Medical Liability Reform

Medical liability reform has been the topic of a heated policy debate since 2000, when liability insurance premiums began to skyrocket.

Fast Facts

- *Proponents of liability reform often argue that the tort system creates an environment of fear for physicians that not only leads them to avoid high-risk specialties but also encourages them to order unnecessary tests and procedures. Page 34.*
- *An analysis of the literature strongly suggests that capping damages has an impact on the rise in medical liability premiums. But caps are only part of the picture. Page 40.*
- *The IOM has helped change the perspective on malpractice reform. The traditional view was that the problem was the malpractice system and that medicine itself was fine. But once the IOM published its reports, people began to see the connection between liability issues and failures in how the healthcare system deals with errors. Page 50.*

Much of the medical liability debate has revolved around limiting the incentives for pursuing potentially costly litigation against physicians, hospitals, and other healthcare providers. States have experimented with refinement of the tort systems with measures such as damage caps, joint-and-several liability rules, and statute-of-limitation restrictions with mixed success.

Proponents of such measures often argue that the tort system creates an environment of fear for physicians that not only leads them to avoid high-risk specialties but also encourages them to order unnecessary tests and procedures to reduce the risk of

LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, LUNESTA administered at bedtime decreased sleep latency and improved sleep maintenance.

Important Safety Information

LUNESTA, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients should not take LUNESTA unless they are prepared to get a full night's sleep. As with other hypnotics, patients receiving LUNESTA should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (eg, operating machinery or driving a motor vehicle) after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of LUNESTA. In clinical trials, the most common adverse events associated with LUNESTA were unpleasant taste, headache, somnolence, dizziness, dry mouth, infection, and pain.

LUNESTA has been classified as a Schedule IV controlled substance. Sedative hypnotics have produced withdrawal signs and symptoms following abrupt discontinuation. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or drug abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic. Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Coadministration of eszopiclone 3 mg and olanzapine 10 mg produced a decrease in DSST scores. The interaction was pharmacodynamic; there was no alteration in the pharmacokinetics of either drug. Coadministration of eszopiclone 3 mg to subjects receiving ketoconazole 400 mg resulted in a 2.2-fold increase in exposure to eszopiclone, but no impact on drug levels of ketoconazole.

Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. The recommended starting dose of LUNESTA for these patients is 1 mg.

As with all sedative/hypnotic drugs, somnambulism (sleep-walking), including eating or driving while not fully awake, with amnesia for the event, has been reported. Additionally, rare cases of severe allergic reactions have been reported. Patients who report these events should discontinue treatment and should not be rechallenged with the drug.

The failure of insomnia to remit after 7 to 10 days of treatment should be medically evaluated.

Please see brief summary of complete prescribing information.

Lunesta®
(eszopiclone)
1, 2 AND 3 MG TABLETS

BRIEF SUMMARY

INDICATIONS AND USAGE
LUNESTA is indicated for the treatment of insomnia. In controlled outpatient and sleep laboratory studies, LUNESTA administered at bedtime decreased sleep latency and improved sleep maintenance.

CONTRAINDICATIONS
None known.

WARNINGS
Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including LUNESTA. Because some of the important adverse effects of LUNESTA appear to be dose-related, it is important to use the lowest possible effective dose, especially in the elderly (see **DOSAGE AND ADMINISTRATION in the Full Prescribing Information**).

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g., aggressiveness and extroversion that seem out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included bizarre behavior, agitation, hallucinations, and depersonalization. Complex behaviors such as "sleep-driving" (i.e., driving while not fully awake after ingestion of a sedative-hypnotic with amnesia for the event) have been reported. These events can occur in sedative-hypnotic-naive as well as in sedative-hypnotic-experienced persons. Although behaviors such as sleep-driving may occur with LUNESTA alone at therapeutic doses, the use of alcohol and other CNS depressants with LUNESTA appears to increase the risk of such behaviors, as does the use of LUNESTA at doses exceeding the maximum recommended dose. Due to the risk to the patient and the community, discontinuation of LUNESTA should be strongly considered for patients who report a "sleep-driving" episode. Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with sleep-driving, patients usually do not remember these events. Amnesia and other neuropsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking, has been reported in association with the use of sedative/hypnotics.

It can rarely be determined with certainty whether a particular instance of the abnormal behaviors listed above are drug-induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

Following rapid dose decrease or abrupt discontinuation of the use of sedative/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant drugs (see **DRUG ABUSE AND DEPENDENCE**).

LUNESTA, like other hypnotics, has CNS-depressant effects. Because of the rapid onset of action, LUNESTA should only be ingested immediately prior to going to bed or after the patient has gone to bed and has experienced difficulty falling asleep. Patients receiving LUNESTA should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination (e.g., operating machinery or driving a motor vehicle) after ingesting the drug, and be cautioned about potential impairment of the performance of such activities on the day following ingestion of LUNESTA. LUNESTA, like other hypnotics, may produce additive CNS-depressant effects when coadministered with other psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs that themselves produce CNS depression. LUNESTA should not be taken with alcohol. Dose adjustment may be necessary when LUNESTA is administered with other CNS-depressant agents, because of the potentially additive effects.

Severe Anaphylactic and Anaphylactoid Reactions
Rare cases of angioedema involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of sedative-hypnotics, including LUNESTA. Some patients have had additional symptoms such as dyspnea, throat closing, or nausea and vomiting that suggest anaphylaxis. Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with LUNESTA should not be rechallenged with the drug.

PRECAUTIONS
General

Timing Of Drug Administration: LUNESTA should be taken immediately before bedtime. Taking a sedative/hypnotic while still up and about may result in short-term memory impairment, hallucinations, impaired coordination, dizziness, and lightheadedness.

Use In The Elderly And/Or Debilitated Patients: Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. The recommended starting dose of LUNESTA for these patients is 1 mg (see **DOSAGE AND ADMINISTRATION in the Full Prescribing Information**).

Use In Patients With Concomitant Illness: Clinical experience with eszopiclone in patients with concomitant illness is limited. Eszopiclone should be used with caution in patients with diseases or conditions that could affect metabolism or hemodynamic responses.

A study in healthy volunteers did not reveal respiratory-depressant effects at doses 2.5-fold higher (7 mg) than the recommended dose of eszopiclone. Caution is advised, however, if LUNESTA is prescribed to patients with compromised respiratory function.

The dose of LUNESTA should be reduced to 1 mg in patients with severe hepatic impairment, because systemic exposure is doubled in such subjects. No dose adjustment appears necessary for subjects with mild or moderate hepatic impairment. No dose adjustment appears necessary in subjects with any degree of renal impairment, since less than 10% of eszopiclone is excreted unchanged in the urine.

The dose of LUNESTA should be reduced in patients who are administered potent inhibitors of CYP3A4, such as ketoconazole, while taking LUNESTA. Downward dose adjustment is also recommended when LUNESTA is administered with agents having known CNS-depressant effects.

Use In Patients With Depression: Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs and symptoms of depression. Suicidal tendencies may be present in such patients, and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Information For Patients: Patient information is printed in the complete prescribing information.

SPECIAL CONCERNS "Sleep-Driving" and other complex behaviors
There have been reports of people getting out of bed after taking a sedative-hypnotic and driving their cars while not fully awake, often with no memory of the event. If a patient experiences such an episode, it should be reported to his or her doctor immediately, since "sleep-driving" can be dangerous. This behavior is more likely to occur when LUNESTA is taken with alcohol or other central nervous system depressants (see WARNINGS). Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with sleep-driving, patients usually do not remember these events.

Laboratory Tests: There are no specific laboratory tests recommended.

Drug Interactions

CNS-Active Drugs

Ethanol: An additive effect on psychomotor performance was seen with coadministration of eszopiclone and ethanol 0.70 g/kg for up to 4 hours after ethanol administration.

Paroxetine: Coadministration of single doses of eszopiclone 3 mg and paroxetine 20 mg daily for 7 days produced no pharmacokinetic or pharmacodynamic interaction.

Lorazepam: Coadministration of single doses of eszopiclone 3 mg and lorazepam 2 mg did not have clinically relevant effects on the pharmacodynamics or pharmacokinetics of either drug.

Olanzapine: Coadministration of eszopiclone 3 mg and olanzapine 10 mg produced a decrease in DSST scores. The interaction was pharmacodynamic; there was no alteration in the pharmacokinetics of either drug.

Drugs That Inhibit CYP3A4 (Ketoconazole): CYP3A4 is a major metabolic pathway for elimination of eszopiclone. The AUC of eszopiclone was increased 2.2-fold by coadministration of ketoconazole, a potent inhibitor of CYP3A4, 400 mg daily for 5 days. C_{max} and $t_{1/2}$ were increased 1.4-fold and 1.3-fold, respectively. Other strong inhibitors of CYP3A4 (e.g., itraconazole, clarithromycin, nefazodone, troleandomycin, ritonavir, nelfinavir) would be expected to behave similarly.

Drugs That Induce CYP3A4 (Rifampicin): Racemic zopiclone exposure was decreased 80% by concomitant use of rifampicin, a potent inducer of CYP3A4. A similar effect would be expected with eszopiclone.

Drugs Highly Bound To Plasma Protein: Eszopiclone is not highly bound to plasma proteins (52-59% bound); therefore, the disposition of eszopiclone is not expected to be sensitive to alterations in protein binding. Administration of eszopiclone 3 mg to a patient taking another drug that is highly protein-bound would not be expected to cause an alteration in the free concentration of either drug.

Drugs With A Narrow Therapeutic Index

Digoxin: A single dose of eszopiclone 3 mg did not affect the pharmacokinetics of digoxin measured at steady state following dosing of 0.5 mg twice daily for one day and 0.25 mg daily for the next 6 days.

Warfarin: Eszopiclone 3 mg administered daily for 5 days did not affect the pharmacokinetics of (R)- or (S)-warfarin, nor were there any changes in the pharmacodynamic profile (prothrombin time) following a single 25-mg oral dose of warfarin.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: In a carcinogenicity study in Sprague-Dawley rats in which eszopiclone was given by oral gavage, no increases in tumors were seen; plasma levels (AUC) of eszopiclone at the highest dose used in this study (16 mg/kg/day) are estimated to be 80 (females) and 20 (males) times those in humans receiving the maximum recommended human dose (MRHD). However, in a carcinogenicity study in Sprague-Dawley rats in which racemic zopiclone was given in the diet, and in which plasma levels of eszopiclone were reached that were greater than those reached in the above study of eszopiclone, an increase in mammary gland adenocarcinomas in females and an increase in thyroid gland follicular cell adenomas and carcinomas in males were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopiclone at this dose are estimated to be 150 (females) and 70 (males) times those in humans receiving the MRHD. The mechanism for the increase in mammary adenocarcinomas is unknown. The increase in thyroid tumors is thought to be due to increased levels of TSH secondary to increased metabolism of circulating thyroid hormones, a mechanism that is not considered to be relevant to humans.

In a carcinogenicity study in B6C3F1 mice in which racemic zopiclone was given in the diet, an increase in pulmonary carcinomas and carcinomas plus adenomas in females and an increase in skin fibromas and sarcomas in males were seen at the highest dose of 100 mg/kg/day. Plasma levels of eszopiclone at this dose are estimated to be 8 (females) and 20 (males) times those in humans receiving the MRHD. The skin tumors were due to skin lesions induced by aggressive behavior, a mechanism that is not relevant to humans. A carcinogenicity study was also performed in which CD-1 mice were given eszopiclone at doses up to 100 mg/kg/day by oral gavage; although this study did not reach a maximum tolerated dose, and was thus inadequate for overall assessment of carcinogenic potential, no increases in either pulmonary or skin tumors were seen at doses producing plasma levels of eszopiclone estimated to be 90 times those in humans receiving the MRHD—i.e., 12 times the exposure in the racemate study.

Eszopiclone did not increase tumors in a p53 transgenic mouse bioassay at oral doses up to 300 mg/kg/day.

Mutagenesis: Eszopiclone was positive in the mouse lymphoma chromosomal aberration assay and produced an equivocal response in the Chinese hamster ovary cell chromosomal aberration assay. It was not mutagenic or clastogenic in the bacterial Ames gene mutation assay, in an unscheduled DNA synthesis assay, or in an *in vivo* mouse bone marrow micronucleus assay.

(S)-N-desmethyl zopiclone, a metabolite of eszopiclone, was positive in the Chinese hamster ovary cell and human lymphocyte chromosomal aberration assays. It was negative in the bacterial Ames mutation assay, in an *in vitro* ^{32}P-postlabeling DNA adduct assay, and in an *in vivo* mouse bone marrow chromosomal aberration and micronucleus assay.

Impairment Of Fertility: Eszopiclone was given by oral gavage to male rats at doses up to 45 mg/kg/day from 4 weeks premating through mating and to female rats at doses up to 180 mg/kg/day from 2 weeks premating through day 7 of pregnancy. An additional study was performed in which only females were treated, up to 180 mg/kg/day. Eszopiclone decreased fertility, probably because of effects in both males and females, with no females becoming pregnant when both males and females were treated with the highest dose; the no-effect dose in both sexes was

5 mg/kg (16 times the MRHD on a mg/m² basis). Other effects included increased preimplantation loss (no-effect dose 25 mg/kg), abnormal estrus cycles (no-effect dose 25 mg/kg), and decreases in sperm number and motility and increases in morphologically abnormal sperm (no-effect dose 5 mg/kg).

Pregnancy

Pregnancy Category C: Eszopiclone administered by oral gavage to pregnant rats and rabbits during the period of organogenesis showed no evidence of teratogenicity up to the highest doses tested (250 and 16 mg/kg/day in rats and rabbits, respectively; these doses are 800 and 100 times, respectively, the maximum recommended human dose [MRHD] on a mg/m² basis). In the rat, slight reductions in fetal weight and evidence of developmental delay were seen at maternally toxic doses of 125 and 150 mg/kg/day, but not at 62.5 mg/kg/day (200 times the MRHD on a mg/m² basis). Eszopiclone was also administered by oral gavage to pregnant rats throughout the pregnancy and lactation periods at doses of up to 180 mg/kg/day. Increased post-implantation loss, decreased postnatal pup weights and survival, and increased pup startle response were seen at all doses; the lowest dose tested, 60 mg/kg/day, is 200 times the MRHD on a mg/m² basis. These doses did not produce significant maternal toxicity. Eszopiclone had no effects on other behavioral measures or reproductive function in the offspring.

There are no adequate and well-controlled studies of eszopiclone in pregnant women. Eszopiclone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor And Delivery: LUNESTA has no established use in labor and delivery.

Nursing Mothers: It is not known whether LUNESTA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when LUNESTA is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of eszopiclone in children below the age of 18 have not been established.

Geriatric Use: A total of 287 subjects in double-blind, parallel-group, placebo-controlled clinical trials who received eszopiclone were 65 to 86 years of age. The overall pattern of adverse events for elderly subjects (median age = 71 years) in 2-week studies with nighttime dosing of 2 mg eszopiclone was not different from that seen in younger adults. LUNESTA 2 mg exhibited significant reduction in sleep latency and improvement in sleep maintenance in the elderly population.

ADVERSE REACTIONS

The premarketing development program for LUNESTA included eszopiclone exposures in patients and/or normal subjects from two different groups of studies: approximately 400 normal subjects in clinical pharmacology/pharmacokinetic studies, and approximately 1550 patients in placebo-controlled clinical effectiveness studies, corresponding to approximately 263 patient-exposure years. The conditions and duration of treatment with LUNESTA varied greatly and included (in overlapping categories) open-label and double-blind phases of studies, inpatients and outpatients, and short-term and longer-term exposure. Adverse reactions were assessed by collecting adverse events, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

Adverse events during exposure were obtained primarily by general inquiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping similar types of events into a smaller number of standardized event categories. In the tabulations that follow, COSTART terminology has been used to classify reported adverse events.

The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while the patient was receiving therapy following baseline evaluation.

Adverse Findings Observed in Placebo-Controlled Trials

Adverse Events Resulting in Discontinuation of Treatment: In placebo-controlled, parallel-group clinical trials in the elderly, 3.8% of 208 patients who received placebo, 2.3% of 215 patients who received 2 mg LUNESTA, and 1.4% of 72 patients who received 1 mg LUNESTA discontinued treatment due to an adverse event. In the 6-week parallel-group study in adults, no patients in the 3 mg arm discontinued because of an adverse event. In the long-term 6-month study in adult insomnia patients, 7.2% of 195 patients who received placebo and 12.8% of 593 patients who received 3 mg LUNESTA discontinued due to an adverse event. No event that resulted in discontinuation occurred at a rate of greater than 2%.

Adverse Events Observed at an Incidence of ≥2% in Controlled Trials. The following lists the incidence (% placebo, 2 mg, 3 mg, respectively) of treatment-emergent adverse events from a Phase 3 placebo-controlled study of LUNESTA at doses of 2 or 3 mg in non-elderly adults. Treatment duration in this trial was 44 days. Data are limited to adverse events that occurred in 2% or more of patients treated with LUNESTA 2 mg (n=104) or 3 mg (n=105) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated patients (n=99).[1]

Body as a whole: headache (13%, 21%, 17%), viral infection (1%, 3%, 3%). Digestive system: dry mouth (3%, 5%, 7%), dyspepsia (4%, 4%, 5%), nausea (4%, 5%, 4%), vomiting (1%, 3%, 0%). Nervous system: anxiety (0%, 3%, 1%), confusion (0%, 0%, 3%), depression (0%, 4%, 1%), dizziness (4%, 5%, 7%), hallucinations (0%, 1%, 3%), libido decreased (0%, 0%, 3%), nervousness (3%, 5%, 0%), somnolence (3%, 10%, 8%). Respiratory system: infection (3%, 5%, 10%). Skin and appendages: rash (1%, 3%, 4%). Special senses: unpleasant taste (3%, 17%, 34%). Urogenital system: dysmenorrhea* (0%, 3%, 0%), gynecomastia** (0%, 3%, 0%).

*Gender-specific adverse event in females

**Gender-specific adverse event in males

[1]Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abnormal dreams, accidental injury, back pain, diarrhea, flu syndrome, myalgia, pain, pharyngitis, and rhinitis.

Adverse events that suggest a dose-response relationship in adults include viral infection, dry mouth, dizziness, hallucinations, infection, rash, and unpleasant taste, with this relationship clearest for unpleasant taste.

The following lists the incidence (% placebo, 1 mg, 2 mg, respectively) of treatment-emergent adverse events from combined Phase 3 placebo-controlled studies of LUNESTA at doses of 1 or 2 mg in elderly adults (ages 65-86). Treatment duration in these trials was 14 days. Data are limited to events that occurred in 2% or more of patients treated with LUNESTA 1 mg (n=72) or 2 mg (n=215) in which the incidence in patients treated with LUNESTA was greater than the incidence in placebo-treated patients.[1]

Body as a whole: accidental injury (1%, 0%, 3%), headache (14%, 15%, 13%), pain (2%, 4%, 5%). Digestive system: diarrhea (2%, 4%, 2%), dry mouth (2%, 3%, 7%), dyspepsia (2%, 6%, 2%). Nervous system: abnormal dreams (0%, 3%, 1%), dizziness (2%, 1%, 6%), nervousness (1%, 0%, 2%), neuralgia (0%, 3%, 0%). Skin and appendages: pruritus: (1%, 4%, 1%). Special senses: unpleasant taste (0%, 8%, 12%). Urogenital system: urinary tract infection (0%, 3%, 0%).

[1]Events for which the LUNESTA incidence was equal to or less than placebo are not listed, but included the following: abdominal pain, asthenia, nausea, rash, and somnolence.

Adverse events that suggest a dose-response relationship in elderly adults include pain, dry mouth, and unpleasant taste, with this relationship again clearest for unpleasant taste. These figures cannot be used to predict the incidence of adverse events in the course of usual medical practice because patient characteristics and other factors may differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators.

The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contributions of drug and non-drug factors to the adverse event incidence rate in the population studied.

Other Events Observed During The Premarketing Evaluation Of LUNESTA. Following is a list of modified COSTART terms that reflect treatment-emergent adverse events as defined in the introduction to the **ADVERSE REACTIONS** section and reported by approximately 1550 subjects treated with LUNESTA at doses in the range of 1 to 3.5 mg/day during Phase 2 and 3 clinical trials throughout the United States and Canada. All reported events are included except those already listed here or listed elsewhere in labeling, minor events common in the general population, and events unlikely to be drug-related. Although the events reported occurred during treatment with LUNESTA, they were not necessarily caused by it.

Events are listed in order of decreasing frequency according to the following definitions: **frequent** adverse events are those that occurred on one or more occasions in at least 1/100 patients; **infrequent** adverse events are those that occurred in fewer than 1/100 patients but in at least 1/1,000 patients; **rare** adverse events are those that occurred in fewer than 1/1,000 patients. Gender-specific events are categorized based on their incidence for the appropriate gender.

Frequent: chest pain, migraine, peripheral edema.

Infrequent: acne, agitation, allergic reaction, alopecia, amenorrhea, anemia, anorexia, apathy, arthritis, asthma, ataxia, breast engorgement, breast enlargement, breast neoplasm, breast pain, bronchitis, bursitis, cellulitis, cholelithiasis, conjunctivitis, contact dermatitis, cystitis, dry eyes, dry skin, dyspnea, dysuria, eczema, ear pain, emotional lability, epistaxis, face edema, female lactation, fever, halitosis, heat stroke, hematuria, hernia, hiccup, hostility, hypercholesteremia, hypertension, hypertonia, hypesthesia, incoordination, increased appetite, insomnia, joint disorder (mainly swelling, stiffness, and pain), kidney calculus, kidney pain, laryngitis, leg cramps, lymphadenopathy, malaise, mastitis, melena, memory impairment, menorrhagia, metrorrhagia, mouth ulceration, myasthenia, neck rigidity, neurosis, nystagmus, otitis externa, otitis media, paresthesia, photosensitivity, reflexes decreased, skin discoloration, sweating, thinking abnormal (mainly difficulty concentrating), thirst, tinnitus, twitching, ulcerative stomatitis, urinary frequency, urinary incontinence, urticaria, uterine hemorrhage, vaginal hemorrhage, vaginitis, vertigo, vestibular disorder, weight gain, weight loss.

Rare: abnormal gait, arthrosis, colitis, dehydration, dysphagia, erythema multiforme, euphoria, furunculosis, gastritis, gout, hepatitis, hepatomegaly, herpes zoster, hirsutism, hyperacusis, hyperesthesia, hyperlipemia, hypokalemia, hypokinesia, iritis, liver damage, maculopapular rash, mydriasis, myopathy, neuritis, neuropathy, oliguria, photophobia, ptosis, pyelonephritis, rectal hemorrhage, stomach ulcer, stomatitis, stupor, thrombophlebitis, tongue edema, tremor, urethritis, vesiculobullous rash.

DRUG ABUSE AND DEPENDENCE

Controlled Substance Class: LUNESTA is a Schedule IV controlled substance under the Controlled Substances Act. Other substances under the same classification are benzodiazepines and the nonbenzodiazepine hypnotics zaleplon and zolpidem. While eszopiclone is a hypnotic agent with a chemical structure unrelated to benzodiazepines, it shares some of the pharmacologic properties of the benzodiazepines.

Abuse, Dependence, and Tolerance

Abuse and Dependence: In a study of abuse liability conducted in individuals with known histories of benzodiazepine abuse, eszopiclone at doses of 6 and 12 mg produced euphoric effects similar to those of diazepam 20 mg. In this study, at doses 2-fold or greater than the maximum recommended doses, a dose-related increase in reports of amnesia and hallucinations was observed for both LUNESTA and diazepam.

The clinical trial experience with LUNESTA revealed no evidence of a serious withdrawal syndrome. Nevertheless, the following adverse events included in DSM-IV criteria for uncomplicated sedative/hypnotic withdrawal were reported during clinical trials following placebo substitution occurring within 48 hours following the last LUNESTA treatment: anxiety, abnormal dreams, nausea, and upset stomach. These reported adverse events occurred at an incidence of 2% or less. Use of benzodiazepines and similar agents may lead to physical and psychological dependence. The risk of abuse and dependence increases with the dose and duration of treatment and concomitant use of other psychoactive drugs. The risk is also greater for patients who have a history of alcohol or drug abuse or history of psychiatric disorders. These patients should be under careful surveillance when receiving LUNESTA or any other hypnotic.

Tolerance: Some loss of efficacy to the hypnotic effect of benzodiazepines and benzodiazepine-like agents may develop after repeated use of these drugs for a few weeks.

No development of tolerance to any parameter of sleep measurement was observed over six months. Tolerance to the efficacy of LUNESTA 3 mg was assessed by 4-week objective and 6-week subjective measurements of time to sleep onset and sleep maintenance for LUNESTA in a placebo-controlled 44-day study, and by subjective assessments of time to sleep onset and WASO in a placebo-controlled study for 6 months.

OVERDOSAGE

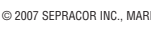
There is limited premarketing clinical experience with the effects of an overdosage of LUNESTA. In clinical trials with eszopiclone, one case of overdose with up to 36 mg of eszopiclone was reported in which the subject fully recovered. Individuals have fully recovered from racemic zopiclone overdoses up to 340 mg (56 times the maximum recommended dose of eszopiclone).

Signs And Symptoms: Signs and symptoms of overdose effects of CNS depressants can be expected to present as exaggerations of the pharmacological effects noted in preclinical testing. Impairment of consciousness ranging from somnolence to coma has been described. Rare individual instances of fatal outcomes following overdose with racemic zopiclone have been reported in European postmarketing reports, most often associated with overdose with other CNS-depressant agents.

Recommended Treatment: General symptomatic and supportive measures should be used along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. Flumazenil may be useful. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate signs should be monitored and general supportive measures employed. Hypotension and CNS depression should be monitored and treated by appropriate medical intervention. The value of dialysis in the treatment of overdosage has not been determined.

Poison Control Center: As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may wish to consider contacting a poison control center for up-to-date information on the management of hypnotic drug product overdosage.

Rx only.



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being found liable for a patient's injury. Defensive medicine has been estimated to cost the U.S. healthcare system tens of billions of dollars every year.

"The dollar cost of the tort system is obscene," says William Plested, MD, immediate past president of the American Medical Association (AMA). "But the psychological, emotional cost is even worse. The only way someone can get a reward for something that goes wrong, even if the doctor tried his best, is to destroy the doctor. And that drives people out of practice, it causes access problems, all kinds of things. The secondary costs of this system—nobody talks about those."

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The physician community has been pushing for action on the medical liability front for the past 30 years, during which time there have been no fewer than three liability crises, hitting physicians and hospitals on a regular ten-year cycle. While many legislative efforts have focused on caps and other revisions to the tort system, ultimately many experts hope that medical liability will move outside the system altogether. More recently, discussion of promising approaches for compensating injured patients without trying to place blame on providers has gained ground. An increasing number of state legislatures have introduced bills to establish demonstration projects, such as health courts, designed as alternatives to the tort system. There is also growing support for federal legislation that would free up new funding to help states that want to set up such alternative systems for compensating patients.

Along with these efforts has come the evolving realization that revamping the medical liability environment, especially one designed to remove blame, will require ramped-up patient safety efforts. A series of Institutes of Medicine (IOM) reports have suggested that medical error rates are shockingly common in the U.S. healthcare system. Since the IOM's first report was pub-

lished in 2001, a new breed of patient-safety researchers has produced a laundry list of recommendations that could lead to a significant decline in unnecessary adverse drug events and other medical errors—and reduce the need for malpractice litigation.

Tort Reform DOA?

Caps on damages and other tort reform measures designed to restrict either the size or quantity of lawsuits have dominated the discussion over medical liability, on both the federal and state levels. Placing limitations on non-economic damages—pain and suffering—has been the most popular measure with the AMA and other physician groups because of its proven record in California, where a cap has been in place since 1975 and where the medical malpractice crisis arguably has been blunted.

"We have 32 years of experience in California that it works. While places without those types of reforms have accelerating costs, California's have been held somewhat in check," says Dr. Plested. While California has not been completely insulated from the crisis, it is a lot better off than places like Florida, which have been especially hard hit by rising liability premiums, he says.

Physicians are also pointing to the example of Texas, which passed a malpractice cap in 2003. While the Texas measure is less restrictive than California's law, allowing plaintiffs to collect the maximum $250,000 from each entity that is a party to the suit, it has created a marked improvement in cost of liability insurance and the number of insurers in the state. It has also resulted in an influx of new physicians, according to Dr. Plested. He says the only downside for Texas has been that the state's medical board has been overwhelmed with licensing requests. "That's a wonderful problem to have when there are places that can't get a doctor," he adds.

But not everyone agrees that malpractice caps bring in doctors or help solve physician shortages. William Sage, MD, JD, Vice Provost for Health Affairs at the University of Texas in Austin, points out that Texas's population is growing rapidly; so while there are a lot of preliminary data to support the notion that physicians are moving to the state, the influx may be in part due to overall population growth. Still, he says, it's likely that the reforms didn't hurt, given physicians' consciousness of the mal-

Caps Only Part of the Picture

Much has been learned from state efforts to control the rising cost of medical liability insurance during the 1970's and 1980's, when the first two medical malpractice crises hit the U.S. health-care system.

An analysis of the literature strongly suggests that capping damages has an impact on the rise in medical liability premiums, says Leonard "Jack" Nelson, III, JD, professor of health law at Samford University in Birmingham, Ala. "It's been a matter of debate for several years, but the better studies have all concluded that damage caps do reduce [the rate of increase in] malpractice liability insurance premiums," says Mr. Nelson, who has been studying this issue with the help of a grant from the Robert Wood Johnson Foundation. Along with two other researchers, he recently published a study in the June edition of *Milbank Quarterly*.

In his recent study of physicians, it was clear that damage caps reduced the amount of money insurance companies paid out in awards and, in turn, reduced how fast liability premiums rose, according to the lead researcher Janelle Guirguis-Blake, MD, assistant professor in the Tacoma Family Medicine Residency Program at the University of Washington in Tacoma. States with total caps had payouts of about 20 percent less than states without caps. States with caps on non-economic damages had malpractice payments that were 26 percent lower, she says.

For example, the average malpractice payment in the District of Columbia between 1999 and 2001 was $500,000, while in Michigan it was around $100,000. That kind of disparity cannot be explained by variations in quality, says Dr. Guirguis-Blake.

A study of hospitals produced similar findings. In states with caps, average malpractice costs per bed were about 22 percent lower than in states without caps. Hospitals in states with caps also paid lower liability premiums, says Charles R. Ellington, MD, JD, lead author and assistant professor at Southern Illinois University School of Medicine in Decatur.

However, lower malpractice costs did not translate into improved financial margins for the hospitals, says Dr. Ellington.

But these cost findings don't reflect the whole picture, warns Dr. Guirguis-Blake. "Cost containment is only one goal of reform," she says. "It just doesn't make sense to have premiums and payments that are on the order of two, three, and four-fold of difference

across states."

If the goal of medical liability reform is to improve quality, then the community may need to look at other measures, such as a no-fault approach, as well, says Dr. Guirguis-Blake. "I want to underscore that we looked at cost, but that is only one issue that has driven the debate. It shouldn't be the first and foremost thought for reform," she says.

Mr. Nelson echoes that caution: "Although caps may reduce malpractice premiums, they may also have an adverse impact on persons who are injured through medical negligence. The lower the cap is—like the California cap, which is $250,000 on non-economic damages—has quite an impact on the most severely injured. So you have to look at that side, too."

It's also not clear what impact the caps have on healthcare costs in general, he warns.

In some cases, premiums actually drop after caps are put in place, but such a drop is not typical, researchers find. What is much more common is that the rise in premiums slows down. However, the amount of money spent on insurance is such a small proportion of total healthcare spending that it is almost impossible to show that caps have any impact on overall healthcare costs. In fact, the study researchers did not find that caps had any effect on the prices individuals pay for health insurance, which undermines one key argument that has been put forward for passing legislation with damage caps.

"Some [physicians may] in good faith believe that it will actually reduce the cost of health care. But at this point there's no evidence of it," Mr. Nelson says.

That belief may influence where physicians decide to practice. A few studies indicate that caps may have an effect on a physician's willingness to practice in a particular state or in a rural area. But the evidence is not strong. Proponents of caps argue that states without caps have access problems because physicians have moved away, stayed away, retired early, or decided to limit their practice due to their liability risk.

"Caps aren't the panacea that proponents say they are. But on the other hand, when the opponents say they don't effect medical liability premiums, they're probably wrong," says Mr. Nelson. "If Congress is going to enact a cap that is like [California's] cap, they need to look more closely at how that might impact severely injured patients and how it might even possibly undermine incentives for injury prevention," he adds.

practice environment.

"For a physician worried about moving to Texas in the middle of a malpractice crisis, I would guess he or she draws some comfort from the passage of a tort reform bill like the one Texas passed in 2003. But I don't know what to say about the data in the long-term statistical sense," he says.

There is a difference, however, between the situation in which California passed cap legislation in 1975 and that in which the Texas caps were passed. Much more data are available now on the impact of reform efforts. In a study that Dr. Sage and colleagues published in the *Journal of the American Medical Association* in June 2005, they reported that, when looked at over long periods of time, the implementation of damage caps was associated with an average three-percent increase in physician supply. For the most part, that rise was not due to physicians moving from one state to another, but to new physicians who were more likely to set up practices in states that had passed such tort reforms and to physicians already in those states who were less likely to retire early.

"Doctors can't really raise prices to a significant degree anymore. Maybe a quarter of the increase in revenue that doctors have generated in response to rising malpractice premiums has come through higher prices. Three-quarters has come through delivering more services," says Dr. Sage. "Doctors aren't being forced out of business, but they seem to be working harder and providing more services to patients," he says.

"That's not trivial," Dr. Sage admits. "Three percent [growth] is about what you would expect if you gave doctors a ten-percent raise in salary. So it's meaningful, but it also does not mean all of a sudden we will have more doctors than we know what to do with."

In another study published in the April 2007 issue of *Health Affairs*, Dr. Sage and colleagues found that in Pennsylvania, one of the states hardest hit by the crisis, there were no large shifts in the availability of physicians in high-risk specialties.

From 1999 to 2003, an average of 15.5 percent of physicians in high-risk specialties left the state each year. That was not a statistically significant difference compared with the 14.5 percent dropout rate seen in the years preceding the state's liability crisis. The study also found that fewer than three percent of

physicians restricted their scope of practice, a more modest finding than previous studies that have asked physicians about their intentions to stop performing major or minor procedures. There was about an eight-percent decrease in obstetrician-gynecologists, although the number of physicians performing deliveries rose during the same period.

One theory is that, while malpractice premiums may affect how hard physicians work, the number of procedures they order, and how satisfied they are with their work, these changes are not enough to actually drive them out of the field in larger numbers than before.

"One of the key unanswered questions about rising malpractice premiums is who actually bears the economic burden of them," says Dr. Sage. "Do doctors feel the pain of rising malpractice premiums; or do they pass it through to patients and health insurers, government payers, and the like?"

A study during the malpractice crisis in the 1980s suggested that higher liability premiums were being passed along to patients in the form of increased prices for physician services. But now there are more controls on physician fees, so it's not clear whether that is still true 20 years later.

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These findings also suggest that there may be another explanation for the increase in volume of physicians' services that have been attributed to both the decrease in Medicare reimbursement under the SGR formula and the practice of defensive medicine.

A number of factors—including study findings such as those discussed above along with a slowing of the rise in liability premiums and the shift of power in Congress—have come together to make the passage of a federal cap on damages seem increasingly unlikely to happen anytime in the near future. Even groups—such as the AMA—that have been stalwart advocates for federal legislation are shifting their focus elsewhere for now.

"What we're talking about is political reality. We have had major pushes for tort reform for years and years, and we always get blocked, even when the Democrats were in the minority," says Dr. Plested.

Dr. Sage believes the national debate over malpractice caps is less about medicine than an attempt by big business to insulate itself against litigation. "Physicians are both the poster children and the free riders on that political process," he says. "The federal debate is entirely a debate about the role of lawyers in society and the large political battles between Republicans and Democrats over lawyering and who gets the campaign contributions associated with it or big business," he says.

At one time it was a debate about medicine, during those earlier malpractice crises when much less was known about the interaction between caps and the availability of medical services. But, Dr. Sage says, for the past ten years it has just been one side or the other using medicine for its own purposes. A decade ago, trial lawyers were working with physicians to improve their rights to sue health maintenance organizations. Once that faded, big business stepped in to try to get rid of the trial lawyers. "That's the political dynamic, and physicians need to know that," he says.

How Health Courts Work

A key element of a health court system must be an all-in scenario whereby physicians and patients agree to pursue any injury complaints through the health court from the very start. How that might work is that, for example, a company that provides medical liability insurance would choose to use health courts and would therefore require all the physicians it covers to process injury claims through that system. In turn, those physicians would require patients to agree to use the courts as well.

"Patients would need to be told, when they decide to see Dr. Johnson, that they are going to be part of this system. If they don't wish to be part of the system, then Dr. Johnson will refer them to another physician," says Michelle Mello, PhD, JD, an associate professor of health policy and law at Harvard University.

Those who are unhappy with the court's decision would be able to first appeal to an administrative panel and then, if still not satisfied,

Healthier Courts

Some contend that the tort system is simply an inappropriate venue for dealing efficiently and effectively with patients injured by the medical system.

"One major problem is the use of the negligence standard, which is punitive and promotes a breakdown of relations between doctors and patients," says Michelle Mello, JD, PhD, associate professor of health policy and law at Harvard University.

The negligence standard is also something that juries really struggle to understand. "Juries do their best, they try very hard, they're often composed of very capable people," says Dr. Mello. "But what they are asked to do is just not fair, which is to decide these very complex cases with no guidelines about what negligence means or what reasonable damages would be in a particular case," she says.

That not only makes it difficult for all parties to feel satisfied about the outcome, it does not send a clear message to the medical community about what it can do to avoid future claims. It also leads to another major problem with the system: cost. Because negligence is such a complicated concept to establish as a practical matter, the litigation ends up being very expensive.

to the tort system. But patients wouldn't be able to decide to go to the tort system until they had tried the case in the health court and appealed to an administrative panel. "What there wouldn't be is an ability to choose at the outset of claim whether to bring it in the tort system or bring it through the health court," says Dr. Mello.

However, similar systems for medical injuries in other countries actually have low appeal rates. "Part of that is because [their health courts] are much more generous about compensating people. So most people who have meritorious claims would not end up being dissatisfied," she explains.

"The question physicians will ask is, 'How do we know the people who come to this system have meritorious claims?'" Dr. Mello says. "And that's a legitimate question, but I do think that this system is going to be pretty well positioned to dispose of non-meritorious claims relatively rapidly, certainly more rapidly than the current system does."

All of these factors make the system not only impenetrable for physicians, but inaccessible for the vast majority of patients who are actually injured. Only a small proportion of patients ever enters the system, and an even smaller group is compensated. One estimate is that 98 percent of patients receive no compensation for their injuries.

"It's too cumbersome to file a claim. It requires attorneys. Attorneys can only take these cases profitably if they involve large damages. And the patient waits three years on average for a decision to be made. So we're spending a lot of money, about 50 cents on the dollar, to get compensation to a very small proportion of injured plaintiffs. That money would be better spent in a system that had lower overhead costs and was easier for people to navigate," Dr. Mello says.

Looking at administrative compensation systems both here—for other types of injuries—and for medical negligence in other countries, overhead rates are closer to 10 to 20 cents on the dollar. Those systems offer injured people better access and more satisfaction with the outcome—often with less acrimony than the tort system used in the United States.

"In many cases, [patients] have the cooperation of their doctors in the process," she says.

Such a process, termed a health court, is one example of a system that has gained a lot of support within the medical community as a possible replacement for compensating patients exclusively through tort law. "The idea is to take medical injury claims out of the courts and put them through an administrative compensation process," says Dr. Mello. Several countries—including New Zealand, Denmark, and Sweden—have instituted similar systems to resolve medical injury claims.

Health courts incorporate a number of features designed to ensure fair and impartial decisions. Cases would not be tried before a jury, but instead before a judge who is a specialist in adjudicating medical injury claims and who has guidelines delineating categories of injuries that—evidence suggests—should be presumptively compensable. What that means is that "most of the time this is the kind of thing that we would give compensation for, so those cases can be fast tracked," says Dr. Mello. In addition to the guidelines, the judge would have access to advice from

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experts assigned by the state rather than hired by either party.

"Most importantly, they would not be making compensation decisions on the basis of whether a doctor was negligent but rather whether the event was avoidable, meaning it should not have happened in a well-designed system of care. That's a standard that is much more generous than the tort standard," she says.

This proposal has caused concern among some physician groups that the courts could end up costing more than the current system. "They are a little weary of expanding the compen-

IOM Report on Medication Errors Recommends Doctors Go Digital

In the Institute of Medicine report "Preventing Medication Errors," patient safety experts estimated that one avoidable medication error occurs per hospitalized patient per day and that more than half a million errors occur among Medicare patients alone each year.

"I am a patient-safety researcher and, as we went through the process…of putting this report together, I was surprised and shocked at just how common and serious a problem this is. I think we all need to wake up and take this more seriously," says Albert Wu, MD, professor of health policy and management and internal medicine at Johns Hopkins School of Medicine in Baltimore.

The IOM panel concluded that there are around 380,000 medication errors in hospitals and 800,000 errors in long-term care facilities annually. It also found that a conservative estimate of preventable adverse drug events among Medicare's ambulatory population would be around 530,000 a year.

"The current process by which medications are prescribed, dispensed, administered, and monitored is characterized by many serious problems that threaten both the safety and the positive outcomes we hope to achieve when we serve patients," says Lyle Bootman, PhD, ScD, co-chair of the IOM committee and a pharmacy professor and researcher at the University of Arizona in Tucson.

The committee concluded that these striking error rates are in part due to a lack of coordination and communication among physicians, pharmacists, and patients about what medications are being taken. It also reported that widespread adoption of electronic prescribing could substantially reduce the number of patients who get the wrong drug, dosage, or mix of medications.

Among the IOM committee's recommendations for improving the

sation standards to provide compensation for more patients," Dr. Mello says. "It's not because they think it's a bad idea to get away from negligence per se—they tend not to like the negligence standard—but it's because we are talking about compensating a lot more people, and that may cost more money. That's something we are looking into now.

"The way we expect to rein in costs is by limiting damages in the cases that do go through. So we think that it will be essentially cost neutral. But there is going to be an element of risk

current system, health information technology—specifically electronic prescribing—topped the list.

"Studies indicate that paper-based prescribing is associated with very high error rates, but electronic prescribing is safer because it eliminates problems with handwriting illegibility and—when combined with decision support tools—automatically alerts prescribers to possible interactions, allergies, and other potential problems," says Dr. Bootman.

Based on its findings, the committee recommended that all physicians have plans to implement electronic prescribing by 2008 and that those systems should be in place and integrated by 2010.

Interest in information technology is skyrocketing among small physician offices, says IOM member Wilson Pace, MD, professor of family medicine at the University of Colorado and director of the National Research Network, which is sponsored by the American Academy of Family Physicians. "Being a physician, I think that e-prescribing is one of the keystones of [the effort to reduce medical errors]. It allows us to apply decision support, it allows us to transmit the information, it allows us to capture medications. It is the key to getting the data you need in an electronic format so that you can apply all the other systems to it," he says. When considering the cost of these systems, physicians need to realize that electronic prescribing is as important as X-ray machines or any other vital clinical tool, Dr. Pace says.

The IOM panel also called for the federal government to play a larger role in pulling together regional and national efforts to study medical errors and to build on recent research findings.

"If harm from medication errors were a single disease, we would be investing more heavily. Research funding from the government for cancer numbers in the billions every year, yet the proportion of people who are affected by medication errors is far greater than that for people with cancer," says Dr. Wu.

when it's tried," Dr. Mello added.

That element of risk means that it is likely to take a push from Congress to get a demonstration project off the ground. States don't have the wiggle room in their budgets to do it alone. For a demonstration to be successful, it will have to reassure physicians and other healthcare providers that government funding will kick in if the project ends up resulting in a lot more claims than predicted.

"There is a lot of potential for federal action to play a catalytic role in spurring action at the state level," says Paul Barringer, JD, head of a health court initiative at Common Good, a Washington, DC, organization established to promote policy change in the legal system.

Bills in the House and Senate have been introduced over the past few years that would provide some funding for states that chose to initiate a pilot project. If such legislation were to pass, the federal government should have no trouble finding a few takers among the dozen or so states where health court bills have already been introduced or are being considered by lawmakers.

"In Massachusetts, there are a couple of folks who have introduced bills in this session including folks who have been really involved with the coverage legislation that passed last year. They see this as an important issue that needs to be addressed as they continue their efforts to improve health care and the functioning of the healthcare system," Mr. Barringer says.

The federal government may also play a more direct role in the evolution of health courts by launching a demonstration project through the Medicare program, says Dr. Sage.

Medicare already has an administrative dispute resolution system in place for adjudicating reimbursement claims. It would not be difficult to build on the existing infrastructure to adjudicate injury claims, he says.

Patient Safety and Communication

State and federal legislative efforts are also increasingly incorporating recommendations that have come out of a series of reports on patient safety produced by the IOM.

The IOM has helped changed the perspective on malpractice reform. The traditional view was that the problem was the malpractice system and that medicine itself was fine. But once the

patient safety movement began and the IOM published its reports, people began to see the connection between liability issues and failures in how the healthcare system deals with errors.

"Medical malpractice is like the Anna Nicole Smith of health policy," says Dr. Sage. "We find it utterly fascinating, but at the end of the day it's not all that important. Patient safety is really important. How doctors and patients relate to each other is really important. But medical malpractice has taken on a life of its own, beyond where it fits in the system."

It is never easy to tell a patient that something has gone wrong with a procedure or his or her condition; however, a growing number of experts say it is usually the best thing a physician can do. The problem is that, in the current environment, doctors rarely feel free to discuss an undesirable outcome, particularly if they have actually made a mistake.

When physicians can sit down with their patients and tell them honestly what has gone wrong, usually it is better for everyone, says Dr. Plested. "You may have done your very best and still have a bad result. If you tell the patient and family that 'I just did everything I can, and this is an awful result,' it helps. Human nature is forgiving," he says.

By reforming or replacing the current environment of blame with a no-fault system, there is the added benefit of being able to collect better, more reliable data on the most common medical mistakes that occur within the healthcare system.

Within the past few years, many state and federal proposals to fix medical liability have included an element of data collection or other patient-safety priority.

"Other countries have demonstrated that you can use these data to learn about medical errors, about patient safety, and about interventions that might make health care safer. That's absolutely something we don't do in our current system," says Dr. Mello.

Despite such benefits, the seeming ebb of the current malpractice crisis makes it unlikely that federal lawmakers will find the political will to pass major liability reforms over the next few years. On the other hand, there is always the possibility that forward-looking state legislatures will try to pass either patient-safety or liability reform measures in the hope of staving off the next medical liability crisis before it hits.