those who had been surgeons longer.

FDA's current policy of restricting information has hampered a full 84% of these orthopedic surgeons, making it more difficult for them to learn about new and alternative uses for drugs and medical devices.
The majority (72%) reported that FDA was only "somewhat" of a hurdle." On the other hand, just 6% indicated FDA actually made it easier for them to get a hold of this "off-label" information.

- ✧ Orthopedic surgeons were more apt to report that FDA's restrictive policies interfered with their ability to learn about new drugs than were other specialists surveyed in past endeavors: 79% of neurologists/neurosurgeons, 77% of emergency room physicians, 65% of oncologists in 2002 and 60% in 1995, and 60% of cardiologists reported FDA bureaucracy hurt them in this manner.

Noteworthy Support for Making Unapproved Drugs —Bearing Warning Labels —Available to Physicians.
A clear majority (70%) of orthopedic surgeons would favor "a proposal to change FDA law so that unapproved drugs or medical devices could be made available to physicians as long as they carried a warning label about their unapproved status."

Approximately one-quarter (26%) of orthopedic surgeons opposed this idea.

- ✧ Joint reconstruction, pediatric, and spinal specialists stood out as more likely than most to advocate wider availability of unapproved drugs.

- ✧ Orthopedic surgeons just starting their careers (in practice 8 years or less) were more likely than others to favor changing FDA law to make unapproved drugs and devices available to doctors.

- ✧ Orthopedic surgeons displayed similar agreement on this point as neurologists/ neurosurgeons (73% "favor"), ER doctors (69%), and oncologists (68% in 2002).

Scientific Research a Major Resource for Orthopedic Surgeons
If current FDA regulations were amended to allow doctors access to unapproved drugs and devices, most orthopedic surgeons say that the major factor that would lead them to utilize such therapies would be "*persuasive published research*" (67%). Other factors, such as foreign approval or the opinions of other doctors, were viewed as less important.

Orthopedic Surgeons Strongly Favor Re-Introducing Vioxx.
In September 2004, pharmaceutical manufacturer Merck & Co. voluntarily withdrew Vioxx, a prescription medication used for treating pain associated with arthritis, from the market after a study found an increased risk for heart attack and stroke in patients taking the drug for more than 18 months.

If it were up to the orthopedic surgeons surveyed, the drug would be back on the market. **A full 80% said they would "make Vioxx available again as a prescription drug,"** compared to just 14% who would like the medication to remain off-limits. These surgeons appear to believe that the benefits of Vioxx outweigh the associated risks —especially for their patients suffering from pain.

- ✧ Shoulder and elbow specialists were among the surgeons most adamant about making Vioxx again available for public consumption.

In Conclusion…

Most orthopedic surgeons surveyed would agree that FDA's approval process for new drugs and medical devices, as well as its restrictions on information about "off-label" uses, compromises patient care and quality of life and could use an overhaul. In general, they held this opinion in greater numbers than other physicians and surgeons surveyed in previous research.

Kellyanne Conway, President and CEO
Shelley West, Project Director
the polling company™, inc.
1220 Connecticut Ave. NW
Washington DC 20036
(202) 667-6557

Date: January 30, 2007

A NATIONAL SURVEY OF ORTHOPEDIC SURGEONS
REGARDING THE
FOOD AND DRUG ADMINISTRATION
AND THE AVAILABILITY OF NEW THERAPIES

Conducted for the **Competitive Enterprise Institute (CEI)**
by **the polling company™ inc.**

January 2007

Web-Based Survey of 175 Orthopedic Surgeons
Margin of Error: +/- 7.4%

1. Over the past five years would you say that your opinion of the FDA's approval process for new drugs and medical devices has gotten better, gotten worse or remained the same?

14% GOTTEN BETTER
30% GOTTEN WORSE
51% REMAINED THE SAME

5% DO NOT KNOW

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

31% TOTAL HELP
4% STRONGLY HELP
27% SOMEWHAT HELP

60% TOTAL HINDER
55% SOMEWHAT HINDER
5% STRONGLY HINDER

8% NEITHER
2% DON'T KNOW

For each of the following statements, please tell me if you strongly agree, somewhat agree, somewhat disagree, or strongly disagree:

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

76% TOTAL AGREE
14% STRONGLY AGREE
62% SOMEWHAT AGREE

22% TOTAL DISAGREE
20% SOMEWHAT DISAGREE
2% STRONGLY DISAGREE

3% DON'T KNOW

4. The additional time it takes for the FDA to approve new drugs and medical devices hurts patients by forcing them to go without potentially beneficial therapies.

73% TOTAL AGREE
13% STRONGLY AGREE
60% SOMEWHAT AGREE

25% TOTAL DISAGREE
22% SOMEWHAT DISAGREE
3% STRONGLY DISAGREE

3% DON'T KNOW

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…

20% TOTAL UNDERSTAND
* COMPLETELY UNDERSTAND THE HUMAN COST
20% SOMEWHAT UNDERSTAND THE HUMAN COST

78% TOTAL DO NOT UNDERSTAND
38% UNDERSTAND ONLY A LITTLE OF THE HUMAN COST
40% DON'T UNDERSTAND THE HUMAN COST AT ALL

2% DON'T KNOW

6. 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 medical device?

12% YES
39% NO
49% SOMETIMES/DEPENDS

* DON'T KNOW

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 medical devices?

84% TOTAL MORE DIFFICULT
12% MUCH MORE DIFFICULT
72% SOMEWHAT MORE DIFFICULT

6% TOTAL LESS DIFFICULT
6% SOMEWHAT LESS DIFFICULT
\- MUCH LESS DIFFICULT

10% DON'T KNOW

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?

78% TOTAL HURT ABILITY TO TREAT PATIENTS
4% FREQUENTLY
54% SOME OF THE TIME
20% AT LEAST ONCE

14% NEVER

7% DO NOT KNOW

9. What would your position be on a proposal to change FDA law so that unapproved drugs or medical 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?

70% TOTAL FAVOR
17% STRONGLY FAVOR
53% SOMEWHAT FAVOR

26% TOTAL OPPOSE
14% SOMEWHAT OPPOSE
12% STRONGLY OPPOSE

4% DON'T KNOW

10. Assume for a moment that a system was in place where unapproved drugs or medical 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? (ROTATED RESPONSES)

67% WHETHER PERSUASIVE PUBLISHED REASEARCH EXISTS ABOUT THE DRUG OR DEVICE
21% WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES
9% WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES

3% DON'T KNOW

11. As you may know, the prescription drug Vioxx was withdrawn from the market in September of 2004. If it were up to you, would you keep Vioxx off the market or make it available again as a prescription drug?

80% MAKE VIOXX AVAILABLE AGAIN AS A PRESCRIPTION DRUG
14% KEEP VIOXX OFF THE MARKET

6% DON'T KNOW

12. How many years have you been in practice as an orthopedic surgeon?

5% 5 YEARS OR LESS
10% 5-8 YEARS
12% 8-12 YEARS
14% 12-15 YEARS
59% MORE THAN 15 YEARS

13. In which area of orthopedic surgery do you specialize? (MULTIPLE RESPONSES ACCEPTED)

62% TOTAL JOINT RECONSTRUCTION
55% SURGICAL SPORTS MEDICINE
48% ORTHOPEDIC TRAUMA
34% SHOULDER AND ELBOW SURGERY
26% HAND SURGERY
16% FOOT AND ANKLE SURGERY
11% PEDIATRIC ORTHOPEDICS
6% SPINE SURGERY
3% MUSCULOSKELETAL ONCOLOGY

9% OTHER
8% GENERAL ORTHOPEDIC SURGEON (VOLUNTEERED)

14. Gender

96% MALE
4% FEMALE

15. Region [5]

24% NORTH EAST
20% NORTH CENTRAL
12% SOUTH CENTRAL
25% SOUTH ATLANTIC
19% WEST

[5] Northeast includes CT, ME, MA, NH, RI, VT, NJ, NY, PA; North Central includes IL, IN, MI, OH, WI, IA, KS, MN, MO, NE, ND, SD; South Central includes AL, KY, MS, TN, AR, LA, OK, TX; South Atlantic includes DC, DE, FL, GA, MD, NC, SC, VA, WV; West includes AZ, CO, ID, MT, NV, NM, UT, WY, AK, CA, HI, OR, WA.

A SIDE-BY-SIDE COMPARISON OF
CEI'S MEDICAL SPECIALIST SURVEYS,
FROM 1995 TO 2007

1. A NATIONAL SURVEY OF ORTHOPEDIC SURGEONS REGARDING THE FOOD AND DRUG ADMINISTRATION AND THE AVAILABILITY OF NEW THERAPIES

Conducted for the **Competitive Enterprise Institute (CEI)**
by **the polling company™ inc.**

January 2007

Web-Based Survey of 175 Orthopedic Surgeons
Margin of Error: +/- 7.4%

1. Over the past five years would you say that your opinion of the FDA's approval process for new drugs and medical devices has gotten better, gotten worse or remained the same?

	Orthopedic Surgeons 2007	Oncologists 2002
GOTTEN BETTER	14%	48%
GOTTEN WORSE	30%	13%
REMAINED THE SAME	51%	39%
DO NOT KNOW	5%	-

2. On balance, do FDA regulations *help* or *hinder* you in using promising new drugs or medical devices in the treatment of your patients?[6]

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL HELP	**31%**	**43%**	**53%**	**46%**	**42%**	**44%**
STRONGLY HELP	4%	9%	19%	13%	20%	8%
SOMEWHAT HELP	27%	34%	34%	32%	22%	36%
TOTAL HINDER	**60%**	**44%**	**33%**	**45%**	**46%**	**43%**
SOMEWHAT HINDER	55%	36%	30%	37%	33%	35%
STRONGLY HINDER	5%	8%	3%	7%	13%	8%
NEITHER	8%	11%	13%	8%	7%	14%
DON'T KNOW/REFUSED	2%	1%	3%	1%	5%	-

For each of the following statements, please tell me if you strongly agree, somewhat agree, somewhat disagree, or strongly disagree:

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

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL AGREE	**76%**	**61%**	**64%**	**67%**	**65%**	**77%**
STRONGLY AGREE	14%	18%	23%	27%	30%	31%
SOMEWHAT AGREE	62%	43%	41%	40%	35%	46%
TOTAL DISAGREE	**22%**	**37%**	**33%**	**28%**	**30%**	**20%**
SOMEWHAT DISAGREE	20%	29%	27%	22%	18%	14%
STRONGLY DISAGREE	2%	8%	6%	6%	12%	6%
NEITHER	-	1%	4%	2%	3%	2%
DON'T KNOW/REFUSED	3%	1%	1%	2%	2%	1%

[6] Prior to 2007 survey of oncologists, respondents were asked if FDA regulations "help or prevent" them from using promising new drugs and medical devices rather than "help or hinder." Additionally, all previous surveys were conducted via a combination of telephone and facsimile methodologies, while the 2007 poll was conducted over the Internet.
Only the 2007 survey asked respondents about Vioxx. For that reason, the Vioxx question is omitted from this comparison with previous surveys.

4. The additional time it takes for the FDA to approve new drugs and medical devices hurts patients by forcing them to go without potentially beneficial therapies.[7]

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL AGREE	**73%**	**60%**	**51%**	**58%**	**57%**	**47%**
STRONGLY AGREE	13%	14%	13%	16%	17%	11%
SOMEWHAT AGREE	60%	46%	38%	42%	40%	36%
TOTAL DISAGREE	**25%**	**39%**	**46%**	**38%**	**37%**	**48%**
SOMEWHAT DISAGREE	22%	28%	31%	27%	21%	34%
STRONGLY DISAGREE	3%	11%	15%	10%	16%	14%
NEITHER	-	1%	3%	3%	5%	4%
DON'T KNOW/REFUSED	3%	-	1%	1%	2%	1%

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…

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL UNDERSTAND	**20%**	**24%**	**22%**	**26%**	**24%**	**19%**
COMPLETELY UNDERSTAND	*	1%	1%	2%	4%	1%
SOMEWHAT UNDERSTAND	20%	23%	21%	23%	20%	18%
TOTAL DO NOT UNDERSTAND	**78%**	**70%**	**73%**	**73%**	**63%**	**74%**
UNDERSTAND ONLY A LITTLE	38%	41%	39%	42%	33%	51%
DON'T UNDERSTAND AT ALL	40%	29%	34%	31%	30%	23%
DON'T KNOW/REFUSED	2%	7%	7%	1%	12%	9%

[7] Prior to 2007, respondents were asked whether the FDA approval process "costs lives" rather than "hurts patients."

6. 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 medical device?

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
YES	12%	34%	13%	18%	21%	16%
NO	39%	58%	82%	79%	67%	76%
SOMETIMES/DEPENDS[8]	49%	1%	2%	2%	5%	4%
DON'T KNOW/REFUSED	*	7%	4%	1%	7%	4%

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 medical devices?

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL MORE DIFFICULT	**84%**	**65%**	**77%**	**79%**	**60%**	**60%**
MUCH MORE DIFFICULT	12%	11%	20%	20%	13%	17%
SOMEWHAT MORE DIFFICULT	72%	54%	57%	59%	47%	43%
TOTAL LESS DIFFICULT	**6%**	**26%**	**13%**	**10%**	**28%**	**28%**
SOMEWHAT LESS DIFFICULT	6%	12%	9%	6%	14%	22%
MUCH LESS DIFFICULT	-	14%	4%	4%	14%	6%
NO IMPACT[9]	-	-	-	-	7%	-
DON'T KNOW/REFUSED	10%	8%	11%	11%	5%	13%

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?

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL HURT ABILITY TO TREAT PATIENTS	**78%**	**77%**	**58%**	**80%**	**71%**	**63%**
FREQUENTLY	4%	7%	4%	4%	7%	11%
SOMETIMES	54%	39%	28%	53%	45%	37%
AT LEAST ONCE	20%	31%	26%	23%	19%	15%
NEVER	14%	21%	42%	18%	28%	36%
DON'T KNOW/REFUSED	7%	1%	1%	1%	1%	1%

[8] In the surveys prior to 2007, "sometimes" was not a read option to respondents. Those who said sometimes volunteered that answer. In 2007, "Sometimes/Depends" was a listed answer choice.
[9] "No Impact" was not a listed option in any of the polls. In those conducted prior to 2007, some respondents volunteered this answer.

9. What would your position be on a proposal to change FDA law so that unapproved drugs or medical 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?

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
TOTAL FAVOR	**70%**	**68%**	**69%**	**73%**	**53%**	**61%**
STRONGLY FAVOR	17%	26%	28%	32%	21%	24%
SOMEWHAT FAVOR	53%	42%	41%	41%	31%	37%
TOTAL OPPOSE	**26%**	**31%**	**29%**	**26%**	**44%**	**37%**
SOMEWHAT OPPOSE	14%	15%	18%	13%	24%	24%
STRONGLY OPPOSE	12%	16%	11%	12%	20%	13%
DON'T KNOW/REFUSED	4%	2%	3%	1%	3%	2%

10. Assume for a moment that a system was in place where unapproved drugs or medical 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? (ROTATED RESPONSES)

	Orthopedic Surgeons 2007	Oncologists 2002	Emergency Rm Physicians 1999	Neurologists & Neurosurgeons 1998	Cardiologists 1996	Oncologists 1995
WHETHER PERSUASIVE PUBLISHED RESEARCH EXISTS ABOUT THE DRUG OR DEVICE	67%	76%	46%	63%	47%	59%
WHETHER THE DRUG OR DEVICE HAS RECEIVED APPROVAL IN OTHER MEDICALLY ADVANCED COUNTRIES	21%	13%	24%	20%	25%	29%
WHETHER THE DRUG OR DEVICE WAS WELL-REGARDED BY PHYSICIAN COLLEAGUES	9%	8%	24%	16%	19%	10%
DON'T KNOW/ REFUSED	3%	3%	7%	1%	10%	2%

$8.00

The Competitive Enterprise Institute is a non-profit public policy organization dedicated to the principles of free enterprise and limited government. We believe that consumers are best helped not by government regulation but by being allowed to make their own choices in a free marketplace. Since its founding in 1984, CEI has grown into an influential Washington institution.

We are nationally recognized as a leading voice on a broad range of regulatory issues ranging from environmental laws to antitrust policy to regulatory risk. CEI is not a traditional "think tank." We frequently produce groundbreaking research on regulatory issues, but our work does not stop there. It is not enough to simply identify and articulate solutions to public policy problems; it is also necessary to defend and promote those solutions. For that reason, we are actively engaged in many phases of the public policy debate.

We reach out to the public and the media to ensure that our ideas are heard, work with policymakers to ensure that they are implemented and, when necessary, take our arguments to court to ensure the law is upheld. This "full service approach" to public policy makes us an effective and powerful force for economic freedom.

Competitive
Enterprise
Institute

1001 Connecticut Avenue, NW
Suite 1250
Washington, DC 20036
202-331-1010
Fax 202-331-0640
www.cei.org