MedWatch Upgrade Urged by FDA’s Pediatric Advisory Panel

BY DEEANNA FRANKLIN
Senior Writer

Rockville, Md. — Panels on the Food and Drug Administration’s Pediatric Advisory Committee strongly urged the FDA to overhaul MedWatch, its voluntary safety information and adverse event reporting program, to make the system less onerous.

Currently, the program entails the submission of a five-page report, and the submission often triggers a follow-up interview via telephone.

“Consider the possibility of streamlining the adverse event reporting system so that people would be less afraid of doing it,” advised Thomas Newman, M.D., of the University of California, San Francisco.

“Create a system that is more specific and less open to interpretation, so that way the data would be stronger and potential-ly cleaner, I recommend another panel member.

Panels suggested making the sys-tem more user-friendly, in addition to having narrative descriptions that are more consistent across categories.

For example, one provider may use a description of “loose stool” while another would use the term “diarrhea.”

“I feel like I’m not serving the gen-eral public or the government of the United States, with the current in-formation that I’m receiving. I am not capable of being assured in any way about safety with the [current] pas-sive surveillance system. We have to get better information,” said Mary Glode, M.D., an infectious diseases specialist with the University of Colora- do, Denver.

FDA representatives acknowledged that underreporting of adverse events and establishing causality are ongoing challenges under the current MedWatch system.

“There’s a lot of missing informa-tion. We try to make the most out of this limited information. It’s a good system to pick up some rare, serious events,” said an FDA representative.

The panels also heard data com-piled as part of the 1-year postexclu-sivity adverse event review program mandated by the Best Pharnaceuti-cal for Children Act.

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Indication: This antihypertensive (ACE inhibitor) is used to treat hy-pertension in patients over 6 years of age.

Pediatric Adverse Events Reported: Three adverse events (AEs) in a year period reviewed, and five total since its approval; all were serious, none were fatal. No patterns discernible in the AEs for benazepril monotherapy. No AEs reported for benazepril’s combi-nation products.

FDA Recommendation: Return to routine monitoring. The agency re-commended routine monitoring of AEs, focusing on serious AEs in all populations, as opposed to giving special atten-tion to all pediatric AEs reported as mandated by the 1-year exclusivity pe-riod.

Panel Recommendation: The panel did not concur, and regarded the data presented as too inadequate for a re-turn to routine monitoring. They recom-mended the FDA “look closely at all case re-port for benazepril for yet another year and then report back to the committee,” said panel chair, P. Joan Chesney, M.D., an in-fectious diseases specialist and direc-tor of academic programs at St. Jude Children’s Research Hospital, Mem-phis.

Esmolol (Brevibloc).

Approved: December 31, 1986, manufactured by Baxter Laboratories.

Indication: No pediatric indication.

There were 13 pediatric AEs reported (9 serious, 3 deaths).

FDA Recommendation: Return to routine monitoring.

Panel Recommendation: The panel did not concur, and regarded the data presented as insufficient. Recom-mended another year-long exclu-sivity period.

Orlistat (Xenical).

Approved: April 23, 1999, manu-factured by Roche.

Indication: A lipase inhibitor for obesity management in conjunction with weight reduction in patients aged 12 years and older with a body mass in-dex greater than 30, or 27 with risk fac-tors (hypertension, diabetes, dys-lipidemia). Less than 1% (about 4,000) annual prescriptions for the drug were for pediatric patients.

Pediatric Adverse Events Reported: Twenty-two pediatric AEs were re-port (21 serious, no deaths). There was one serious AE reported during the 1-year postexclusivity period.

FDA Recommendation: Return to routine monitoring.

Panel Recommendation: The panel concurred.

Glyburide-Metformin (Glucovanse).

Approved: July 31, 2000, manufactur-ied by Bristol-Myers Squibb Co.

Indication: An antihyperglycemic for the adjunct treatment of type 2 diabetics who are already on diet and exer-cise, as well as a second-line treat-ment for type 2 diabetes if metformin or sulfonylurea fail. The glyburide stimulates release of insulin while the metformin improves glucose toler-ance.

Pediatric Adverse Events Reported: No AEs reported in this population since Glucovance’s approval. Both drugs have minimal use in pediatric patients.

FDA Recommendation: Return to routine monitoring for the drug com-bination.

Panel Recommendation: The panel concurred.

Atovaquone-Proguanil (Malarone Pe-diatrie).

Approved: July 14, 2000, manufactur-ied by GlaxoSmithKline

Indication: An antimalarial used in the treatment of Plasmodium falci-parum malaria in patients over 5 kg and prophylaxis in patients over 1 kg.

Pediatric Adverse Events Reported: Seven AEs were reported during the 1-year postexclusivity period (six serious, no deaths). There were 17 AEs re-ported since the drug’s approval (15 se-rious, 3 deaths).

FDA Recommendation: Return to routine monitoring.

Panel Recommendation: The panel unanimously concurred.

Nelfinavir Mesylate (Viracept).

Approved: March 14, 1997, manu-factured by Pfizer Inc.

Indication: A protease inhibitor in-dicated for the treatment of HIV in-fection in patients over 2 years of age.

Accounted for about 16.4% of the 1.9 million prescriptions dispensed in this drug class from Sept. 2003 to Aug. 2004.

Pediatric Adverse Events Reported: There were 377 AEs reported since the drug’s approval (374 serious, 19 deaths). During the 1-year postexclusivity period, there were 30 AEs re-port (30 serious, 2 deaths).

FDA Recommendation: Return to routine monitoring.

Panel Recommendation: The panel agreed.

Alternatives Could Improve Health Care Coverage

BY JENNIFER SILVERMAN
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Washington — Rewarding states based on how they cover their adult uninsured Amer-i-cans, Henry J. Aaron said at the annual meeting of the National Governors Association.

Following up on a trend that has already affect-ed the physician community, Mr. Aaron proposed a “pay-for-performance” system, where states could receive federal grants based on their ‘actual mea-sured progress of increasing the number and proportion of state residents covered by health insur-ance.” The grants would be set to cover much or all of the costs of extending coverage.

“Any state that succeeded in boosting a fraction of its population [covered by] health insurance would receive federal assistance. No such progress would receive nothing,” said Mr. Aaron, senior fellow for economic studies at the Brookings Institution.

The federal government should first define a standard for health insurance coverage, Mr. Aaron said, suggesting that the minimum be “similar to the actuarial value of the Federal Employees Health Benefits Program.”

His plan would also include a first “no harm” standard, prohibiting states from materially eroding coverage for the current Medicaid population. Even now, Medicaid is substantially less costly than private insurance of the same scope, Mr. Aaron said.

“[States] also need flexibility to modernize Medi-caid but within the limits that maintain the per-capita protection of the most vulnerable popula-tions in our nation,” Mr. Aaron said.

Within these broad guidelines, states should be encouraged to pursue any approach that with-increase the proportion of state residents with health insurance coverage, he continued. Depending on local conditions and political preferences, states could use refundable tax credits or vouchers to promote individual insurance.

States could also facilitate new insurance groups by allowing churches, unions, and the like to cre-ate association health plans; extend Medicaid or the State Children’s Health Insurance Program; impose employer mandates; or try to create an intrastate single-payer plan. None of these would be manda-tory, he said.

Another panelist, Stuart M. Butler, Ph.D., vice president, domestic and economic policy studies, the Heritage Foundation, Washington, suggested that Congress enact a policy “toolbox” that would make a range of ideas available to states. Under such an approach, states could propose an initiative for pre-serving coverage, selecting certain elements from the toolbox, and negotiating with the U.S. Health and Human Services department on appropriate waivers to pull such an option together, he explained.

In an attempt to maintain and extend the func-tional equivalent of Medicaid during these very tight budget times, states could seek an enhanced federal refundable tax credit from the policy tool-box, using additional federal funds to create pur-chasing alliances or pools, he said. The key is to make sure that Medicaid populations are protect-ed, “encouraging innovations through the states [and] rewarding pay-for-performance successes by the states, to reach these goals.”

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