Governor Brown, Address the Poor Performance of California’s State Medical Board

The following is a reprint of an August 9, 2011, Public Citizen letter to California Gov. Edmund G. Brown urging him to take the necessary steps to correct the dangerous shortcomings of the state medical board.

Dear Governor Brown:

I am writing you about two related, serious concerns involving the Medical Board of California (also referred to as “Medical Board”):

A. The delinquent manner in which the Medical Board is enforcing the state’s medical practice act and, therefore, not protecting California patients from a large number of physicians with demonstrably, and previously proven, poor records

B. The worsening overall disciplinary-action performance of California over the past 13 years compared with that of other states

This report documents the failure of the Medical Board to take any disciplinary action against 710 physicians in California, all of whom were disciplined (had clinical privilege actions against them) by California health care organizations, mainly hospitals, but also by other health care organizations such as health maintenance organizations (HMOs) and ambulatory surgical centers.

Of these 710 physicians, the health care organizations’ peer reviewers determined that 102 were an “Immediate Threat to Health or Safety” of patients. The peer reviewers had seriously disciplined almost all of them, yet the Medical Board still took no disciplinary action. If the Medical Board had seriously disciplined California physicians in 2010 at the rate at which it had in 1997, when it ranked 18th in the country in the rate of serious disciplinary actions, there would have been 164 more physicians seriously disciplined in 2010 than there actually were.

I hope, because of the threat posed to California patients by such dangerously inadequate medical board activity, you will order an independent investigation of these serious problems.

A. Public Citizen analysis of California health care organization actions in National Practitioner Data Bank (NPDB) Public Use Data File

California clinical privilege actions

Of an estimated 900,000 or more physicians who have practiced in the U.S. from 1990 to 2009, only 10,672 — barely more than one percent — have ever had a clinical privilege disciplinary action reported to the NPDB, a repository of all state disciplinary actions and medical malpractice payouts as well as clinical privilege actions against physicians.2 Thus, when hospitals or other organizations finally do take such actions against a physician, the basis for the action and the type of action are usually quite serious.

Based on our analysis of the NPDB Public Use Data File, across an almost 19-year time frame (September 1990 through the end of 2009), California health care organizations have taken disciplinary action against 1,312 California physicians. Although 46 percent (604 physicians) of these physicians have also had a disciplinary action by the Medical Board, 54 percent (710 physicians) have never had any board disciplinary action, despite the seriousness of what they were found to have done and the usually serious actions meted out against them by California hospitals and other health care organizations.

While 462 (65 percent) of these physicians had one clinical privilege action reported to the NPDB, 248 (35 percent) had multiple sanctions reported (including 20 physicians with five or more sanctions and one physician with 12 disciplinary actions). None of these sanctions, however, have ever been matched with any Medical Board of California licensure action.

Medical Board of California has taken no action against 102 physicians considered to be an ‘Immediate Threat to Health or Safety’ of patients

Nationally, those physicians against whom clinical privilege actions were taken include 220 physicians

see BROWN, page 2

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considered an “Immediate Threat to Health or Safety” of patients but untouched by any state medical board licensure action. Strikingly, 102 (46 percent) of these 220 are California physicians, although California has only about 12 percent of the physicians licensed in the U.S. Furthermore, nine (9 percent) of these 102 California physicians have had two hospital peer review reports, each for being identified as an “Immediate Threat to Health or Safety” of patients. Yet the Medical Board has taken no action against any of these 102 physicians.

The severity of the actions against these 102 physicians can be seen in the hospitals’ or other health care entities’ NPDB descriptions:

• 71 reports showing “Summary/Emergency Suspension of Privileges”;
• 19 reports indicating “Summary/Emergency Limitation of Privileges”; and
• 5 reports showing “Revocation of Clinical Privileges.”

The duration of these serious actions can also be seen from the NPDB data:

• 28 reports indicating these physicians had lost privileges or had privileges restricted “permanently”; and
• 82 reports showing “indefinite” length suspension or restriction of privileges.

Other serious reasons for hospital or other health care organization actions that did not result in Medical Board actions

In addition to the 102 doctors found to be an “Immediate Threat to Health or Safety” of patients, our analysis focused on five other categories of the most serious reasons for hospital disciplinary actions.

Ninety-two (13 percent) of the 710 physicians who have never been disciplined by hospitals or other health care facilities because of reasons that included:

• “Substandard or Inadequate Care”;
• “Substandard or Inadequate Skill Level”;
• “Unable to Practice Safely”;
• “Unable to Practice Safely (Alcohol or Other Substance Abuse)” and
• “Unable to Practice Safely (Physical Illness or Impairment)”.

Eighty-two of these physicians had one such report, while eight had two, one had three and one had five.

Of the 710 physicians with California hospital actions but no Medical Board action, 447 (63 percent) had the most serious kinds of hospital actions given: either termination or restriction of their admitting privileges permanently or for one year or more. Forty-nine of the 447 physicians had two serious actions (permanent termination or loss of privileges for more than one year), eight had three serious actions and five had four serious actions.

Specific examples of California physicians

Examples of California physicians with hospital or other clinical privilege actions but no Medical Board actions include the following (their identities and those of the hospitals have been deleted in the NPDB Public Use Data File; thus we can only use their coded identification numbers):

Physician number 2111

This doctor had three clinical privilege actions: two in 2007 and one in 2008. One of the 2007 actions resulted in a permanent loss of privileges and was taken because the practitioner was considered an “Immediate Threat to Health or Safety.” The other two hospital actions resulted in indefinite suspension of privileges. The doctor also had eight medical malpractice payouts for the period 1991-2008, totaling approximately $2 million. All medical malpractice payments were
surgery related; one case involved wrong diagnosis, while another was for failure to perform a procedure.

Physician number 3869

This practitioner had two clinical privilege actions in 2009, one of which resulted in permanent loss of privileges and was taken because the doctor was considered an “Immediate Threat to Health or Safety.” The second clinical privilege action resulted in an indefinite suspension of privileges. The physician also had six medical malpractice payments totaling approximately $454,000 for the period 1992-2008. Two of these payouts were for improper performance (surgery related), one was for improper management (surgery related), one was for delay in performance (monitoring related) and one was for improper technique (treatment related). One of the patients suffered major permanent injury.

Physician number 181182

This doctor had a total of seven clinical privilege action reports: two in 2002, one in 2003, three in 2008 and one in 2009. Two of the reports involved “Summary/Emergency Suspension of Privileges,” one of which was for “Immediate Threat to Health or Safety.” Other reasons for hospital peer review actions included incompetence, substandard care and failure to provide medically reasonable care. The physician had privileges suspended indefinitely for four of the actions and had permanent suspension for three actions.

Physician number 15605

This practitioner had five clinical privilege action reports: three in 2002, one in 2003 and one in 2004. The 2003 report was a “Summary/Emergency Suspension of Privileges” for being an “Immediate Threat to Health or Safety.” Four of the adverse actions involved an indefinite penalty period. The doctor also had one approximately $15,000 medical malpractice payout in 2002 for improper performance (surgery related).

Physician number 237311

This doctor had six clinical privilege action reports: one in 2006, three in 2007 and two in 2008. One of the 2008 hospital actions was a “Summary/Emergency Suspension of Privileges” for being an “Immediate Threat to Health or Safety.” For all six peer review actions, the practitioner received an indefinite suspension of privileges. There was also a medical malpractice payment of approximately $140,000 for improper performance (surgery related) in 2009.

Physician number 221937

This doctor had six clinical privilege action reports: two in 2005, one in 2007, one in 2008 and two in 2009. One of the 2005 actions was a “Summary/Emergency Suspension of Privileges” for substandard care, and the other was a suspension of clinical privileges for “Unable to Practice Safely.” The 2007 hospital action was a “Revocation of Clinical Privileges” and was taken because of substandard care. The 2008 action involved the physician voluntarily giving up privileges while under investigation. One of the two 2009 hospital actions involved “Summary/Emergency Suspension of Privileges” for “Immediate Threat to Health or Safety.” The other 2009 action was also for “Immediate Threat to Health or Safety.” All six clinical privilege actions resulted in an indefinite penalty period.

Physician number 5039

This practitioner had a clinical privilege action report involving suspension of privileges in 1991 and 15 medical malpractice reports totaling approximately $1.9 million between 1993 and 2009. The reasons for the malpractice payouts, as described in the NPDB Public Use Data File, included two cases of retained foreign body (surgery related) and two cases of improper performance; one patient suffered significant permanent injury. As of December 2009, there had been no Medical Board of California action against this physician in the 18 years since the suspension of privileges.

B. Recent worsening of the rate of serious state medical board disciplinary actions in California compared to that of other states

Using the Federation of State Medical Boards (FSMB) annual data on the number of disciplinary actions taken against doctors, Public Citizen annually calculates the rate of serious disciplinary actions (revocations, surrenderings, suspensions and probations/restrictions per 1,000 doctors) in each state and compiles a national report ranking each state medical board for the average of the three most recent years.4

In our rankings, California had previously, for nine years (1997-2005), stood among the top one-half of states, ranking as high as 18th in 1997. Starting in 2006 and continuing through the most recent ranking (2010), however, the rate of disciplinary actions has consistently been lower. California ranked 27th in 2006, 36th in 2007, 43rd in 2008, 41st in 2009 and 35th in 2010.

If the rate of serious disciplinary actions against California physicians had been as high in 2010 as it was in 1997, there would have been 164 more California physicians with such serious actions in 2010 than there actually were. That is, had the rate of serious disciplinary actions per 1,000 physicians been 4.13 instead of 2.61, there would have been 481 serious actions in 2010 instead of the 317 actually taken by the
Medical Board performance problems identified in 2005 still not addressed

In November 2005, the Medical Board Enforcement Program Monitor ("Enforcement Monitor") issued the final report on the performance of the Medical Board of California. Unfortunately, almost six years later, some of the most significant recommendations from the report have yet to be implemented. For example, the Enforcement Monitor noted:

1. Transfer of Medical Board investigators to the Department of Justice (i.e., Attorney General’s Office) where they could work more seamlessly with the prosecutors of the Health Quality Enforcement Section.

2. Although the Medical Board received a 30 percent increase in physician licensing fees, which are the sole source of funding for the Medical Board, such an increase has apparently not resulted in an increase in Board enforcement staff. [In a letter to Public Citizen from the Medical Board dated May 27, 2011, it stated that 20 percent of the positions at the Board were currently unfilled, the implication being for budgetary reasons.]

The issue of understaffing and its impact on patient safety in California have also been noted in the earlier April 12, 2011, letter Public Citizen received from the Division of Legal Affairs, Department of Consumer Affairs. The letter noted that the lack of resources may affect the Medical Board’s ability to follow up on the 710 physicians Public Citizen identified as having had clinical privilege disciplinary actions, including 102 who were disciplined because they were an immediate threat to the health or safety of patients. Thus, none of these 102 physicians had action taken against them by the Medical Board of California.

The importance of clinical privilege reports to the Medical Board was addressed by the Enforcement Monitor. In the initial report, the Enforcement Monitor was required to analyze the sources of information to the Medical Board that most reliably led to Medical Board disciplinary action in “priority cases” as those are defined in the California Business and Professions Code section 2220.05. This statutory provision requires the Medical Board to prioritize its investigations and prosecutorial resources to ensure that physicians representing the greatest threat of harm are identified and disciplined expeditiously. Six years ago, the Enforcement Monitor’s analysis revealed that mandatory reports to the Medical Board under Business and Professions Code section 800, et. seq. — including section 805 reports of adverse peer review action against physician privileges — “continue to be high-yield sources of information leading to disciplinary actions in priority cases.”

The Enforcement Monitor’s final report further underscored the importance of clinical privilege reports to the Medical Board’s process of detecting physician misconduct. The final report noted: “During 2004-2005, the principal sources of complaints referred for investigation were mandatory reports required by Business and Professions Code section 800, etc. [sic] seq., especially 805 reports of adverse peer review actions taken by hospitals (74 percent of section 805 reports were referred for investigation).”

The Enforcement Monitor’s final report also noted that the 30 percent increase in licensing fees would provide resources to potentially shorten case-processing times. Under California Business and Professions Code section 2319, the California statutory goal is 180 days. That is, the law requires that no more than 180 days elapse upon receipt of a complaint and completion of the investigation. According to the Medical Board of California’s most recent annual report (fiscal year 2009-2010), it took, on average, a total of 404 days, or 1.1 years, to process a complaint and conduct the investigation. The annual report further notes that it took, on average, 878 days, or 2.4 years, to process complaints from intake to disciplinary action.

Further action regarding the Medical Board of California

This letter has outlined Public Citizen’s findings that:

A. The Medical Board has failed to take any disciplinary action against 710 physicians who have been disciplined by hospital or other peer review (102 of these physicians have been found to be an immediate threat to health or safety of patients);

B. There has been a significant decline in the Medical Board’s rate of serious discipline of physicians, as determined by Public Citizen’s annual ranking of medical boards; and

C. Significant recommendations, including recommendations to give priority to such peer review actions against doctors, from the Enforcement Monitor’s 2005 final report remain unimplemented.

We urge you, as chief executive of California, to take the necessary steps to improve patient safety in the state.
by addressing the performance of the Medical Board.

Such action should include ordering Medical Board follow-up to Public Citizen’s March 14, 2011, letter to the Medical Board in which we asked that it work with the Health Resources and Services Administration, Department of Health & Human Services, to identify the 710 California-licensed physicians with clinical privilege actions but no Medical Board action, and to identify the 102 who are considered an “Immediate Threat to Health or Safety” of patients. We also asked that once the practitioners are identified the Medical Board take the appropriate follow-up action (see our March 14 letter for details).

In two letters to Public Citizen (an initial April 12, 2011, letter and a follow-up May 27, 2011, letter), the Medical Board of California declined to make a specific commitment in response to our request. In fact, as of July 29, 2011, the Medical Board of California had taken no action to follow up with the Health Resources and Services Administration to identify the 710 California physicians.10

We also urge you to take the necessary steps to fully implement key recommendations from the Enforcement Monitor’s 2005 report.

A copy of this letter is being sent to the appropriate legislative committees in the California legislature for their consideration.

Thank you for your consideration of this request.

Sincerely,

Sidney Wolfe, M.D.
Director
Public Citizen’s Health Research Group

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**Poor Performance of California’s State Medical Board references**

1 As of June 30, 2010, 77 percent of all such disciplinary actions in California, called “clinical privilege actions” and reported to the National Practitioner Data Bank, were from hospitals. The remaining actions were from other health care entities such as HMOs and ambulatory surgical centers.

2 According to data from the federal NPDB, as of three years ago, barely one-half of American hospitals had taken even a single action against physicians with admitting privileges at that hospital at any time during the almost 20 years that the NPDB had been in operation (since September 1990). Hospitals are required to report clinical privilege actions to the NPDB when they restrict or revoke clinical privileges for more than 30 days for reasons involving performance or conduct. As of June 30, 2010, about 82.5 percent of all clinical privilege actions reported to the NPDB for the entire country came from hospitals; the remaining clinical privilege reports represent reporting by managed-care organizations and other health care entities such as ambulatory surgical centers.

3 According to American Medical Association data, in 2009 there were 116,489 doctors in California and 958,335 in all 50 states plus the District of Columbia. This data does not include territories or osteopathic physicians.


6 California Business and Professions Code §2220.05(a).


8 Fellmeth JF, Papageorge TA. Final Report, Medical Board of California Enforcement Program Monitor. San Diego: Center for Public Interest Law, University of San Diego School of Law; 2008:53.


10 July 29, 2011, email. Health Resources and Services Administration to Public Citizen.
Product Recalls

This section includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements (www.fda.gov/Safety/Recalls/EnforcementReports/default.htm), and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

Recalls and Field Corrections: Drugs – Class I
Indicates a problem that may cause serious injury or death

Nite Rider Maximum Sexual Enhancer for Men (one capsule inside), Volume of product in commerce: 9,600 capsules. Marketed without an NDA/ANDA: FDA laboratory analysis identified sildenafil, an ingredient in an FDA-approved drug to treat erectile dysfunction, in this product. Lot #s: All lots distributed from June 1, 2008, to Jan. 7, 2011. Kanec USA Inc.


Recalls and Field Corrections: Drugs – Class II
Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Allopurinol, 50 mg per half-tab (½ Allopurinol 100-mg tab) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 350207, expiration date 11/09/2011. Safecor Health LLC.

Amiodarone HCL, 100 mg per half-tab (½ Amiodarone HCL 200-mg tab) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #s: 326177, expiration date 07/15/2011; 333272, expiration date 08/18/2011. Safecor Health LLC.

Aripiprazole, 2.5 mg per half-tab (½ Abilify 5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 312651, expiration date 04/23/2011. Safecor Health LLC.

Aripiprazole, 5 mg per half-tab (½ Abilify 10-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #s: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Aripiprazole, 10 mg per half-tab (½ Abilify 20-mg tab) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #s: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Aripiprazole, 15 mg per half-tab (½ Abilify 30-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #s: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Aspirin, 40.5 mg per half-tab (½ Aspirin low-dose 81-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 339015, expiration date 09/17/2011. Safecor Health LLC.


Aspirin for Children, 40.5 mg per half-tab (½ Children’s Aspirin 81-mg tablet), per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #s: 309023, expiration date 04/05/2011; 310461, expiration date 04/09/2011; 344661, expiration date 10/15/2011. Safecor Health LLC.

Atenolol, 12.5 mg per half-tab (½ Atenolol 25-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #s: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.


Baclofen, 5 mg per half-tab (½ Baclofen 10-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Bisoprolol Fumarate, 2.5 mg per half-tab (½ Bisoprolol Fumarate 5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 332404, expiration date 08/12/2011; 333273, expiration date 08/18/2011. Safecor Health LLC.

Buspirone HCL, 2.5 mg per half-tab (½ Buspirone HCL 5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Candesartan Cilexetil, 2 mg per half-tab (½ Atacand 4-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 343063, expiration date 10/07/2011. Safecor Health LLC.

Candesartan Cilexetil, 4 mg per half-tab (½ Atacand 8-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Captopril, 6.25 mg per half-tab (½ Captopril 12.5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Carbidopa, 12.5 mg and b) Levodopa 50 mg per half-tablet (½ Carbidopa/Levodopa 25/100-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Cyclobenzaprine Hydrochloride Tablets (10 mg), USP, 1,000-count bottle. Volume of product in commerce: 10,071 bottles. CGMP deviations: Some tablets may not conform to weight specifications. Lot #: 703327, expiration date 01/2011; 315316, expiration date 02/2012. Pliva Krakow.

Digoxin, 62.5 mcg per half-tab (½ Digoxin 125-mg tablet) per blister (Lanoxin equivalent). Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 332404, expiration date 08/12/2011; Safecor Health LLC.

Diphenhydramine HCL, 6.25 mg per half-tab (½ Benadryl 12.5-mg dissolving tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 313695, expiration date 04/29/2011. Safecor Health LLC.

Donepezil HCL, 5 mg half-tablet (½ Aricept 10-mg tablet) per blister. Volume of product in unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Escitalopram, 10 mg per half-tab (½ Lexapro 20-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Escitalopram Oxalate, 5 mg per half-tab (½ Lexapro 10-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Fludrocortisone Acetate, 0.05 mg per half-tab (½ Fludrocortisone Acetate 0.1-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Furosemide, 10 mg per half-tab (½ Furosemide 20-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Glimepiride, 0.5 mg per half-tab (½ Glimepiride 1-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Hydralazine HCL, 12.5 mg per half-tab (½ Hydralazine HCL 25 mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Hydralazine HCL Tablets, USP, 10 mg and 50 mg; packaged in cartons of 10 blister cards containing 10 tablets each (100 tablets). Volume of product in commerce: 12,734 unit dose cartons. Tablet thickness: Some tablets may not conform to weight requirements/specifications. Lot #: Multiple lots affected. Contact your pharmacist. UDL Laboratories Inc.
DRUGS AND DIETARY SUPPLEMENTS (continued)

Hydralazine Hydrochloride Tablets, USP, 10, 25 and 50 mg, a) 100-count bottle and b) 1,000-count bottle; 100 mg. Volume of product in commerce: 70,432 bottles. Tablet thickness: Some tablets may not conform to weight requirements/specifications. Lot #: Multiple lots affected. Contact your pharmacist. Teva Pharmaceuticals USA Inc.

Hydrochlorothiazide, 6.25 mg per half-tab (½ Hydrochlorothiazide 12.5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 341552, expiration date 09/30/2011. Safecor Health LLC.


Labetalol, 50 mg per half-tab (½ Labetalol 100-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 332403, expiration date 08/12/2011. Safecor Health LLC.

Lansoprazole Delayed-Release Capsules, USP, 30 mg, 30-count capsules. Volume of product in commerce: 155,636 bottles. Discoloration: Some capsules may not meet the appearance specifications. Pellet color varies from white to pink (pellet color spec is off-white to beige). Lot #: 44L031, 44L032, expiration date 01/2012. Teva Pharmaceuticals USA Inc.

Levothyroxine Sodium, 12.5 mcg per half-tab (½ Levothyroxine Sodium 25-mcg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 314496, expiration date 05/04/2011; 339759, expiration date 09/21/2011. Safecor Health LLC.

Levothyroxine Sodium, 12.5 mcg per half-tab (½ Synthroid 0.025-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 330360, expiration date 04/29/2011. Safecor Health LLC.

Levooxy Tablets (levothyroxine sodium), USP, 75 mcg, 1,000-count bottle. Volume of product in commerce: 2,555 bottles. Adulterated presence of foreign tablets: The firm received a complaint of a single 200-mcg Levooxy tablet comingle in a 1,000-count bottle of Levooxy tablets, USP 75 mcg. Lot #: 60809, expiration date 03/31/2012. King Pharmaceuticals.

Loratadine, 5 mg per half-tab (½ Loratadine 10-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s 340249, expiration date 06/30/2011; 325875, expiration date 07/08/2011. Safecor Health LLC.

Memantine HCL, 5 mg per half-tab (½ Namenda 10-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s 330887, 335243, 338923, 342502, 347644, expiration date 10/28/2011. Safecor Health LLC.

Mercaptopurine, 25 mg per half-tab (½ Mercaptopurine 50-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 322268, expiration date 06/18/2011. Safecor Health LLC.

Metaxalone, 400 mg per half-tab (½ Skelaxin 800-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 334219, expiration date 08/25/2011. Safecor Health LLC.

Metformin HCL, 250 mg per half-tab (½ Metformin HCL 500-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s 336512, expiration date 08/21/2011; 350211, expiration date 11/09/2011; 328063, expiration date 07/20/2011. Safecor Health LLC.

Metocarbamol, 250 mg per half-tab (½ Methocarbamol 500-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 314496, expiration date 05/04/2011. Safecor Health LLC.

Metoprolol Succinate ER, 12.5 mg per half-tab (½ Metoprolol Succinate ER 25-mg tablet) per blister (Toprol-XR Equivalent). Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s 317880, expiration date 05/26/2011; 334700, expiration date 08/25/2011. Safecor Health LLC.

Metoprolol Succinate ER, 12.5 mg per half-tab (½ Toprol XL 25-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Metoprolol Tartrate 12.5 mg per half-tab (½ Metoprolol Tartrate 25-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Metoprolol XL (succinate), 12.5 mg per half-tab (½ Metoprolol Succinate ER 25-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 334726, expiration date 08/25/2011. Safecor Health LLC.
Mirtazapine, 7.5 mg per half-tab (½ Mirtazapine 15-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Misoprostol, 25 mcg per quarter-tab (¼ Misoprostol 100-mcg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Misoprostol, 50 mcg per half-tab (½ Cytotec 100-mcg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 308760, expiration date 03/31/2011. Safecor Health LLC.

Misoprostol, 50 mcg per half-tab (½ Misoprostol 100-mcg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Nabumetone, 250 mg per half-tab (½ Nabumetone 500-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 321867, expiration date 06/16/2011. Safecor Health LLC.

Nitrostat Tablets (nitroglycerin), USP, 0.4 mg. Volume of product in commerce: unknown. Adulterated presence of foreign tablets: A bottle of Nitrostat 0.6-mg tablets, lot # V100546, was discovered in a folding carton of Nitrostat 0.4 mg, lot # V100670. Nitrostat 0.6 mg, lot # V100546, is not intended for sale in the U.S. market. Lot #: 100670, expiration date 09/2012. Pfizer Pharmaceuticals LLC.

Nitrostat Tablets (nitroglycerin), USP, 0.6 mg. Volume of product in commerce: unknown. Adulterated presence of foreign tablets: A bottle of Nitrostat 0.6-mg tablets, lot # V100546, was discovered in a folding carton of Nitrostat 0.4 mg, lot # V100670. Nitrostat 0.6 mg, lot # V100546, is not intended for sale in the U.S. market. Lot #: V100546, expiration date 03/2011. Pfizer Pharmaceuticals LLC.

Olanzapine, 5 mg per half-tab (½ Zyprexa 10-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Oxybutynin, 2.5 mg per half-tab (¼ Oxybutynin Chloride 5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 333040, expiration date 08/17/2011. Safecor Health LLC.

Paroxetine Tablets, USP, 20 mg, 90-count bottle. Volume of product in commerce: 14,484 bottles. CGMP deviations: Firm’s laboratory investigations were not performed in accordance with strict adherence to the “FDA Guidance for Industry — Investigating Out-of-Specification Test Results for Pharmaceutical Production.” Lot #: 07Y085. Teva Pharmaceuticals USA Inc.

Phenytoin, 25 mg per half-tab (½ Dilantin Infatab 50-mg tablet) per blister, chewable. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 314428, expiration date 05/04/2011. Safecor Health LLC.

Propafenone HCL, 75 mg per half-tab (½ Propafenone HCL 150-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 350214, expiration date 11/09/2011. Safecor Health LLC.

Pyrazinamide, 250 mg per half-tab (½ Pyrazinamide 500-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Quinapril, 2.5 mg per half-tab (½ Quinapril HCL 5-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Risperidone, 0.125 mg per half-tab (¾ Risperidone 0.25-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 344154, expiration date 10/13/2011. Safecor Health LLC.

Risperidone Tablets, 60-count bottles, a) 2 mg and b) 3 mg. Volume of product in commerce: 40,416 bottles. Chemical contamination. Lot #: a) 0LG175, expiration date 08/2012; b) 0GG904, expiration date 05/2012. Ortho-McNeil Pharmaceutical Inc.

Sotalol HCL, 40 mg per half-tab (½ Sotalol HCL 80-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

Spirinolactone, 12.5 mg per half-tab (½ Spirinolactone 25-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.
**DRUGS AND DIETARY SUPPLEMENTS (continued)**

**Torsemide Tablets**, 100 mg, 100-count bottle. Volume of product in commerce: 3,900 bottles. Adulterated presence of foreign tablets: One lot of torsemide 100 mg tablets, 60-count bottle, may contain torsemide 10 mg tablets. Lot #: E100688; expiration date 09/2012. Hetero Drugs Ltd.

**Tramadol HCL**, 25 mg per half-tablet (½ Tramadol HCL 50-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.

**Trazodone HCL**, 25 mg per half-tablet (½ Trazodone HCL 50-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s: Multiple lots affected. Contact your pharmacist. Safecor Health LLC.


**Warfarin Sodium**, 0.5 mg per half-tab (½ Coumadin 1-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #:s: 307389, expiration date 03/22/2011; 343982, expiration date 10/15/2011; 319328, expiration date 06/02/2011. Safecor Health LLC.

**Warfarin Sodium** (Crystalline Warfarin Sodium Isopropanol Clathrate), 0.5 mg per half-tab (½ Jantoven 1-mg tablet) per blister. Volume of product in commerce: unknown. Marketed without an approved NDA/ANDA: Split tabs distributed as an unapproved new drug. Lot #: 328607, expiration date 07/22/2011. Safecor Health LLC.

**CONESUMER PRODUCTS**

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the CPSC, call its hotline at (800) 638-2772. The CPSC website is www.cpsc.gov. Visit www.recalls.gov for information about FDA recalls and recalls issued by other government agencies.

<table>
<thead>
<tr>
<th>Name of Product; Problem; Recall Information</th>
</tr>
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<tbody>
<tr>
<td><strong>Acacia Chair</strong>. The chair can collapse when weight is placed on it, posing a fall hazard to consumers. Ross Stores Inc., at (877) 455-7677 or <a href="http://www.rossstores.com">www.rossstores.com</a>.</td>
</tr>
<tr>
<td><strong>Chanel Silk Scarves, Dresses, Skirts and Blouses</strong>. The garments fail to meet the federal flammability standard for wearing apparel, posing a fire hazard to consumers. Chanel Inc., at (800) 550-0005 or <a href="mailto:ConsumerRelations@chanelusa.com">ConsumerRelations@chanelusa.com</a>.</td>
</tr>
<tr>
<td><strong>Circo Children’s Task Lamps</strong>. Lamps can overheat, causing the adhesive inside the lamp socket to melt and migrate into the bulb area of the socket. The cooled glue can adhere to the light bulb base and make the bulb difficult to remove, which can result in a broken light bulb, posing a risk of laceration to consumers. Melted flammable glue that migrates onto the electrical components of the lamp poses a risk of fire. Target Corp., at (800) 440-0680 or <a href="http://www.target.com">www.target.com</a>.</td>
</tr>
<tr>
<td><strong>DUI Weight and Trim System Classic and DUI Weight and Trim System II</strong>. Manufacturing defects in the lanyard connecting the handle to the pocket or the cable securing the pocket to the harness can prevent the weight pockets from easily detaching from the harness and releasing the weights when the handle is pulled. This poses a drowning hazard to consumers. Diving Unlimited International Inc., at (800) 325-8439 or <a href="http://www.DUI-Online.com">www.DUI-Online.com</a>.</td>
</tr>
<tr>
<td><strong>Electric Baseboard and Fan Heater Thermostats</strong>. The thermostats can overheat, causing them to melt and smoke. This poses a burn hazard to the consumer. Honeywell International Inc., at (888) 235-7363 or <a href="http://www.yourhome.honeywell.com/T4700">www.yourhome.honeywell.com/T4700</a>.</td>
</tr>
<tr>
<td><strong>Explorer and Hammerhead Strollers</strong>. The brake mechanism on the strollers can fail, posing an injury hazard. Phil&amp;teds USA Inc., at (855) 652-9019 or <a href="http://www.philandteds.com/support">www.philandteds.com/support</a>.</td>
</tr>
<tr>
<td><strong>Homelite Surface Cleaner Attachments</strong>. The surface-cleaner attachment’s nozzle and spray bar can break and detach, striking and/or breaking the unit’s plastic housing. The broken nozzle, spray bar and/or plastic housing can strike consumers, posing a laceration hazard. Homelite Consumer Products Inc., at (800) 867-9624 or <a href="http://www.homelite.com">www.homelite.com</a>.</td>
</tr>
<tr>
<td><strong>Kohler Purist, Pinstripe and Finial glass shower doors</strong>. The hinge panel of the shower door can shatter, posing a laceration hazard. Kohler Co., at (866) 782-6329 or <a href="http://www.kohler.com">www.kohler.com</a>.</td>
</tr>
</tbody>
</table>
CONSUMER PRODUCTS (continued)

Little People Builders’ Load ‘n Go Wagon. The back of the wagon’s plastic handle has molded-in reinforcement. This design adds stiffness and facilitates children gripping the handle. The handle poses a laceration hazard if a child falls on it. Fisher-Price, at (800) 432-5437 or www.service.mattel.com.

Mini Stars Building Sets. Plastic knobs can break from the center of the stars, posing a choking hazard to young children. Edushape Ltd., at (800) 404-4744 or www.edushape.com.

Mizuno Supreme Series and Ballpark Pro Baseball and Softball Gloves. Some gloves were found to contain a variety of molds that could cause respiratory or other infections in individuals with chronic health problems or in individuals who have impaired immune systems. Mizuno USA Inc., at (800) 451-7913.

Pogo Sticks. The bottom rubber tip attached to the pogo-stick frame can wear out prematurely, posing a fall hazard to consumers. Also, the end caps on the handlebars can come off, exposing sharp edges. This poses a laceration hazard to consumers. Bravo Sports, at (855) 469-3429 or www.bravopogorecall.com.

Safety Latches and Outlet Covers. The screws on the safety latches and outlet covers can loosen and/or break. When this happens, young children can gain access to electrical outlets and other potentially hazardous items. Prime-Line, at (855) 839-9555 or www.prime-line-products.com.

Scorpio and Absorbica Shock Absorbing Lanyards. Some lanyards are missing a safety stitch on the attachment loop, which can cause the lanyard to disconnect from the climbing harness, posing a fall hazard to consumers. Petzl America Inc., at (877) 740-3826 or www.petzl.com.

Task Force 5-Ton Electric Log Splitters. The electric log splitters have a hydraulic arm that, during use, slides under the handle used to move the machine. The moving hydraulic arm poses a laceration- or amputation-injury hazard to individuals who place their hands on that handle while the splitter is in operation. Changzhou Globe Tool Group Co. Ltd., at (866) 456-8934 or logsplitter@sunrisetools.ca.


OUTRAGE, from page 12

than for other types of care, so institutions frequently restrict access as stringently as possible, often, as in our study, by requiring that a patient have an in-system primary care provider (even though the insurer requires no referral). Many private practitioners refuse to accept insurance payments altogether. Improved reimbursements for psychiatric care will be an important step in reducing the barriers to care experienced by patients with severe depression.”

Rather than admitting to these serious access problems, a BCBSMA official tried to intimidate the researchers. I sent the following e-mail to BCBSMA objecting to this attempted harassment:

“I have just received a copy of an e-mail you sent Wednesday objecting to a study published July 21st in the Annals of Emergency Medicine, concerning extremely limited access to Blue Cross Blue Shield psychiatrists in the metropolitan Boston area.

“Your response to this study is intemperate and heavy-handed. You [BCBSMA] stated that:

“We are VERY concerned about the use of BCBSMA’s name and brand in a published study without BCBSMA authorization. We’d like to talk with you about that.”

“It is absurd for BCBSMA to require authorization to either do a study of physicians with whom it contracts or in order to use BCBSMA’s name and brand in conjunction with this study.

“Please send me a copy of the BCBSMA policy manual that specifies the need for such censorship.” ✤

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Outrage of the Month! Further Arguments for Eliminating the Private U.S. Health Insurance Industry

A study by Harvard medical researchers, published last month in the journal Archives of Emergency Medicine, documented the extraordinary difficulty insured patients with an acute psychiatric emergency had in obtaining an appointment for follow-up with Boston-area psychiatrists.

Study personnel posed as patients insured by BlueCross BlueShield of Massachusetts (BCBSMA) PPO, the largest insurer in that state. They called every BCBSMA-contracted mental health facility within a 10-mile radius of downtown Boston, stating they had been evaluated in an emergency department for depression and discharged with instructions to obtain a psychiatric appointment within two weeks — that is, they signaled they needed urgent psychiatric care.

Only eight of the 64 facilities (12.5 percent) listed by BlueCross as preferred providers offered appointments; only 4 (6.3 percent) offered an appointment within two weeks.

The authors of the study stated:

“This result confirms our suspicion that even for patients with private insurance, mental health services in the Boston area are severely limited, which is in line with national data showing limited availability: for example, two thirds of primary care physicians report that they cannot obtain outpatient mental health services for patients who need them.

“Our inadequate mental health system has widespread social effects. A third of the homeless and more than half of all prison and jail inmates have mental illness. The nation’s Emergency Departments are de facto psychiatric wards, with 79 percent of emergency physicians reporting that their hospitals board psychiatric patients for whom appropriate treatment resources could not be found, sometimes for days.

“Although there are many contributors to the inadequacy of our mental health system, managed care has hit psychiatric services hard. Private insurers aggressively constrain patients’ access to services by stringently limiting provider networks.

“As our study shows, this is often covert; insurers provide lists of in-network providers, but most are unavailable. Reimbursements for psychiatric services are far lower.