

What you should bargain for in a restrictive covenant

Don't be afraid to ask for what you want. And if you're hiring, be flexible and know what's reasonable and what's not.

By David J. Schiller, J.D.

Everywhere you look in medicine, professional alliances are shifting. Hospitals are swallowing up practices. Soloists and groups are merging to stay competitive.

If you're caught up in this maelstrom, you'll probably be a party to—or maybe a victim of—a restrictive covenant. And you'd better stay aware of what these sometimes-tricky agreements might mean to you in a changing medical marketplace.

Suppose you sell your practice to a hospital and become its employee, only to discover you hate the arrangement. Can you back out? Or maybe you're merging with a large group. What about

the patients you bring with you? Could you retain "rights" to them if you break away later? Or maybe you and your partner will be signing on with an HMO. Must a restrictive covenant be part of the entry fee?

To many doctors, it may seem that the side demanding a covenant—a group, clinic, hospital—has most of the power. But that can work for you, especially today. In this area, judges may favor the little guy against the big bully; that's most often the case, though, when the doctor who'll be facing a covenant's restraints is not a former partner

or owner, but an ex-employee. And in the current medical marketplace, you're more likely than ever to be working as an employee.

Before you start feeling too warm and fuzzy toward the courts, however, be aware of three things. First, even the most soft-hearted judge is constrained by rules and precedents. Second, at some point

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in your professional life, you may well be on the apparent "bully" side—but you'll see yourself as seeking justified protection against unfair competition. Finally, it's better not to go to court at all if you can avoid it. For all three reasons, your safest course is to be aware of how things look from both sides of the bargaining table.

To do that, you may have to go through some shifts in perspective. Those could stand you in good stead in your own negotiations.

The side that grabs too much may get nothing

"So if you leave the group, the contract you signed cuts you off from practicing in almost all of Trenton?" I asked the young dermatologist. He nodded. "Don't worry," I told him. "That may be good news."

The doctor looked puzzled. He'd come to me because he was dissatisfied with practicing in a large group, but his contract said that if he left, he couldn't practice for two years within a 12-mile radius. That hadn't seemed to me too onerous, until he'd added, "But we practice out of three offices, and those restrictions apply to each of the three." He'd brought a map and drawn circles around each office, showing that if he left the group, a large piece of the city would be a forbidden zone.

How was that good news? Because that strict a covenant probably wasn't fully enforceable—or perhaps wasn't enforceable at all.

Here's why: A restrictive covenant is an agreement not to compete in a certain area for a certain length of time. In other words,

A covenant hits you very harshly? Don't give up; that may turn out to be good news.

it's a restraint-of-trade agreement, and our laws generally favor competition. That doesn't mean covenants won't ever be enforced. They can be upheld if they're reasonable, and even states that restrict covenants sharply may allow them in some cases—but not necessarily just as written. Often, despite what an agreement says, courts will pay heed to what actually fits the situation.

That's what I told the dermatologist. "Out in the countryside, a group might need to draw patients from a wide area to survive—from as far as 40 or 50 miles away. But Trenton is a midsize city. Keeping you out of a large district here won't seem reasonable or necessary to a judge."

The young doctor's specialty favored him too. "Maybe patients will travel eight or 10 miles or more to a doctor they'll see for just a few visits—a surgeon, for example," I said. "But people often see a dermatologist regularly for long periods. They want someone close by. So you're likely to draw mainly from people living near your office, and so are your partners. That's another good argu-

ment against the restriction."

A too-strict covenant may even backfire, I told the dermatologist. If there's a 6-mile restriction around a clinic when 4 miles might seem fairer, a judge may simply cut down the mileage limitation. But if the protection seems way out of line, as in this case, a judge may throw out the whole covenant.

Limiting a doctor's activities unnecessarily may fail also. Let's say a gastroenterologist going to work for a hospital is asked to sign a covenant restricting his right to practice his subspecialty. That's reasonable. But if the covenant seeks to restrict his practice of general internal medicine, it will try any court's patience.

The courts may grant less protection to bigger organizations because they generally need it less than individual doctors do. Moreover, courts today are increasingly protecting patients' right to choose medical providers. Keep those points in mind when you negotiate with a clinic, hospital, or large group. And if you're on the side that's insisting on a covenant? Better limit it to the narrowest protection that you really need.

That's why I had no quarrel with the two-year time limit in the dermatologist's agreement. I think two years is fair. Many covenants ask for three to five years; that's overkill. If a doctor doesn't treat patients for two years, I'd assume those patients will find another practitioner. Moreover, doctors have to eat; a two-year period is certainly enough to ensure that a physician will become established elsewhere.

As for my dermatologist client, we quickly negotiated his mileage limit down to a more reasonable

BRIEF SUMMARY

Contraindications: Severe LV dysfunction (see *Warnings*), hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no pacemaker is present), 2nd- or 3rd-degree AV block (if no pacemaker is present), atrial flutter/fibrillation with an accessory bypass tract (eg, WPW or LGL syndromes), hypersensitivity to verapamil.

Warnings: Verapamil should be avoided in patients with severe LV dysfunction (eg, ejection fraction < 30%) or moderate to severe symptoms of cardiac failure and in patients with any degree of ventricular dysfunction if they are receiving a beta-blocker. Control milder heart failure with optimum digitalization and/or diuretics before Calan SR is used. Verapamil may occasionally produce hypotension. Elevations of liver enzymes have been reported. Several cases have been demonstrated to be produced by verapamil. Periodic monitoring of liver function in patients on verapamil is prudent. Some patients with paroxysmal and/or chronic atrial flutter/fibrillation and an accessory AV pathway (eg, WPW or LGL syndromes) have developed an increased antegrade conduction across the accessory pathway bypassing the AV node, producing a very rapid ventricular response or ventricular fibrillation after receiving I.V. verapamil (or digitalis). Because of this risk, oral verapamil is contraindicated in such patients. AV block may occur (2nd- and 3rd-degree, 0.8%). Development of marked 1st-degree block or progression to 2nd- or 3rd-degree block requires reduction in dosage or, rarely, discontinuation and institution of appropriate therapy. Sinus bradycardia, 2nd-degree AV block, sinus arrest, pulmonary edema and/or severe hypotension were seen in some critically ill patients with hypertrophic cardiomyopathy who were treated with verapamil.

Precautions: Verapamil should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdosage. Verapamil may decrease neuromuscular transmission in patients with Duchenne's muscular dystrophy and may prolong recovery from the neuromuscular blocking agent vecuronium. It may be necessary to decrease verapamil dosage in patients with attenuated neuromuscular transmission. Combined therapy with beta-adrenergic blockers and verapamil may result in additive negative effects on heart rate, atrioventricular conduction and/or cardiac contractility; there have been reports of excessive bradycardia and AV block, including complete heart block. The risks of such combined therapy may outweigh the benefits. The combination should be used only with caution and close monitoring. Decreased metoprolol and propranolol clearance may occur when either drug is administered concomitantly with verapamil. A variable effect has been seen with combined use of atenolol. Chronic verapamil treatment can increase serum digoxin levels by 50% to 75% during the first week of therapy, which can result in digitalis toxicity. In patients with hepatic cirrhosis, verapamil may reduce total body clearance and extrarenal clearance of digoxin. The digoxin dose should be reduced when verapamil is given, and the patient carefully monitored. Verapamil will usually have an additive effect in patients receiving blood-pressure-lowering agents. Disopyramide should not be given within 48 hours before or 24 hours after verapamil administration. Concomitant use of flecainide and verapamil may have additive effects on myocardial contractility, AV conduction, and repolarization. Combined verapamil and quinidine therapy in patients with hypertrophic cardiomyopathy should be avoided, since significant hypotension may result. Concomitant use of lithium and verapamil may result in an increased sensitivity to lithium (neurotoxicity), with either no change or an increase in serum lithium levels; however, it may also result in a lowering of serum lithium levels. Patients receiving both drugs must be monitored carefully. Verapamil may increase carbamazepine concentrations during combined use. Rifampin may reduce verapamil bioavailability. Phenobarbital may increase verapamil clearance. Verapamil may increase serum levels of cyclosporin. Verapamil may inhibit the clearance and increase the plasma levels of theophylline. Concomitant use of inhalation anesthetics and calcium antagonists needs careful titration to avoid excessive cardiovascular depression. Verapamil may potentiate the activity of neuromuscular blocking agents (curare-like and depolarizing); dosage reduction may be required. There was no evidence of a carcinogenic potential of verapamil administered to rats for 2 years. A study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor, and delivery only if clearly needed. Verapamil is excreted in breast milk; therefore, nursing should be discontinued during verapamil use.

Adverse Reactions: Constipation (7.3%), dizziness (3.3%), nausea (2.7%), hypotension (2.5%), headache (2.2%), edema (1.9%), CHF, pulmonary edema (1.8%), fatigue (1.7%), dyspnea (1.4%), bradycardia: HR < 50/min (1.4%), AV block: total 1°, 2°, 3° (1.2%), 2° and 3° (0.8%), rash (1.2%), flushing (0.6%), elevated liver enzymes, reversible non-obstructive paralytic ileus. The following reactions, reported in 1.0% or less of patients, occurred under conditions where a causal relationship is uncertain: angina pectoris, atrioventricular dissociation, chest pain, claudication, myocardial infarction, palpitations, purpura (vasculitis), syncope, diarrhea, dry mouth, gastrointestinal distress, gingival hyperplasia, ecchymosis or bruising, cerebrovascular accident, confusion, equilibrium disorders, insomnia, muscle cramps, paresthesia, psychotic symptoms, shakiness, somnolence, arthralgia and rash, exanthema, hair loss, hyperkeratosis, macules, sweating, urticaria, Stevens-Johnson syndrome, erythema multiforme, blurred vision, gynecomastia, galactorrhea/hyperprolactinemia, increased urination, spotty menstruation, impotence.

2/13/92 • P91CA7196V

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6 miles, and his practice—in Trenton—is doing fine.

**What's the penalty?
Think this out carefully**

Besides time and area restrictions, a covenant's other essential element is its penalty. What happens to a doctor who violates the covenant?

That may be negotiable too, as another of my clients found out when we worked out details of his buy-in agreement. He was a Pennsylvania urologist who had started working for a partnership a few years earlier. Under his employment contract, he'd agreed to a routine covenant in case he left the group. No penalty for violation was specified, but none was needed. Pennsylvania allows injunctions.

By the time of the buy-in discussions, the urologist was in a far stronger bargaining position, with a local following. We quickly whittled the covenant's penalty clause down to a splinter: A breach would mean paying \$25,000.

My client was then netting about \$150,000. So after a falling-out with his partners a couple of years later, he set up shop nearby and happily paid the penalty as a start-up cost. After all, he was spending more than that for his new computer, and now he'd have plenty of old names to punch into it.

In short, the urology group blew it. Reviewing our proposed "penalty," the doctors' attorney should have asked them, "Would you agree to sell a big piece of your practice for \$25,000? That's what you're doing." That goof points up a standard rule: A covenant doesn't amount to much without real teeth in it.

What should the group have done instead? Maybe it should have stuck with the injunction. That certainly has a lot of scare value. You can almost see the cigar-chomping sheriff rushing in and nailing the door shut. Even a temporary injunction might have held the urologist up for a couple of years, until the matter got to trial.

But some states won't permit a remedy as radical as an injunction. Even in those that do, courts may not go along when it appears an established group is trying to squelch competition. The group would usually have to show that by breaching the covenant, the departing doctor would cause harm that no money could compensate for. That's a tough case to make, especially for a powerful group or institution.

Even the easier option of suing for money damage may prove fruitless, when heavyweight plaintiffs have a large market share. A judge may have trouble staying awake as a lawyer tries to show how much patient loss a lone doctor can inflict on a 30-doctor group or a 300-bed hospital.

That's all good news, if you're the doctor who'd be impeded by a covenant. Yet consider what you'd have to go through if you had to defend yourself in a covenant lawsuit, especially one brought by a deep-pockets plaintiff like a hospital or big clinic. You'd have papers to file, answers to prepare, meetings with lawyers—and fees to pay. Even if you were confident of winning, that would be exhausting emotionally, not to mention financially. You might be tempted to throw in the towel. So negotiate a

Brief Summary:

Contraindications: Patients who have had allergic reactions to NAPROSYN® ANAPROX® or ANAPROX® DS or in whom aspirin or other NSAIDs induce the syndrome of asthma, rhinitis, and nasal polyps. Because anaphylactic reactions usually occur in patients with a history of such reactions, question patients for asthma, nasal polyps, urticaria, and hypotension associated with NSAIDs before starting therapy. If such symptoms occur, discontinue the drug.

Warnings: Serious GI toxicity such as bleeding, ulceration, and perforation, can occur at any time, with or without warning symptoms, in patients treated chronically with NSAIDs. Remain alert for ulceration and bleeding even in the absence of previous GI tract symptoms. In clinical trials, symptomatic upper GI ulcers, gross bleeding or perforation occur in about 1% of patients treated for 3-6 months, and in about 2-4% of patients treated for one year. Inform patients of signs and/or symptoms of serious GI toxicity and what steps to take if they occur. Studies have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Except for a prior history of serious GI events and other risk factors associated with peptic ulcer disease, such as alcoholism, smoking, etc., no risk factors (e.g., age, sex) have been associated with increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less well and most spontaneous reports of fatal GI events are in this population. In considering the use of relatively large doses (within the recommended dosage range), sufficient benefit should be anticipated to offset the potential increased risk of GI toxicity.

Precautions: DO NOT GIVE NAPROSYN® (NAPROXEN) CONCOMITANTLY WITH ANAPROX® OR ANAPROX® DS (NAPROXEN SODIUM) SINCE THEY CIRCULATE IN PLASMA AS THE NAPROXEN ANION. Acute interstitial nephritis with hematuria, proteinuria, and nephrotic syndrome has been reported. Patients with impaired renal function, heart failure, liver dysfunction, patients taking diuretics, and the elderly are at greater risk of overt renal decompensation. If this occurs, discontinue the drug. Use with caution and monitor serum creatinine and/or creatinine clearance in patients with significantly impaired renal function. Use caution in patients with baseline creatinine clearance less than 20 mL/minute. Use the lowest effective dose in the elderly or in patients with chronic alcoholic liver disease or cirrhosis. Borderline elevations of liver tests may occur in up to 15% of patients. Elevations of SGPT or SGOT occurred in controlled trials in less than 1% of patients. Severe hepatic reactions, including jaundice and fatal hepatitis, have been reported rarely. If liver disease develops or if systemic manifestations occur (e.g., eosinophilia or rash), discontinue therapy. If steroid dosage is reduced or eliminated during therapy, do so slowly and observe patients closely for adverse effects, including adrenal insufficiency and exacerbation of arthritis symptoms. Determine hemoglobin values periodically for patients with initial values of 10 grams or less who receive long-term therapy. Peripheral edema has been reported. For patients with restricted sodium intake, note that each tablet contains approximately 25 or 50 mg (1 or 2 mEq) sodium. Use with caution in patients with fluid retention, hypertension or heart failure. The drug may reduce fever and inflammation, diminishing their diagnostic value. Conduct ophthalmic studies if any change or disturbance in vision occurs. **Information for Patients:** Side effects can cause discomfort and, rarely, more serious side effects, such as GI bleeding, may result in hospitalization and even fatal outcomes. Physicians may wish to discuss with patients potential risks and benefits of NSAIDs, particularly when they are used for less serious conditions where treatment without NSAIDs may be acceptable. Patients should use caution for activities requiring alertness if they experience drowsiness, dizziness, vertigo or depression during therapy.

Laboratory Tests: Because serious GI tract ulceration and bleeding can occur without warning symptoms, follow chronically treated patients and inform them of the importance of the follow-up. **Drug Interactions:** Use caution when giving concomitantly with coumarin-type anticoagulants; a hydantoin, sulfonamide or sulfonylurea; furosemide; lithium; beta-blockers; probenecid; or methotrexate.

Drug/Laboratory Test Interactions: May decrease platelet aggregation and prolong bleeding time or increase urinary values for 17-ketogenic steroids. Temporarily stop therapy for 72 hours before adrenal function tests. May interfere with urinary assays of 5HIAA. **Carcinogenesis:** A 2-year rat study showed no evidence of carcinogenicity. **Pregnancy:** Category B. Do not use during pregnancy unless clearly needed. Avoid use during late pregnancy. **Nursing Mothers:** Avoid use. **Pediatric Use:** Single doses of 2.5-5 mg/kg (as naproxen suspension), with total daily dose not exceeding 15 mg/kg/day, are safe in children over 2 years of age.

Adverse Reactions: In a study, GI reactions were more frequent and severe in rheumatoid arthritis patients on 1650 mg/day naproxen sodium than in those on 825 mg/day. In children with juvenile arthritis, rash and prolonged bleeding times were more frequent, GI and CNS reactions about the same, and other reactions less frequent than in adults. Incidence Greater Than 1%, Probable Causal Relationship: GI: The most frequent complaints related to the GI tract: constipation, heartburn, abdominal pain, nausea, dyspepsia, diarrhea, stomatitis. CNS: headache, dizziness, drowsiness, light-headedness, vertigo. Dermatologic: itching (pruritus), skin eruptions, ecchymoses, sweating, purpura. Special Senses: tinnitus, hearing disturbances, visual disturbances. Cardiovascular: edema, dyspnea, palpitations. General: thirst. *Incidence of reported reaction 3%-9%. Where unmarked, incidence less than 3%. Incidence Less Than 1%: Probable Causal Relationship: GI: abnormal liver function tests, colitis, GI bleeding and/or perforation, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting. Renal: glomerular nephritis, hematuria, hyperkalemia, interstitial nephritis, nephrotic syndrome, renal disease, renal failure, renal papillary necrosis. Hematologic: agranulocytosis, eosinophilia, granulocytopenia, leukopenia, thrombocytopenia. CNS: depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness. Dermatologic: alopecia, photosensitive dermatitis, skin rashes. Special Senses: hearing impairment. Cardiovascular: congestive heart failure. Respiratory: eosinophilic pneumonitis. General: anaphylactoid reactions, menstrual disorders, pyrexia (chills and fever). Causal Relationship Unknown: Hematologic: aplastic anemia, hemolytic anemia. CNS: aseptic meningitis, cognitive dysfunction. Dermatologic: epidermal necrolysis, erythema multiforme, photosensitivity reactions resembling porphyria cutanea tarda and epidermolysis bullosa, Stevens-Johnson syndrome, urticaria. GI: non-peptic GI ulceration, ulcerative stomatitis. Cardiovascular: vasculitis. General: angioneurotic edema, hyperglycemia, hypoglycemia.

Overdosage: May have drowsiness, heartburn, indigestion, nausea, vomiting. A few patients have had seizures. Empty stomach and use usual supportive measures. In animals 0.5 g/kg of activated charcoal reduced plasma levels of naproxen. **Dosage and Administration for Mild to Moderate Pain, Dysmenorrhea and Acute Tendinitis and Bursitis:** Recommended starting dose is 550 mg, followed by 275 mg every 6 to 8 hours. Total daily dose should not exceed 1375 mg. **Dosage and Administration for Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis:** Recommended dose in adults is 275 mg or 550 mg twice daily. In patients who tolerate lower doses well, the dose may be increased to 1650 mg per day for limited periods when a higher level of anti-inflammatory/analgesic activity is required. At this dosage, physicians should observe sufficient increased clinical benefits to offset potential increased risk.

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Revised 9/90



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02-0276-42-04BS

covenant carefully, and before signing, think hard about whether you could live with it if you had to.

Now let's look at the covenant from the other side. Suppose your group is trying to specify the covenant's penalty. A dollar figure for damages—like that urological group's \$25,000—may be absurd, and even a sensible one may look quaint in a few years. Some agreements contain formulas based on the estimated value of good will or actual practice receipts, but those add unwieldy complications. My suggestion: Use a percentage of the exiting doctor's W-2 income for a stated period. That leaves nothing to argue about and stays up to date—and it's hard to juggle without taking on Uncle Sam.

As for enforcement, getting litigation under way is a powerful weapon. It can win a case long before you get to court. Even the serious threat of litigation can be potent.

Filling in the blanks: There's a lot to cover

Beyond the basics, covenants involve plenty of other angles.

Don't overlook the key ones.

For example: What might a covenant exclude? One of my clients, an overworked pediatrician, was eager to water down his covenant to attract a likely associate. First, we minimized the employee doctor's limits on time and space. "And if he leaves," the pediatrician added, "he wants the right to take along any patients he's brought with him."

That exclusion is common, so I concurred. But the prospective partner also mentioned inquiries about his practice from pregnant women. "If they later come in with newborns," my client said, "he wants to count the infants as patients he brought in." That was a new one to me, but it wasn't unreasonable, so we also excluded those babies-to-be. Ultimately, we even excluded the office staffer who'd be coming in with the new partner. He could invite her along, too, if he ever left.

There's a moral here. Be like this new doctor when you negotiate. Don't be afraid to ask for what you want. And if you're hiring and want good people, be flexible and

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INDICATIONS AND USAGE: *Paxil* is indicated for the treatment of depression.

CONTRAINDICATIONS: Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. (See WARNINGS.)

WARNINGS: Interactions with MAOIs may occur. Given the fatal interactions reported with concomitant or immediately consecutive administration of MAOIs and other SSRIs, do not use *Paxil* in combination with a MAOI or within 2 weeks of discontinuing MAOI treatment. Allow at least 2 weeks after stopping *Paxil* before starting a MAOI.

PRECAUTIONS: As with all antidepressants, use *Paxil* cautiously in patients with a history of mania.

Use *Paxil* cautiously in patients with a history of seizures. Discontinue it in any patient who develops seizures.

The possibility of suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Write *Paxil* prescriptions for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

Reversible hyponatremia has been reported, mainly in elderly patients, patients taking diuretics or those who were otherwise volume depleted.

Clinical experience with *Paxil* in patients with concomitant systemic illness is limited. Use cautiously in patients with diseases or conditions that could affect metabolism or hemodynamic responses. Observe the usual cautions in cardiac patients. In patients with severe renal impairment (creatinine clearance <30 mL/min) or severe hepatic impairment, a lower starting dose (10 mg) should be used.

Caution patients about operating hazardous machinery, including automobiles, until they are reasonably sure that *Paxil* therapy does not affect their ability to engage in such activities. Tell patients 1) to continue therapy as directed; 2) to inform physicians about other medications they are taking or plan to take; 3) to avoid alcohol while taking *Paxil*; 4) to notify their physicians if they become pregnant or intend to become pregnant during therapy, or if they are nursing.

Concomitant use of *Paxil* with tryptophan is not recommended. Use cautiously with warfarin. When administering *Paxil* with cimetidine, dosage adjustment of *Paxil* after the 20 mg starting dose should be guided by clinical effect. When co-administering *Paxil* with phenobarbital or phenytoin, no initial *Paxil* dosage adjustment is needed; base subsequent changes on clinical effect. Concomitant use of *Paxil* with drugs metabolized by cytochrome P₄₅₀2D₆ (antidepressants such as nortriptyline, amitriptyline, imipramine, desipramine and fluoxetine; phenothiazines such as thioridazine; Type 1C antiarrhythmics such as propafenone, flecainide and encainide) or with drugs that inhibit this enzyme (e.g., quinidine) may require lower doses than usually prescribed for either *Paxil* or the other drug; approach concomitant use cautiously. Administration of *Paxil* with another tightly protein-bound drug may shift plasma concentrations, resulting in adverse effects from either drug. Concomitant use of *Paxil* and alcohol in depressed patients is not advised. Undertake concomitant use of *Paxil* and lithium or digoxin cautiously. If adverse effects are seen when co-administering *Paxil* with procyclidine, reduce the procyclidine dose.

In 2-year studies, a significantly greater number of male rats in the 20 mg/kg/day group developed reticulum cell sarcomas vs. animals given doses of 1 or 5 mg/kg/day. There was also a significantly increased linear trend across dose groups for the occurrence of lymphoreticular tumors in male rats. Although there was a dose-related increase in the number of tumors in mice, there was no drug-related increase in the number of mice with tumors. The clinical significance of these findings is unknown. There is no evidence of mutagenicity with *Paxil*. Serotonergic compounds are known to affect reproductive function in animals. Impaired reproductive function in rats (i.e., reduced pregnancy rate, increased pre- and post-implantation losses, decreased viability of pups) was found at *Paxil* doses 15 or more times the highest recommended human dose.

Pregnancy Category B. Reproduction studies performed in rats and rabbits at doses up to 50 and 6 times the maximum recommended human dose have revealed no evidence of teratogenic effects or of selective toxicity to the fetus. However, there are no adequate and well-controlled studies in pregnant women. *Paxil* should be used in pregnancy only if the benefits outweigh the risks. The effect of *Paxil* on labor and delivery in humans is unknown. Paroxetine is secreted in human milk; exercise caution when administering *Paxil* to a nursing woman.

Safety and effectiveness in children have not been established.

In worldwide *Paxil* clinical trials, 17% of *Paxil*-treated patients were 265 years of age. Pharmacokinetic studies revealed a decreased clearance in the elderly; however, there were no overall differences in the adverse event profile between older and younger patients.

ADVERSE REACTIONS: Incidence in Controlled Trials—Commonly Observed Adverse Events in Controlled Clinical Trials: The most commonly observed adverse events

associated with the use of *Paxil* (incidence of 5% or greater and incidence for *Paxil* at least twice that for placebo) were: asthenia (15% vs. 6%), sweating (11% vs. 2%), nausea (26% vs. 9%), decreased appetite (6% vs. 2%), somnolence (23% vs. 9%), dizziness (13% vs. 6%), insomnia (13% vs. 6%), tremor (8% vs. 2%), nervousness (5% vs. 3%), ejaculatory disturbance (13% vs. 0%) and other male genital disorders (10% vs. 0%). Twenty-one percent (881/4,126) of *Paxil* patients in worldwide clinical trials discontinued treatment due to an adverse event. The most common events (≥1%) associated with discontinuation and considered to be drug related include: somnolence, insomnia, agitation, tremor, anxiety, nausea,

diarrhea, dry mouth, vomiting, asthenia, abnormal ejaculation, sweating. The following adverse events occurred in 6-week placebo-controlled trials of similar design at a frequency of 1% or more.

Body as a Whole: headache, asthenia, abdominal pain, fever, chest pain, trauma, back pain. **Cardiovascular:** palpitation, vasodilation, postural hypotension. **Dermatologic:** sweating, rash. **Gastrointestinal:** nausea, dry mouth, constipation, diarrhea, decreased appetite, flatulence, vomiting, oropharynx disorder, dyspepsia, increased appetite. **Musculoskeletal:** myopathy, myalgia, myasthenia. **Nervous System:** somnolence, dizziness, insomnia, tremor, nervousness, anxiety, paresthesia, libido decreased, agitation, drugged feeling, myoclonus, CNS stimulation, confusion. **Respiration:** respiratory disorder, yawn, pharyngitis. **Special Senses:** blurred vision, taste perversion. **Urogenital System:** ejaculatory disturbance, other male genital disorders, urinary frequency, urination disorder, female genital disorders.

Studies show a clear dose dependency for some of the more common adverse events associated with *Paxil* use. There was evidence of adaptation to some adverse events with continued *Paxil* therapy (e.g., nausea and dizziness). Significant weight loss may be an undesirable result of *Paxil* treatment for some patients but, on average, patients in controlled trials had minimal (about 1 lb) loss. In placebo-controlled clinical trials, *Paxil*-treated patients exhibited abnormal values on liver function tests no more frequently than placebo-treated patients.

Other Events Observed During the Premarketing Evaluation of Paxil: During premarketing assessment, multiple doses of *Paxil* were administered to 4,126 patients; and the following adverse events were reported. Note: "frequent" = events occurring in at least 1/100 patients; "infrequent" = 1/100 to 1/1000 patients; "rare" = less than 1/1000 patients. Events are classified within body system categories and enumerated in order of decreasing frequency using the following definitions. It is important to emphasize that although the events occurred during *Paxil* treatment, they were not necessarily caused by it.

Body as a Whole: frequent: chills, malaise; infrequent: allergic reaction, carcinoma, face edema, moniliasis, neck pain; rare: abscess, adrenergic syndrome, cellulitis, neck rigidity, pelvic pain, peritonitis, ulcer. **Cardiovascular System:** frequent: hypertension, syncope, tachycardia; infrequent: bradycardia, conduction abnormalities, electrocardiogram abnormal, hypotension, migraine, peripheral vascular disorder; rare: angina pectoris, arrhythmia, atrial fibrillation, bundle branch block, cerebral ischemia, cerebrovascular accident, congestive heart failure, low cardiac output, myocardial infarct, myocardial ischemia, pallor, phlebitis, pulmonary embolus, supraventricular extrasystoles, thrombosis, varicose vein, vascular headache, ventricular extrasystoles. **Digestive System:** infrequent: bruxism, dysphagia, eructation, glossitis, increased salivation, liver function tests abnormal, mouth ulceration, rectal hemorrhage; rare: aphthous stomatitis, bloody diarrhea, bulimia, colitis, duodenitis, esophagitis, fecal impactions, fecal incontinence, gastritis, gastroenteritis, gingivitis, hematemesis, hepatitis, ileus, jaundice, melena, peptic ulcer, salivary gland enlargement, stomach ulcer, stomatitis, tongue edema, tooth caries. **Endocrine System:** rare: diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis. **Hemic and Lymphatic Systems:** infrequent: anemia, leukopenia, lymphadenopathy, purpura; rare: abnormal erythrocytes, eosinophilia, leukocytosis, lymphedema, abnormal lymphocytes, lymphocytosis, microcytic anemia, monocytosis, normocytic anemia. **Metabolic and Nutritional:** frequent: edema, weight gain, weight loss; infrequent: hyperglycemia, peripheral edema, thirst; rare: alkaline phosphatase increased, bilirubinemia, dehydration, gout, hypercholesterolemia, hypocalcemia, hypoglycemia, hypokalemia, hyponatremia, SGOT increased, SGPT increased. **Musculoskeletal System:** infrequent: arthralgia, arthritis; rare: arthrosis, bursitis, myositis, osteoporosis, tetany. **Nervous System:** frequent: amnesia, CNS stimulation, concentration impaired, depression, emotional lability, vertigo; infrequent: abnormal thinking, akinesia, alcohol abuse, ataxia, convulsions, depersonalization, hallucinations, hyperkinesia, hyperreflexia, incoordination, lack of emotion, manic reaction, paranoid reaction; rare: abnormal electroencephalogram, abnormal gait, antisocial reaction, choreoathetosis, delirium, delusions, diplopia, drug dependence, dysarthria, dyskinesia, dystonia, euphoria, fasciculations, grand mal convulsion, hostility, hyperalgesia, hypokinesia, hysteria, libido increased, manic-depressive reaction, meningitis, myelitis, neuropathy, nystagmus, paralysis, psychosis, psychotic depression, reflexes increased, stupor, withdrawal syndrome. **Respiratory System:** frequent: cough increased, rhinitis; infrequent: asthma, bronchitis, dyspnea, epistaxis, hyperventilation, pneumonia, respiratory flu, sinusitis; rare: carcinoma of lung, hiccups, lung fibrosis, sputum increased. **Skin and Appendages:** frequent: pruritus; infrequent: acne, alopecia, dry skin, ecchymosis, eczema, furunculosis, urticaria; rare: angioedema, contact dermatitis, erythema nodosum, maculopapular rash, photosensitivity, skin discoloration, skin melanoma. **Special Senses:** infrequent: abnormality of accommodation, ear pain, eye pain, mydriasis, otitis media, taste loss, tinnitus; rare: amblyopia, cataract, conjunctivitis, corneal ulcer, exophthalmos, eye hemorrhage, glaucoma, hyperacusis, otitis externa, photophobia.

Urogenital System: infrequent: abortion, amenorrhea, breast pain, cystitis, dysmenorrhea, dysuria, menorrhagia, nocturia, polyuria, urethritis, urinary incontinence, urinary retention, urinary urgency, vaginitis; rare: breast atrophy, breast carcinoma, breast neoplasm, female lactation, hematuria, kidney calculus, kidney function abnormal, kidney pain, mastitis, nephritis, oliguria, prostatic carcinoma, vaginal moniliasis.

Non-U.S. Postmarketing Reports

Voluntary reports of adverse events that have been received since market introduction and may have no causal relationship with *Paxil* include elevated liver function tests (the most severe case was a death due to liver necrosis, and one other case involving grossly elevated transaminases associated with severe liver dysfunction) and toxic epidermal necrolysis.

DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: *Paxil* is not a controlled substance. Evaluate patients

carefully for history of drug abuse and observe such patients closely for signs of *Paxil* misuse or abuse (e.g., development of tolerance, increments of dose, drug-seeking behavior).

BRS-PX.L5

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don't insist on unreasonable covenants.

Here are more issues to explore:

►Geographic limits. That New Jersey dermatology group with three offices overreached, yet its basic concept wasn't out of line. Any group writing a covenant might attempt to cover satellite offices, including future ones. But an employee doctor shouldn't agree automatically. Like my client, he might at least cut down the mileage in a multiple-office situation. Another client even got her covenant limited to the main office, where she'd be seeing most patients.

►Free tryout. When negotiating an employment contract, some doctors ask for a trial period during which they can walk away with no restrictions. When I represent employers, I caution them that granting this is risky; yet some feel that a 30- or 60-day "window" is reasonable. If you're the employee, try for such a provision.

►Firing "without cause." Contracts often give an employer the right to terminate a doctor without cause. That's certainly harsh, but it's really just a pressure valve. It lets a group terminate a young associate when, for example, they simply don't get along. However, a doctor employee should insist on separation pay after a "without cause" firing. He or she should also negotiate for a trade-off—say, easing or even canceling other restrictions in the covenant. Failing that, the employee should argue for a quid pro quo: that the covenant be canceled if the employee quits "with good reason."

►Fencing off the covenant. Suppose a doctor's contract with a

group says she must be informed about termination three months in advance, but the group slips up, and actually gives her only 10 weeks' notice. Can that nullify the covenant? It might.

But the group might be protected anyway, if its covenant says that its obligations are separate from the rest of the employment agreement.

► **Extending a covenant.** Doctors often neglect to renew their formal agreements. So an employer is wise to include language in a covenant stating, for instance, it will apply "during the term of this contract and thereafter." If the agreement doesn't specify this sort of automatic extension of the covenant, an employee is better off not raising the issue. Once alerted, the employer will probably insist on such language. But if an agreement says nothing about extending the term of the covenant, a court may well favor the employee in a disagreement.

► **Piracy.** A group's ex-associate sets up shop outside the contractually proscribed region. All seems within the covenant agreement until the group finds that its patients are receiving lovely four-color flyers inviting them to "visit Dr. X's new office." That sort of thing explains why covenants usually stipulate that a departing doctor can't solicit patients left behind. Covenants also routinely specify that listings of patients and referring doctors are confidential and proprietary and can't be removed or copied. A doctor might agree to all that, yet ask for the right to treat patients who follow of their own accord.

► **Consideration.** That's a legal term meaning "what you get for agreeing

Having a penalty for violation that's too low is like selling part of a practice—cheap.

to a contract." A covenant isn't good unless the person accepting the restrictions has gotten *something*. If you sign a covenant as part of an employment agreement, for example, the covenant's good. Your "consideration" was the employment itself. But when you're already at work in a practice, your employment deal has obviously been closed. If you're asked to sign a covenant then, it won't be valid unless you get something additional for it.

Say you're an employer who forgot to have a physician agree to sign a covenant when you hired him. Too bad. You can't just ask him nicely to sign it now. You'll have to provide something to make the agreement valid—maybe a bonus or a raise. And if you're the physician who's asked to sign without receiving anything in exchange, decline politely and explain why. Then decide what to ask for.

Different settings? Look into different deals

When signing on as a hospital employee, don't let covenant complications throw you. Doctor-

hospital employment contracts often say, for instance, that termination means you have to give up staff privileges. Then why fight over a covenant, you might think, if you may not be practicing nearby anyway?

But don't let the threat of losing hospital privileges intimidate you. Doctors successfully reapply for staff privileges all the time. In fact, in negotiating with a hospital, you might get aggressive. Hospitals eager to sign doctors up often bend the terms considerably. Some will even eliminate a covenant altogether.

HMO agreements may demand the tightest restrictions of all—with probably the least justification. An HMO, after all, controls the reimbursement purse strings. Obviously, you can't easily compete with an HMO, which gives you a good case against any tough covenant that the organization wants you to sign. Still, some HMOs maintain a "take it or leave it" attitude when a doctor tries to discuss terms. But others, realizing their power over patients, don't worry much about covenants. Don't ever assume you won't be able to negotiate; try for what you want, and you may get all you aim for.

When you work out a covenant, bargain carefully and hard, no matter who the employer is. You can't blithely assume the covenant won't be utilized. As a lawyer, I've seen plenty of professional honeymoons end in professional divorce. If that happens to you, the terms hammered out in negotiations may determine how you practice medicine for the foreseeable future. ■