Pharmaceutical Industry’s Ad Guidelines Draw Fire

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

ew voluntary guidelines for di-
rect-to-consumer prescription
drug advertising released by the
Pharmaceutical Research and Manufac-
turers of America have drawn criticism
from politicians and consumer groups
who say they don’t go far enough.

While I wish the PhRMA guidelines
would have gone further and proposed
a moratorium on DTC (direct to consumer)
advertising of newly approved drugs, I
hope individual pharmaceutical manufac-
turers will seriously consider such a mea-
sure,” Senate Majority Leader Bill Frist,
M.D. (R-Tenn.), said in a statement. Sidney
Wölfe, M.D. director of the Public Citizen
Health Research Group, called the PhRMA
announcement “a meaningless attempt to
fool people into believing the guidelines
are stronger than they really are.” The
guidelines were released in August at
an American Leg-
islative Exchange
Council meeting in
Dallas. They call for phar-
maceutical manufacturers
to educate physicians
to educate consumers.

The centerpiece is the notion that the
companies are committing an appropriate
amount of time to educate health care
professionals about new medications and
new indications . . . to make sure physi-
cians and other providers know about
the medicines and benefits before,” direct-
to-consumer advertising campaigns are
undertaken. Billy Tauzin, CEO of PhRMA
and a former congressman from Louisi-
a, said at a press conference
sponsored by PhRMA.

The length of time the companies will
take to educate physicians will depend on
several factors, including whether the drug
is a life-saving one and how complex the
risk-benefit profile is, Mr. Tauzin said.

Other provisions of the voluntary guide-
lines, which 23 companies have signed
onto, include:

▶ DTC ads should be balanced, and discuss
both the benefits and risks of the medica-
tion. The information should be present-
ed in “clear, understandable language,
without distraction from the content.”

▶ Ads should be targeted to avoid audi-
ences that are not age-appropriate. For
example, Karen Katen, president of Pfiz-
er Human Health, said that her company
would not run a television advertisement
for Viagra (sildenafil) during the Super
Bowl, when young children may be
watching.

▶ Companies should submit new DTC
print and television advertisements to the
FDA before releasing them. PhRMA board
chair Bill Weldon said this does not mean
that companies would submit an ad
to the FDA on Tuesday and then run it on Wed-
nesday. “The intent is to make sure that
FDA has been able to comment on any
programs prior to significant advertising,” said
Mr. Weldon, who is also chairman and
CEO of Johnson & Johnson.

▶ Ads that identify a product by name
should include the product’s indications as
well as its risks and benefits. This means
no more ads that just give the name of the
medication and tell what it’s for, Mr. Tauzin
said.

PhRMA also will convene an indepen-
dent board in about a year to get outside
opinion on whether the companies are fol-
lowing the guidelines. The panel will in-
clude experts in health care, broadcasting,
and other relevant disciplines.

The voluntary guidelines are available at
www.phrma.org/publications/policy/
admin/2005-08.02.1194.pdf.

Policy & Practice

Pharmaceutical Residents Increasing

The number of psychiatric residents is
increasing modestly, according to a res-
cident census conducted by the Ameri-
can Psychiatric Association. As of Aug.
30, the total number of psychiatric res-
idents increased 1.6% over the previ-
ous year. U.S. medical graduates in-
creased 4%, and women residents were
up 3.5%, the census showed. Psycho-
sonology, medicine, a new psychiatric
subspecialty, had 60% female fellows.
The top three most popular subspe-
cialties were child and adolescent psy-
chiatry, addiction psychiatry, and foren-
sic psychiatry; all subspecialties had
increasing numbers of fellows except
for geriatric psychiatry. Geographical-
ly, the highest concentration of res-
dients was in New York-state, followed
by California.

Data on Youth Suicide Attempts

About 900,000 children aged 12-17
planned to commit suicide during their
worst or most recent episode of
major depression, according to data
from the Substance Abuse and Mental
Health Services Administration. Of those
who planned suicide, 712,000 at-
tempted it. The report, which was
compiled using data from the 2004
National Survey on Drug Use and
Health, defined a ‘major depressive
epis
dose’ as a period of at least 2 weeks in
which a person experienced a de-
pressed mood or loss of interest or
pleasure in daily activities, and had at
least five of nine symptoms of de-
pression listed in the DSM-IV. “Suicide
is a preventable tragedy,” said Charles
Curie, the SAMHSA administrator. “It is
a thief that sets no boundaries and
seeks victims of all ages.”

Public Health Unpreparedness

Many local public health agencies are
ill-prepared to learn about and respond
to naturally occurring outbreaks of
deadly infectious diseases or acts of
bioterrorism, a test by the RAND Cor-
poration has found. To conduct the test,
researchers posed as local physi-
cians who were reporting fictitious cas-
es of botulism, anthrax, smallpox,
 bubonic plague, and other diseases to
19 public health agencies in 18 states na-
tionwide. (Agency directors agreed in
advance to participate in the test, but
did not tell their staff members.) In one
case, after listening to a description of
the classic symptoms of bubonic plague
a public health worker advised the
 caller not to worry because no sim-
lar cases had been reported. Another
caller who reported a botulism case
was told: “You’re right; it does sound
like botulism. I wouldn’t worry too
much if I were you.” The article ap-
ppears in the Aug. 30 online edition of
Health Affairs.

Drug Abuse Counseling Protocol

SAMHSA has issued a new Treatment
Improvement Protocol designed to help
 substance abuse counselors work-
 ing with clients in the criminal justice
system. The guidelines, known as TIP
44, provide information on screening,
assessments, treatment services, and
follow-up care for people in various
criminal justice settings. For example,
they note that in the pretrial setting,
treatment professionals need to be care-
ful not to coerce clients into waiving
due process rights. The guidelines also
explain that in prison drug abuse treat-
ment followed by community-based
continuing care appears to reduce short-term recidivism and re-
lapse rates. The guidelines are available online at www.samhsa.gov/news/

Part B Premiums on the Rise

Medicare Part B monthly premiums will be
$88.50 in 2006, an increase of $10.30 from the current $78.20 premi-
um, the Centers for Medicare and Medicaid Services reported.

The agency cited continued rapid growth in the intensity and use of Part B services as the main reason for the increase. “This growth is seen in physician office visits, lab tests, minor procedures, and physician-administered drugs.” No
includes rapid growth in hospital out-
patient services,” CMS said in a state-
ment. They also said that “part of the
premium increase is necessary to in-
crease assets to fund future pur-
poses, are held in the Part B trust
fund.” Though premiums are rising,
most Medicare beneficiaries will see
significantly lower out-of-pocket health
care costs in 2006 because of the sav-
ings in drug costs from the new
Medicare prescription drug benefit, the
agency contends.

Employer Health Coverage Declines

The percentage of businesses offering
health insurance to employees has de-
clined over the past 5 years as the cost
of providing insurance benefits out-
paces inflation and wage growth,
according to the 2005 Annual Employer
Health Benefits Survey, conducted by the
Kaiser Family Foundation and Health
Research and Educational Trust. The
survey found that three of five firms (60%) offered coverage to workers in
2005, a decrease from 69% in 2000 and
totally from fewer small businesses of-
fering health benefits, as nearly all busi-
nesses (98%) with 200 or more work-
ners offer such benefits,” the news
release stated. The survey found that
20% of employers that offer health in-
surance currently provide a high de-
ductible health plan option. Very large
companies—those with 5,000 or more
employees—are significantly more
likely than smaller ones to offer a high
deductible plan option, with 33% of
offering such an option in 2005. High-de-
ductible health plans are defined in the
survey as plans with at least a
$1,000 deductible for single coverage
or at least a $2,000 deductible for family
coverage. In the meantime, relatively
few workers are enrolled in ‘con-
sumer-driven’ plans, despite their
growing availability.

—Joyce Frieden with staff reports