PAs and malpractice

CASE STUDY EXAMINES YOUR LITIGATION RISKS— AND THE FINDINGS MAY SURPRISE YOU

[By **MATT LEDGES**, *MD, MS, PA*; **MICHAEL VICTOROFF**, *MD*; and **ADIT A. GINDE**, *MD, MPH*]

Claims and suits against physician assistants (PAs) and their supervising physicians are rare, and the outcomes usually are favorable for the defense. Some risks remain, however, and understanding agency law, liability, and the elements necessary for malpractice claims may give you a better vantage point in preventing lawsuits or winning them.

The PA profession has grown tremendously since its birth in the 1960s. Today, PAs are licensed in all 50 states and practice in most specialties and settings. The profession's popularity also is evident in an increasing number of PA schools, numerous independent rankings and growth projections, and recent global expansion.[1-3]

Yet controversy remains regarding how PAs' malpractice litigation risk compares with that of physicians and to what extent doctors' risk of malpractice litigation is affected by supervising PAs. The dependent practice model remains at the core of the PA profession. It also fuels much of this debate, however.

LEGAL FRAMEWORK

The nature of a dependent practice unites PAs and physicians not only in individual patient care but also in any litigation that may develop as a result. The legal principle of agency is the basis of the PA-doctor relationship and underlies most states' statutes governing PA practice. Generally, agency law holds a supervising physician liable: 1) for his or her own negligent acts (direct liability); or 2) for the negligent acts of a subordinate PA (vicarious liability).[4]

Negligence claims are generally required to have four basic elements:

- The provider owed a duty to care.
- The provider breached that duty.
- The breach proximately caused an injury.
- The injury resulted in compensable legal damages.

In practice, both direct and vicarious liability may be alleged in a single case.

DIRECT LIABILITY

A PA acts with authority if the supervising doctor approves his or her conduct. In such cases, if the PA breaches his or her duty to the patient, the physician may be held directly liable. The doctor also may be held directly liable if he or she is negligent in selecting, supervising, or otherwise controlling the PA.

Negligent selection is a type of direct liability claim in which the physician can be liable for hiring a PA if the doctor knew or should have known the PA had some dangerous propensity. Here, the plaintiff must prove that the act of hiring the PA proximately caused injury and that the physician would have discovered the PA's propensities with reasonable diligence.

Negligent supervision is another type of direct liability claim; the acts of the doctor (and not necessarily those of the PA) are at issue. State statutes codify supervision requirements and, by extension, what constitutes negligent supervision. Statutes vary by state, but most address issues related to physician presence, acceptable PA-doctor ratios, and chart review obligations.[5]

Dynamic elements of PA practice such as clinical setting, level of experience, and employment duration may affect these requirements. Additionally, some states differentiate between primary and secondary supervisory relationships, adding to the complexity of what constitutes diligent supervision.

VICARIOUS LIABILITY

Agency law provides that a physician also may be held vicariously liable for negligent acts by a PA. *Respondeat superior*, Latin for "let the master answer," is

the primary vehicle used to assert this type of liability. This principle provides that an employer is subject to liability for torts—civil wrongs—committed by employees acting within the scope of their employment.

The PA's status as employee or independent contractor is irrelevant as long as the patient reasonably believes the PA has authority to act on the doctor's behalf. *Respondeat superior* claims differ from negligent selection and negligent supervision claims in that the physician may be held solely liable for the negligent acts of the PA. In fact, under this principle, the supervising doctor may not have been present or even aware of the patient encounter.

These legal principles fuel competing theories comparing PAs and physicians. Some suggest that because PA school is shorter in duration than medical school and residency, PAs inherently have more litigation risk. This theory seems to rest on an assumption that shorter formal education translates to more errors of cognition and judgment and, therefore, more litigation risk.

In contrast, some suggest that PAs carry less litigation risk than their doctor counterparts, for two primary reasons. First, PAs commonly treat patients with less acute conditions and leave more complicated cases to physicians. This argument assumes that patients with lower acuity complaints are less likely to suffer harm and are less litigious.

The second argument is that two heads are better than one. The success of the pilot/co-pilot model is based on the fact that although two people both may make mistakes, it is unlikely they will each make the same mistake. The odds that the doctor and PA will make identical mistakes at the same time should be lower for the same reason. This argument contends that a culture of collaboration reduces injury—a critical tenet of risk management.

So which theory is correct? Are PAs involved in more or less malpractice litigation than physicians? Does intensity of doctor supervision affect the outcome of claims and suits?

As with the practice of medicine itself, the devil is in the details. Complexities of individual cases, heterogeneity of claims analyses, varying state statutes, and malpractice environments have limited discussion in the literature to case reports. Although such reports illustrate legal concepts or offer cautionary tales, they do not provide the necessary context to accurately gauge PA malpractice litigation risk.

PHYSICIANS SUED MORE OFTEN

We conducted the largest case series of PA claims to date, to analyze PA and physician malpractice litigation risk. Our primary aim was to determine the rate of claims and suits brought against PAs versus doctors. Our secondary aims were to evaluate how intensity of supervision may factor into the outcome of the case, and to determine whether any other factors were more associated with cases that resulted in a settlement versus cases that were dismissed or otherwise not pursued.

TABLE 1

Rates of claims and suits against Colorado physician assistants compared with physicians, by year and gender

Characteristics	Provider-years	Claims/suits per 1,000 provider-years	P value
Provider type			<0.001
Physician assistants	5,204	5.8	
Physicians	21,393	38.2	
Provider type-year			
Physician assistants			0.006
2002-2004	2,176	9.2	
2005-2007	3,028	3.3	
Physicians			0.68
2002-2004	10,991	37.7	
2005-2007	10,402	38.8	
Provider type-gender			
Physician assistants			0.12
Male	1,889	7.9	
Female	3,315	4.5	
Physicians			<0.001
Male	15,730	41.1	
Female	5,663	30.2	

To quantify PA and physician malpractice litigation risk, we performed a structured chart review of all claims and suits brought against Colorado-licensed PAs from January 1, 2002, to December 31, 2009. We limited our data collection to PAs and doctors who were insured by COPIC.

COPIC insures about three-fourths of physicians and two-thirds of PAs in the Colorado private market, making it the largest private professional liability carrier in the state. We used COPIC's definition of a claim: "Any demand for damages, arising from professional activity or circumstances, brought by a patient or patient representative, indicating the possibility of legal action."

With approval from the Colorado Multiple Institutional Review Board (COMIRB), we reviewed claim summaries, medical records, depositions, and other legal documents. We recorded data using a standardized data collection form. We identified a total of 34 claims and suits against Colorado-licensed PAs over an 8-year period, 32 of which were no longer active at the time of our analysis. Because Colorado statutes require that claims and suits be brought within 2 years from the time harm was first recognized, we limited our risk calculations and analysis of temporal trends

to the first 6 years of our 8-year study to account for much of this reporting lag.

Overall, PAs experienced 5.8 claims and suits per 1,000 provider years, whereas the doctors' rate was nearly seven times higher at 38.2 (see Table 1). Between 2002 and 2007, the rate of claims and suits against PAs dropped by nearly two-thirds, wheras the rate against physicians increased marginally.

Gender appeared to play a significant role in the rate of claims and suits against both PAs and doctors. Female providers experienced a considerably lower rate of claims and suits compared to their male counterparts.

Table 2 summarizes the clinical characteristics of the 34 claims and suits brought against PAs. A majority of cases involved primary care and emergency medicine/urgent care, each accounting for 14 cases (41%). Over one-half of the cases occurred in an outpatient setting.

Seven of the 34 cases began as claims but did not progress to lawsuits, whereas the remaining 27 did. Twenty cases (59%) were dismissed or otherwise not pursued, 11 (32%) settled, and two remained open (6%). Only one case went to trial and was successfully defended.

The most common presenting complaints involved the musculoskeletal, gastrointestinal, and neurologic systems, corresponding to 44%, 21%, and 15% of the cases, respectively. The most common patient outcomes were either a complication or worsening of the problem (41%), development of a new problem (32%), and death (21%). We found no injury alleged in two of the 34 cases.

The three categories of supervision were spread nearly equally: both the PA and physician examined the patient in 12 cases (35%), the doctor discussed the patient with the PA but did not examine the patient in nine cases (26%), and the

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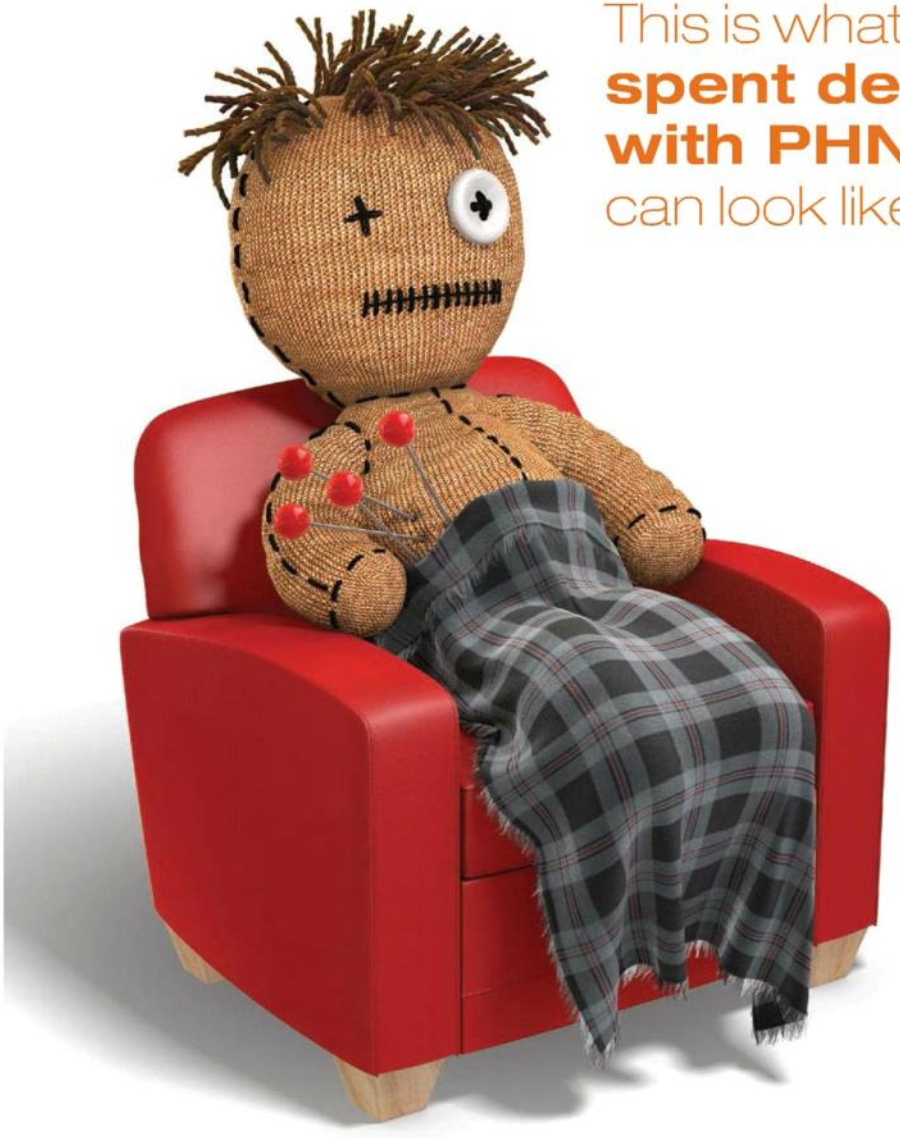
TABLE 2

Characteristics of claims and suits brought against Colorado physician assistants, 2002 to 2009

Characteristics	All cases N=34	Went away N=20	Settled/Went to trial N=14
Physician assistant			
Male gender	**18** (53%)	**11** (55%)	**6** (50%)
Setting			
Outpatient	**19** (56%)	**12** (60%)	**7** (58%)
Emergency department	**11** (32%)	**7** (35%)	**3** (25%)
Other	**4** (12%)	**1** (5%)	**2** (17%)
Specialty			
Primary care	**14** (41%)	**10** (50%)	**3** (25%)
EM/urgent care	**14** (41%)	**8** (40%)	**6** (50%)
Other	**6** (18%)	**2** (10%)	**3** (25%)
Years of experience, median (range)	**8** (0-23)	**8** (0-23)	**8** (2-15)
Intensity of physician supervision			
Examined by physician	**12** (35%)	**6** (30%)	**5** (42%)
Discussed with physician	**9** (26%)	**5** (25%)	**3** (25%)
Physician not involved	**13** (38%)	**9** (45%)	**4** (33%)
Patient			
Age in years, median (range)	**34** (0-82)	**43** (9-64)	**39** (0-82)
Male gender	**18** (53%)	**12** (60%)	**6** (50%)
Body system			
Gastrointestinal	**7** (21%)	**3** (15%)	**3** (25%)
Musculoskeletal	**15** (44%)	**11** (55%)	**3** (25%)
Neurological	**5** (15%)	**3** (15%)	**2** (17%)
Other	**7** (21%)	**3** (15%)	**4** (33%)
Outcome			
Problem worsened/complication	**14** (41%)	**10** (50%)	**4** (33%)
New problem	**11** (32%)	**3** (15%)	**6** (50%)
Death	**7** (21%)	**5** (25%)	**2** (17%)
No harm	**2** (6%)	**2** (10%)	**0** (0%)
Cause of outcome			
Lack of data	**13** (38%)	**9** (45%)	**4** (33%)
Error in cognition/judgment/knowledge	**7** (21%)	**2** (10%)	**5** (42%)
Patient factors	**1** (3%)	**0** (0%)	**1** (8%)
NA/could not be determined	**13** (38%)	**9** (45%)	**2** (17%)
Action			
Type			
Claim	**7** (21%)	**6** (30%)	**1** (8%)
Suit	**27** (79%)	**14** (70%)	**11** (92%)
Supervising physician named	**27** (79%)	**14** (70%)	**12** (100%)
Outcome			
Went away	**20** (59%)	**20** (100%)	NA
Settled	**11** (32%)	NA	**11** (32%)
Defended/went to trial	**1** (3%)	NA	**1** (3%)
Open	**2** (6%)	NA	NA
Total settlement, median (IQR range)			
Physician assistants	**$100K** ($13K to $925K)	NA	**$100K** ($13K to $925K)
Physicians	**$200K** ($159K to $390K)	NA	**$200K** ($159K to $390K)
Cost to defend, median (IQR range)			
Physician assistants	**$26K** ($53K to $428K)	**$16K** ($99K to $168K)	**$41K** ($53K to $428K)
Physicians	**$36,313** ($86K to $351K)	**$28K** ($86K to $134K)	**$79K** ($30K to $351K)



This is what **a day spent dealing with PHN pain** can look like.

Indication and Usage

GRALISE™ is indicated for the management of postherpetic neuralgia (PHN). GRALISE is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

Important Safety Information

GRALISE is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

Please see Brief Summary of Prescribing Information.
For full Prescribing Information and Medication Guide, please visit www.GRALISE.com.

Give your patients

Depomed

with PHN **the full day**

with ***NEW*** once-daily GRALISE

Reduce the burdens of postherpetic neuralgia (PHN). **NEW** GRALISE offers **24-hour pain control, once-daily oral dosing, favorable tolerability,** and **effective 2-week titration.**[1,2]

Effective 24-hour pain control[1]

Significant and lasting improvement in pain scores in clinical trials.

Once-daily oral dosing with the evening meal[1,2]

Patented polymer technology allows for peak plasma levels during the night and low rates of side effects.

Favorable tolerability profile[1,2]

There was a reported incidence of dizziness (10.9% vs 2.2% placebo), somnolence (4.5% vs 2.7% placebo), and peripheral edema (3.9% vs 0.3% placebo) at 1800 mg once daily.

Reach an effective dose in 2 weeks[1]

Titration to an 1800 mg dose in 2 weeks.

Indication and Usage

GRALISE™ is indicated for the management of postherpetic neuralgia (PHN). GRALISE is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.

Important Safety Information

GRALISE is contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

The most common adverse reaction to GRALISE (≥5% and twice placebo) is dizziness.

Across all GRALISE clinical trials the other most common adverse reactions (≥2% vs placebo) are somnolence, headache, peripheral edema, diarrhea, dry mouth, and nasopharyngitis. The types and incidence of adverse events were similar across age groups except for peripheral edema, which tended to increase in incidence with age.

Antiepileptic drugs (AEDs) including gabapentin, the active ingredient in GRALISE, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Please see Brief Summary of Prescribing Information on next page. For full Prescribing Information and Medication Guide, please visit www.GRALISE.com.

References: 1. GRALISE [prescribing information]. Menlo Park, CA: Depomed Inc.; April 2011. **2.** Data on file. Depomed Inc.

NEW Gralise™ once-daily (gabapentin) tablets

FOR THE FULL DAY

GRALISE™ (gabapentin) tablets

BRIEF SUMMARY: For full prescribing information, see package insert.

INDICATIONS AND USAGE
GRALISE is indicated for the management of Postherpetic Neuralgia (PHN). **GRALISE is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration.**

DOSAGE AND ADMINISTRATION
Postherpetic neuralgia
- Titrate GRALISE to an 1800 mg dose taken orally once daily with the evening meal. GRALISE tablets should be swallowed whole. Do not split, crush, or chew the tablets.
- If GRALISE dose is reduced, discontinued, or substituted with an alternative medication, this should be done gradually over a minimum of one week or longer (at the discretion of the prescriber).
- Renal impairment: Dose should be adjusted in patients with reduced renal function. GRALISE should not be used in patients with CrCl less than 30 or in patients on hemodialysis.
- In adults with postherpetic neuralgia, GRALISE therapy should be initiated and titrated as follows:

Table 1 GRALISE Recommended Titration Schedule

	Day 1	Day 2	Days 3-6	Days 7-10	Days 11-14	Day 15
Daily dose	300 mg	600 mg	900 mg	1200 mg	1500 mg	1800 mg

CONTRAINDICATIONS
GRALISE is contraindicated in patients with demonstrated hypersensitivity to the drug or its ingredients.

Table 2 GRALISE Dosage Based on Renal Function

	Once-daily dosing
Creatinine clearance (mL/min)	GRALISE dose (once daily with evening meal)
≥60	1800 mg
30-60	600 mg to 1800 mg
<30	GRALISE should not be administered
Patients receiving hemodialysis	GRALISE should not be administered

WARNINGS AND PRECAUTIONS
GRALISE is not interchangeable with other gabapentin products because of differing pharmacokinetic profiles that affect the frequency of administration. The safety and effectiveness of GRALISE in patients with epilepsy has not been studied. **Suicidal Behavior and Ideation** Antiepileptic drugs (AEDs), including gabapentin, the active ingredient in GRALISE, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Table 3 Risk by Indication for Antiepileptic Drugs (including gabapentin, the active ingredient in Gralise) in the Pooled Analysis

Indication	Epilepsy	Psychiatric	Other	Total
Placebo patients with events per 1000 patients	1.0	5.7	1.0	2.4
Drug patients with events per 1000 patients	3.4	8.5	1.8	4.3
Relative risk: incidence of events in drug patients/incidence in placebo patients	3.5	1.5	1.9	1.8
Risk difference: additional drug patients with events per 1000 patients	2.4	2.9	0.9	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials for epilepsy than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications. Anyone considering prescribing GRALISE must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which products containing active components that are AEDs (such as gabapentin, the active component in GRALISE) are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated. Patients, their caregivers, and families should be informed that GRALISE contains gabapentin which is also used to treat epilepsy and that AEDs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers. **Withdrawal of Gabapentin** Gabapentin should be withdrawn gradually. If GRALISE is discontinued, this should be done gradually over a minimum of 1 week or longer (at the discretion of the prescriber). **Tumorigenic Potential** In standard preclinical *in vivo* lifetime carcinogenicity studies, an unexpectedly high incidence of pancreatic acinar adenocarcinomas was identified in male, but not female, rats. The clinical significance of this finding is unknown. In clinical trials of gabapentin therapy in epilepsy comprising 2,085 patient-years of exposure in patients over 12 years of age, new tumors were reported in 10 patients, and preexisting tumors worsened in 11 patients, during or within 2 years after discontinuing the drug. However, no similar patient population untreated with gabapentin was available to provide background tumor incidence and recurrence information for comparison. Therefore, the effect of gabapentin therapy on the incidence of new tumors in humans or on the worsening or recurrence of previously diagnosed tumors is unknown.

ADVERSE REACTIONS
Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. A total of 359 patients with neuropathic pain associated with postherpetic neuralgia have received GRALISE at doses up to 1800 mg daily during placebo-controlled clinical studies. In clinical trials in patients with postherpetic neuralgia, 9.7% of the 359 patients treated with GRALISE and 6.9% of 364 patients treated with placebo discontinued prematurely due to adverse reactions. In the GRALISE treatment group, the most common reason for discontinuation due to adverse reactions was dizziness. Of GRALISE-treated patients who experienced adverse reactions in clinical studies, the majority of those adverse reactions were either "mild" or "moderate". Table 4 lists all adverse reactions, regardless of causality, occurring in at least 1% of patients with neuropathic pain associated with postherpetic neuralgia in the GRALISE group for which the incidence was greater than in the placebo group.

Table 4 Treatment-Emergent Adverse Reaction Incidence in Controlled Trials in Neuropathic Pain Associated with Postherpetic Neuralgia (Events in at Least 1% of all GRALISE-Treated Patients and More Frequent Than in the Placebo Group)

Body system—preferred term	GRALISE N=359, %	Placebo N=364, %
Ear and Labyrinth Disorders		
Vertigo	1.4	0.5
Gastrointestinal Disorders		
Diarrhea	3.3	2.7
Dry mouth	2.8	1.4
Constipation	1.4	0.3
Dyspepsia	1.4	0.8
General Disorders		
Peripheral edema	3.9	0.3
Pain	1.1	0.5
Infections and Infestations		
Nasopharyngitis	2.5	2.2
Urinary tract infection	1.7	0.5
Investigations		
Weight increased	1.9	0.5
Musculoskeletal and Connective Tissue Disorders		
Pain in extremity	1.9	0.5
Back pain	1.7	1.1
Nervous System Disorders		
Dizziness	10.9	2.2
Somnolence	4.5	2.7
Headache	4.2	4.1
Lethargy	1.1	0.3

In addition to the adverse reactions reported in Table 4 above, the following adverse reactions with an uncertain relationship to GRALISE were reported during the clinical development for the treatment of postherpetic neuralgia. Events in more than 1% of patients but equally or more frequently in the GRALISE-treated patients than in the placebo group included blood pressure increase, confusional state, gastroenteritis viral, herpes zoster, hypertension, joint swelling, memory impairment, nausea, pneumonia, pyrexia, rash, seasonal allergy, and upper respiratory infection. **Postmarketing and Other Experience with other Formulations of Gabapentin** In addition to the adverse experiences reported during clinical testing of gabapentin, the following adverse experiences have been reported in patients receiving other formulations of marketed gabapentin. These adverse experiences have not been listed above and data are insufficient to support an estimate of their incidence or to establish causation. The listing is alphabetized: angioedema, blood glucose fluctuation, breast hypertrophy, erythema multiforme, elevated liver function tests, fever, hyponatremia, jaundice, movement disorder, Stevens-Johnson syndrome. Adverse events following the abrupt discontinuation of gabapentin immediate release have also been reported. The most frequently reported events were anxiety, insomnia, nausea, pain and sweating.

DRUG INTERACTIONS
An increase in gabapentin AUC values has been reported when administered with hydrocodone as well as with morphine. An antacid containing aluminum hydroxide and magnesium hydroxide reduced the bioavailability of gabapentin immediate release by about approximately 20%, but by only 5% when gabapentin was taken 2 hours after antacids. It is recommended that GRALISE be taken at least 2 hours following antacid administration. There are no pharmacokinetic interactions between gabapentin and the following antiepileptic drugs: phenytoin, carbamazepine, valproic acid, phenobarbital, and naproxen. Cimetidine decreased the apparent oral clearance of gabapentin by 14% and creatinine clearance by 10%. The effect of gabapentin immediate release on cimetidine was not evaluated. This decrease is not expected to be clinically significant. Gabapentin immediate release (400 mg three times daily) had no effect on the pharmacokinetics of norethindrone (2.5 mg) or ethinyl estradiol (50 mcg) administered as a single tablet, except that the C_{max} of norethindrone was increased by 13%. This interaction is not considered to be clinically significant. Gabapentin immediate release pharmacokinetic parameters were comparable with and without probenecid, indicating that gabapentin does not undergo renal tubular secretion by the pathway that is blocked by probenecid.

USE IN SPECIFIC POPULATIONS
Pregnancy Pregnancy Category C: Gabapentin has been shown to be fetotoxic in rodents, causing delayed ossification of several bones in the skull, vertebrae, forelimbs, and hindlimbs. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. To provide information regarding the effects of *in utero* exposure to GRALISE, physicians are advised to recommend that pregnant patients taking GRALISE enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. This can be done by calling the toll free number 1-888-233-2334, and must be done by patients themselves. Information on the registry can also be found at the website http://www.aedpregnancyregistry.org/. **Nursing Mothers** Gabapentin is secreted into human milk following oral administration. A nursed infant could be exposed to a maximum dose of approximately 1 mg/kg/day of gabapentin. Because the effect on the nursing infant is unknown, GRALISE should be used in women who are nursing only if the benefits clearly outweigh the risks. **Pediatric Use** The safety and effectiveness of GRALISE in the management of postherpetic neuralgia in patients less than 18 years of age has not been studied. **Geriatric Use** The total number of patients treated with GRALISE in controlled clinical trials in patients with postherpetic neuralgia was 359, of which 63% were 65 years of age or older. The types and incidence of adverse events were similar across age groups except for peripheral edema, which tended to increase in incidence with age. GRALISE is known to be substantially excreted by the kidney. Reductions in GRALISE dose should be made in patients with age-related compromised renal function. [see Dosage and Administration]. **Hepatic Impairment** Because gabapentin is not metabolized, studies have not been conducted in patients with hepatic impairment. **Renal Impairment** GRALISE is known to be substantially excreted by the kidney. Dosage adjustment is necessary in patients with impaired renal function. GRALISE should not be administered in patients with CrCl between 15 and 30 or in patients undergoing hemodialysis [see Dosage and Administration].

DRUG ABUSE AND DEPENDENCE
The abuse and dependence potential of GRALISE has not been evaluated in human studies.

OVERDOSAGE
A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis, sedation, hypoactivity, or excitation. Acute oral overdoses of gabapentin immediate release in humans up to 49 grams have been reported. In these cases, double vision, slurred speech, drowsiness, lethargy and diarrhea were observed. All patients recovered with supportive care. Gabapentin can be removed by hemodialysis. Although hemodialysis has not been performed in the few overdose cases reported, it may be indicated by the patient's clinical state or in patients with significant renal impairment.

CLINICAL PHARMACOLOGY
Pharmacokinetics *Absorption and Bioavailability* Gabapentin is absorbed from the proximal small bowel by a saturable L-amino transport system. Gabapentin bioavailability is not dose proportional; as the dose is increased, bioavailability decreases. When GRALISE (1800 mg once daily) and gabapentin immediate release (600 mg three times a day) were administered with high fat meals (50% of calories from fat), GRALISE has a higher C_{min} and lower AUC at steady state compared to gabapentin immediate release. Time to reach maximum plasma concentration (T_{max}) for GRALISE is 8 hours, which is about 4-6 hours longer compared to gabapentin immediate release.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility Gabapentin was given in the diet to mice at 200, 600, and 2000 mg/kg/day and to rats at 250, 1000, and 2000 mg/kg/day for 2 years. A statistically significant increase in the incidence of pancreatic acinar cell adenoma and carcinomas was found in male rats receiving the high dose; the no-effect dose for the occurrence of carcinomas was 1000 mg/kg/day. Peak plasma concentrations of gabapentin in rats receiving the high dose of 2000 mg/kg/day were more than 10 times higher than plasma concentrations in humans receiving 1800 mg per day and in rats receiving 1000 mg/kg/day peak plasma concentrations were more than 6.5 times higher than in humans receiving 1800 mg/day. The pancreatic acinar cell carcinomas did not affect survival, did not metastasize and were not locally invasive. The relevance of this finding to carcinogenic risk in humans is unclear. Studies designed to investigate the mechanism of gabapentin-induced pancreatic carcinogenesis in rats indicate that gabapentin stimulates DNA synthesis in rat pancreatic acinar cells *in vitro* and, thus, may be acting as a tumor promoter by enhancing mitogenic activity. It is not known whether gabapentin has the ability to increase cell proliferation in other cell types or in other species, including humans. Gabapentin did not demonstrate mutagenic or genotoxic potential in 3 *in vitro* and 4 *in vivo* assays. No adverse effects on fertility or reproduction were observed in rats at doses up to 2000 mg/kg (approximately 11 times the maximum recommended human dose on an mg/m² basis).

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Gralise™ once-daily (gabapentin) tablets

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PA did not consult with the supervising physician in the remaining 13 cases (38%). Of the 27 cases (79%) where both the PA and the supervising doctor were named in a claim or suit, the physician had examined the patient nearly 50% of the time.

Although being named as a defendant has important psychological and practical ramifications, the outcome of the case has a greater effect on a provider's future practice. Therefore, we performed a subgroup analysis based on the final disposition of the case (see Table 2).

A greater proportion of cases that were not pursued involved musculoskeletal complaints compared with cases that settled. No patient or provider characteristics, however, including intensity of supervision, were significantly associated with patient outcome or the final disposition of the case.

Of the 11 cases that settled, the median settlement for PAs was $100,000 compared with $200,000 for doctors. Although claims and suits against PAs usually settled for half what claims and suits against physicians did, their interquartile range of payments was substantially greater: $12,500 to $925,000 and $159,000 to $390,000, respectively.

The median cost to defend a claim or suit varied considerably depending on the final disposition. If the case was dismissed or otherwise not pursued, the median defense cost for doctors was $28,000. If the case was settled or went to trial, the median cost was $79,000. Defense expenses for PAs were considerably less, at $16,000 and $41,000, respectively.

ROLE OF DIRECT SUPERVISION

Despite having a much lower rate of malpractice litigation, we found that the distribution of claim and suit outcomes involving Colorado PAs closely approximates that of a recent nationwide study of claim and suit outcomes against physicians.[6]

Supervising doctors evaluated the patient or were consulted by the PA in two-thirds of all cases that ended in a monetary settlement or that went to trial. This high rate of direct supervision in cases the plaintiff pursued to litigation suggests that:

- PAs are involved in litigation for generally the same reasons as physicians.
- Direct supervision does not appear to protect against malpractice litigation risk.

A study of sufficient size comparing PAs who have been involved in litigation with a cohort of those who have not, based on level of supervision, may better address this issue.

Although harm is a basic component of malpractice claims, severity of harm did not correlate with case outcome. In fact, of the seven cases involving death, only two ended in a monetary settlement. The rest were dismissed or otherwise not pursued. Musculoskeletal complaints were the most common presenting problem and represented the greatest number of settlements. It is unclear whether this finding reflects the PAs' patient population or the high volume of musculoskeletal complaints that providers face.

Provider gender was the only other factor that appeared to be associated with increased litigation risk. Gender differences in liability risk among doctors, however, have been shown to disappear after adjusting for factors such as specialty and patient volume.[7] Because we were unable to account for these factors in our study, we were unable to evaluate this hypothesis regarding PAs.

Finally, errors and outcomes are rarely related. Serious errors may occur without causing adverse events. Regrettable outcomes may occur despite the highest standard of care. In malpractice litigation, the quality of care delivered may not be the dominant factor that determines whether a claim prevails.

GREATEST DETERMINANT FOR RISK

For physicians, specialty is the single greatest determinant for liability risk.[7] Because our database did not categorize all PAs by specialty, we were unable to account for this factor in our risk calculations. We were also unable to account for additional factors including patient acuity and practice volume.

Another limitation of our study was a small number of PA claims and suits, despite a relatively large number of provider-years. Although the rate of claims and suits achieves statistical significance, the subgroup analysis lacked statistical power. Additionally, our data did not attempt to address any possible difference in a practice's claims experience before and after employing a PA.

Further, our study was limited to providers insured by COPIC in Colorado. Although COPIC is the dominant professional liability insurer in the state, academic institutions were not represented in this study. Although PAs and doctors have similar policy limits, some PAs may have been subsumed under a professional corporation and may not have been identified in the study population.

Finally, the malpractice environment in a given state is largely dictated by statutes governing the practice of medicine. In this respect, Colorado has a somewhat more favorable environment for medical practice than some other states. It is unclear how our data would generalize to states with different legal environments.

MITIGATING LITIGATION RISK

The overarching goals of healthcare risk management are to identify and reduce the risk of harm to patients and providers. Once risk is identified, a thorough evaluation must take place to develop risk reduction strategies. Identifying avoidable error is a key component of this approach.

Although PAs have a much lower rate of claims and suits than physicians, they are not immune to malpractice allegations. To protect both patients and practices, employers should be diligent in hiring and credentialing. Reducing direct doctor liability for the acts of PAs begins with the selection process. Verify education and licensure, and check for board actions in every state where the PA has practiced. Query the National Practitioner Data Bank. Perform a criminal background check and contact all references. It is also appropriate to contact past supervising physicians and coworkers, even if they are not listed on a resume.

To reduce your risk of negligent supervision, it is critical to establish protocols and practice policies. These protocols and policies should outline problems, treatments, procedures, and other matters that the PA is expected to manage independently (allowing for retrospective quality review) and those for which real-time consultation is expected. Keep records of periodic evaluations and chart reviews. Many state statutes require such supervisory steps, but it is good practice to consider them minimum standards even where they are not mandated.

A culture of collaboration is essential for effective PA/doctor partnerships and quality care. If you are a supervising physician, be available and approachable whenever PAs ask for help. Simply waiting for PAs to ask for help, though, may not always be sufficient. Invite consultation with questions such as, "Have you seen any interesting cases lately?"

Document all consultations. A simple note referencing discussion or examination by the supervising doctor is sufficient. When a PA consults a physician from outside his or her practice, the consultant's specific recommendations should be documented. Many times, consultants will not include a note in the chart unless they evaluate the patient. And because these brief interactions may be considered a form of supervision, it is essential that PAs document these consultations.

To reduce your risk of vicarious liability, PAs must keep their knowledge and skills current. Providing a continuing education allowance is a good start. Include PAs in continuing education activities alongside other practice providers. It's a good habit to schedule regular provider meetings to discuss policies and best practices.

Finally, it is essential that liability insurance for doctors and PAs address both joint and separate liability, because litigation aimed at PAs routinely involves their supervising physicians.

MORE SIMILARITIES THAN DIFFERENCES

Based on this large, structured chart review, we have found that PAs and their supervising doctors experience a low rate of malpractice litigation compared with physicians overall. Direct supervision does not appear to protect against litigation. Although we were not able to adjust for provider specialty or patient acuity, case outcomes involving PAs and doctors closely parallel outcomes involving only physicians. This finding suggests that more similarities than differences may exist between the malpractice risk of doctors and PAs. ME

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Ledges, top, is an emergency medicine physician and emergency department director of midlevel providers for TEAMHealth West at North Colorado Medical Center, Greeley. He is also the owner and manager of Physician Assistant Solutions. Victoroff, middle, is chief medical officer at Lynxcare and a risk management consultant at COPIC, where he manages the taxonomy of medical errors and researches liability implications of electronic information systems. Ginde, bottom, is a practicing emergency physician at University of Colorado Hospital and conducts health policy research as an assistant professor of emergency medicine and epidemiology at the University of Colorado, Denver. Send your feedback to medec@advanstar.com.