

Pharmaceutical Liability Study Report on Findings

Prepared for:

U.S. Chamber Institute for Legal Reform

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Background and Purpose

The U.S. Chamber Institute for Legal Reform commissioned Harris Interactive to conduct a study on the issue of pharmaceutical product liability litigation. This study was conducted among three target populations: physicians, pharmacists, and patients.

The primary objectives of this research are to:

- ✓ Determine the level of concern toward malpractice lawsuits among physicians/pharmacists
- ✓ Observe what actions physicians/pharmacists may take to avoid possible malpractice litigation involving drugs that may be involved in product liability litigation
- ✓ Determine if information provided in the patient packet insert included with prescription medications results in patients not taking prescription medication indicated and properly prescribed to them by their physician
- ✓ Measure patient awareness of advertisements for product liability litigation, and what actions they may take as a result of seeing such an advertisement
- ✓ Investigate patient concern toward the effect of product liability litigation on new product development and availability



Methodology

Study results are based on interviews among three target groups in the U.S.: physicians, pharmacists, and patients.

Physicians

250 interviews were conducted online among physicians from January 21 – February 7, 2003. Physicians within five medical specialties were interviewed, including: primary care, OB/GYN, gastroenterology, pediatrics, and general surgery. Results were then weighted by known demographic variables for physicians.

The sampling error for physicians is +/- 6.9%.

Pharmacists

251 interviews were conducted by telephone among full-time pharmacists from January 23 – February 12, 2003. Results were then weighted by known demographic variables for pharmacists.

The sampling error for pharmacists is +/- 6.2%.

Patients

301 interviews were conducted online among patients from January 31 – February 7, 2003. Patients qualified for the study if they have been diagnosed with at least one of eight specified medical conditions: high cholesterol, hypertension, arthritis, depression, obesity, diabetes, heart disease, or stomach ulcers.

The sampling error for patients is +/- 5.6%.

Executive Summary



Executive Summary

Pharmaceutical product liability litigation is a major concern for medical professionals and patients alike.

Though patient packet inserts are still regarded as a valuable resource for patients, many medical professionals feel that product liability litigation is a critical factor in making these inserts more complicated than they need to be.

- A large number of medical professionals report that patients have stopped or refused certain medications prescribed to them because they discovered the drug was involved in product liability litigation.

Malpractice lawsuits are a real concern for most doctors and many pharmacists. In order to lower the risk of being sued, many doctors and pharmacists have taken steps to protect themselves.

- Two in five doctors have avoided prescribing an appropriate prescription medication because they were aware that the drug might be involved in product liability litigation.
- A similar number of pharmacists say that they often over-emphasize possible side effects associated with prescription drugs to avoid potential malpractice litigation.

Patients are aware of product liability litigation, and are concerned that it prevents pharmaceutical companies from pursuing research in certain product areas.

Executive Summary: Physicians



Executive Summary - Physicians

Most doctors feel that pharmaceutical product liability litigation has a widespread impact in the medical profession.

While the vast majority of physicians agree that patient packet inserts are a valuable resource to patients, many feel the information contained in them is more complicated than it needs to be – and that product liability litigation is central to the problem.

- Three-quarters (74%) of doctors feel that the information provided to patients in the patient packet insert is more complicated than it needs to be.
- Among these, nearly all doctors (91%) believe that product liability litigation plays a central role in making drug information too complicated.

A significant number of doctors say that their patients have stopped or refused to take medication prescribed to them because they discovered the drug might be involved in product liability litigation.

- Two in five (38%) physicians report that their patients have stopped taking a drug that was properly prescribed for them because they found out the drug might be involved in litigation.
- Three in ten (29%) say that patients have refused to take a drug prescribed for them for similar reasons.



Executive Summary - Physicians

Groundless malpractice litigation, or the threat of it, is a major concern for all doctors and has caused a significant number of doctors to avoid certain treatments as a result.

Doctors are personally concerned about groundless litigation, and some have taken steps to avoid possible litigation.

- Two-thirds of doctors (67%) say that they are personally *very* concerned about groundless litigation.
- In fact, two in five (43%) have avoided prescribing a particular drug because they were aware that drug might be involved in product liability litigation.

Two in five (40%) doctors are aware of other physicians who have been sued by patients who have experienced side effects from a prescribed drug, leading them to think this type of litigation is a common practice.

- In fact, most (57%) doctors are concerned that they may be sued by a patient who experiences side effects from a drug they prescribed, even when the drug is indicated and properly prescribed.

Executive Summary: Pharmacists



Executive Summary - Pharmacists

Pharmaceutical product liability litigation has also caused pharmacists to take action to protect themselves.

Like doctors, most pharmacists are familiar with the patient packet insert provided to patients, and feel it is a valuable resource for patients.

- However, one-half (51%) of pharmacists believe that the information in the patient packet insert is more complex than it should be, and that product liability litigation plays a very important role in this (61%).

In order to avoid potential malpractice litigation, a significant number of pharmacists over-emphasize possible side effects associated with the prescription medications given to their patients.

- Two in five (39%) pharmacists say that they do this often (29%) or very often (10%).

Furthermore, two in five pharmacists report that their patients have stopped taking a medication (44%) or refused to take a medication (40%) that has been properly prescribed for them because they discovered the drug might be involved in pharmaceutical product liability litigation.

Executive Summary: Patients



Executive Summary - Patients

Nearly all patients recall receiving a patient packet insert with their prescription medications, and a significant number has refused to take a drug because of information contained in the insert.

Patients would be concerned about taking a drug if the patient packet insert warned of possible serious side effects, and some would not take the medication as a result.

- Seven in ten (69%) patients would be concerned about taking a particular drug if the packet insert warned of possible serious side effects – one in five (22%) would be very concerned.
- In fact, one in five (20%) patients have not taken a particular drug prescribed for them because of information about possible serious side effects contained in the patient packet insert.



Executive Summary - Patients

Advertisements run by law firms about product liability litigation directed at pharmaceutical companies are seen as common by most patients, however, few have seen such an advertisement for a drug they were taking.

Most patients (86%) would be concerned if they saw an advertisement for a lawsuit over a drug they were taking, and nine in ten (90%) would consult their doctor if this happened.

- One in five (21%) patients have seen advertisements for litigation over a drug they were taking.
- One-quarter or less would immediately stop taking the drug (25%) or call the law firm in the advertisement (19%).
 - ❖ Only one in ten (8%) has ever had to take any of these actions.

Nearly three in four patients (72%) think that law firms commonly file product liability lawsuits against drug companies when only a small number of people have suffered unavoidable side effects.

- Furthermore, patients believe that when other people qualify for such a lawsuit, they commonly join in it, even if they themselves had not experienced any side effects (86%).
- However, if the patient was in the same situation, few say that they would likely join a lawsuit if they had not experienced any side effects from the drug (27%).



Executive Summary - Patients

Patients are concerned that product liability litigation threatens new research and development that could benefit people with illnesses.

Seven in ten (71%) patients believe that product liability litigation, or the fear of it, has caused pharmaceutical companies to avoid research and development in certain product areas.

- Patients are concerned (80%) that groundless litigation prevents drug companies from developing new drugs that could benefit others in the future.

Detailed Findings

Physicians

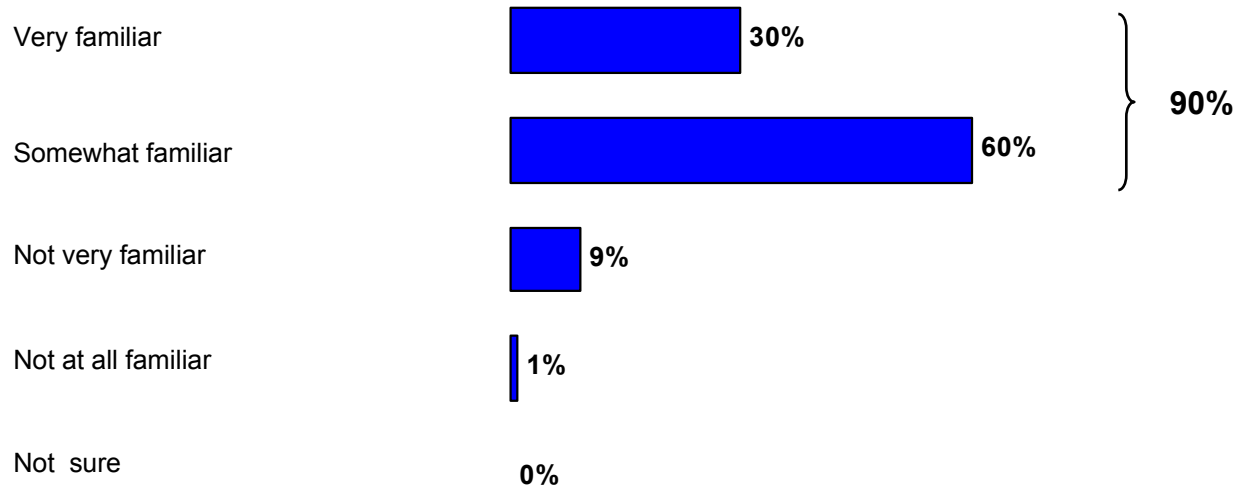


Familiarity with Patient Packet Inserts

Nine in ten (90%) physicians report that they are familiar with information contained in the patient packet inserts provided with prescription medications.

- Three in ten (30%) say that they are very familiar with this information.

How familiar would you say you are with the information provided to patients with prescription drugs, sometimes called the patient packet insert?



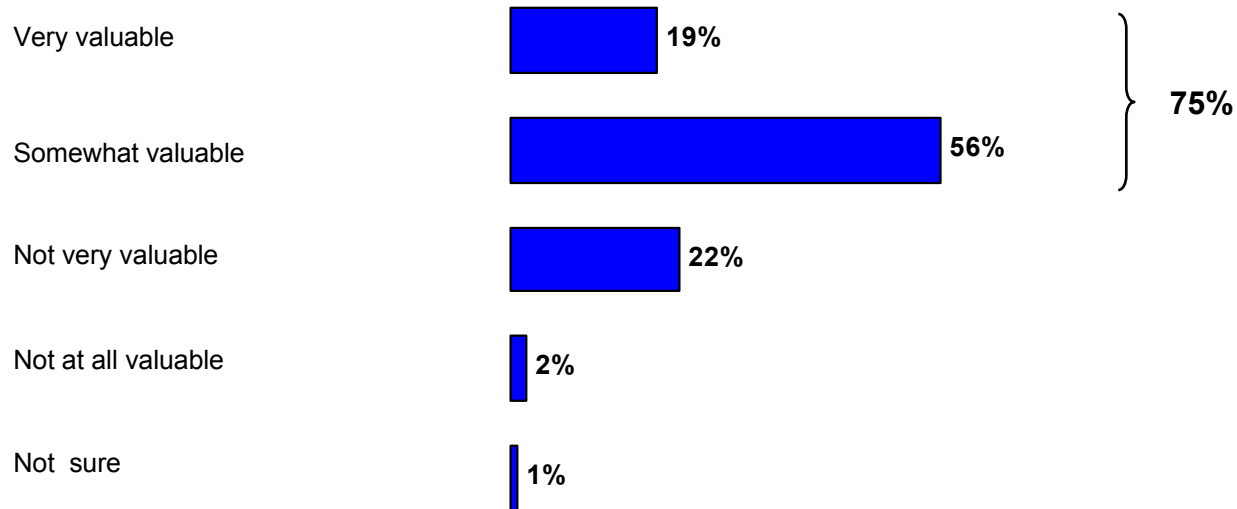


Value of Patient Packet Inserts

Overall, the majority of doctors (75%) consider the information provided in patient packet inserts to be valuable to patients.

- However, only one in five (19%) believes that the information contained in the packet insert is *very* valuable to the patient.

And how valuable to patients do you think the information provided in patient packet inserts is?



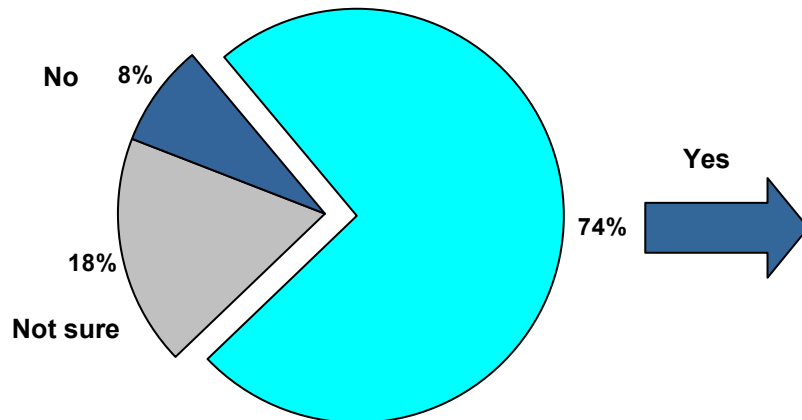


Influence of Product Liability Litigation on Patient Packet Inserts

Three in four (74%) doctors feel that the information contained in the patient packet insert is more complicated than it needs to be – and that product liability litigation plays a critical role in making it complicated.

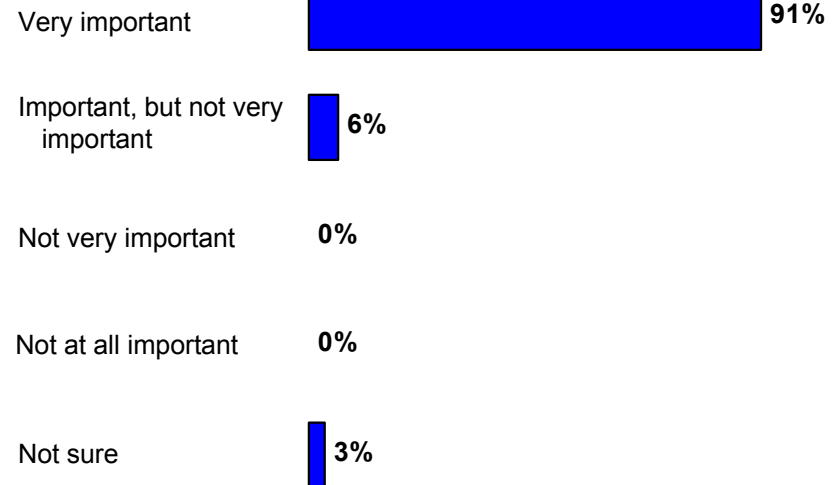
- In fact, nine in ten (91%) physicians who think the information is too complicated believe that product liability litigation is central to the problem.

In your opinion, is the information provided in patient packet inserts more complicated than it needs to be?



How important a role do you think product liability litigation, or fear of product liability litigation, has played in making patient packet inserts more complicated than they need to be?

Base: Think information is more complicated than it needs to be (n=193)



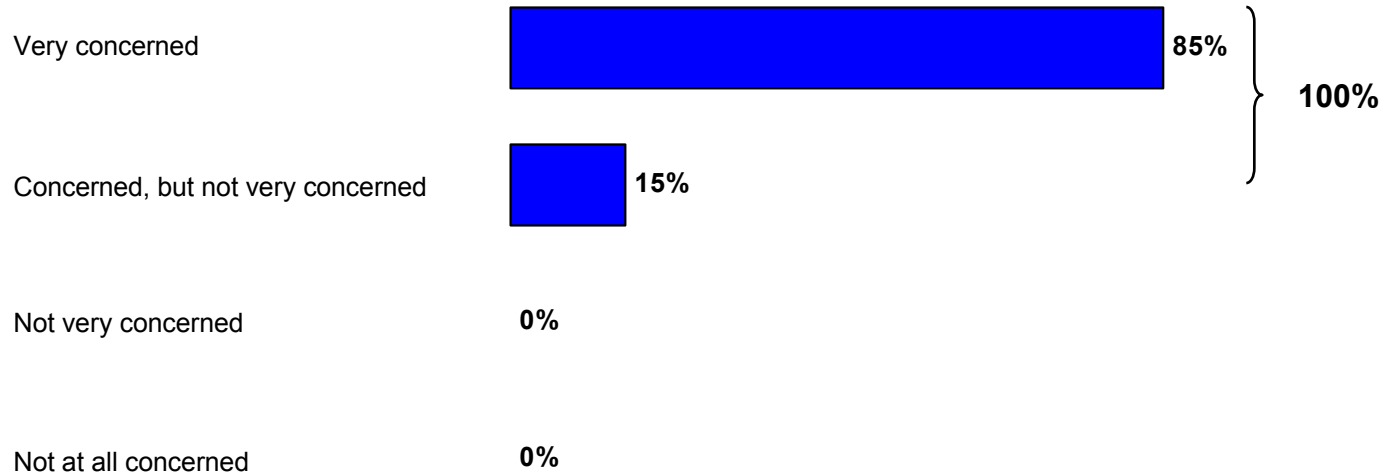


General Concern Toward Malpractice Litigation

Doctors unanimously agree that groundless malpractice litigation, or the threat of it, is a major concern to doctors.

- 85% of physicians are *very* concerned about malpractice litigation.

Overall, how concerned do you think doctors are about groundless malpractice litigation or threat of malpractice litigation?



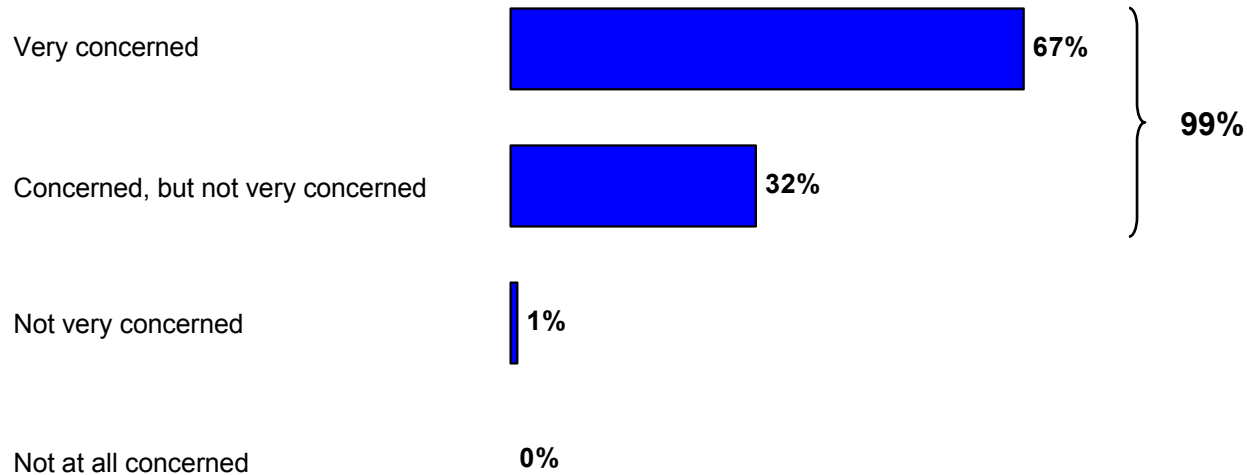


Personal Concern Toward Malpractice Litigation

Nearly all physicians (99%) are personally concerned that they may be the target of groundless litigation or threat of litigation.

- Two-thirds (67%) say that they are very concerned that they personally may be involved in groundless litigation.

And how concerned are you personally about groundless litigation or the threat of litigation?

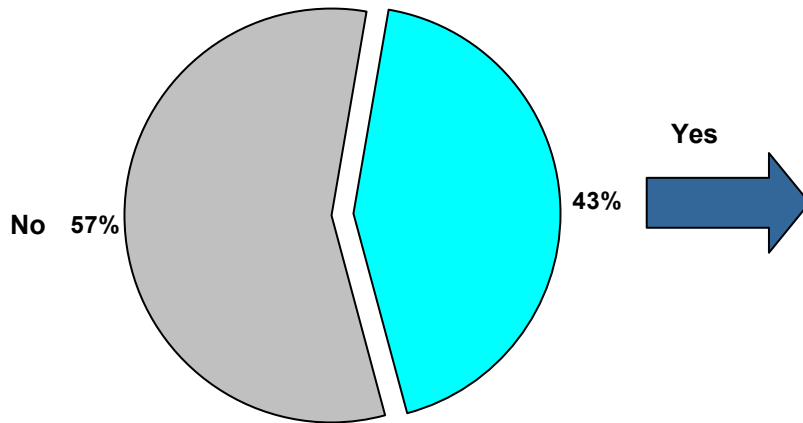


Avoidance of Treatment Options as a Result of Groundless Litigation

A sizeable number of physicians (43%) have avoided prescribing a particular drug, that was appropriate for a patient, because they were aware that it might be involved in product liability litigation.

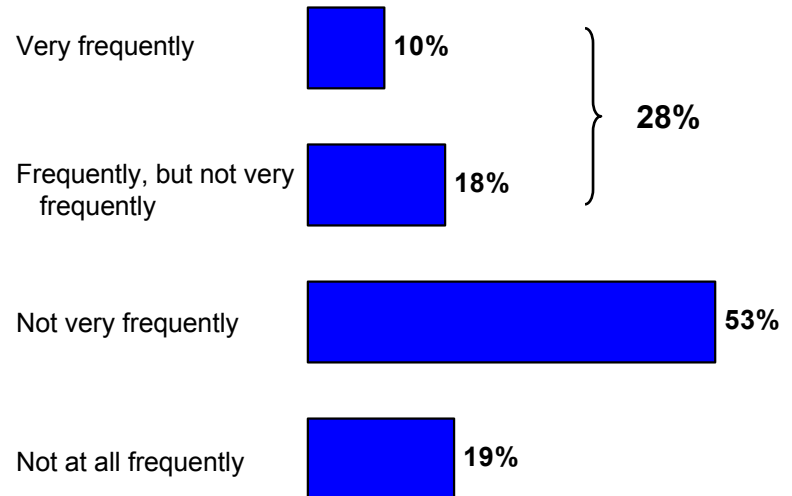
- Of those who have avoided an appropriate drug treatment because of liability, few (28%) have had to do so frequently.

Have you ever avoided prescribing a particular drug to a patient, which was appropriate under the circumstances, because you were aware the drug might be involved in product liability litigation you consider to be groundless?



How frequently have you had to avoid prescribing a drug because it might be involved in product liability litigation you consider to be groundless?

Base: Have avoided prescribing a drug b/c of liability litigation (n=105)



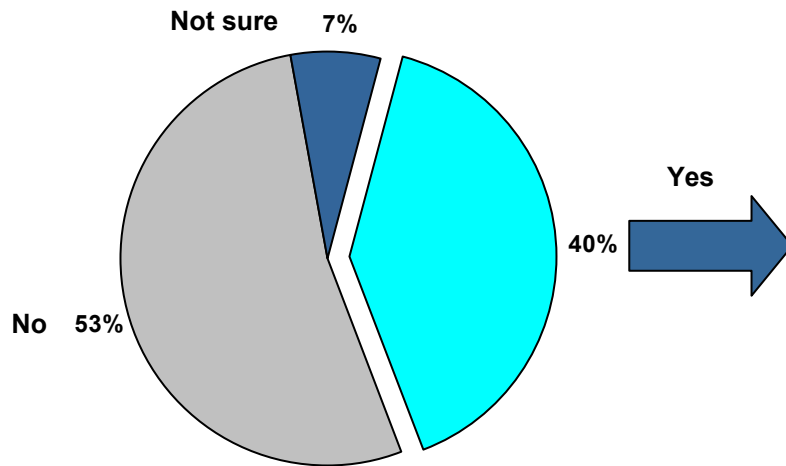


Litigation Due to Side Effects of Prescribed Drug

Two in five (40%) physicians know of colleagues who have been sued by patients who experienced side effects from a drug, even when the drug was indicated and properly prescribed.

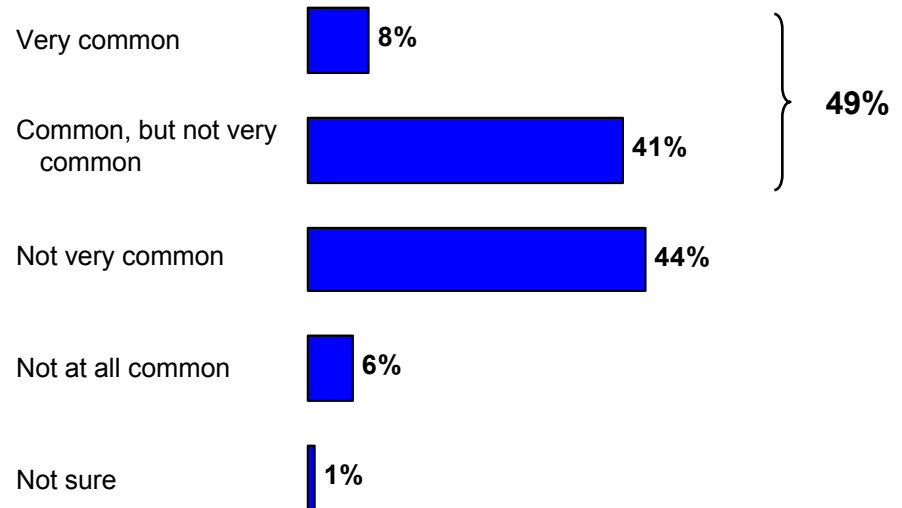
- Of those who are aware of patients suing a doctor over a properly prescribed drug, one-half (49%) feels that it is a common occurrence.

Are you aware of any doctors who have been sued by patients who experienced side effects from a particular drug, even when the drug was indicated and properly prescribed?



How common do you think it is that doctors are sued by patients who experience side effects from a drug, even when the drug is indicated and properly prescribed?

Base: Aware of doctors who have been sued by patients (n=94)



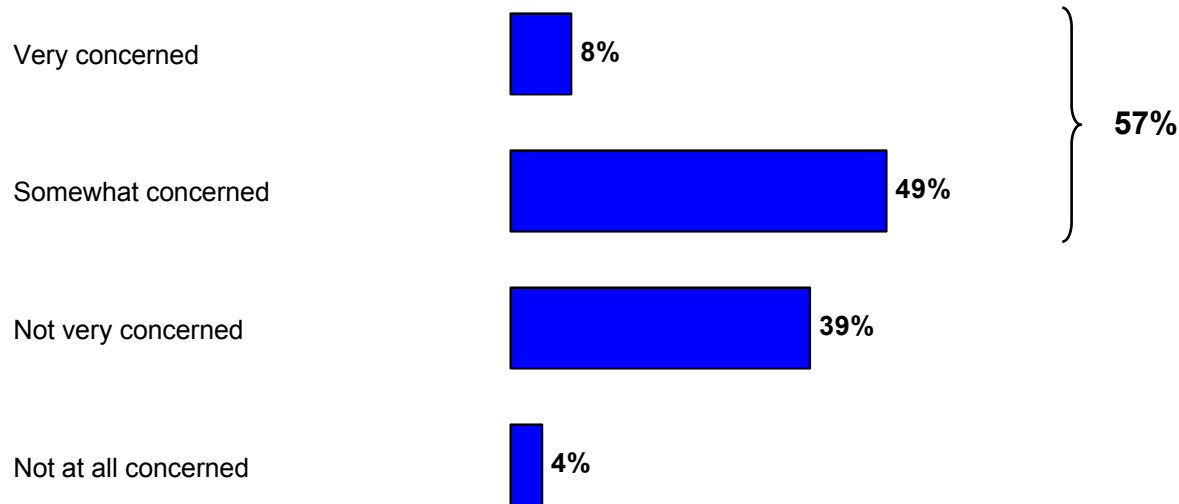


Personal Litigation Due to Side Effects of Properly Prescribed Drug

The majority of doctors (57%) are concerned that they might be sued by a patient who experiences side effects from a prescribed drug, even if the drug is indicated and properly prescribed.

- However, less than one in ten (8%) are very concerned about this occurring.

How concerned are you that you might be sued by a patient who experiences side effects from a prescribed drug, even when that drug is indicated and properly prescribed?



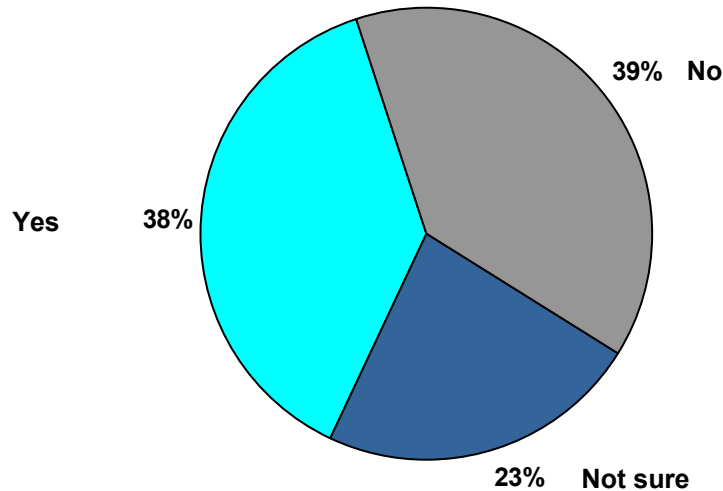


Patients Stopped Taking Medication Due to Litigation

Two in five (38%) doctors know of patients who have stopped taking a medication that was properly prescribed for them because the patient discovered the drug was involved in product liability litigation.

As far as you know, have any of your patients ever stopped taking a medication that was properly prescribed for them because they found out the drug might be involved in product liability litigation?

Base: Those responding (n=200)



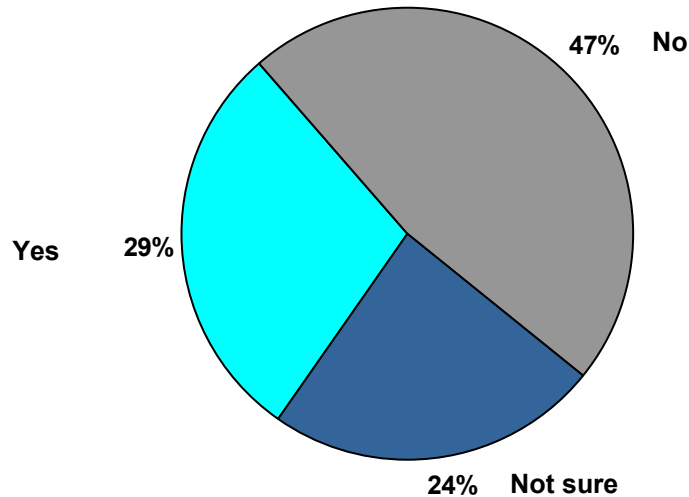


Patients Refused to Take Medication Due to Litigation

Three in ten (29%) doctors have had patients refuse to take a drug prescribed for them because they were aware that the drug was involved in product liability litigation.

As far as you know, have any of your patients ever refused to take a drug that was properly prescribed for them because they found out the drug might be involved in product liability litigation?

Base: Those responding (n=200)



Pharmacists

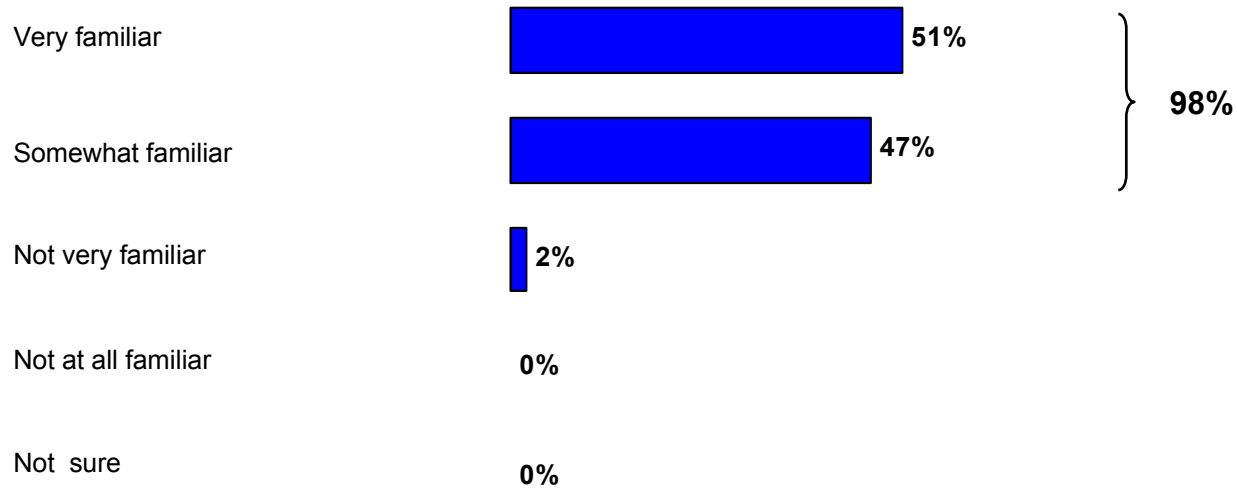


Familiarity with Patient Packet Inserts

Like doctors, nearly every pharmacist surveyed (98%) is familiar with the informational insert known as the patient packet insert.

- Half of pharmacists (51%) say that they are very familiar with the information they provide to patients with prescription drugs.

How familiar would you say you are with the information provided to patients with prescription drugs, sometimes called the patient packet insert?



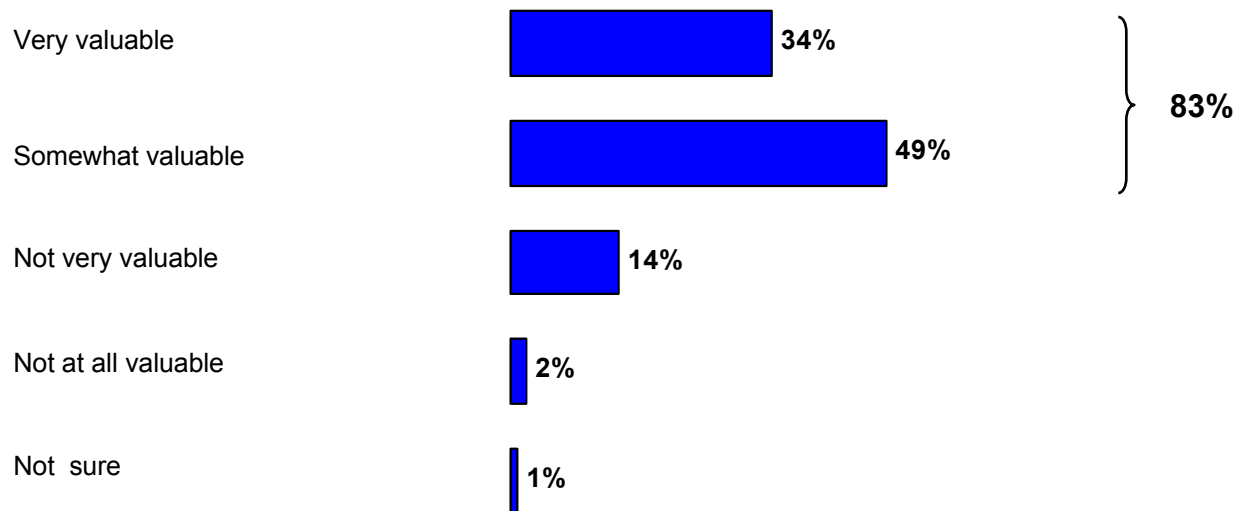


Value of Patient Packet Inserts

Most pharmacists (83%) feel that the information provided in patient packet inserts is a valuable resource to patients.

- One in three (34%) feels that this information is *very* valuable to their patients.

And how valuable to patients do you think the information provided in patient packet inserts is?



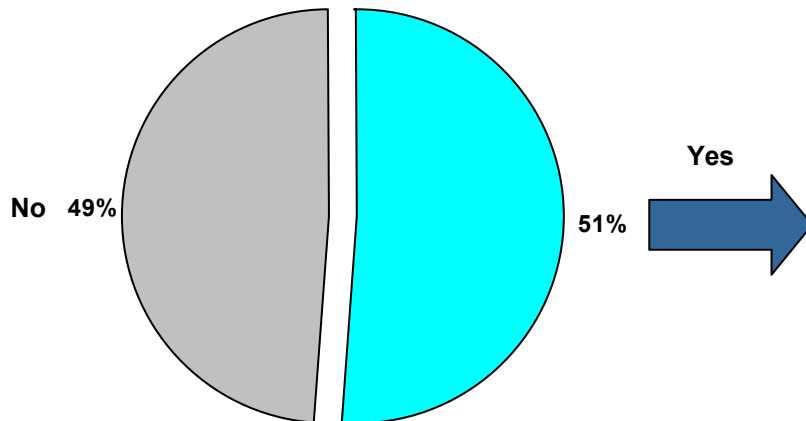


Influence of Product Liability Litigation on Patient Packet Inserts

Half of pharmacists (51%) believe that the information given to patients in the patient packet insert is too complicated – and that product liability litigation is central to making it complex.

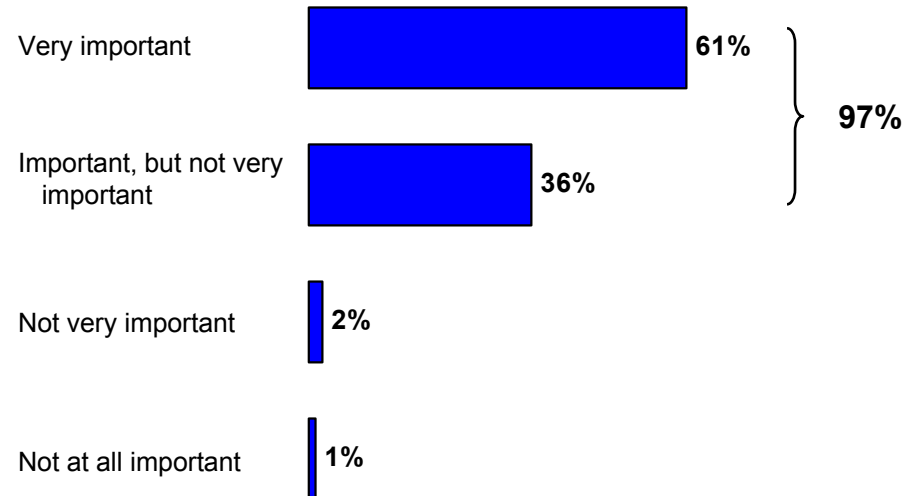
- Many of those who feel the informational packet given to patients with their prescriptions is too complicated also believe that product liability litigation plays a *very important* role in making it more complicated than necessary (61%).

In your opinion, is the information provided in patient packet inserts more complicated than it needs to be?



How important a role do you think product liability litigation, or fear of product liability litigation, has played in making patient packet inserts more complicated than they need to be?

Base: Think information is more complicated than it needs to be (n=127)



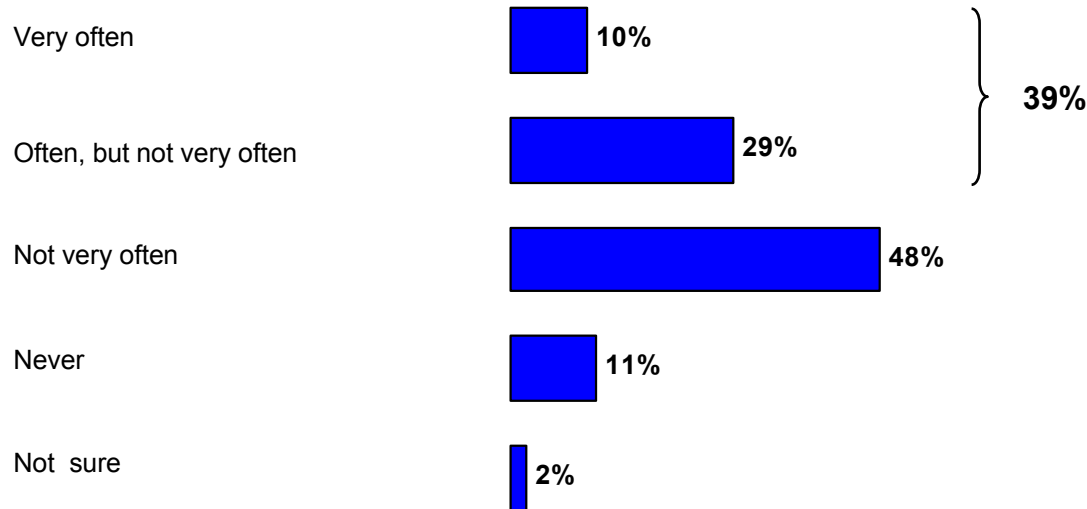


Frequency of Actions to Reduce Risk of Litigation

In order to avoid possible malpractice litigation, two in five (39%) pharmacists say that they often over-emphasize the possible side effects of prescription drugs to patients.

- One in ten (10%) does this with their patients *very often*.

How often would you say you over-emphasize the possible side effects of prescription drugs to patients in order to decrease the possibility of being involved in malpractice litigation?

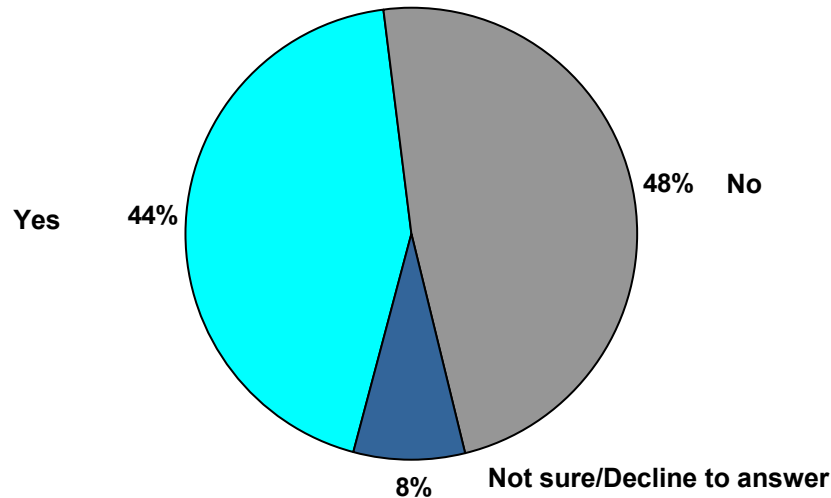




Patients Stopped Taking Medication Due to Litigation

Over two in five (44%) pharmacists report that some their patients have stopped taking medication that was properly prescribed for them because they found out the drug might be involved in product liability litigation.

As far as you know, have any of your patients ever stopped taking a medication that was properly prescribed for them because they found out the drug might be involved in product liability litigation?

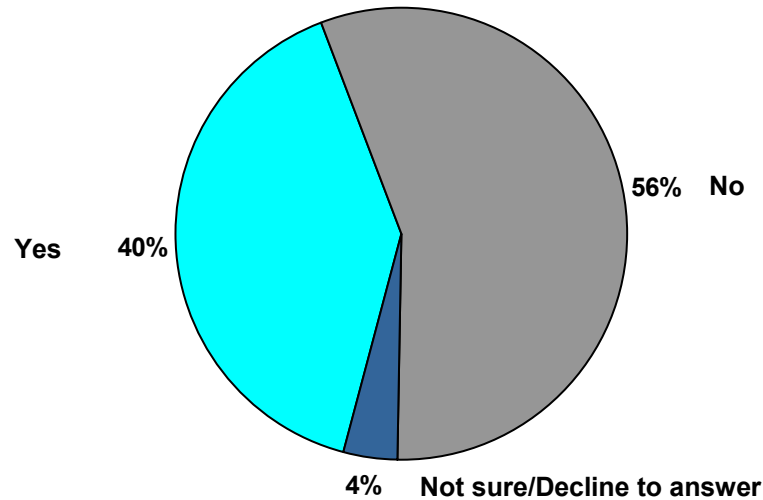




Patients Refusal to Take Medication Due to Litigation

Two in five (40%) pharmacists also report that patients have refused to take a properly prescribed drug because the patient knew the medication was involved in product liability litigation.

As far as you know, have any of your patients ever refused to take a drug that was properly prescribed for them because they found out the drug might be involved in product liability litigation?



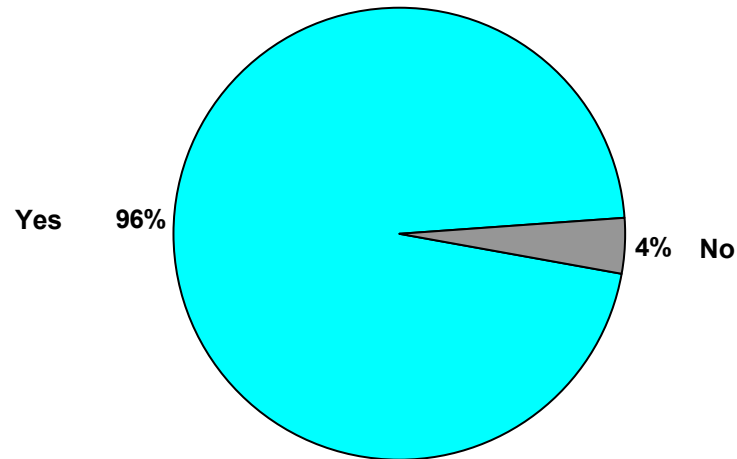
Patients



Awareness of Patient Packet Insert

Nearly all patients (96%) recall receiving a patient packet insert with their prescription medications from their pharmacist.

As you may know, pharmacies are required to include written information about possible drug side effects when you purchase prescription medications, known as the patient packet insert. Do you recall ever having received information like this when you purchased prescription medications from your pharmacy?



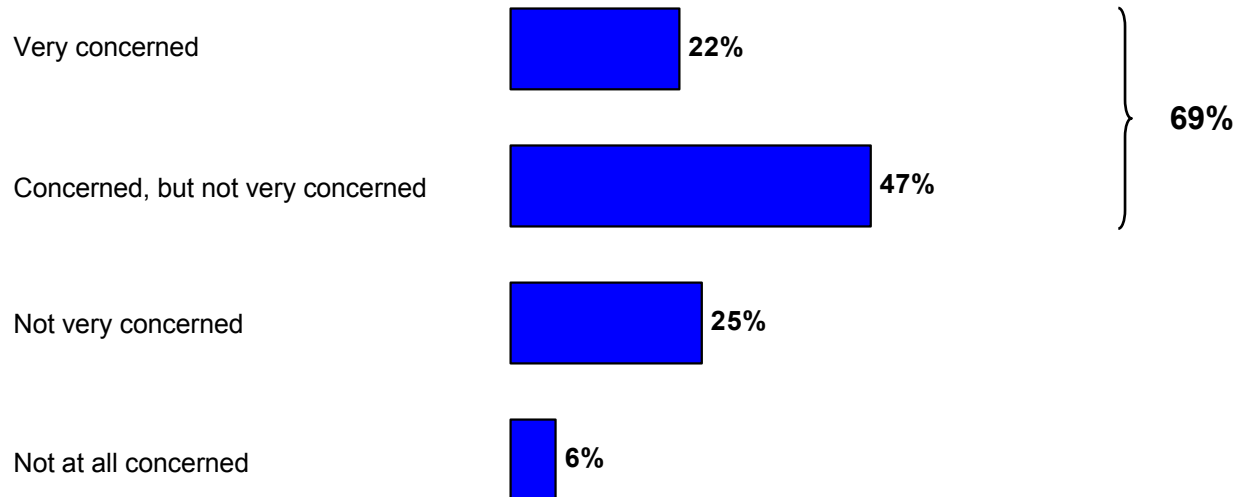


Concern About Taking Prescription Medication Due to Possible Serious Side Effects

The majority of patients (69%) would be concerned about taking a drug if the patient packet insert warned of serious possible side effects.

- One in five (22%) would be very concerned about taking the medication.

If you received a patient packet insert that warned of possible serious side effects associated with the drug you were prescribed, how concerned would it make you about taking that drug?

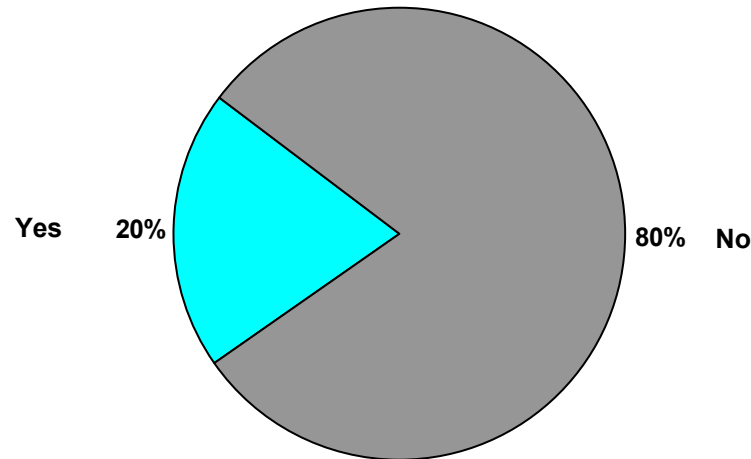




Refusal to Take a Drug Due to Possible Side Effects

One in five (20%) patients have not taken a particular drug prescribed by their doctor as a result of reading information about possible serious side effects provided by the patient packet insert.

Have you ever not taken a particular drug that was prescribed for you by your doctor as a result of information about possible serious side effects provided to you in the patient packet insert?

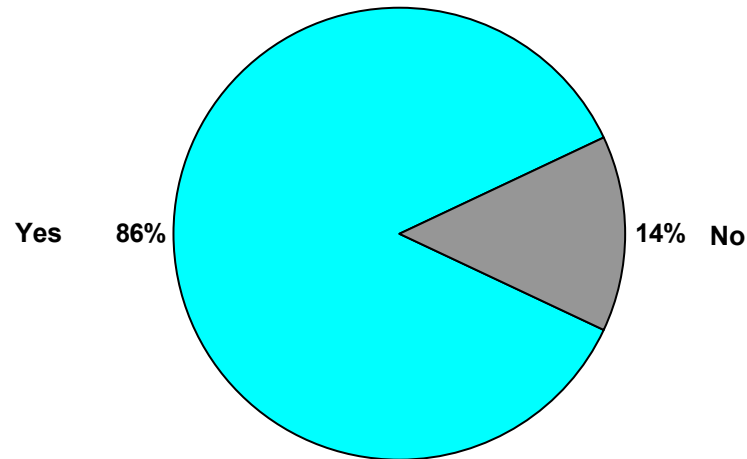




Awareness of Product Liability Litigation Advertisements

Most patients (86%) are aware of advertisements run by law firms about product liability lawsuits directed at pharmaceutical companies over a specific drug.

As you may know, law firms sometimes run advertisements alerting the public to the fact that they are suing a pharmaceutical company over a specific drug. Have you seen or heard any advertisements like these?

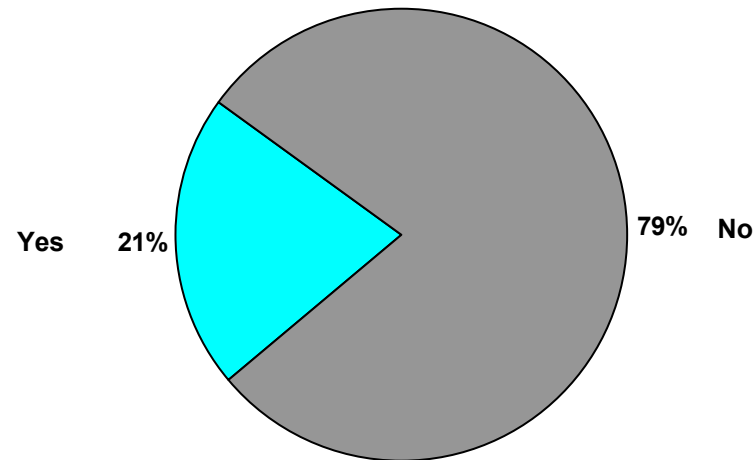




Awareness of Litigation Advertisements for a Drug Patient was Taking

One in five (21%) patients have seen an advertisement for litigation over a drug they were taking.

Have you ever seen an advertisement by a law firm, indicating they were suing the manufacturer of a drug you were taking over that particular drug?



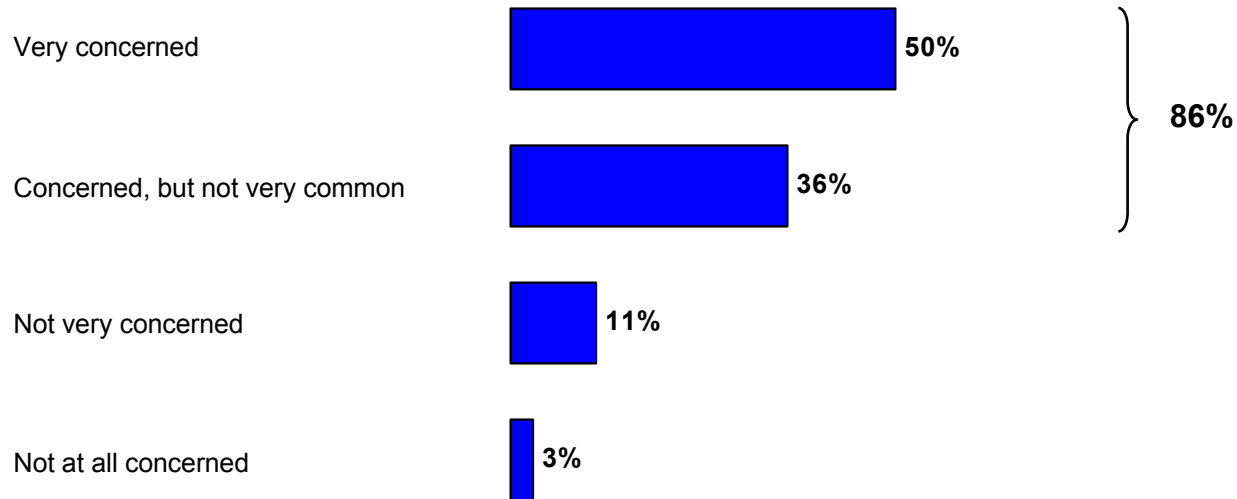


Concern as a Result of Product Liability Litigation Advertisements

Nearly nine in ten (86%) patients would be concerned if they saw an advertisement regarding litigation over a drug they were taking.

- Half (50%) would be *very* concerned if they saw such an advertisement.

How concerned would you be if you were taking a drug, prescribed by your doctor, and saw an advertisement by a law firm indicating they were suing the manufacturer over the drug you were taking?





Actions Would Take as a Result of Litigation Advertisement

If patients saw an advertisement for litigation over a drug they were taking, most would consult their doctor (90%). Approximately one in five would immediately stop taking the drug (25%) or call the law firm in the advertisement (19%).

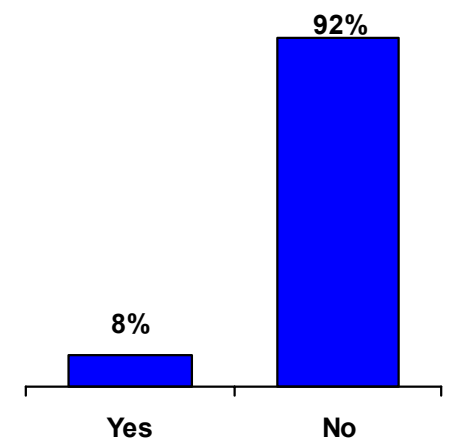
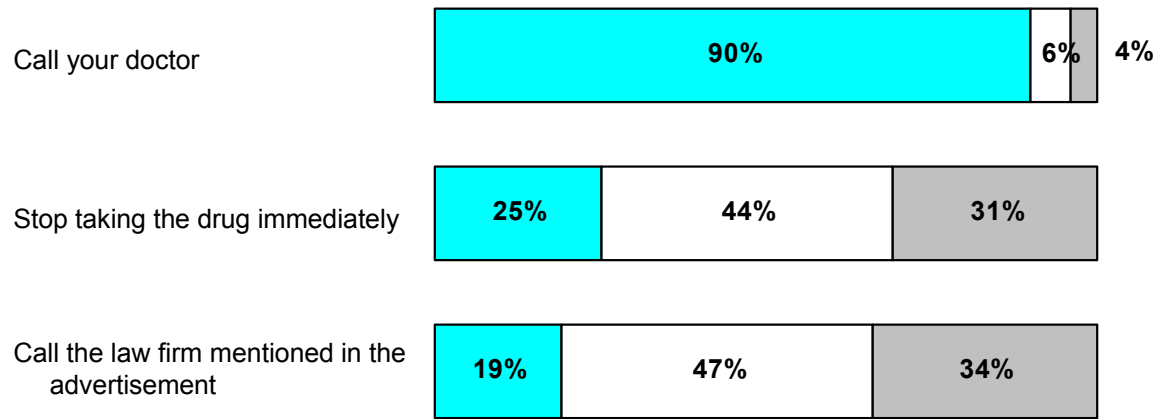
- Less than one in ten (8%) patients have ever had to do any of these actions as a result of viewing such an advertisement.

Suppose you were taking a drug, prescribed by your doctor, and saw an advertisement by a law firm indicating they were suing the manufacturer of the drug you were taking over that particular drug. Please indicate whether you would do each of the following:

Have you ever had to do any of these because you saw an advertisement by a law firm indicating they were suing the manufacturer of a drug you were taking over that particular drug?

Base: Would do any of these action

Yes, Would
 No, Would Not
 Not Sure



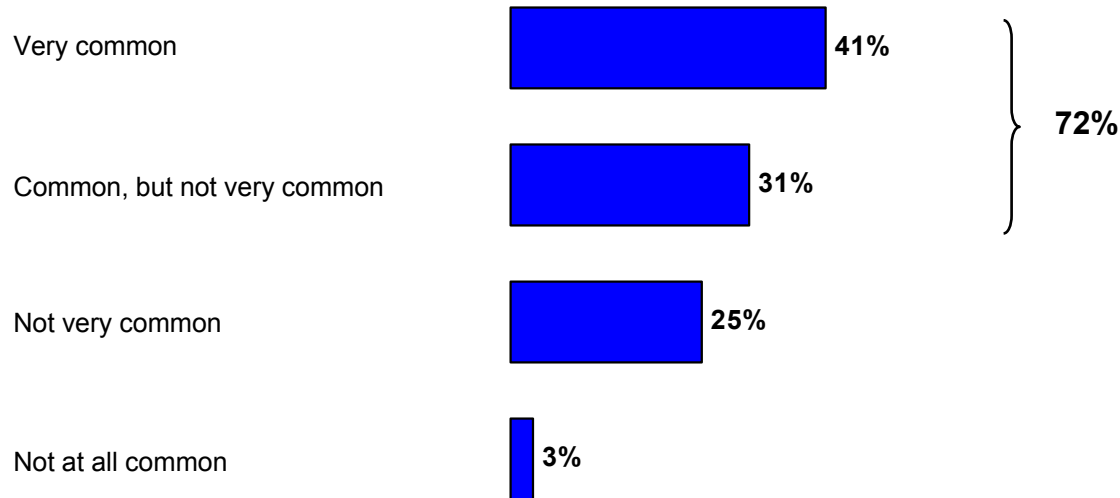


Frequency of Liability Litigation Against Pharmaceuticals

Most patients (72%) believe that it is common for law firms to file product liability lawsuits against drug companies when only a small number of people have experienced unavoidable side effects from a drug.

- Two in five (41%) think that it is *very* common for law firms to do this.

Many beneficial drugs can cause unavoidable side effects. In your opinion, how common is it for law firms to file product liability lawsuits against drug companies when only a small number of people taking a particular drug have experienced unavoidable side effects?



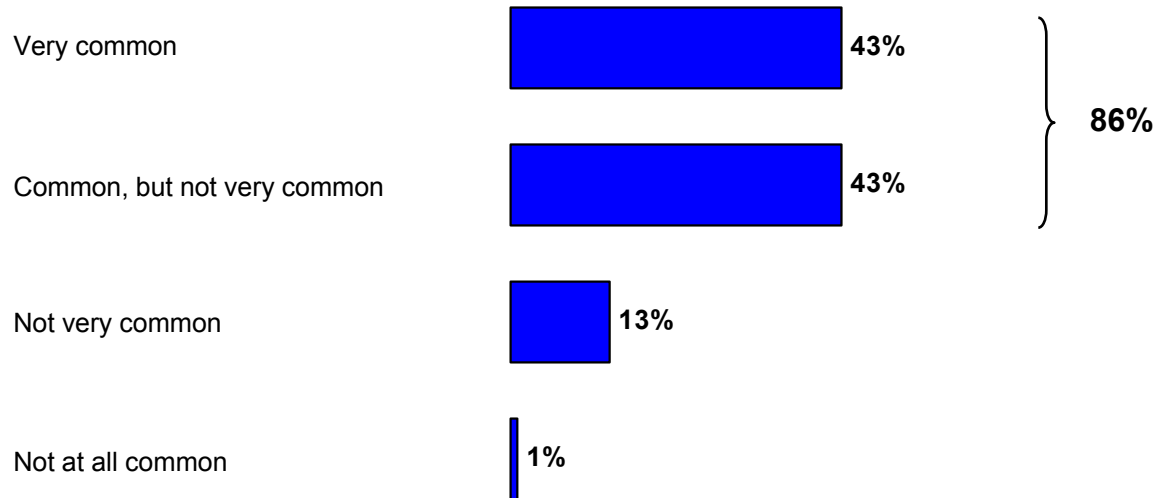


Frequency of Participating in Lawsuit

Although few patients say they would join a lawsuit over a drug if they had not experienced side effects, the majority (86%) think that it is common for other people to join these lawsuits.

- Two in five (43%) believe it is *very* common for people to join a lawsuit over a drug they were taking, even if they had not experienced any side effects from the drug.

When other people qualify for a lawsuit against a pharmaceutical firm for a drug they are taking, but have not experienced side effects from that drug, how common do you think it is for them to join the lawsuit?

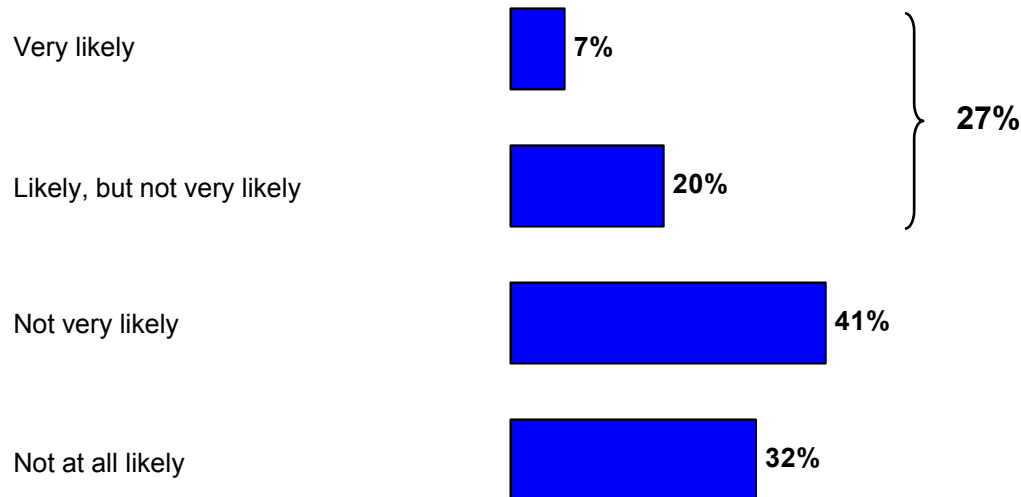




Likelihood of Participating in Lawsuit

One-quarter of patients (27%) say they would be likely to join a lawsuit against a pharmaceutical company if they had not experienced any side effects from that particular drug.

If you found out that you qualified to participate in a lawsuit against a pharmaceutical firm for a drug you were taking, but had not experienced, and were not likely to experience, any side effects from that drug, how likely would you be to join the lawsuit?



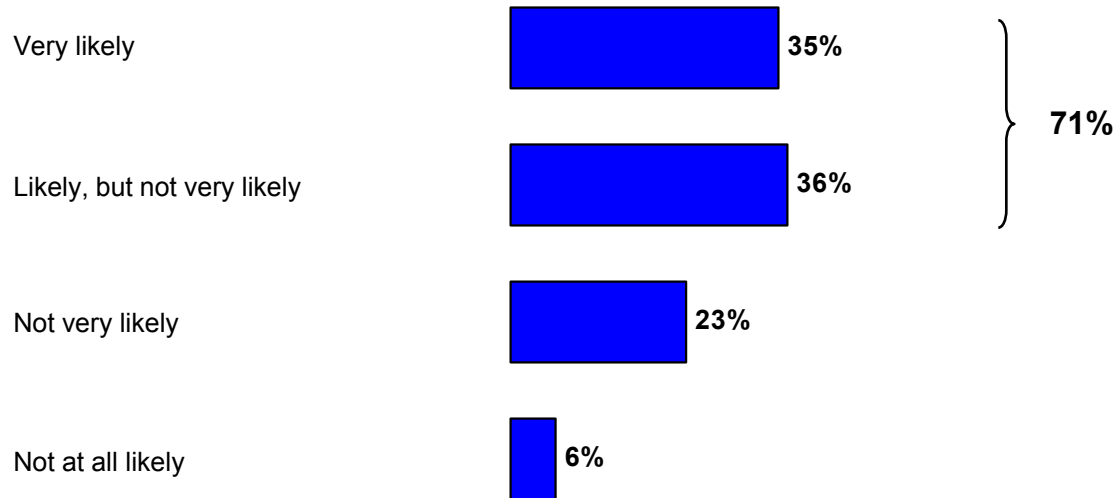


Likelihood of Avoiding R/D as a Result of Litigation

The majority of patients (71%) feel that product liability litigation, or the fear of litigation, has likely caused pharmaceutical companies to avoid research in certain product areas.

- Over a third (35%) say it is *very* likely that companies have avoided drug research because they fear groundless product liability litigations.

How likely do you think it is that pharmaceutical companies avoid research and development in certain product areas, such as contraceptives, because of groundless product liability litigation or fear of product liability litigation?



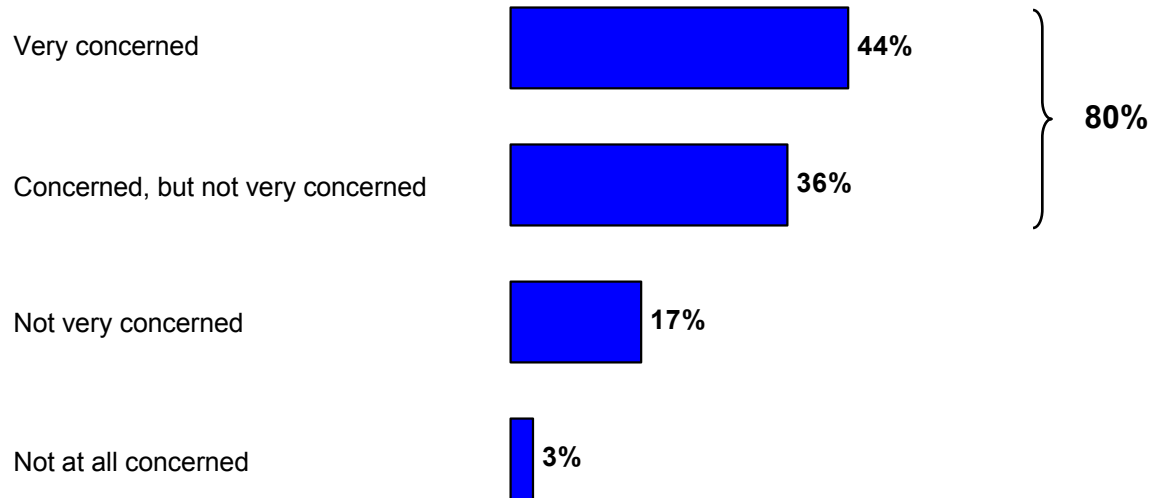


Concern that Litigation May Prevent Development of Beneficial Drugs

Four in five (80%) patients are concerned that groundless product liability litigation prevents pharmaceutical companies from developing new and beneficial drugs.

- Nearly half (44%) say they are *very* concerned that this may be occurring.

How concerned are you that groundless product liability litigation, or fear of product liability litigation, against pharmaceutical companies keeps them from developing new drugs that could someday help people with diseases?



Respondent Profile: Physicians



Respondent Profile - Physicians

<u>Gender</u>	<u>%</u>
Male	70
Female	30

<u>Practice Type</u>	<u>%</u>
Office-based	82
Hospital-based	13
Other	5

<u>Age</u>	<u>%</u>
25 – 34	14
35 – 39	15
40 – 49	29
50 – 59	27
60 – 64	8
65 or older	7
Mean (years)	47.3
Median (years)	47.0

<u>Medical Specialty</u>	<u>%</u>
Primary Care	18
Pediatrics	20
Gastroenterology	17
OB/GYN	29
General Surgery	16

<u>Region</u>	<u>%</u>
East	26
South	32
Midwest	23
West	19

<u>Years in Practice</u>	<u>%</u>
5 years or less	16
6 – 10 years	15
11 – 15 years	12
16 years or more	57
Mean (years)	17.3
Median (years)	19.0

Respondent Profile: Pharmacists



Respondent Profile - Pharmacists

<u>Gender</u>	<u>%</u>
Male	71
Female	29

<u>Pharmacy Type</u>	<u>%</u>
Independent	27
Chain	48
Hospital	1
Other	3
Not sure/Decline to answer	20

<u>Region</u>	<u>%</u>
East	23
South	37
Midwest	22
West	18

<u># of Prescriptions Filled Per Week</u>	<u>%</u>
Less than 500	7
500 – 749	11
750 – 999	12
1000 – 1249	13
1250 – 1499	8
1500 – 1999	12
2000 or more	12
Not sure/Decline to answer	22
Mean (years)	1,593
Median (years)	1,154

<u>Years as Pharmacist</u>	<u>%</u>
5 years or less	13
6 – 10 years	15
11 – 15 years	10
16 years or more	42
Not sure/Decline to answer	20
Mean (years)	17.9
Median (years)	17.0

Respondent Profile: Patients



Respondent Profile - Patients

<u>Gender</u>	<u>%</u>
Male	43
Female	57

<u>Income</u>	<u>%</u>
Less than \$20,000	13
\$20,000 < \$35,000	18
\$35,000 < \$50,000	19
\$50,000 < \$75,000	20
\$75,000 < \$100,000	11
\$100,000 or more	8
Decline to answer	11
Mean (in \$000s)	54.0
Median (in \$000s)	41.9

<u>Age</u>	<u>%</u>
18 – 24	4
25 – 29	4
30 – 34	4
35 – 39	6
40 – 44	11
45 – 49	14
50 – 54	15
55 – 59	14
60 – 64	12
65 or older	17
Mean (years)	51.3
Median (years)	52.0

<u>Education</u>	<u>%</u>
High school or less	21
Some college	34
Associate's degree	10
College graduate	14
Post graduate study	21



Respondent Profile - Patients

<u>Diagnosed Medical Conditions</u>	<u>%</u>
<i>Multiple responses allowed</i>	
High Cholesterol	42
Hypertension	38
Arthritis	38
Obesity	33
Depression	31
Diabetes	28
Heart Disease	22
Stomach Ulcers	16

<u>Currently Take Prescription Medication for Medical Condition</u>	<u>%</u>
<i>Summary of Yes</i>	
High Cholesterol	64
Hypertension	86
Arthritis	39
Obesity	6
Depression	67
Diabetes	86
Heart Disease	72
Stomach Ulcers	44

<u>Region</u>	<u>%</u>
East	25
South	26
Midwest	29
West	20