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JANUARY 1/8, 1982

American Medical

NEWS

FDA drops mandatory PPI plan

The Food and Drug Administration (FDA) has dropped its plan to require prescription drugs to carry patient package inserts (PPIs) that some physicians have said would interfere with the physician/patient relationship.

CITED AS a reason for ending the mandatory plan was the acceleration of voluntary efforts in the private sector to assume responsibility for educating patients about drugs.

The FDA announcement referred to the American Medical Association program to develop and make available a series of patient medication instruction sheets (PMIs) to supplement prescription drug information provided orally by physicians.

The new AMA-PMI program offers "a

practical alternative to the mandatory PPIs that were under consideration by the FDA," said Leonard D. Fenninger, MD, AMA vice president for medical education and scientific affairs.

The FDA proposed to rescind its plan to test PPIs for 10 drugs over a three-year

AMA report

period. The proposal will permit 60 days for public comment.

In a joint statement, Richard S. Schweiker, secretary of the Dept. of Health and Human Services, and FDA Commissioner Arthur Hull Hayes Jr., MD, said the government remained committed to the need for patients to have more

information about prescription drugs.

Their review of the 10-drug pilot program, however, showed that it had significant limitations and imposed unreasonable constraints on the health care system, they said.

"WE HAVE LEARNED during our review that many physicians, pharmacists, and other health professionals believe there are more effective and cost-efficient ways to bring information to consumers," the statement said.

Secretary Schweiker and Commissioner Hayes noted that the AMA Board of Trustees had approved the PMI program, under which physicians would be provided with drug information leaflets that they can modify to meet individual

(See FDA . . . , p. 34)

Poland halts shipments of medical goods

Shipments of badly needed medical supplies to Poland have been halted by the imposition of martial law there, say officials from the Polish American Congress (PAC) and Project HOPE.

"It's pretty hard to get stuff in when the airports and seaports are closed," said John Walsh Jr., vice president of development for Project HOPE.

Given Poland's uncertain political climate, neither the PAC nor Project HOPE is sure the lifeline of drugs and disposable medical supplies ever will be re-established.

Without the trade union Solidarity's participation in the program, there is no assurance the drugs will arrive at their intended destinations, said Eugene Rossypal, spokesman for the PAC, a Chicago-based umbrella organization that represents some 3,000 Polish-American groups.

"I'm sure the Polish government would accept medical supplies from us, but

(See Shipments . . . , p. 22)

Competition, capitalization costs to bind more MDs into corporate groups

The day of the solo professional practitioner is on its way out, predicts Irwin

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