

ACP: American Health Care Ranks Near Bottom

BY JOEL B. FINKELSTEIN
Contributing Writer

WASHINGTON — Despite the rhetoric favored by presidential candidates, the U.S. health care system is not the best in the world, but ranks near the bottom on most measures when compared with other industrialized nations, according to an American College of Physicians' report.

"I'm not pleased to say this, but when it comes to health care, too many of us simply are not getting the kind of health care that we need and deserve and, in fact, many Americans do not have access to even basic health care," said Dr. David Dale, president of the American College of Physicians, speaking at the release of the college's annual State of the Nation's Health Care report at a conference sponsored by AcademyHealth.

Citing data culled from the Commonwealth Fund, the World Health Organization, and other sources, Dr. Dale noted that the United States ranks behind other industrialized nations in terms of access and equity, in helping patients lead healthier lives, in preventable deaths, and in infant mortality. The United States ranks second to last in overall quality of care, edging out only Canada—a country that spends half as much per capita on health care.

In fact, the United States spends more than double the amount most nations spend on health care, yet continues to have poorer access and outcomes, according to Dr. Dale.

And if U.S. health care spending continues to grow at its current pace, it can be expected to increase from 16% of gross domestic product in 2007 to 25% by 2025, according to Peter Orszag, Ph.D., director of the Congressional Budget Office, in congressional testimony that was delivered on the same day as ACP's report.

Efforts to enact major reform of the health care system have consistently failed in the past, but the projected spending growth may force the issue this time

around, said Robert Doherty, the college's senior vice president of governmental affairs. "Health care will become so expensive that the country will no longer be able to support it," he said.

In releasing its annual report, the ACP used the opportunity to call for a political commitment to provide universal coverage, bolster primary care, reform the payment system, reduce administrative costs, implement health information technology, and support effectiveness research.

The group also sent a "candidates pledge" outlining these goals to each of the presidential hopefuls as well as to the

'By November, millions of Americans will have heard the [American Medical Association's] concern that one in seven of us is uninsured.'

group's membership, who can in turn hand them to candidates for Congress.

"The pledge will help ACP members ask the tough questions of candidates. The number of candidates who actually sign the pledge will be less important than how many of them end up advocating for the policies," according to Mr. Doherty.

The American Medical Association launched a national ad campaign that has

been designed to spark discussion during the presidential campaigns about the problem of the uninsured.

"By November, millions of Americans will have heard the AMA's concern that one in seven of us is uninsured," Dr. Samantha Rosman, AMA board member, said in a statement.

Although the two physicians groups are not working together on these campaigns, they share a common end, Mr. Doherty said. "Part of our hope is to provoke a debate within the profession itself about what is the most effective way of getting everyone covered in this country.

"But I don't think there is a real disagreement within the profession on the goal," he said.

ACP has launched a Web site that provides comparisons of the presidential candidates' health care proposals: www.acponline.org/advocacy/where_we_stand/election.

Table 10:
Percent of RA Patients Reporting Adverse Events in Controlled Clinical Trials*

Event	Placebo Controlled		Active Controlled (Study III)	
	Placebo [†] (N = 152)	ENBREL (N = 349)	MTX (N = 217)	ENBREL (N = 415)
Injection site reaction	10	37	7	34
Infection (total)**	32	35	72	64
Non-upper respiratory infection (non-URI)**	32	38	60	51
Upper respiratory infection (URI)**	16	29	39	31
Headache	13	17	27	24
Nausea	10	9	29	15
Rhinitis	8	12	14	16
Dizziness	5	7	11	8
Pharyngitis	5	7	9	6
Cough	3	6	6	5
Asthenia	3	5	12	11
Abdominal pain	3	5	10	10
Rash	3	5	23	14
Peripheral edema	3	2	4	8
Respiratory disorder	1	5	NA	NA
Dyspepsia	1	4	10	11
Sinusitis	2	3	3	5
Vomiting	-	3	8	5
Mouth ulcer	1	2	14	6
Alopecia	1	1	12	6
Pneumonitis ("MTX lung")	-	-	2	0

* Includes data from the 6-month study in which patients received concurrent MTX therapy.

[†] The duration of exposure for patients receiving placebo was less than the ENBREL-treated patients.

** Infection (total) includes data from all three placebo-controlled trials. Non-URI and URI include data only from the two placebo-controlled trials where infections were collected separately from adverse events (placebo N = 110, ENBREL N = 213).

In controlled trials of RA and psoriatic arthritis, rates of serious adverse events were seen at a frequency of approximately 5% among ENBREL- and control-treated patients. In controlled trials of plaque psoriasis, rates of serious adverse events were seen at a frequency of < 1.5% among ENBREL- and placebo-treated patients in the first 3 months of treatment. Among patients with RA in placebo-controlled, active-controlled, and open-label trials of ENBREL, malignancies (see **WARNINGS: Malignancies**, **ADVERSE REACTIONS: Malignancies**) and infections (see **ADVERSE REACTIONS: Infections**) were the most common serious adverse events observed. Other infrequent serious adverse events observed in RA, psoriatic arthritis, ankylosing spondylitis, or plaque psoriasis clinical trials are listed by body system below:

- Cardiovascular: heart failure, myocardial infarction, myocardial ischemia, hypertension, hypotension, deep vein thrombosis, thrombophlebitis
- Digestive: cholecystitis, pancreatitis, gastrointestinal hemorrhage, appendicitis
- Hematologic/Lymphatic: lymphadenopathy
- Musculoskeletal: bursitis, polymyositis
- Nervous: cerebral ischemia, depression, multiple sclerosis (see **WARNINGS: Neurologic Events**)
- Respiratory: dyspnea, pulmonary embolism, sarcoidosis
- Skin: worsening psoriasis
- Urogenital: membranous glomerulonephropathy, kidney calculus

In a randomized controlled trial in which 51 patients with RA received ENBREL 50 mg twice weekly and 25 patients received ENBREL 25 mg twice weekly, the following serious adverse events were observed in the 50 mg twice weekly arm: gastrointestinal bleeding, normal pressure hydrocephalus, seizure, and stroke. No serious adverse events were observed in the 25 mg arm.

Adverse Reactions in Patients with JIA

In general, the adverse events in pediatric patients were similar in frequency and type as those seen in adult patients (see **WARNINGS** and other sections under **ADVERSE REACTIONS**). Differences from adults and other special considerations are discussed in the following paragraphs.

Severe adverse reactions reported in 69 JIA patients ages 4 to 17 years included varicella (see also **PRECAUTIONS: Immunizations**), gastroenteritis, depression/personality disorder, cutaneous ulcer, esophagitis/gastritis, group A streptococcal septic shock, Type 1 diabetes mellitus, and soft tissue and post-operative wound infection.

Forty-three of 69 (62%) children with JIA experienced an infection while receiving ENBREL during three months of study (part 1 open-label), and the frequency and severity of infections was similar in 58 patients completing 12 months of open-label extension therapy. The types of infections reported in JIA patients were generally mild and consistent with those commonly seen in outpatient pediatric populations. Two JIA patients developed varicella infection and signs and symptoms of aseptic meningitis which resolved without sequelae.

The following adverse events were reported more commonly in 69 JIA patients receiving 3 months of ENBREL compared to the 349 adult RA patients in placebo-controlled trials. These included headache (19% of patients, 1.7 events per patient-year), nausea (9%, 1.0 events per patient-year), abdominal pain (19%, 0.74 events per patient-year), and vomiting (13%, 0.74 events per patient-year).

In open-label clinical studies of children with JIA, adverse events reported in those aged 2 to 4 years were similar to adverse events reported in older children.

In post-marketing experience, the following additional serious adverse events have been reported in pediatric patients: abscess with bacteremia, optic neuritis, pancytopenia, seizures, tuberculous arthritis, urinary tract infection (see **WARNINGS**), coagulopathy, cutaneous vasculitis, and transaminase elevations. The frequency of these events and their causal relationship to ENBREL therapy are unknown.

Patients with Heart Failure

Two randomized placebo-controlled studies have been performed in patients with CHF. In one study, patients received either ENBREL 25 mg twice weekly, 25 mg three times weekly, or placebo. In a second study, patients received either ENBREL 25 mg once weekly, 25 mg twice weekly, or placebo. Results of the first study suggested higher mortality in patients treated with ENBREL at either schedule compared to placebo. Results of the second study did not corroborate these observations. Analyses did not identify specific factors associated with increased risk of adverse outcomes in heart failure patients treated with ENBREL (see **PRECAUTIONS: Patients with Heart Failure**).

Adverse Reaction Information from Spontaneous Reports

Adverse events have been reported during post-approval use of ENBREL. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to ENBREL exposure.

Additional adverse events are listed by body system below:

- Body as a whole: angioedema, fatigue, fever, flu syndrome, generalized pain, weight gain
- Cardiovascular: chest pain, vasodilation (flushing), new-onset congestive heart failure (see **PRECAUTIONS: Patients with Heart Failure**)
- Digestive: altered sense of taste, anorexia, diarrhea, dry mouth, intestinal perforation
- Hematologic/Lymphatic: adenopathy, anemia, aplastic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia (see **WARNINGS**)
- Hepatobiliary: autoimmune hepatitis
- Musculoskeletal: joint pain, lupus-like syndrome with manifestations including rash consistent with subacute or discoid lupus
- Nervous: paresthesias, stroke, seizures, and central nervous system events suggestive of multiple sclerosis or isolated demyelinating conditions such as transverse myelitis or optic neuritis (see **WARNINGS**)
- Ocular: dry eyes, ocular inflammation
- Respiratory: dyspnea, interstitial lung disease, pulmonary disease, worsening of prior lung disorder
- Skin: cutaneous vasculitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, pruritus, subcutaneous nodules, urticaria

Rx Only. This brief summary is based on ENBREL prescribing information v. 33: 03/2008

Manufactured by: Immunex Corporation
Thousand Oaks, CA 91320-1799

U.S. License Number 1132

Marketed by Amgen and Wyeth Pharmaceuticals

© 1998 – 2008 Immunex Corporation. All rights reserved.

Immunex U.S. Patent Numbers: 5,395,760; 5,605,690; 5,945,397; 6,201,105; 6,572,852; Re. 36,755

AMGEN Wyeth®

For more information please call 1-888-436-2735
or visit www.enbrel.com

© 2008 Amgen, Thousand Oaks, CA 91320 and Wyeth Pharmaceuticals Inc., Philadelphia, PA 19101. All rights reserved. 222725-01

INDEX OF ADVERTISERS

Actelion Pharmaceuticals, Inc. Tracleer	12a-12b	McNeil-PPC, Inc. Tylenol	20
Bayer HealthCare LLC ALEVE	27	Pfizer, Inc. Arthrotec	32-34
Centocor, Inc. Remicade Corporate	24a-24d, 25-26 39	Rexall Sundown, Inc. Osteo Bi-Flex	9
Endo Pharmaceuticals Inc. Opana ER	15-18	Roche Laboratories Inc. Corporate	10-11
Ferring Pharmaceuticals Inc. Euflexxa	41-42	Springer Textbook	28
Genentech, Inc. Rituxan	3-5	UCB, Inc. Corporate	36-37
Gilead Sciences, Inc. Corporate	7	University of Pittsburgh Medical Center Corporate	23
GlaxoSmithKline OS-CAL	19, 31	Wyeth Pharmaceuticals Inc. Enbrel	45-48