

# Texas Physicians Seek Board Enforcement Reforms

BY MARY ELLEN SCHNEIDER  
Senior Writer

Physicians in Texas are working to change the way the state board of medical examiners disciplines doctors by adding more due process to the system.

"The state board really is overstepping its bounds in terms of reviewing standard of care issues," said Clyde A. Henke, M.D., an ob.gyn. in San Angelo, Tex., who has

called for reform of the state board's rules.

Dr. Henke noted that ob.gyns. are already under pressure to drop obstetrics due to high premiums, low managed care payments, and now aggressive sanctioning of physicians by the state board.

In September 2003, the Texas legislature gave the Texas State Board of Medical Examiners new authority to regulate medical practice through the passage of Senate Bill 104. This year, the legislature will review how the agency has used those new pow-

ers during its Sunset Review Process, which occurs every 12 years.

S.B. 104 gave the board a 60% increase in funding in fiscal year 2003 to be used to pay expert physician consultants, more competitive salaries to retain staff, and 20 additional full-time employee positions.

A major change made as a result has been the implementation of a new investigation module, said Donald W. Patrick, M.D., executive director of the Texas State Board of Medical Examiners. This new process is used to assess the approximately 6,000 complaints that the board receives each year.

In a national ranking of serious disciplinary actions taken against physicians in 2003, Public Citizen's Health Research Group ranked Texas in the middle—23rd out of the 50 states plus the District of Columbia.

During the board's process, a complaint is initially assessed by a nurse investigator, who refers potential violations to a physician of the same specialty as the physician named in the complaint. The complaint is then assessed by up to three expert physicians, before it can be referred on to an informal settlement conference that involves mediation between the physician and the board.

Ultimately, complaints that can't be resolved during an informal settlement conference are forwarded to the State Office of Administrative Hearings for a hearing before an administrative law judge.

Board enforcement actions have increased about threefold since fiscal year 2001 and today average about 300 per year, Dr. Patrick said, adding that the increase is due largely to changes begun in 2002 when the board began to hire more lawyers and address their large backlog of cases.

Before the board instituted its current investigation process, cases were filed against physicians immediately and consequently immediately affected their records, Dr. Patrick said. The new system is designed to give physicians more opportunities to defend their records, he said.

But critics say the increased enforcement is an overreaction to negative press reports about a lack of action by the board and negative feedback about the tort reform legislation recently passed in the state.

"There was a lot of heat put on the state board," said Dave Kittrell, M.D., chair of the Texas section of the American College of Obstetricians and Gynecologists.

Although the board has the duty to make sure that physicians are competent, a lot of good physicians are getting "caught up in the net," Dr. Henke said.

In his opinion, standard of care issues are best addressed first at the local level through county medical societies and the peer review and credentialing committees of hospitals. The state board should con-

centrate on areas such as fraud, substance abuse, and the inability of physicians to safely perform their duties, Dr. Henke said.

Once the state medical board begins to meddle in clinical decision making, there could be dangerous consequences, he said.

The Texas Medical Association has pushed for a strong state medical board and wanted the board to have increased funding and better investigative powers, said Paul B. Handel, M.D., a member of the Texas Medical Association's board of trustees and chair of the ad hoc committee on Sunset Review of the State Board of Medical Examiners, which has spent the

and a one-year study of once weekly FOSAMAX® (alendronate sodium) 70 mg) the rates of discontinuation of therapy due to any clinical adverse experience were 2.7% for FOSAMAX 10 mg/day vs. 10.5% for placebo, and 6.4% for once weekly FOSAMAX 70 mg vs. 8.6% for placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in 2% of patients treated with either FOSAMAX or placebo are presented in the following table.

Osteoporosis Studies in Men Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥2% of Patients				
	Two-year Study		One-year Study	
	FOSAMAX 10 mg/day % (n=146)	Placebo % (n=95)	Once Weekly FOSAMAX 70 mg % (n=109)	Placebo % (n=58)
<b>Gastrointestinal</b>				
acid regurgitation	4.1	3.2	0.0	0.0
flatulence	4.1	1.1	0.0	0.0
gastroesophageal reflux disease	0.7	3.2	2.8	0.0
dyspepsia	3.4	0.0	2.8	1.7
diarrhea	1.4	1.1	2.8	0.0
abdominal pain	2.1	1.1	0.9	3.4
nausea	2.1	0.0	0.0	0.0

#### Prevention of osteoporosis in postmenopausal women

The safety of FOSAMAX tablets 5 mg/day in postmenopausal women 40-60 years of age has been evaluated in three double-blind, placebo-controlled studies involving over 1,400 patients randomized to receive FOSAMAX for either two or three years. In these studies the overall safety profiles of FOSAMAX 5 mg/day and placebo were similar. Discontinuation of therapy due to any clinical adverse experience occurred in 7.5% of 642 patients treated with FOSAMAX 5 mg/day and 5.7% of 649 patients treated with placebo.

In a one-year, double-blind, multicenter study, the overall safety and tolerability profiles of once weekly FOSAMAX 35 mg and FOSAMAX 5 mg daily were similar.

The adverse experiences from these studies considered by the investigators as possibly, probably, or definitely drug related in 1% of patients treated with either once weekly FOSAMAX 35 mg, FOSAMAX 5 mg/day or placebo are presented in the following table.

Osteoporosis Prevention Studies in Postmenopausal Women Adverse Experiences Considered Possibly, Probably, or Definitely Drug Related by the Investigators and Reported in ≥1% of Patients				
	Two/Three-Year Studies		One-Year Study	
	FOSAMAX 5 mg/day % (n=642)	Placebo % (n=648)	Once Weekly FOSAMAX 5 mg/day % (n=361)	Once Weekly FOSAMAX 35 mg % (n=362)
<b>Gastrointestinal</b>				
dyspepsia	1.9	1.4	2.2	1.7
abdominal pain	1.7	3.4	4.2	2.2
acid regurgitation	1.4	2.5	4.2	4.7
nausea	1.4	1.4	2.5	1.4
diarrhea	1.1	1.7	1.1	0.6
constipation	0.9	0.5	1.7	0.3
abdominal distention	0.2	0.3	1.4	1.1
<b>Musculoskeletal</b>				
musculoskeletal (bone, muscle or joint) pain	0.8	0.9	1.9	2.2

#### Concomitant use with estrogen/hormone replacement therapy

In two studies (of one and two years' duration) of postmenopausal osteoporotic women (total: n=853), the safety and tolerability profile of combined treatment with FOSAMAX 10 mg once daily and estrogen ± progestin (n=354) was consistent with those of the individual treatments.

#### Treatment of glucocorticoid-induced osteoporosis

In two, one-year, placebo-controlled, double-blind, multicenter studies in patients receiving glucocorticoid treatment, the overall safety and tolerability profiles of FOSAMAX 5 and 10 mg/day were generally similar to that of placebo. The adverse experiences considered by the investigators as possibly, probably, or definitely drug related in 1% of patients treated with either FOSAMAX 10 mg/day (n=157), FOSAMAX 5 mg/day (n=161), or placebo (n=159), respectively, were: **Gastrointestinal:** abdominal pain (3.2%; 1.9%; 0.0%), acid regurgitation (2.5%; 1.9%; 1.3%), constipation (1.3%; 0.6%; 0.0%), melena (1.3%; 0.0%; 0.0%), nausea (0.6%; 1.2%; 0.6%), diarrhea (0.0%; 0.0%; 1.3%); **Nervous System/Psychiatric:** headache (0.6%; 0.0%; 1.3%).

The overall safety and tolerability profile in the glucocorticoid-induced osteoporosis population that continued therapy for the second year of the studies (FOSAMAX: n=147) was consistent with that observed in the first year.

#### Paget's disease of bone

In clinical studies (osteoporosis and Paget's disease), adverse experiences reported in 175 patients taking FOSAMAX 40 mg/day for 3-12 months were similar to those in postmenopausal women treated with FOSAMAX 10 mg/day. However, there was an apparent increased incidence of upper gastrointestinal adverse experiences in patients taking FOSAMAX 40 mg/day (17.7% FOSAMAX vs. 10.2% placebo). One case of esophagitis and two cases of gastritis resulted in discontinuation of treatment.

Additionally, musculoskeletal (bone, muscle or joint) pain, which has been described in patients with Paget's disease treated with other bisphosphonates, was considered by the investigators as possibly, probably, or definitely drug related in approximately 6% of patients treated with FOSAMAX 40 mg/day versus approximately 1% of patients treated with placebo, but rarely resulted in discontinuation of therapy. Discontinuation of therapy due to any clinical adverse experience occurred in 6.4% of patients with Paget's disease treated with FOSAMAX 40 mg/day and 2.4% of patients treated with placebo.

#### Laboratory Test Findings

In double-blind, multicenter, controlled studies, asymptomatic, mild, and transient decreases in serum calcium and phosphate were observed in approximately 18% and 10%, respectively, of patients taking FOSAMAX versus approximately 12% and 3% of those taking placebo. However, the incidences of decreases in serum calcium to <8.0 mg/dL (2.0 mM) and serum phosphate to <2.0 mg/dL (0.65 mM) were similar in both treatment groups.

#### Post-Marketing Experience

The following adverse reactions have been reported in post-marketing use:

**Body as a Whole:** hypersensitivity reactions including urticaria and rarely angioedema. Transient symptoms of myalgia, malaise and rarely, fever have been reported with FOSAMAX, typically in association with initiation of treatment. Rarely, symptomatic hypocalcemia has occurred, generally in association with predisposing conditions.

**Gastrointestinal:** esophagitis, esophageal erosions, esophageal ulcers, rarely esophageal stricture or perforation, and oropharyngeal ulceration. Gastric or duodenal ulcers, some severe and with complications have also been reported (see WARNINGS, PRECAUTIONS, Information for Patients, and DOSAGE AND ADMINISTRATION).

**Skin:** rash (occasionally with photosensitivity), pruritus, rarely severe skin reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

**Special Senses:** rarely uveitis, rarely scleritis.

For more detailed information, please read the complete Prescribing Information.

FOSAMAX is a registered trademark of Merck & Co., Inc.



© 2004 Merck & Co., Inc., Whitehouse Station, NJ 08889, USA. All rights reserved.

20406286(1)(025)-FOS



© ARTHUR SPRAGG

"The state board really is overstepping its bounds in terms of reviewing standard of care issues," said Dr. Clyde A. Henke.

last year assessing the board. But there is a sense that some investigations have been "heavy handed" toward physicians, he said.

Quality of care cases need to be reviewed simultaneously by three physicians who are boarded in the same specialty as the doctor they are investigating. It's critical that physicians are evaluated by others in their specialty, Dr. Handel said, and reviewing the cases at the same time creates a good interchange among the physicians.

In addition, the ad hoc committee is seeking more "due process rights" for physicians including the presumption of innocence, the right to access details of the complaints against them, the right of discovery, the right to present witnesses and cross-examine witnesses, and the right to appeal.

The current level of due process and justice for physicians "could be significantly better," Dr. Handel said.

But Dr. Patrick maintains that the new system provides more opportunities than ever for the physician to offer evidence in their defense. The process is deliberative and takes about 9 months. "This process is not one day you get a complaint and the next day you're in chains," he said.

And physicians that have complaints filed against them are already being evaluated by physicians in their specialty, he said. A simultaneous review, however, would significantly slow down the process.

As the board continues to implement the new process, more physicians are beginning to realize that it is good for the profession because it instills public confidence, Dr. Patrick said.

"The point is that it is a balancing act. Many cases are balancing acts. It's a tension between the doctors and the public," he said.

# Texas Physicians Seek Board Enforcement Reforms

BY MARY ELLEN SCHNEIDER  
Senior Writer

Physicians in Texas are working to change the way the state board of medical examiners disciplines doctors by adding more due process to the system.

"The state board really is overstepping its bounds in terms of reviewing standard of care issues," said Clyde A. Henke, M.D., an ob.gyn. in San Angelo, Tex., who has called for reform of the state board's rules.

Dr. Henke noted that ob.gyns. are already under pressure to drop obstetrics due to high premiums, low managed care payments, and now aggressive sanctioning of physicians by the state board.

In September 2003, the Texas legislature gave the Texas State Board of Medical Examiners new authority to regulate medical practice through the passage of Senate Bill 104. This year, the legislature will review how the agency has used

those new powers during its Sunset Review Process, which occurs every 12 years.

S.B. 104 gave the board a 60% increase in funding in fiscal year 2003 to be used to pay expert physician consultants, more competitive salaries to retain staff, and 20 additional full-time employee positions.

A major change made as a result has been the implementation of a new investigation module, said Donald W. Patrick, M.D., executive director of the Texas State Board of Medical Examiners. This new process is used to assess the approximately 6,000 complaints that the board receives each year.

In a national ranking of serious disciplinary actions taken against physicians in 2003, Public Citizen's Health Research Group ranked Texas in the middle—23rd out of the 50 states plus the District of Columbia. During the board's process, a complaint is initially assessed by a nurse investigator, who refers potential violations to a physician of the same specialty as the physician named in the complaint. The complaint is then assessed by up to three expert physicians, before it can be referred on to an informal settlement conference that involves mediation between the physician and the board.

Ultimately, complaints that can't be resolved during an informal settlement conference are forwarded to the State Office of Administrative Hearings for a hearing before an administrative law judge.

Board enforcement actions have increased about threefold since fiscal year 2001 and today average about 300 per year, Dr. Patrick said, adding that the increase is due largely to changes begun in 2002 when the board began to hire more lawyers and address their large backlog of cases.

Before the board instituted its current

investigation process, cases were filed against physicians immediately and consequently immediately affected their records, Dr. Patrick said. The new system is designed to give physicians more opportunities to defend their records, he said.

But critics say the increased enforcement is an overreaction to negative press reports about a lack of action by the board and negative feedback about the tort reform legislation recently passed in the state.

"There was a lot of heat put on the state board," said Dave Kittrell, M.D., chair of the Texas section of the American College of Obstetricians and Gynecologists.



"The state board really is overstepping its bounds in terms of reviewing standard of care issues," said Dr. Clyde A. Henke.

Although the board has the duty to make sure that physicians are competent, a lot of good physicians are getting "caught up in the net," Dr. Henke said.

In his opinion, standard of care issues are best addressed first at the local level through county medical societies and the peer review and credentialing committees of hospitals. The state board should concentrate on areas such as fraud, substance abuse, and the inability of physicians to safely perform their duties, Dr. Henke said.

Once the state medical board begins to meddle in clinical decision making, there could be dangerous consequences, he said.

The Texas Medical Association has pushed for a strong state medical board and wanted the board to have increased funding and better investigative powers, said Paul B. Handel, M.D., a member of the Texas Medical Association's board of trustees and chair of the ad hoc committee on Sunset Review of the State Board of Medical Examiners, which has spent the last year assessing the board. But there is a sense that some investigations have been "heavy handed" toward physicians, he said.

Quality of care cases need to be reviewed simultaneously by three physicians who are boarded in the same specialty as the doctor they are investigating. It's critical that physicians are evaluated by others in their specialty, Dr. Handel said, and reviewing the cases at the same time creates a good interchange among the physicians.

In addition, the ad hoc committee is seeking more "due process rights" for physicians including the presumption of innocence, the right to access details of the complaints against them, the right of discovery, the right to present witnesses and cross-examine witnesses, and the right to appeal.

The current level of due process and justice for physicians "could be significantly better," Dr. Handel said.

But Dr. Patrick maintains that the new system provides more opportunities than ever for the physician to offer evidence in their defense. The process is deliberative and takes about 9 months. "This process is not one day you get a complaint and the next day you're in chains," he said.

And physicians that have complaints filed against them are already being eval-

uated by physicians in their specialty, he said. A simultaneous review, however, would significantly slow down the process.

As the board continues to implement the new process, more physicians are beginning to realize that it is good for the profession because it instills public confidence, Dr. Patrick said.

"The point is that it is a balancing act. Many cases are balancing acts. It's a tension between the doctors and the public," he said. ■

## Redefine Success.



Will you count your wealth in dollars earned or lives changed? Contact the Peace Corps today, and learn how you can make a difference that adds up to a better world and a better you.

## Peace Corps

Redefine your world.



[www.peacecorps.gov](http://www.peacecorps.gov)

800-424-8580