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President's Report

Medical Board of California's New Officers for 2002-2003 3

2

4

Update Regarding Changes to CME Requirements



.

Health Services HIV Reporting Regulations 5

Lyme Disease Case Numbers Increase Nationally **8**

West Nile Virus	
Surveillance	
in California	9
New 2002 STD	
Treatment Guidelines	10
News From the	
U.S. Food and Drug	
Administration	15
Safe Medication	
Management	
for the Elderly Patient	16
Administrative Actions	18

Medical Board of California Meetings

2002

Aug. 1-3	San Francisco

Nov. 7-9 San Diego

All meetings are open to the public.

Action Report Medical Board of California

Board Proposes New Information Disclosure Policy

Last summer, the Medical Board of California appointed a Public Information Disclosure Committee, comprised of three physician and three public members. The purpose of the Committee was to comprehensively review the Board's public disclosure policies and methods—not only *what* was considered public record, but *how* it was being presented. From November 2001 through January 2002, the Committee held four public meetings statewide, taking testimony from organizations representing the public interest, organized medicine, malpractice insurers, and interested individuals.

As a result of these meetings and the Committee's deliberations, the presentation on the Board's Web site of its individual physician records has been revamped to be more readerfriendly. A notice at the top of each record will make clear what information is and is not available from the Board. Explanations of all enforcement-related terms will be provided, as will a link to the Medical Practice Act. The disclaimers that put the information in context have been carefully rewritten to be more understandable. The gender of the physician will be added, and when the Board has information on practice specialty, additional postgraduate training information, and language proficiencies obtained via license application and renewal, these items also will be included.

At the meeting of the Board held on May 11, 2002, the Committee recommended that additional information be disclosed by the Board on its Web site and to callers about physicians. The Board supported the Committee's recommendations, which include:

(Continued on page 7)

2001-2002 Sunset Review: How it Affects the Medical Board of California

The Medical Board underwent a Sunset Review this year, which is an examination of a state agency (i.e., a board or committee) by the Legislature. It is designed to determine if the agency is necessary and whether it should continue to exist in its present form or if changes to operation are required. During the process, suggestions are solicited on changes that need to be made in the agency to ensure public protection. A Joint Legislative Sunset Review Committee (JLSRC) composed of Senate and Assembly members receive written and verbal testimony from the boards and committees as well as the public and interested professional

organizations in open hearings at the State Capitol in Sacramento. Based on the testimony, the JLSRC makes recommendations that are incorporated into a Sunset Review bill. Such a bill would not only enact changes within a practice act but also ensure the particular board or committee continues to exist. If the JLSRC or the Legislature fail to produce or pass a bill, the board or committee is abolished.

The JLSRC identified a number of concerns reflecting its belief that enhancements in consumer protection are warranted.

(Continued on page 6)

THE MISSION OF THE MEDICAL BOARD OF CALIFORNIA

The mission of the Medical Board of California is to protect consumers through proper licensing of physicians and surgeons and certain allied health professions and through the vigorous, objective enforcement of the Medical Practice Act.

President's Report

I am grateful to have been elected the new President of the Medical Board of California at the Board's last meeting in May. Although this is still a relatively new Board, it has proven itself to be decidedly committed to its charge, innovative, and proactive, and I intend to continue this course while revamping the structure of how the Board has done business in the past.

The first job of every member of this Board is to protect the best interest of the public. Members of this Board will work with one another as a full Board in our interactions with the public, the media, special interest groups, the Legislature, the Department of Consumer Affairs (the agency that oversees the Medical Board) and others. We cannot optimally achieve

our goal of patient protection without the cooperation of others in the regulatory system, such as:

- administrative law judges, on whom we rely for guidance in many cases, and whose recommendations must be consistent. We must bring them more fully into our circle, and enhance their knowledge of significant aspects of medical practice if they are to fulfill their role.
- courts, too, must be included in our efforts so that they may more effectively perform their duty to report, enabling the Medical Board to better protect patients.
- medical staffs of hospitals, who must provide effective peer review, as they are the best mechanism for establishing competence. They are already required by law to perform and report peer review; they must be encouraged to do so in order to effectively meet these critical ethical and legal obligations.

A key priority of mine in the evaluation and renovation of the Board's effectiveness is through a formal strategic planning process. The full Board and key members of its staff will review each of the Board's major functions, identifying areas that need improvement and generating action plans to meet specific objectives.

To achieve our work, I have developed a committee system, by which every member of the Board serves not



Gary Gitnick, M.D. President of the Board

only on one of the Board's two divisions (licensing and medical quality), but also on a committee of the Board. These committees are charged with assessing and enhancing the performance of the Board in the following key areas:

• Development, working with the Legislature, of a plan for the provision of healthcare for all Californians, regardless of economic status. I am seriously concerned about the lack of adequate healthcare of the underserved, the indigent, and the uninsured.

• Development of an outstanding public notification system, to advance the Board's public outreach. The public must know about the Medical Board and its services, and all that we can possibly notify them about their doctors.

- Strict oversight of the Board's licensing and enforcement functions to assure that they are operating at full capacity to protect patients.
- Examination of the provision of non-conventional medicine in this state, including an assessment as to whether it can be better regulated by the Medical Board or should be overseen by another, new board.
- Recertification plans for specialty boards and offshore schools certified by the Medical Board, to assess their continuing relevance and efficacy.
- Recognition of excellence in the healthcare delivery system by individual physicians, e.g., via volunteerism, heroism, service beyond the call of duty, or brilliance in medicine. This committee's work will not involve the expenditure of licensing fees or General Fund money. This state is blessed with a huge number of very good, dedicated, hard-working doctors and they deserve recognition beyond the very small handful of their patients.

This is an ambitious agenda. We recognize well that our goals will be best achieved with the participation of all parties affected. I welcome the Board's critics to continue their scrutiny and suggested improvements of the functions of the Board. In our ongoing efforts, we will strive to maintain mutual respect and rise to the highest level of integrity.

Medical Board of California's New Officers for 2002-2003

Full Board:

President: Vice President: Secretary: Gary Gitnick, M.D. Hazem H. Chehabi, M.D. Mitchell S. Karlan, M.D.

Division of Licensing:

President: Vice President: Secretary: Mitchell S. Karlan, M.D. James A. Bolton, Ph.D. Richard D. Fantozzi, M.D.

Division of Medical Quality:

President: Vice President: Secretary: Ronald H. Wender, M.D. Lorie G. Rice, M.P.H. Ronald L. Morton, M.D.

American Psychiatric Alliance Lauds Board's Diversion Program

The Medical Board of California's Diversion Program, for physicians with substance abuse problems, received a special recognition award from the American Psychiatric Alliance last April.

The award honored the Diversion Program for continued support and promotion of the Elsa Barton Scholarship Fund, a program of the American Psychiatric Association Alliance, an organization that supports and assists the American Psychiatric Association. The scholarship provides financial assistance to enable a spouse/partner or dependent of a disabled, impaired, or deceased physician to continue or begin post secondary education.

During the last five years, the Committee received more applications, and awarded more scholarships to family members, from the California Diversion Program than from any other organization.

The Program was praised for helping the Alliance "reach families who are trying to help themselves continue to be active, productive members of their communities during very difficult times for the whole family."

New California HealthCare Foundation Journal Series to Educate Providers about Medical Errors

The California HealthCare Foundation has sponsored a new journal series to help providers reduce medical errors through individual case presentations.

California HealthCare Foundation is an independent philanthropy that focuses on informing health policy decisions, advancing efficient business practices, improving the quality and efficiency of care delivery, and promoting informed healthcare and coverage decisions.

The first article in the eight-part series, titled "Quality Grand Rounds," appears in the June 4 issue of the *Annals of Internal Medicine*. The article features a case study of an unidentified hospital where 17 medical errors allowed a patient to be subject to an "invasive procedure intended for another patient."

The series also provides information to help patients avoid medical errors. To read the series' first and subsequent articles, visit the California HealthCare Foundation's Web site at: www.chcf.org/press.

Update Regarding Changes to the CME Requirements as a Result of AB 487 (Aroner)

Pain management and the treatment of terminally ill patients is now a mandatory part of the continuing medical education (CME) requirements for physicians.

With the passage of AB 487 (Business and Professions Code section 2190.5), physicians are now required to complete a mandatory one-time requirement of 12 credit hours of CME in the subjects of pain management and the treatment of terminally ill and dying patients.

Following are some frequently asked questions regarding CME:

Why is this important?

It is the intent of the Legislature that this requirement will serve to broaden and update the knowledge base of all

CONTINUING MEDICAL EDUCATION

The San Diego Academy of Family Physicians and the University of California, San Diego Physician Assessment and Clinical Education (PACE) Program present:

AB 487: Get A Grip On Pain — An Evidence-Based Approach for Pain Management and Palliative Care

(Fulfills California's New State Licensing Requirement)

September 14-15, 2002 Town and Country Resort & Convention Center 500 Hotel Circle North San Diego, CA 92108

This course serves to broaden and update the knowledge base of all physicians by presenting a comprehensive, evidence-based approach to the subjects of pain management and the treatment of the terminally ill patient. Course fee: \$250

The American Academy of Family Physicians designates this continuing medical education activity for a maximum of 12 hours in category 1 credit towards the AMA Physician's Recognition Award.

For a brochure or registration information, contact the San Diego Academy of Family Physicians by phone: (619) 422-1186, fax : (619) 476-1536 or e-mail: mtc@mtcsd.com.

physicians related to the appropriate care and treatment of patients suffering from pain as well as the appropriate care and treatment of terminally ill and dying patients.

Who is covered by this requirement?

This requirement applies to most physicians. However, those physicians who are currently practicing in pathology or radiology are exempted, by law, from this requirement.

When must this requirement be completed?

Physicians who were granted licensure prior to Jan.1, 2002 will need to complete this requirement by Dec. 31, 2006. All physicians licensed on or after Jan. 1, 2002 will need to complete this requirement within four years of initial licensure or by the second renewal date, whichever occurs first.

Which courses are acceptable?

Currently, acceptable programs and courses are those relating to pain management and/or end-of-life care which qualify for Category I credit from: 1) the California Medical Association, 2) the American Medical Association, 3) the American Academy of Family Physicians, and 4) the Accreditation Council for Continuing Medical Education.

How is completion reported to the Medical Board?

Self-certification of satisfactory completion of course work in both areas must be reported to the Medical Board on the renewal application form. Every year a random sample of physicians is selected for a CME audit by the Board. In the event of an audit, official documentation will need to be provided. Official documentation may include brochures, announcements or flyers and certificates of attendance, which indicate clearly that the courses relate to pain management and end-of-life care.

Are the 12 hours of CME on pain and end-of-life care required in addition to the current CME requirements?

No. This 12-hour requirement will be counted as part of the minimum 100 hours of approved CME required every four years.

Additional information related to CME is available on the Board's Web site (click on "Services for Licensees"), or a copy of the brochure "Continuing Medical Education Requirements for Physicians Licensed by the Medical Board of California" may be obtained by calling the Board's Consumer Information Unit at (916) 263-2382. The complete text of AB 487 as well as the impacted sections of the Business and Professions Code (2313, 2190.5, and 2241.6) may be found at www.leginfo.ca.gov.

CONTINUING MEDICAL EDUCATION

The California Medical Association with the CMA Foundation, in cooperation with the California Coalition for Compassionate Care, The Permanente Medical Group Inc., Office of Physician Education and Development, and Kaiser Permanente, Fresno present:

Education for Physicians in End-of-Life Care (EPEC)

This Education for Physicians on End-of-life Care (EPEC) course has been designed to meet the AB 487, 12-unit continuing medical education requirement in pain management and end-of-life care.

It is designed to give practicing physicians the core clinical skills needed to improve their competence and confidence in dealing with:

- Decisions related to life-sustaining therapy
- Pain and other symptom management
- Depression, anxiety, delirium
- Physician, patient and family relationships
- Priorities and goals of care and treatment
- Advance care planning
- The last hours of life

Physicians who attend the two-day EPEC course will be better able to:

- Assess and treat pain and other symptoms that are common in dying patients
- Use effective communication skills in conversations with patients and family members in a variety of difficult end-of-life situations
- Identify and appreciate sources of satisfaction in delivering quality end-of-life care
- Recognize and attend to the psychosocial, cultural and spiritual needs of patients and their families

Course fee: \$295, includes breakfast and lunch both days, and syllabus.

The Nov. 4-5 course at Tenaya Lodge in Yosemite, Calif., was listed as full as the *Action Report* went to press. However, additional courses will be scheduled. For information on upcoming courses, see future editions of the *Action Report*.

For registration information call Marge Ginsburg, Sacramento Healthcare Decisions, at (916) 851-2828.

Health Services HIV Reporting Regulations

On May 2, 2002, California's regulations for reporting HIV infection by use of a non-name code were approved by the Office of Administrative Law and filed with the Secretary of State, to become effective July 1, 2002.

The Office of AIDS within the California Department of Health Services has begun the process of contacting and training local health departments and plans are in place to train other reporting entities.

HIV surveillance data will help to reliably reflect the course of the HIV epidemic, reveal trends in HIV transmission, and assist in targeting HIV education, prevention, and care efforts. Under the new regulations, laboratories and healthcare providers will report "confirmed HIV tests" to the local health officer.

The healthcare provider will report the case using a non-name code that consists of an individual's Soundex code (a phonetic, alphanumeric formula which converts the last name into an algorithm), complete date of birth, gender, and the last four digits of the Social Security Number (SSN). If the last four digits of the SSN are not available, four digits of zero will be used. Detailed Soundex instructions are located on the Office of AIDS' Web site at: www.dhs.ca.gov/AIDS.

The HIV reporting regulations will be published in the California Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 1, Article 3.5, Sections 2641.5 - 2643.2 and have been posted on the Office of AIDS' Web site.

The entire regulations package (which contains the Final Statement of Reasons, a listing of those who provided input during the public comment period, and the Department's response to public comments) will soon be posted on the Office of Regulations' Web site at:

www.applications.dhs.ca.gov/regulations.

For more information regarding HIV reporting, please contact your local health department or Jim Creeger, Chief, HIV/AIDS Case Registry, Office of AIDS at (916) 322-1065.

2001-2002 Sunset Review: How it Affects the Medical Board of California

(continued from page 1)

The outcome of this most recent Sunset Review resulted in Senate Bill 1950 (Figueroa), which extends the sunset dates for the Medical Board of California and the Physician Assistant Committee to July 1, 2005 and makes other changes to the Board and Committee pursuant to recommendations of the JLSRC.

Following is a synopsis of the content of the Board's Sunset Review:

Per current law, the Board was required to prepare a comprehensive written report detailing the Board's operations. This report was distributed to all members of the JLSRC in November 2001. Following the filing of the report, the JLSRC submitted 32 questions that reflected its interest in assuring that the Board functions efficiently and effectively. A Legislative Sunset Review hearing was held on December 4, 2001 at which five Medical Board members provided answers to the Committee's questions. After the Board's responses were heard, the public was invited to speak.

Testimony was presented from the California Medical Association, the Union of American Physicians and Dentists, California Citizens for Health Freedom, among other parties, including a few persons who had been disciplined by the Board. The majority of the testimony concerned alternative medicine and midwifery. The concerns raised by those who testified focused on the disciplinary actions of the Board against those practitioners who employ alternative modalities in their medical practice, and the desire for some legislative relief to allow various practices to be performed without the fear of adverse action.

Over a period of 19 days in April 2002, the Board received and responded to more than 150 additional questions that were submitted by the JLSRC. The questions focused on the Board's complaint process, investigations, interim suspension orders, accusations, public disclosure policy, section 805 (hospital peer review) reports, and reports of medical malpractice settlements and judgments.

A second Sunset Review hearing was held May 1, 2002, further issues of concern were reviewed, and the JLSRC made specific recommendations to the Board. Briefly, the recommendations were:

- #1: The Director of the Department of Consumer Affairs should appoint an Enforcement Program Monitor to the Board whose duties would include monitoring and evaluating the Board's disciplinary system and reporting findings and recommendations to the Department and the Legislature every six months.
- #2: The Board should continue efforts to improve communication with consumers who file complaints

with the Board. Over the next two years, it should continue to assess consumer satisfaction with handling of complaints and provide quarterly progress reports to the Department.

#3: The JLSRC believes that the Board's current disclosure policy, including the information available on its Web site, does not accurately reflect whether an individual physician has a history that could influence the decision a patient may make regarding his or her choice of a physician. For example, the Board's Web site does not disclose to the public what categories of information are and are NOT available, and are considered important, by the Board, medical malpractice insurers, HMOs and hospitals for investigation and disciplinary purposes. Even if the Board were to disclose these categories of information, the JLSRC believed that the Board is not obtaining sufficient information to ensure that the information is complete. The Public Information Disclosure Committee of the Board had already been addressing this question (see related article on page 1).

The JLSRC recommended that the Board be required to disclose the following additional categories of information:

- 1) Misdemeanor convictions, if substantially related to the practice of medicine.
- 2) Civil judgments, whether or not vacated by a settlement after entry of the judgment, that were not reversed on appeal; and arbitration awards arising from a claim or action for damages for death or personal injury caused by the physician and surgeon's negligence, error, or omission in practice, or rendering of unauthorized professional services. The number and amounts of settlements of these sorts of claims or actions, in the amount of \$30,000 or more, in the possession, custody, or control of the Board shall be disclosed, accompanied by the average number of settlements and average amounts for the physician's or surgeon's specialty or subspecialty and disclaimers pursuant to Business and Professions Code section 803.1(c) explaining the reasons that a physician or surgeon might settle a claim of this nature without being at fault.
- 3) Current American Board of Medical Specialty certification or equivalent board as approved by the Medical Board of California.

(Continued on page 7)

2001-2002 Sunset Review

(continued from page 6)

- 4) Approved postgraduate training.
- 5) Completed investigations that have been referred to the Attorney General for the filing of an accusation, unless it has been rejected by the Attorney General. (As the Action Report goes to press, these proposals are pending in the Legislature in SB 1950 and are subject to change.)
- #4: The JLSRC recommended increasing the Board by two public members who would be assigned to the Division of Medical Quality. The Board would then consist of 12 physicians and nine public members. The Division of Medical Quality would consist of 14 members of the

Board, six of whom would be public members.

#5: Physicians and surgeons should continue to be regulated by the Medical Board of California, but the Board should report to the JLSRC at the next scheduled JLSRC meeting on its progress in implementing these recommendations.

The Department of Consumer Affairs and the Medical Board appreciate the importance of the Sunset Review process. As the Board's mission is to protect consumers through the proper licensing of physicians and surgeons and vigorous, objective enforcement of the Medical Practice Act, periodic review of the Board's systems and operations is beneficial to promote greater effectiveness.

Board Proposes New Information Disclosure Policy

(continued from page 1)

- Malpractice settlement information reported to the Board on all licensees. This information would be provided in context, given the physician's specialty and size of the award so the public has a picture of how the licensee's malpractice track record fits into the context of that medical specialty area.
- Misdemeanor convictions reported to the Board that are substantially related to the qualifications, functions and duties of a physician.
- Any public information in the possession of the Board that may have an adverse impact on the safe delivery of medical care by a physician; e.g., physicians required to register as sex offenders.
- The names of physicians whose fully investigated cases have been referred to the Office of the Attorney General for the filing of a formal accusation.

NOTE: These provisions have been included in SB 1950 (Figueroa). As the *Action Report* goes to press, the provisions are under discussion in the Legislature. The final form of disclosure is subject to legislative approval.

The Board views this vote as one important step in achieving its mission of consumer protection through public education. While the Board recognizes the controversial nature of these proposals, it regards as critical that it meets its first obligation — protection of healthcare consumers by providing them with information that is vital to making important healthcare choices.

The Board understands and appreciates that some in the physician community are particularly concerned about the Board's proposal to disclose malpractice settlement information on its Web site. The information that would be provided *already is public record*; the Board's proposal simply makes such information available in a consolidated location rather than by requiring access of the civil index at multiple county clerks offices or superior courts to locate the same information.

Disclosure of malpractice settlements via the California Medical Board's Web site is an idea whose time is well upon us. Ten other states already provide such information. In this era of increasing information disclosure, California is in fact behind the pack. A study, published in January 2002 by the Pew Internet and American Life Project, found that the Internet has had a "significant" impact on healthcare decisions for more than 15 million Americans in the last two years. As use of the Internet continues to grow, so will the potential for such an impact, and the need for credible information sources.

The Board now looks forward to continuing to work cooperatively with the Legislature, consumers, physicians, insurers, and other interested parties to effectively implement these changes and find additional ways to ensure the public receives accurate, timely and useful information when making decisions about healthcare services from California's physicians.

Physicians are encouraged to visit the Board's Web site at www.medbd.ca.gov (on the home page "Find Your Doctor" and "Check Your Doctor Online") and examine their record for accuracy. Any corrections should be reported to the Board's Division of Licensing via fax: (916) 263-2944.

Lyme Disease Case Numbers Increase Nationally Vaccine Removed From Market

California Department of Health Services

The October 2001 *Action Report* included an update article on the epidemiology of Lyme disease (LD) in California. This addendum alerts physicians to two recent announcements pertinent to this tick-borne disease.

In January 2002, the Centers for Disease Control and Prevention (CDC) reported that the total number of LD cases reported in 2000 (17,730) increased by 8%

compared to 1999 (16,273). The reported incidence of Lyme disease (per 100,000 population) increased nationwide by about 60% between 1991 (3.96) and 2000 (6.3). In California, despite documented epidemiological elements favorable for the transmission of LD and an expanding population increasingly in contact with natural environments, the yearly number of reported cases has decreased from 265 in 1991 to fewer than 100 cases each year since 1995.

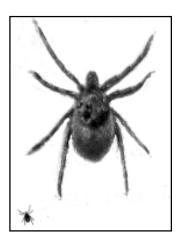
Nevertheless, Lyme disease remains an important vector-borne disease in California because the potential risk of exposure to infected nymphal western black-legged ticks can be moderate to high in some localities.

Title 17 of the California Code of Regulations requires that physicians report all newly diagnosed cases of LD to their local health department. In addition to LD, ticks in California

can potentially transmit other disease agents. These diseases are also reportable and include ehrlichiosis, Rocky Mountain spotted fever, babesiosis, tularemia, and relapsing fever.

In February 2002, GlaxoSmithKline Pharmaceuticals announced the removal of LYMErixä vaccine, citing poor sales. Tick-bite prevention remains the cornerstone for reducing the risk of exposure to Lyme and other tickborne diseases. Physicians are encouraged to remind patients to take precautions, such as wearing light-colored clothing and using tick repellents, while in areas with ticks. Prompt removal of ticks (<24 hours) can prevent transmission of the etiologic agent of LD. The tick should be removed by grasping it with fine-pointed tweezers and pulling it gently but firmly straight out.

For information on Lyme and other vector-borne diseases



Western black-legged tick, shown actual size at left.

Source: California Department of Health Services in California, please visit the California Department of Health Services (DHS) Division of Communicable Disease Control Web site: www.dhs.ca.gov/ps/ dcdc/html/disbindex.htm, or contact DHS at (916) 324-3738.

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West Nile Virus Surveillance in California

By Evelyn Tu, Project Coordinator California Department of Health Services, Division of Communicable Disease Control

The California Department of Health Services (DHS) seeks the participation of physicians and other healthcare providers in an effort to monitor West Nile (WN) virus in California. WN virus has not yet been detected in California. A strong surveillance system is needed to track West Nile activity, and healthcare providers play an important role in the detection of WN virus. The following recommendations and resources should be useful in the diagnosis and surveillance for WN virus.

As the arbovirus season is beginning, it is critical that healthcare providers immediately report all suspected cases of viral encephalitis, viral meningitis, and Guillain-Barré Syndrome to the local health departments. Local health officials will help to coordinate testing with the DHS. Local health departments will have all the appropriate forms and information needed to refer the case to DHS for testing.

WN virus is an arbovirus that was first isolated in Uganda in 1937. In the flavivirus family, WN virus is one of the most widespread flaviviruses and is endemic in Africa, Europe, Asia, and the Middle East. It is closely related to St. Louis encephalitis virus, Kunjin virus, and Japanese encephalitis virus. WN virus was first detected in the Western Hemisphere in 1999 in the New York area and is spreading at an alarming rate. Since 1999, it has spread westward to 28 states. In 2001, 66 human cases were identified with 9 deaths.

The virus is transmitted to humans by the bite of an infected mosquito. Infection with WN virus may have varying clinical presentations. Most people who are infected with WN virus have *no symptoms*. For approximately every 150 infected persons, only 1 person will have clinical disease. Some cases may result in a *mild febrile illness*. Signs include fever, headache, body aches, and occasionally with skin rash and swollen lymph nodes.

In the West Nile outbreak in New York City, clinical features included encephalitis with muscle weakness (39%), encephalitis without muscle weakness (22%), and aseptic meningitis (32%). *Aseptic Meningitis* cases should also be considered for WN virus infection. More severe infections may result in *encephalitis*. Symptoms include headache, fever, disorientation, coma, tremors, seizures, muscle weakness, and rarely, death. Infection may also result in an *atypical Guillain-Barré syndrome*. The elderly are at highest risk of disease and mortality.

Surveillance for WN virus in California includes several components: human case surveillance, mosquito testing and control, veterinary equine surveillance, sentinel chicken testing, and dead bird surveillance and testing. Veterinarians should refer cases of non-human mammalian encephalitis to the Veterinary Public Health Section of the Department of Health Services. Dead birds lacking obvious signs of trauma should be reported to DHS' toll-free number (877) WNV-BIRD. Mosquito pools are collected and tested for various arboviruses, including WN virus. Statistics and information on WN virus are available at http://westnile.ca.gov.

Human testing and surveillance are provided through DHS. Since 1999, California's WN virus human surveillance focused on encephalitis cases. The California Encephalitis Project currently tests for many agents, including enterovirus, herpes simplex virus, Epstein-Barr Virus, and arboviruses (St. Louis Encephalitis, Western Equine Encephalitis, and WN virus).

In 2002, testing will be expanded to include adults with aseptic meningitis or atypical Guillain-Barré Syndrome. Cases of encephalitis may be included in the California Encephalitis Project upon further consultation with the clinician. Expanded testing is available as cases are evaluated. Aseptic meningitis cases will be tested for both arboviruses and enteroviruses. Guillain-Barré cases will be tested for both arboviruses and herpes viruses.

Testing is available on both cerebrospinal fluid (CSF) and sera through DHS. The most sensitive screening test for WN virus is the IgM-capture enzyme linked immunosorbent assay (ELISA). Serologic testing will be done on all cases. Polymerase chain reaction (PCR) will only be done on select cases.

For further information, you may contact Evelyn Tu, Viral and Rickettsial Disease Laboratory, CDHS, 850 Marina Bay Parkway, Richmond, CA 94804. (510) 307-8606, or e-mail: etu@dhs.ca.gov.

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New 2002 STD Treatment Guidelines

By Gail Bolan, M.D., Chief, STD Control Branch California Department of Health Services

In May 2002, the Centers for Disease Control and Prevention (CDC) issued updated STD treatment guidelines, the first time these evidence-based guidelines have been revised since 1998. This article will highlight the major changes called for by the new guidelines. A two-page summary table of the recommended treatment regimens is included as an insert in this edition of the Action Report.* The entire 2002 Treatment Guidelines can be found at www.cdc.gov/std/treatment.

Resistant Gonorrhea in California

While most of the guidelines apply to the entire nation, due to rising levels of fluoroquinolone-resistant gonorrhea in California, the California Department of Health Services has announced new treatment guidelines for gonorrhea. These are based on the CDC's national recommendations.

Until recently, resistant gonorrhea has largely been concentrated among patients who acquired their infections in Asia or the Pacific, including Hawaii. According to data from the national Gonococcal Isolate Surveillance Project (GISP), which actively monitors antimicrobial susceptibility of isolates from male patients with urethral infections attending STD clinics in San Francisco, Orange County, Long Beach and San Diego, the level of resistance to fluoroquinolones has rapidly increased in the past four years. In 1998, only 0.2% of cases were resistant; this rose to 0.6% in 1999, 1.1% in 2000, 2.7% in 2001, and to nearly 7% in the first quarter of 2002.

In response to this increase, the California Department of Health Services Sexually Transmitted Disease Control Branch and the California STD Controllers Association have issued the following guidelines:

- 1) Avoid the use of fluoroquinolones (ciprofloxacin, ofloxacin, and levofloxacin) to treat gonorrhea in California.
- 2) Instead, antibiotics of choice to treat uncomplicated gonococcal infections of the cervix, urethra, and rectum include:
 - Ceftriaxone 125 mg intramuscularly in a single dose, *or*
 - ♦ Cefixime 400 mg orally in a single dose
- 3) The antibiotic of choice to treat gonococcal infections of the pharynx:
 - Ceftriaxone 125 mg intramuscularly in a single dose
 - ♦ Cefixime is not recommended by the CDC to treat

pharyngeal infections because of a relative lack of published data demonstrating efficacy. However, providers may chose cefixime because of the ease of oral administration. If cefixime is used to treat pharyngeal infection, a test-of-cure (TOC)¹ is recommended.

- 4) For patients with significant anaphylaxis-type (IgEmediated) allergies to penicillin, where the use of cephalosporins is a concern or patients with allergies to cephalosporins:
 - **Spectinomycin** 2 g intramuscularly in a single dose, *or*
 - ♦ **Fluoroquinolone** with test-of-cure (TOC)¹, *or*
 - ♦ Azithromycin 2 g orally in a single dose with testof-cure (TOC)¹
- 5) For the treatment of pelvic inflammatory disease (PID), the CDC guidelines should be followed. However, if the gonorrhea test is positive in a patient receiving a fluoroquinolone regimen, a test-of-cure (TOC)¹ should be performed.
- 6) Co-treatment of chlamydia for patients with gonorrhea is still recommended unless chlamydia infection has been ruled out using sensitive test technology, e.g., a nucleic acid amplification test (NAAT). Recommended antibiotics for the treatment of chlamydial infection include:
 - Azithromycin (1 g orally in a single dose), or
 Doxycycline (100 mg orally twice a day for 7
- days). Clinicians need to be alert to the failure of any patient to respond to any recommended gonorrhea therapy. If clinicians encounter a treatment failure after a recommended regimen in the absence of reexposure, they need to take necessary steps to culture the organism.

Prevention of STDs

The 2002 guidelines encourage healthcare providers to focus on risk assessment and counseling, in addition to the clinical aspects of STD control, screening, and treatment. Providers are encouraged to use client-centered counseling approaches. In particular, under the new section on men who have sex with men, risk assessment of all male patients is highlighted. More information on risk assessments and client-centered counseling is available at www.stdhivtraining.org.

(Continued on page 11)

HEALTH NEWS

New 2002 STD Treatment Guidelines (continued from page 10)

Recent studies have shown that nonoxynol-9, a commonly used spermicide contraceptive, can cause genital lesions in the vagina and may damage the lining of the rectum, increasing the risk of HIV transmission. Therefore, the new guidelines recommend that spermicides, especially those that contain N-9, should not be used for STD and HIV prevention or for use during anal intercourse; condoms lubricated with N-9 are more expensive and offer no additional protection, so are no longer recommended.

Men Who Have Sex With Men

Increases in unprotected sex, syphilis, and gonorrhea have all been documented among men who have sex with men in California. The new STD guidelines recommend annual screening for STDs, including HIV, chlamydia (anal and

urethral), syphilis, and gonorrhea (anal, pharyngeal and urethral), as well as vaccination against hepatitis A and B. If patients report multiple anonymous partners, or sex in conjunction with illicit drugs, they should be screened at 3 to 6 month intervals.

Pregnant Women

It is now recommended that all pregnant women be screened for chlamydia at the first pre-natal visit. For those women at higher risk of chlamydia (less than 25 years of age or if they report new or multiple partners) a second chlamydia screening test should be obtained at the beginning of the third trimester. The 2002 guidelines encourage healthcare providers to focus on risk assessment and counseling, in addition to the clinical aspects of STD control, screening, and treatment. Providers are encouraged to use client-centered counseling approaches.

Pelvic Inflammatory Disease

The new guidelines add levofloxacin, 500 mg po or IV qd x 14 days as a recommended regimen that can be used instead of ofloxacin if necessary. However, in California, if gonoccocal PID is documented, and fluoroquinolones were used for PID treatment, then a test of cure is recommended to rule out resistant gonorrhea infection.

Vaginal Infections

Trichomoniasis:

To treat trichomoniasis, the guidelines stress that metronidazole gel is ineffective and should not be used. The only recommended regimen is oral metronidazole. However, if infections are nonresponsive to therapy, providers should consult with the CDC at (404) 639-8371

> because of concerns of emerging metronidazole-resistant trichomoniasis in the United States.

Bacterial Vaginosis:

Prior to abortions, hysterectomies, or other invasive procedures, providers should consider screening and treating for bacterial vaginosis to reduce upper genital tract infections and complications. The guidelines conclude that clindamycin regimens are somewhat less effective than metronidazole regimens for bacterial vaginosis treatment. When prescribing metronidazole gel, dosing should be changed from BID to qd. Oral clindamycin is now a

Women who have had a preterm delivery should be screened for bacterial vaginosis during the first trimester of any subsequent pregnancies. However, routine screening of all pregnant women for either bacterial vaginosis or trichomoniasis is not recommended.

Chlamydia

The CDC has expanded its recommendation for chlamydia screening among younger women. Providers should annually screen sexually active adolescent girls (19 years and younger), and young adult women (20 to 25 years old). All women with chlamydia infections should be rescreened three to four months after treatment is completed, or whenever they next present for care, since reinfection confers an elevated risk for pelvic inflammatory disease.

recommended regimen for treating bacterial vaginosis in pregnant women.

Vulvovaginal Candidiasis:

The guidelines provide a distinction between complicated and uncomplicated vulvovaginal candidiasis (VVC). For uncomplicated VVC, butoconazole sustained-release intravaginal preparation as a single application has been added to the recommended regimen. Vaginal cultures should be obtained in women with recurrent VVC to confirm diagnosis and to identify species.

Each individual episode of recurrent VVC caused by *Candida albicans* should be treated with 7-14 days of topical therapy or a 150-mg oral dose of fluconazole

(Continued on page 14)

California STD Treatment Guidelines For Adults and Adolescents 2002

These guidelines for the treatment of patients with STDs reflect the 2002 CDC STD Treatment Guidelines and the Region IX Infertility Clinical Guidelines. The focus is primarily on STDs encountered in office practice. These guidelines are intended as a source of clinical guidance; they are not a comprehensive list of all effective regimens. To report STD infections; request assistance with confidential notification of sexual partners of patients with syphilis, gonorrhea, chlamydia or HIV infection; or to obtain additional information on the medical management of STD patients, call the County Health Department. The California STD/HIV Prevention Training Center is an additional resource for training and consultation in the area of STD clinical management and prevention, at (510) 883-6600 or **www.stdhivtraining.org**.

DISEASE	RECOMMENDED REGIMENS	DOSE/ROUTE	ALTERNATIVE REGIMENS
CHLAMYDIA			
Uncomplicated Infections Adults/Adolescents ¹	 Azithromycin or Doxycycline² 	1 g po 100 mg po bid x 7 d	 Erythromycin base 500 mg po qid x 7 d or Erythromycin ethylsuccinate 800 mg po qid x 7 d or Ofloxacin² 300 mg po bid x 7 d or Levofloxacin² 500 mg po qd x 7 d
Pregnant Women ³	 Azithromycin or Amoxicillin or Erythromycin base 	l g po 500 mg po tid x 7 d 500 mg po qid x 7 d	 Erythromycin base 250 mg po qid x 14 d or Erythromycin ethylsuccinate 800 mg po qid x 7 d or Erythromycin ethylsuccinate 400 mg po qid x 14 d
GONORRHEA ⁴	The second s	The second second second second	the second s
Uncomplicated Infections Adults/Adolescents	 Cefixime⁵ or Ceftriaxone plus⁴ A chlamydia recommended regimen listed above 	400 mg po 125 mg IM	 Spectinomycin ^{4,5} 2 g IM or Ciprofloxacin^{2,4,6} 500 mg po or Ofloxacin^{2,4,6} 400 mg po or Levofloxacin^{2,4,6} 250 mg po or Azithromycin⁶ 2 g po
Pregnant Women	 Ceftriaxone or Cefixime⁵ plus⁴ A chlamydia recommended regimen listed above 	125 mg IM 400 mg po	• Spectinomycin ^{4,5} 2 g IM
PELVIC INFLAMMATORY DISEASE ⁷	Parenteral ⁸ Either Cefotetan or Cefoxitin plus Doxycycline² or Clindamycin plus Gentamicin Oral/IM Either Ceftriaxone or Cefoxitin with Probenecid plus Doxycycline² 	2 g IV q 12 hrs 2 g IV q 6 hrs 100 mg po or IV q 12 hrs 900 mg IV q 8 hrs 2 mg/kg IV or IM followed by 1.5 mg/kg IV or IM q 8 hrs 250 mg IM 2 g IM 1 g po 100 mg po bid x 14 d	 Parenteral⁸ Either Ofloxacin^{2,9} 400 mg IV q 12 hrs or Levofloxacin^{2,9} 500 mg IV qd plus Metronidazole 500 mg IV q 8 hrs or Ampicillin/Sulbactam 3 g IV q 6 hrs plus Doxycycline² 100 mg po or IV q 12 hrs Oral Either Ofloxacin^{2,9} 400 mg po bid x 14 d or Levofloxacin^{2,9} 500 mg po QD x 14 d plus Metronidazole 500 mg po bid x 14 d
MUCOPURULENT CERVICITIS ⁷	Azithromycin or Doxycycline ²	1 g po. 100 mg po bid x 7 d.	 Erythromycin base 500 mg po qid x 7 d or Erythromycin ethylsuccinate 800 mg po qid x 7 d or Ofloxacin^{2,9} 300 mg po bid x 7 d or Levofloxacin^{2,9} 500 mg po qd x 7 days
NONGONOCOCCAL URETHRITIS ⁷	 Azithromycin or Doxycycline 	1 g po 100 mg po bid x 7 d	 Erythromycin base 500 mg po qid x 7 d or Erythromycin ethylsuccinate 800 mg po qid x 7 d or Ofloxacin 300 mg po bid x 7 d or Levofloxacin 500 mg po qd x 7 days
EPIDIDYMITIS ⁷	Likely due to Gonorrhea or Chlamydia • Ceftriaxone plus Doxycycline Likely due to enteric organisms • Ofloxacin ⁹ or • Levofloxacin ⁹	250 mg IM 100 mg po bid x 10 d 300 mg po bid x 10 d 500 mg po qd x 10 d	
TRICHOMONIASIS ¹⁰	Metronidazole	2 g po	* Metronidazole 500 mg po bid x 7 d
BACTERIAL VAGINOSIS			
Adults/Adolescents.	 Metronidazole or Clindamycin cream¹¹ or Metronidazole gel 	500 mg po bid x 7 d 2%, one full applicator (5g) intravaginally qhs x 7 d 0.75%, one full applicator (5g) intravaginally qd x 5 d	 Metronidazole 2 g po or Clindamycin 300 mg po bid x 7 d or Clindamycin ovules 100 g intravaginally qhs x 3 d
Pregnant Women	Metronidazole or Clindamycin	250 mg po tid x 7 d 300 mg po bid x 7 d	
CHANCROID	Azithromycin or Ceftriaxone or Ciprofloxacin ²	1 g po 250 mg IM 500 mg po bid x 3 d	Erythromycin base 500 mg po tid x 7 d
LYMPHOGRANULOMA VENEREUM	Doxycycline ²	100 mg po bid x 21 d	 Erythromycin base 500 mg po qid x 21 d or Azithromycin 1 g po qd x 21 d

1. Annual screening for women age 25 years or younger. Nucleic Acid Amplification Tests (NAATS) are recommended. Women with chlamydia should be rescreened 3-4 months after treatment.

2. Contraindicated for pregnant and nursing women.

- 3. Test-of-cure follow-up is recommended because the regimens are not highly efficacious (Amoxicillin and Erythromycin) or the data on safety and efficacy are limited (Azithromycin).
- 4. Co-treatment for chlamydia infection is indicated unless chlamydia infection has been ruled out using sensitive technology or if 2g Azithromycin dose is used.
- 5. Not recommended for pharyngeal gonococcal infection.
- 6. Test-of-cure follow-up is recommended to ensure patient does not have an untreated infection from a resistant gonorrhea strain.

7. Testing for gonorrhea and chlamydia is recommended because a specific diagnosis may improve compliance and partner management and these infections are reportable by CA State Law.

- 8. Discontinue 24 hours after patient improves clinically and continue with oral therapy for a total of 14 days.
- 9. If gonorrhea is documented, test-of-cure follow-up is recommended to ensure patient does not have untreated resistant gonorrhea infection.
- 10. If reinfection is ruled out and persistence of trichomonas is documented, evaluate for metronidazole-resistant T. vaginalis. Referral to CDC at (404) 639-8371.

11. Might weaken latex condoms and diaphragms because oil-based.

California STD Treatment Guidelines For Adults and Adolescents 2002

DISEASE	RECOMMENDED REGIMENS	DOSE/ROUTE	ALTERNATIVE REGIMENS
HUMAN PAPILLOMAVIRU			
External Genital/ Perianal Warts	 Patient Applied Podofilox¹² 0.5% solution or gel or Imiquimod¹³ 5% cream Provider Administered Cryotherapy or Podophyllin¹² resin 10%-25% in tincture of benzoin or Trichloroacetic acid (TCA) or Bichloroacetic acid (BCA) 80%- 90% or Surgical removal 		Alternative Regimen • Intralesional interferon or • Laser surgery
Mucosal Genital Warts	 Cryotherapy or TCA or BCA 80%-90% or Podophyllin¹² resin 10%-25% in tincture of benzoin or Surgical removal 	Vaginal, urethral meatus, and anal Vaginal and anal Urethral meatus only Anal warts only	
HERPES SIMPLEX VIRUS		And waits only	
First Clinical Episode of Herpes	Acyclovir or Acyclovir or Famciclovir or Valacyclovir	400 mg po tid x 7-10 d 200 mg po 5/day x 7-10 d 250 mg po tid x 7-10 d 1 g po bid x 7-10 d	
Episodic Therapy for Recurrent Episodes	Acyclovir or Acyclovir or Acyclovir or Famciclovir or Valacyclovir or Valacyclovir or	400 mg po tid x 5 d 200 mg po 5/day x 5 d 800 mg po bid x 5 d 125 mg po bid x 5 d 500 mg po bid x 3-5 d 1 g po qd x 5 d	
Supressive Therapy	Acyclovir or Famciclovir or Valacyclovir or Valacyclovir	400 mg po bid 250 mg po bid 500 mg po qd 1 g po qd	
HIV Infection ¹⁵		1 01 1	
Episodic Therapy for Recurrent Episodes	Acyclovir or Acyclovir or Famciclovir or Valacyclovir	400 mg po tid x 5-10 d 200 mg po 5/day x 5-10 d 500 mg po bid x 5-10 d 1 g po bid x 5-10 d	
Suppressive Therapy	Acyclovir or Fanciclovir or Valacyclovir	400-800 mg po bid-tid 500 mg po bid 500 mg po bid	
SYPHILIS			
Primary, Secondary, and Early Latent	Benzathine penicillin G	2.4 million units IM	 Doxycycline^{2,16} 100 mg po bid x 2 weeks or Tetracycline^{2,16} 500 mg po qid x 2 weeks or Ceftriaxone¹⁶ 1 g IM or IV qd x 8-10 d or Azithromycin¹⁶ 2 g po
Late Latent and Unknown duration	Benzathine penicillin G	7.2 million units, administered as 3 doses of 2.4 million units IM, at 1-week intervals	• Doxycycline ² 100 mg po bid x 4 weeks or • Tetracycline ² 500 mg po qid x 4 weeks
Neurosyphilis ¹⁷	Aqueous crystalline penicillin G	18-24 million units daily, administered as 3-4 million units IV q 4 hrs x 10-14 d	 Procaine penicillin G, 2.4 million units IM qd x 10-14 d plus Probenecid 500 mg po qid x 10-14 d or Ceftriaxone¹⁶ 2 g IM or IV qd x 10-14 d
Pregnant Women ¹⁸	C Descarthles contraits et	La succession of the second	
Primary, Secondary, and Early Latent Late Latent	Benzathine penicillin G Benzathine penicillin G	2.4 million units IM 7.2 million units, administered as	None
and Unknown duration		3 doses of 2.4 million units IM, at 1-week intervals	
Neurosyphilis ¹⁷	Aqueous crystalline penicillin G	18-24 million units daily, administered as 3-4 million units IV q 4 hrs x 10-14 d	 Procaine penicillin G, 2.4 million units IM q d x 10-14 d plus Probenecid 500 mg po qid x 10-14 d
HIV Infection	A Dependence and stilling C	Cox activity and the second	2 10 100
Primary, Secondary and Early Latent Late Latent, and	Benzathine penicillin G Benzathine penicillin G	2.4 million units IM 7.2 million units, administered as	Doxycycline ^{2,16} 100 mg po bid x 2 weeks or Tetracycline ^{2,16} 500 mg po qid x 2 weeks None
Unknown duration ¹⁸ with normal CSF Exam		3 doses of 2.4 million units IM, at 1-week intervals	· Ivone
Neurosyphilis ¹⁷	Aqueous crystalline penicillin G	18-24 million units daily, administered as 3-4 million units IV q 4 hrs x 10-14 d	 Procaine penicillin G, 2.4 million units IM q d x 10-14 d plus Probenecid 500 mg po qid x 10-14 d

12. Contraindicated during pregnancy.

13. Safety in pregnancy has not been well established.

14. Counseling about natural history, asymptomatic shedding, and sexual transmission is an essential component of herpes management.

15. If lesions persist or recur while receiving antiviral treatment, HSV resistance should be suspected and a viral isolate should be obtained for sensitivity testing.

16. Because efficacy of these therapies has not been established and compliance of some of these regimens difficult, close follow-up is essential. If compliance or follow-up cannot be ensured, then patient should be desensitized and treated with benzathine penicillin.

17. One dose of 2.4 million units of Benzathine penicillin G recommended at completion of neurosyphilis therapy.

18. Patients allergic to penicillin should be treated with penicillin after desensitization.



New 2002 STD Treatment Guidelines

(continued from page 11)

repeated 3 days later to achieve mycologic remission before initiating a maintenance antifungal regimen. Recommended regimens for maintenance should be continued for 6 months, and include clotrimazole (500 mg dose vaginal suppositories once weekly), ketoconazole (100 mg dose once daily), fluconazole (100-150 mg dose once weekly), and intraconazole (400 mg dose once monthly or 100 mg dose once daily).

For non-albicans VVC, the first-line therapy should be longer (7-14 days) with a non-fluconazole azole drug. If recurrence occurs, 600 mg of boric acid in a gelatin capsule is recommended, administered vaginally once daily for 2 weeks. Another option is flucytosine; however, referral to a specialist is advised. If non-albicans VVC continues to recur, a maintenance regimen of 100,000 units of nystatin delivered daily via vaginal suppository has been successful.

Syphilis

Ceftriaxone 1 gm IV/IM qd x 8-10 days or azithromycin 2 g in a single dose has been added after doxycycline and tetracycline as possible alternative therapies for early syphilis but the importance of clinical and serologic followup is stressed because efficacy data are limited; also, use in HIV-positive patients has not been studied.

Serofast nontreponemal tests in early syphilis with a normal CSF should be retreated with Benzathine Penicillin G 2.4 mu IM weekly for three weeks. After this treatment, if the serologic titer remains serofast, no further intervention is warranted unless the titer has a sustained four-fold increase for longer than two weeks. These patients should be followed with a serologic test for syphilis on an annual basis to ensure the serofast titer does not increase.

A new alternative treatment for neurosyphilis patients with a non-IgE mediated penicillin allergy is ceftriaxone 2 gm IV/ IM qd x 10 to 14 days. Again, because data on efficacy are limited, close follow-up is essential.

Herpes

New serologic testing procedures may help providers diagnose and manage HSV-2. The new guidelines include an expanded discussion of male condoms, transmission risk, type-specific serologic testing, and the risk of neonatal infection in pregnant women.

Better-defined doses of acyclovir to use in HIV-infected patients have been added to these guidelines. Recommended regimens for episodic therapy of recurrent infection in HIVpositive individuals include acyclovir 200 mg po five times a day, or 400 mg po tid for 5 to 10 days, or famciclovir 500 mg po bid for 5 to 10 days, or valacyclovir 1 g po bid for 5 to The neonatal herpes treatment recommendations have been changed to acyclovir 20 mg/kg IV q 8 hours for 21 days for disseminated and CNS disease and 14 days for disease limited to skin and mucous membranes.

Genital Warts

The new guidelines include a new emphasis on education and counseling, and recommend that providers educate patients that condoms may provide only limited protection. Podophyllin resin has been removed as a recommended treatment for vaginal warts but podofilox and imiquimod have been added for distal meatal warts. HPV nucleic acid testing may be useful in the triage of women with ASCUS pap tests.

Sexual Assault

Chlamydia nucleic acid amplification tests (NAATs) may now be used as a test for legal evidence in adults and adolescents. These should be confirmed with a second FDA-approved NAAT with a different chlamydia nucleic acid target. In children, chlamydia NAATs may be used as an alternative test for legal evidence if chlamydia culture is not available but confirmation with a second FDA-approved NAAT that targets a different sequence is essential. Postexposure prophylaxis should be considered in cases where the risk of HIV exposure in the assault appears to be significant.

Questions or concerns regarding these guidelines should be addressed to your local STD Controller or the California STD/HIV Prevention Training Center at (510) 883-6600 or by writing:

STD/HIV Prevention Training Center 1947 Center Street, Suite 201 Berkeley, CA 94704

*Additional copies of this article and the two-page summary table may be found at www.stdhivtraining.org or by calling the STD/HIV Prevention Training Center at (510) 883-6600.

Note:

¹ Ideally, the test-of-cure should be both a culture test so that the isolate can be tested for antimicrobial susceptibility and a nucleic acid amplification test to maximize sensitivity. If only a non-culture test is used, positive results should be followed up with a culture and susceptibility testing before the patient receives an alternative treatment.



News From the U.S. Food and Drug Administration

OK to Approve Certain Pharmaceuticals Based on Animal Efficacy Data

The Food and Drug Administration has amended its regulations so that certain human drugs and biologics intended to reduce or prevent serious or life-threatening conditions may be approved for marketing based on evidence of effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible. The agency is taking this action because it recognizes the need for adequate medical responses to protect or treat individuals exposed to lethal or permanently disabling toxic substances or organisms.

This new rule will apply when adequate and well-controlled clinical studies in humans cannot be ethically conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers. Products evaluated for effectiveness under this rule will be evaluated for safety under preexisting requirements for establishing the safety of new drug and biological products. For more information contact FDA Public Affairs, Northern California (510) 337-6736 or Southern California (949) 798-7611.

Recent Device Approvals

- SIR-Spheres[®] consists of tiny spheres of yttrium-90, a radioactive substance, that are injected into the liver to treat cancer.
- Lorad Digital Breast Imager (LDBI) digital mammography produces pictures of the breast using xrays. Instead of film, this process uses detectors that change the x-rays into electrical signals, which are then converted to an image. Digital mammography is used for both screening and diagnosis.
- QuickSeal Arterial Closure System stops bleeding in the femoral artery after cardiac catheterization.
- CONTAK CD® system implantable cardioverter defibrillator (ICD) that also delivers cardiac resynchronization therapy (CRT) for certain patients with advanced heart failure.

For more information:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/MDA/mda-list.cfm?list=1.

Reuse: Change in enforcement approach to Hospital Single Use Devices reprocessors

FDA has begun to inspect hospital Single Use Devices (SUD) reprocessors. These inspections will cover all three classes (I, II, and III) of medical devices. The change in FDA's reuse policy concerns the focus and possible outcomes of these inspections. The focus will be to assess hospitals' compliance with the Agency's post-market regulatory requirements. However, the Agency does not intend to take enforcement actions against hospitals if they are found not to be in compliance with these requirements. Rather, FDA plans to spend the next year educating hospitals on complying with the post-market requirements.

This policy will remain in effect until August 14, 2002, provided that the hospitals are taking steps to correct the violations noted during the inspection and that the violations do not pose a serious public health risk.

This revised policy does not apply to third party reprocessors.

For more information: www.fda.gov/cdrh/reuse/reuse-letter-092501.html.

Consumers Needed to Serve on Advisory Panels

Physicians: If you are aware of a consumer who might be interested, please share this information.

The Center for Devices and Radiological Health (CDRH) is seeking qualified consumers to serve as nonvoting representatives on the following Medical Device Panels:

Medical Devices Panels	Date Needed
Anesthesiology and Respiratory Therapy	Immediately
Gastroenterology and Urology	Jan. 1, 2003
General Hospital and Personal Use	Jan. 1, 2003
Immunology	Mar. 1, 2003
Microbiology	Mar. 1, 2003
Molecular and Clinical Genetics	June 1, 2003
Radiological	Feb. 1, 2003

Advisory panels consist of individuals who are recognized as experts in their field from many different sectors including medical professionals, scientists and researchers, lawyers, industry leaders, academicians and consumer advocates.

For additional information on the advisory committee process, you can access the June 12, 2002 Federal Register notice at: www.fda.gov/OHRMS/DOCKETS/98fr/ 061202a.htm.

If you have consumer affiliations and are interested in serving on one of the medical device panels, please submit a curriculum vitae or a resume as soon as possible to: Linda Ann Sherman, Advisory Committee and Oversight Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or e-mail to: LSHERMAN@OC.FDA.GOV.

Safe Medication Management for the Elderly Patient

By Cheryl Phillips, M.D.

Medical Director, Skilled Nursing and Chronic Care, Sutter Health

A recent JAMA article (December 12, 2001) defined inappropriate medication use as a "major patient safety concern, especially for the elderly population." This paper followed recommendations of a consensus panel published in the Archives of Internal Medicine (July 28, 1997) that identified high-risk drugs and common drug-drug interactions in patients over age 65. (Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. Archives of Internal Medicine 1997; 157:1531-6.) Why the concern for medication use in this population? The elderly are extensive users of both prescription and over-the-counter medications. Although they represent 16 percent of the population, they use approximately one-third of all medications (Health Affairs, 1995). Furthermore, the elderly are 7 times more likely to experience an adverse drug reaction and account for 50 percent of all medication-related deaths.

What makes the elderly patient different from a younger adult when it comes to prescribing medications? As we reflect back to basic science training, we remember the four general pharmacokinetic factors that contribute to drug clearance: absorption; metabolism; distribution and excretion. Absorption is primarily impacted in two ways. First, aging typically results in decreased gastric acidity that can reduce drug absorption of those drugs that require an acidic environment. Secondly, the small intestines have a decrease in the mucosal surface area of about 30 percent. Overall, these result in only a small overall impact on medication management. Metabolism is primarily a function of the liver. Decreased hepatic blood flow, decreased liver size and decreased first-pass metabolism that occur with aging directly impacts the metabolism of many drugs such as calcium channel blockers and tricyclic antidepressants.

Distribution is significantly affected by the physiologic changes in aging. Patients over age 65 typically have a decrease in total body water by 10-15 percent and an average decrease in lean body mass of 12 percent in females and 18 percent in males. The result is an increase in the percent of total body fat, an increased storage of lipophillic drugs and a decreased volume of distribution (Vd) for water-soluble drugs. Furthermore, chronically ill elders typically have a decrease in serum albumin levels of 15-25 percent which leads to an increased free fraction of acidic drugs such as phenytoin and warfarin. The change in renal excretion and clearance is determined to be the most important cause of adverse drug events in the elderly. Agerelated changes in the kidney include decreases in renal size, glomerular filtration rate, number of functioning glomeruli and renal blood flow. It is critical to estimate a

patient's creatinine clearance, corrected for age, before determining the dose of a renally-excreted drug such as digoxin.

When addressing "suboptimal" prescribing patterns for the elderly, there are three categories to address: 1) overuse or polypharmacy; 2) inappropriate medication choice or indication; 3) underuse of appropriate medications. Polypharmacy can either be defined by an actual count or as a measure of more medications given than are clinically appropriate for a specific patient. Community-living American seniors take an average of 2.7 to 4.2 prescription medications. The risk that an elder will experience an adverse drug event doubles when the number of meds increases from 1 to 4 drugs. This risk climbs to a 14-fold risk for those taking 7 meds! A frequent driver behind polypharmacy is the practice of treating a side effect of one medication with another drug. Inappropriate medications are those that pose a high risk for a given patient, when another (or no medication) would be safer. Common highrisk categories that warrant careful consideration before prescribing include: long-acting benzodiazepines; certain analgesics (i.e. propoxyphene and meperidine); anticholinergic medications (both prescription and over-thecounter); and cardiac glycosides (ex: digoxin). "Underutilization" refers to those medications that have evidence to support their use, and yet may be overlooked in an elderly population. A recent study in JAMA (Allison, 2000) reviewed 114,000 admissions and found that the likelihood of ACE inhibitors ordered at the time of hospital discharge for a patient with a diagnosis of congestive heart failure was 58-63 percent. In the same light, the use of Betablockers post myocardial infarction was only 39-48 percent.

Elders typically bear the burden of chronic illness and therefore take the greatest number of medications. Because of physiologic changes related to both disease and normal aging, vigilance on the part of all prescribing clinicians is essential. The following suggestions summarize key steps to improve medication safety for seniors:

- Obtain a thorough medication history including herbs, supplements and over-the-counter medications. Ask about use, don't just get a list.
- "Start low and go slow" when beginning a new medication; but don't forget to "go" – that is, make sure that the patient has had a trial of maximum dose BEFORE adding another medication for the same indication.

(Continued on page 17)

Safe Medication Management for the Elderly Patient (continued from page 16)

- Avoid treatment of side effects of one drug by adding another drug.
- Consider "therapeutic untrials." Many drugs were started years ago for indications that now may be uncertain.
- Encourage patients to discard "old" medications.
- Look for potential drug interactions with EACH new medication.
- Look for potential adverse drug reactions (sideeffects) with each new symptom.
- Give patients verbal and written instructions discuss medications, their indications and potential side-effects.
- Consider appropriateness of dosage form and affordability of each medication. Can the patient take the drug? Can the patient afford the drug?
- Look to non-medication interventions, when possible (ex: insomnia).

The nation is currently engaged in a strong debate over medication cost and coverage through federal or private benefits. How seniors will pay for their medications is clearly critical. However, what is often lost in this discussion is HOW are we as clinicians, patients and families, managing the current drug treatment plan. Questions we need to ask are: Are all the drugs truly necessary? Are there less expensive or non-med alternatives? Can one medication replace several others? Can the dosing be simplified? The newest or most expensive drug is not always the best, but some older medications have a greater risk of side effects than newer alternatives. The most critical element of medication management in the elderly is thoughtful dialogue between the clinician and patient. Knowing what the person is taking, why they are taking it and how they are responding sets the framework to minimize the risk of an adverse drug reaction and to optimize the therapeutic outcome of the treatment plan.

Common Drugs	That Warrant Conside		ing to the Elderry
Drug/Class	Examples	Concern	Alternatives
Long acting benzo- diazepines	flurazepam, diazepam, chlordiazepoxide	May produce prolonged sedation, increasing risk falls and fractures	Short acting benodiazepines
Propoxyphene and combination products		Offers few advantages over acetaminophen, yet has risk for increased confusion	Acetaminophen
Meperidine		Delayed clearance, increased risk of CNS toxicity/seizures and confusion	Morphine, hydro- morphone
Tricyclic anti- cholinergics	amitriptyline, doxepin	Strong anticholinergic and sedative properties	SSRIs
Anticholinergics	GI antispasmodics, OTC antihistamines, antinausea, and sleep meds	Constipation, falls, confusion, urinary retention	Consider non- med options
Cardiac Glycoside	Digoxin	Often has reduced renal clearance, doses should rarely exceed 0.125 mg/dl	

Common Drugs That Warrant Consideration Before Prescribing to the Elderly

ADMINISTRATIVE ACTIONS: FEBRUARY 1, 2002 TO APRIL 30, 2002

PHYSICIANS AND SURGEONS

ALPERN, GARY MELVIN, M.D. (G25029) Thousand Oaks, CA

B&P Code §§2234(e), 2354. Stipulated Decision. Terminated from the Medical Board's Diversion Program due to failure to abstain from alcohol use/ consumption. Revoked, stayed, 7 years probation with terms and conditions. February 13, 2002

BOUNDS, TERRELL BUDDY, JR., M.D. (G20279) Brooksville, FL

B&P Code §141(a). Stipulated Decision. Disciplined by Florida for performing a release of proximal pulley on the right ring finger of a patient, when the surgery was to be performed on the right long finger. Public Letter of Reprimand. March 7, 2002

BRANOVAN, MUSYA, M.D. (A42539) Los Angeles, CA

B&P Code §2236(a). Stipulated Decision. Convicted of mail fraud. Charged with engaging in acts of dishonesty and corruption, creating false medical records, failing to maintain accurate medical records and committing insurance fraud. Revoked, stayed, 5 years probation with terms and conditions.

BRISTO, LIONEL DE CARLO, M.D. (G32500) Chino Hills, CA

B&P Code §§490, 2052, 2234(a), 2236(a), 2238, 2306. Stipulated Decision. Convicted of 1 count of practicing medicine without a license. Revoked, stayed, 35 months probation with terms and conditions including 30 days actual suspension. March 28, 2002

BROTON, JAY CARTER, M.D. (A77946) San Diego, CA

B&P Code §§480(a)(3), 2239. Stipulated Decision. Committed acts of unprofessional conduct due to a history of alcohol dependency and 3 convictions for driving under the influence of alcohol. Probationary license issued, 5 years probation with terms and conditions. February 14, 2002

BURMAN, LEONARD J., M.D. (C20254) Victor, NY B&P Code §§141(a), 2234(b)(e), 2266, 2305. Disciplined by New York for applying clamps to both fallopian tubes of a patient without medical indication; failing to get informed consent for a sterilization procedure; failing to maintain a complete and accurate medical record for a patient. Revoked. March 7, 2002

February 11, 2002

Explanation of Disciplinary Language and Actions

Example: "May 10, 2002" at the bottom of the summary means the date the disciplinary decision goes into operation.

"Gross negligence" — An extreme deviation from the standard of practice.

"Incompetence" — Lack of knowledge or skills in discharging professional obligations.

"Judicial review is being pursued" — The disciplinary decision is being challenged through the court system-Superior Court, maybe Court of Appeal, maybe State Supreme Court. The discipline is currently in effect.

"Probationary License" — A conditional license issued to an applicant on probationary terms and conditions. This is done when good cause exists for denial of the license application.

Examples: Complete a clinical training program. Take educational courses in specified subjects. Take a course in Ethics. Pass an oral clinical exam. Abstain from alcohol and drugs. Undergo psychotherapy or medical treatment. Surrender your DEA drug permit. Provide free services to a community facility.

"Public Letter of Reprimand" — A lesser form of discipline that can be negotiated for minor violations before the filing of formal charges (accusations). The licensee is disciplined in the form of a public letter.

"Revoked" — The license is canceled, voided, annulled, rescinded. The right to practice is ended.

"Revoked, stayed, 5 years probation on terms and conditions, including 60 days suspension" — "Stayed" means the revocation is postponed, put off. Professional practice may continue so long as the licensee complies with specified probationary terms and conditions, which, in this example, includes 60 days actual suspension from practice. Violation of probation may result in the revocation that was postponed.

"Stipulated Decision" — A form of plea bargaining. The case is negotiated and settled prior to trial.

"Surrender" — Resignation under a cloud. While charges are pending, the licensee turns in the license - subject to acceptance by the relevant board.

"Suspension from practice" — The licensee is prohibited from practicing for a specific period of time.

"Temporary Restraining Order" -A TRO is issued by a Superior Court Judge to halt practice immediately. When issued by an Administrative Law Judge, it is called an ISO (Interim Suspension Order).

CHA, SOON MYUNG, M.D. (A39746)

Los Angeles, CA

B&P Code §2234(b). Stipulated Decision. Failed to secure adequate blood products in a timely manner to a patient who had placenta previa. Revoked, stayed, 5 years probation with terms and conditions. February 8, 2002

CHANDLER, DAVID RAY, M.D. (G50692) Gulf Breeze, FL

B&P Code §141(a). Stipulated Decision. Disciplined by Florida for performing surgery on the left long finger of a patient, when the surgery was to be performed on the left thumb. Public Letter of Reprimand. February 7, 2002

CHANG, CANDACE SHIAO-RONG, M.D. (A62000) Monterey Park, CA

B&P Code §§490, 2234, 2236(a), 2236(1)(a).

Stipulated Decision. Criminal convictions for 7 counts of conspiracy, insurance fraud, Medi-Cal Fraud, grand theft, and unlawful rebates. Revoked, stayed, 7 years probation with terms and conditions. March 21, 2002

CHAO, TSAI CHUNG, M.D. (A51533) New York, NY

B&P Code §§141(a), 2305, 2234(c). Stipulated Decision. Disciplined by New York for repeated negligent acts in ordering and performing testing without justification, failing to record test results, and failing to interpret test results so as to order the correct and necessary tests. Suspended, stayed, 3 years probation with terms and conditions. February 8, 2002

CHEIN, EDMUND Y.M., M.D. (A38678) Palm Springs, CA

B&P Code §2234. Charged with prescribing human growth hormone for a patient without medical indication. Revoked, stayed, placed on probation until terms and conditions are completed, including 10 ½ months suspension, with credit for 10 ½ months already served. March 29, 2002

CHEN, YUAN-FEI CHANG, M.D. (G73324) Diamond Bar, CA

B&P Code §§810, 2234(e), 2236(a), 2261, 2262, 2266. Stipulated Decision. Criminal convictions for 4 counts of knowingly billing Medicare for physical therapy services actually provided by an acupuncturist not eligible for Medicare reimbursement; billing for office visits for patients not examined or treated, and entering false information in patient charts to facilitate fraudulent claims for physical therapy. Revoked, stayed, 3 years probation with terms and conditions. February 8, 2002

CHIU, KWANG POUNG, M.D. (C37989) San Pablo, CA

B&P Code §2234. Stipulated Decision. No admissions but charged with gross negligence, negligence and incompetence for failure to monitor and manage 3 patients with obstetric complications. Revoked, stayed, 10 years probation with terms and conditions. March 6, 2002

DINGLASAN, GUALBERTO RIOFLORIDO, M.D. (A38324) Glendora, CA

B&P Code §§2234(a), 2236(a). Convicted of a felony for making terrorist threats. Revoked, stayed, 5 years probation with terms and conditions. March 29, 2002

ELLIS, JOHN GREGORY, M.D. (G70713) Temecula, CA

B&P Code §2234(c). Stipulated Decision. Charged with repeated negligent acts for failing to recommend surgery to a patient during 2 office visits for treatment of a right distal radius and ulnar fracture. Public Letter of Reprimand. March 4, 2002

FENICHEL, ADAM SETH, M.D. (G75828) Winter Park, FL

B&P Code §§141(a), 2305. Stipulated Decision. Disciplined by Florida for inappropriately performing a carpal tunnel release procedure on a patient before proceeding with the planned trigger thumb release procedure, and failing to obtain appropriate authorization before performing the carpal tunnel release procedure. Public Reprimand. February 18, 2002

FORESTI-LORENTE, ROMILDA FLAVIA, M.D. (A42248) San Francisco, CA

B&P Code §2234. Stipulated Decision. No admissions but charged with gross negligence and incompetence in failing to take adequate steps to reach or obtain a diagnosis of 1 patient's complaints, and/or in failing to ensure that the patient obtained the necessary consultations; and failing to adequately advise the patient of the potential consequences of failure to obtain a consultation. Public Reprimand. April 18, 2002

GARDNER, DAVID GEORGE, M.D.

(G21702) Calabasas, CA

B&P Code §§2234, 2236(a). Stipulated Decision. Convicted of a felony for money laundering involving monetary instruments exceeding a value of \$5,000. Revoked, stayed, 5 years probation with terms and conditions including 60 days actual suspension. March 28, 2002

HARRIS, JEFFREY DAVID, M.D. (G38541) North Woodmere, NY

B&P Code §§141(a), 2305. Stipulated Decision. Disciplined by New York for unprofessional conduct for failing to maintain records in the care and treatment of 19 patients. Public Reprimand. February 19, 2002

ITO, KAREN MACHIKO, M.D. (A66216) Rancho Palos Verdes, CA

B&P Code §§2234(a)(b)(c)(e), 2238, 2261, 2266. Stipulated Decision. Committed acts of unprofessional conduct, gross negligence, repeated negligent acts, fraudulent, dishonest and/or corrupt acts, violated drug statutes or regulations by prescribing dangerous drugs without medical indication; false representation on a medical document; and failed to maintain adequate records by obtaining prescriptions by forging other physicians' names. Revoked, stayed, 7 years probation with terms and conditions including 60 days actual suspension. February 4, 2002

JACKSON, OSCAR FRANCIS, M.D. (G48655) Fullerton, CA

B&P Code §2234(b)(d). Stipulated Decision. Committed acts of gross negligence and incompetence in the care and treatment of 1 patient during an appendectomy. Revoked, stayed, 5 years probation with terms and conditions including 90 days actual suspension. March 18, 2002

JENNINGS, RAYMOND D., M.D. (A20599) Deer Park, CA

B&P Code §2236(a). Stipulated Decision. Convicted of violating Penal Code section 135 (destroying evidence). No admissions but charged with dishonesty, unprofessional conduct, gross negligence, and incompetence in the care and treatment of 1 elderly patient. Revoked, stayed, 3 years probation with terms and conditions. March 11, 2002

KHAN, SHAGUFTA PARVIN, M.D. (A29867) San Diego, CA

B&P Code §2264. Stipulated Decision. Aided and abetted the unlicensed practice of medicine. Revoked, stayed, 7 years probation with terms and conditions including 6 months actual suspension. April 15, 2002

LAM, SYLVIA Y., M.D. (C42338) Hoffman Estate, IL

B&P Code §§141(a), 2234. Stipulated Decision. Disciplined by Illinois for unprofessional conduct in failing to adequately maintain medical records for a minor patient and failure to document telephone contacts with the patient's parents. Public Letter of Reprimand. February 5, 2002

LAMM, JAMES L.D., M.D. (C20468) San Francisco, CA

B&P Code §§725, 2234(c), 2238, 2242, 2248, 2266. Stipulated Decision. Engaged in unprofessional conduct, gross negligence, incompetence, repeated negligent acts, and failure to maintain adequate medical records in the care and treatment of 5 patients for excessive and inappropriate prescribing of controlled substances. Revoked, stayed, 5 years probation with terms and conditions. March 25, 2002

LANG, L. KHADIJAH, M.D. (G66503) Los Angeles, CA

B&P Code §§725, 2234(b)(c). Stipulated Decision. Admitted to committing acts of gross negligence, repeated negligent acts, and excessive use of diagnostic procedures in the care and treatment of 9 patients. Revoked, stayed, 7 years probation with terms and conditions including 90 days actual suspension. February 8, 2002

LANGE, DENNIS ANDREW, M.D. (G75237) Mountain View, CA

B&P Code §§822, 2239(a). Unlawful use of drugs and mental illness. Revoked, stayed, 8 years probation with terms and conditions. February 21, 2002

LEE, SALVACION MIRAFUENTES, M.D. (A45616) Bell Canyon, CA

B&P Code §§490, 2234(e), 2236(a). Stipulated Decision. Engaged in unprofessional conduct for committing acts of dishonesty or corruption; convicted of a felony for conspiracy to commit bribery by allowing respiratory and pulmonary care service providers to use his Medicare service provider number in exchange for reimbursements. Revoked, stayed, 4 years probation with terms and conditions including 30 days actual suspension. February 8, 2002

LIN, JOHN, M.D. (A39314) Los Angeles, CA B&P Code §§2234(b)(c)(d), 2242. Stipulated Decision. Committed acts of gross negligence, incompetence and repeated negligence in the care and treatment of 3 patients and charged with prescribing without a good faith examination in the care and treatment of 1 patient. Revoked, stayed, 5 years probation with terms and conditions. April 11, 2002

MAECK, BENJAMIN HARRIS, M.D. (A71812) San Francisco, CA

B&P Code §2234. Stipulated Decision. Felony conviction for willful infliction of corporal injury on spouse or cohabitant; failed to comply with terms of Board-ordered probation. Revocation, stayed, 3½ years probation with terms and conditions. March 8, 2002 MANN, THOMAS ANDREW, M.D. (G84725) Roseville, CA

B&P Code §§141(a), 2234. Stipulated Decision. Disciplined by Colorado for care rendered to a patient which failed to conform to minimal standards of acceptable medical practice. Public Letter of Reprimand. April 9, 2002

MCCANN, GERALD J., M.D. (A21167) Norwalk, CA B&P Code §§581, 2234(b)(c)(d)(e), 2216, 2238, 2261, 2262, 2266, 4172. Committed acts of gross negligence, repeated negligent acts, incompetence, aiding and abetting the unlicensed practice of medicine, operating an uncertified surgical center, failing to maintain adequate and accurate records, violation of drug laws, public communication of false, fraudulent, misleading or deceptive statements or claims, and dishonesty. Revoked, stayed, 7 years probation with terms and conditions including 90 days actual suspension. February 22, 2002

MCLEOD, WILLIAM BRYCE, M.D. (A39318) Rancho Cucamonga, CA

B&P Code §2234. Committed acts of unprofessional conduct in the care and treatment of 5 patients. Revoked, stayed, 5 years probation with terms and conditions. February 6, 2002

MILLER, JOHN EDWARD, M.D. (G52628) Los Angeles, CA

B&P Code §§822, 2234, 2236(a). Felony conviction for unlawful interference with a helicopter by flashing bright lights at a police helicopter; ability to practice medicine safely is impaired due to mental illness. Revoked. April 18, 2002

NOORANI, ASHRAF SHEIKHTAYAB, M.D. (A33148) San Jose, CA

B&P Code §§2234(a)(c), 2266. Stipulated Decision. Failed to maintain adequate and legible documentation of medical history; examination and plans of treatment; failed to evaluate a patient for potential complications of diabetes; and failed to make timely evaluations of a patient when confined to a skilled nursing facility. Public Letter of Reprimand. March 13, 2002

PATEL, BAKULKUMAR KANTILAL, M.D. (A45267) Foothill Ranch, CA

B&P Code §2234(c). Committed unprofessional conduct and repeated negligent acts in the care and treatment of 1 patient. Public Reprimand. February 6, 2002

POPOV, ALEXANDER, M.D. (A78244) Los Angeles, CA

B&P Code §480(a)(1)(2)(3). Stipulated Decision. Failed to disclose a conviction of driving under the influence when submitting a license application. Probationary license issued, 5 years probation with terms and conditions. February 11, 2002

REYNOLDS, RAYMOND DONALD, M.D. (G4823) Beverly Hills, CA

B&P Code §§725, 2234(b)(e), 2238, 2239(d), 2242, 2266. Committed acts of unprofessional conduct and gross negligence in the use or prescribing of controlled substances, dishonesty, failed to maintain adequate and accurate medical records, excessively prescribed or administered drugs or treatment, prescribed without a good faith prior examination and medical indication, and prescribing, selling, or furnishing of drugs to an addict. Revoked. April 22, 2002

ROBINSON, RHONDA LUCIA, M.D. (A77973) Bakersfield, CA

B&P Code §820. Stipulated Decision. Applicant's ability to practice medicine safely impaired due to mental illness. Probationary license granted, 5 years probation with terms and conditions. February 21, 2002

ROZENGURT, MARK, M.D. (A37948) San Francisco, CA

B&P Code §2234. Stipulated Decision. No admissions but charged with gross negligence, excessive prescribing, prescribing to an addict, and failure to maintain adequate medical records. Failed to properly complete written prescription forms, enabling 1 patient to fraudulently obtain multiple refills. Revoked, stayed, 3 years probation with terms and conditions. March 8, 2002

RUIZ, RUBEN MENA, III, M.D. (A78287) El Segundo, CA

B&P Code §§480(a)(3), 2234. Stipulated Decision. Engaged in the unlicensed practice of medicine by continuing to train without a physician's license beyond the 2 years permitted under B&P Code section 2065. Probationary license issued, 5 years probation with terms and conditions. February 6, 2002

SCHUG, WOLFGANG GUENTER, M.D. (A41434) Clearlake, CA

B&P Code §2234(b). Stipulated Decision. Failed to take immediate action to hydrate an 11-month-old patient after receiving laboratory values and reviewing vital signs; gross negligence for failing to appreciate the significance of the laboratory values; allowed the patient to leave the hospital and be transferred by the patient's parents to another hospital although the patient was in imminent danger and the standard of care mandated further action before transfer. Public Reprimand. February 14, 2002

SEKARAN, MURUGAYYAN RAJA, M.D. (A26411) Sacramento, CA

B&P Code §2234(b). Stipulated Decision. Committed acts of gross negligence in failing to schedule, recommend or obtain postoperative surveillance measures in 1 patient diagnosed with embryonal carcinoma. Public Reprimand. February 22, 2002

SHIH, HSIEN SHOU, M.D. (A41812) Arcadia, CA B&P Code §§490, 822, 2234(e), 2236(a). Convicted of both felony hit-and-run and petty theft; possessing arsenal of unregistered weapons, committed an act of dishonesty in completing and submitting an application for medical staff privileges by failing to disclose previous hospital disciplinary action, and unprofessional conduct resulting from mental illness and abuse of prescription medications. Suspended from practice until the Board determines, based on competent evidence, that with due regard for the public health and safety, the physician's right to practice his profession may be safely reinstated. April 29, 2002

SMITH, RODNEY LESTER, M.D. (A49472) Phoenix, AZ

B&P Code §§141(a), 2305. Stipulated Decision. Disciplined by Arizona for unprofessional conduct in failing to adequately resuscitate 1 patient suffering from multiple traumatic injuries; attempting peritoneal lavage without on-site surgical backup and facilities; performing an exploratory laparotomy without being qualified to do so, and without benefit of anesthesia or an operating room, despite the fact that Air-Evac was present and ready to transport the patient to an appropriate facility. Revoked, stayed, 5 years probation with terms and conditions. February 4, 2002

SPEARS, KELVIN L., M.D. (G67140) Alexandria, LA B&P Code §2234. Stipulated Decision. Unprofessional conduct in failing to meet the standard of care in treatment of an infant in the emergency room. Public Letter of Reprimand. April 4, 2002

SRINARAYANA, HANUMAIAH, M.D. (A37753) El Campo, TX

B&P Code §§141(a), 821, 2305. Disciplined by Arizona for unprofessional conduct in failing to comply with Board-ordered evaluation. Revoked. February 25, 2002

STANTON, FRANCIS XAVIER, JR., M.D. (G53287) La Jolla, CA

B&P Code §822. Stipulated Decision. License suspended until the Division determines that it has received competent evidence of the absence or control of the self-use and administration of controlled substances/dangerous drugs, including mental and physical illness that impairs his ability to practice medicine safety. April 22, 2002

TIBBLES, JAY HAROLD, M.D. (G35467) Fontana, CA B&P Code §§2234(b), 2236(a). Stipulated Decision. Convicted of 6 felony counts of unlawful attempt to commit lewd acts with a child and 5 felony counts of unlawful attempt to send harmful matter to a child under 14 years of age with intent to seduce the child. Revoked. April 8, 2002

TOWNE, LOUIS CY, M.D. (A21199) San Diego, CA B&P Code §§2234(b)(c), 2266. Stipulated Decision. Charged with gross and repeated acts of negligence in the care and treatment of 1 patient and with failure to maintain adequate and accurate records in the care and treatment of 3 patients. Revoked, stayed, 5 years probation with terms and conditions. April 17, 2002

VALCARCEL, JORGE ALBERTO, M.D. (A36796) Bell, CA

B&P Code §§820, 821, 2234(d). Stipulated Decision. Charged with incompetence and unprofessional conduct in that ability to practice medicine is impaired due to mental illness or physical illness affecting competency and demonstrated a lack of ability to discharge the responsibilities and duties of his licensure; failed to undergo the compelled psychiatric evaluation and psychological testing ordered. Revoked. March 7, 2002

ZAVALA-ROMAN, LUIS MANUEL, M.D. (A43883) Fremont, CA

B&P Code §2234(c). Stipulated Decision. Negligence in care and treatment of a patient who presented with a suprasellar mass, and failure to order and evaluate a cerebral angiogram preoperatively. Public Reprimand. April 18, 2002

ZELYONY, ISAAK, M.D. (A35962) Los Angeles, CA B&P Code §§725, 2234(b)(c)(d), 2264, 2266, 2285, 2400. Stipulated Decision. Charged with aiding and abetting the practice of medicine by a non-licensee and a non-medical corporation, practicing under a fictitious name without a permit, negligence, repeated negligence, incompetence, excessive prescribing or treatment, and failing to maintain adequate records. Revoked, stayed, 5 years probation with terms and conditions. April 26, 2002

DOCTORS OF PODIATRIC MEDICINE

SERBIN, MARTIN EDD, D.P.M. (EFE969) Fullerton, CA B&P Code §725. Stipulated Decision. Committed acts of excessive use of treatment facilities. Public Reprimand. March 18, 2002

SIEGEL, JEFFREY STUART, D.P.M. (E3352) Long Beach, CA

B&P Code §2234(c). Stipulated Decision. Failure to properly evaluate and treat a postsurgical infection; failure to adhere to the standard of practice in the basic principles of wound management. Public Letter of Reprimand. February 22, 2002

PHYSICIAN ASSISTANTS

ROBINSON, KEVIN, P.A. (PA12720) Paramount, CA B&P Code §2234. Stipulated Decision. Failed to comply with terms and conditions of probation. Revoked, stayed, 2 years probation added to former probation order with terms and conditions. February 21, 2002

VENTOCILLA, EDWIN GARCIA, P.A. (PA16349) Los Gatos, CA

B&P Code §§480(a)(1)(3), 490, 3527(a). Convicted of 2 counts of battery on a co-worker while on duty. License granted, revoked, stayed, 5 years probation with terms and conditions. March 6, 2002

VERNON, ELFRIEDE ELISABETH, P.A. (PA13986) Merced, CA

B&P Code §§726, 2234(b), 3527(a). Stipulated Decision. Committed acts of unprofessional conduct, gross negligence and sexual misconduct with a patient. Revoked, stayed, 3 years probation with terms and conditions. February 25, 2002

Drug or Alcohol Problem?

If you are concerned about a fellow physician who you think is abusing alcohol or other drugs or is mentally ill, you can get assistance by asking the Medical Board's Diversion Program to intervene.

ALL CALLS ARE CONFIDENTIAL

(916) 263-2600

Medical Board of California Physician Diversion Program 1420 Howe Avenue, Suite 14 Sacramento, CA 95825

SURRENDER OF LICENSE WHILE CHARGES PENDING

PHYSICIANS AND SURGEONS

BARCAN, ANDREW M., M.D. (GFE23055) Thousand Oaks, CA March 26, 2002

BAYHAM, WILBUR C., M.D. (G2179) Phoenix, AZ March 25, 2002

DEGASTON, ALEXIS NEAL, M.D. (A34642) Moreno Valley, CA April 22, 2002

FAM, FARID HANNA, M.D. (A33454) Fresno, CA April 12, 2002

FISHER, STEPHEN NEAL, M.D. (G54042) Pittsburgh, PA April 10, 2002

KEEHAN, MICHAEL FRANCIS, M.D. (G18940) Hacienda Heights, CA March 8, 2002

LAKE, STEPHEN, M.D. (CFE31281) Beverly Hills, CA March 19, 2002

ORI, VINCENT EGIDIO, M.D. (G41587) Roseville, CA April 23, 2002

THOMAS, RICHARD W., M.D. (A17585) South Pasadena, CA March 7, 2002

WOODS, KENNETH BRUCE, M.D. (G39798) Roseville, CA April 2, 2002

ZEMELMAN, HAROLD N., M.D. (AFE16458) Rancho Palos Verdes, CA February 13, 2002

ZIERING, WILLIAM H., M.D. (G7842) Fresno, CA February 28, 2002

DOCTOR OF PODIATRIC MEDICINE

BILINSKY, RONALD DAVID, D.P.M. (E2227) Los Angeles, CA March 26, 2002 Department of Consumer Affairs Medical Board of California 1426 Howe Avenue Sacramento, CA 95825-3236

Business and Professions Code Section 2021(b) & (c) require physicians to inform the Medical Board in writing of any name or address change.



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A OTION DEPONT JULY 2002			

ACTION REPORT - JULY 2002 Candis Cohen, Editor (916) 263-2389

For copies of this report, fax your request to (916) 263-2387 or mail to: Medical Board, 1426 Howe Avenue, Suite 54, Sacramento, CA 95825. The *Action Report* also is available in the "Publications" section of the Board's Web site: www.medbd.ca.gov.