

- pb. - Domestic Policy Council -

5 years ago -

^{let military}
FDA reg ~~let~~ ^{waivers} informed consent

- wartime use - ~~hadn't~~ ^{had} to show
infeasibility

- generic reg - put quichecks in place

- military asked to waive i.c. for 3

drugs

granted
plus
waivers

- P.B.

- vaccine against botulism

withdrew

- cream supposed to put on parts of
your body to protect from
chemicals

even though they didn't have to get i.c. -

had to get each person's fact sheet

keep records as best they can. -

no data follow-up. (reg. as part of
required IND). -

{ granted IND
gave troops the drug

Schwartzkopf. - in war theater -
req. informed consent for bot
vaccine. -

Pres. Commission / Rockefeller hearings - Gulf
war syndrome.

- FDA says didn't do good job
- military admits it didn't do good
job.

Military wants to make reg final -
broad range of comments. - (5 yrs ago)

Presidential Commission had sessions in it. -
FDA said would open again - asked
for more comments on things Pres.
Commission has found.

FDA not comfortable w/waiver

Sid Wolfe - military knew it could
be harmful. - but
didn't disclose w/waiver.

other day

Military was going to do war games - asked
that he waive consent for pata. d.

serious nerve disorder —

p.d. —

drug of choice for — megesthine
gravis —

- take 20 times
- don't have major side effects.
- v. safe drugs at higher doses —

~~the~~

(NDA)

Friday military submitted new drug application —

- did NDA for valium —
- never approved something that isn't approved for other uses — not likely to approve it this way —
- lack of useful data —

Have been using p.d. for 20 years —

- in military manual
- don't take it when ordered — can't marshalable offense

Repropose — Q is — tighten it up —

— put out a rule that

doesn't permit waivers

— will waive i.c. for new drug —

— meet w/ DOD in the next two weeks ^{situation} w/

—

— w.

— Next couple of months

~~Interns - Stated Program~~

Jill

HM 223-1826 (cf)

202-986-3899 (CDC)

Working Friday

Ros pyromech-Becty in
Rm 1 - New permits
6-6575.

Q

F.D.A. Is Urged to End Pentagon Waiver on Experimental Drugs

WASHINGTON, May 7 (AP) — The Food and Drug Administration should revoke the military's ability to give soldiers experimental drugs without their consent because of mistakes made during the Persian Gulf war, consumer and veterans' groups said today.

Dr. Sidney Wolfe of the consumer advocacy group Public Citizen said the Defense Department did not tell the agency that an experimental drug given to soldiers in the gulf war might have hurt their chances of surviving a nerve-gas attack.

The military also violated an agreement with the F.D.A. that the soldiers would be told the drug pyridostigmine bromide was experimental and would be monitored for side effects, Dr. Wolfe contended in a petition filed with the agency.

Thousands of gulf war veterans say they have suffered mysterious illnesses since the conflict. Recent independent animal studies have suggested that pyridostigmine bromide and insect repellents the soldiers used could have caused a toxic reaction that is cited as one of the

combination of symptoms that make up war syndrome.

Charles Sheehan-Miles of the National Gulf War Resource Center, which joined the petition, said the troops needed the protection every American citizen is given.

Federal law requires that Americans be fully informed about an experimental drug before consenting to take it. But the F.D.A. waived that requirement in 1991 when the Pentagon said it did not have time to gain the consent of 600,000 troops headed for the gulf war.

The agency is now considering whether to make that waiver permanent so soldiers can be given experimental drugs quickly during any military crisis.

In a statement, the Pentagon said today that it would continue to use the earlier waiver if an emergency arose before the agency settled the issue. But it defended its use of pyridostigmine bromide.

The Pentagon denied improperly collecting data for the F.D.A. but acknowledged, "It is likely that information was not thoroughly disseminated to the individual service member."

Pyridostigmine bromide is not approved as a pretreatment against nerve gas, but the F.D.A. agreed to let soldiers take it based on Army animal studies showing it protected against certain types of gas. Had soldiers been gassed, they would have taken F.D.A.-approved antidotes as well.

But Iraq stockpiled another nerve agent, sarin, during the gulf war, and another Army animal study, which Dr. Wolfe sent the F.D.A. today, concluded that pretreatment with pyridostigmine bromide actually decreased the effectiveness of the two

nerve-gas antidotes for sarin.

The Army submitted the sarin study for publication in a journal on Feb. 11, 1991, just weeks after the gulf war started — and a month after the F.D.A. agreed to let the military give soldiers pyridostigmine bromide without their consent.

Dr. Wolfe contended that the Army knew the study's results as early as November 1990 and that the F.D.A. should have seen the data before making its decision.

10-State Swath of the West Will Soon Hit 75 M.P.H.

By JAMES BROOKE

DENVER, May 7 — Eastern drivers mapping out routes for Western vacations this summer can plan on the shortest driving times in a generation.

Over the next month, five states — Colorado, Idaho, Nebraska, New Mexico and Utah — will phase in 75-mile-per-hour speed limits on rural Interstate highways. Five other states — Arizona, Montana, Nevada, South Dakota and Wyoming — recently raised their limits, so the new additions will create a solid bloc of 10 Western states where the speed limit will be at least 75 m.p.h.

Moving faster than desert road-runners, Western legislatures raced to raise speed limits after President Clinton signed legislation last November that abolished the 21-year-old national maximum speed limit.

Critics say accidents will soar as drivers cope with speed limits sharply higher than the 55 m.p.h. that was the rule less than a decade ago.

As highway travel times drop, some worry about the casualty count.

While proponents argued that the higher speed limits would merely legalize existing driving speeds, highway patrol officers across the West report that they are issuing double and triple the volume of tickets they once did as drivers test the new limits. Officers say they have eliminated the old "fudge factor," where they stopped only those drivers going more than 10 miles an hour over the speed limit. And state legislatures have beefed up fines for speeding.

To advocates of fast driving, today's Westerners are recapturing a way of life their parents lost in 1974, when Washington braked drivers na-

tionwide in an effort to save gasoline after Arab oil-producing nations imposed an embargo on the United States for supporting Israel in its October 1973 war with Egypt and Syria.

Indeed, for six of the states, the new 75-m.p.h. speed limits simply mark a reversion to the pre-1974 status quo. "This is the first step in devolution of power from Washington," said State Representative Ron May, a Republican who sponsored Colorado's new speed limit law.

But this spring, with higher speed limits and gasoline prices at their highest levels in five years, fuel bills are likely to soar in the West.

"Going 75 instead of 55 results in an average 50 percent increase in fuel consumption," said John M. DeCicco, senior research associate for the American Council for an Energy Efficient Economy, a nonprofit research group in Washington.

With great distances to travel, Westerners are particularly sensitive about gasoline prices. Last year the average Wyoming resident spent \$734 on gasoline — slightly more than double the amount paid by the average resident of New York State or Washington, D.C., where distances are shorter and public transportation is widespread.

With a small population scattered over wide-open spaces, Westerners regard fast driving as a quality-of-life issue.

"Going from 65 to 75 adds 110 hours to my year," said Tom Polk, a salesman operating out of Omaha who drives 50,000 miles a year to cover his seven-state territory. Noting that some overnight road trips are now day trips, he added, "When you have a family, being home an extra three or four nights a month — that's a big deal."

Ten years ago, it would take a Wyoming driver who obeyed Washington's 55-m.p.h. limit nearly six hours to drive the 322 miles separating Cheyenne and Sheridan. Today, at 75 m.p.h., that drive takes 4 hours and 20 minutes.

In Montana, where new daytime speed limits carry no number and are defined simply as "reasonable



Ellen Jaskol/Rocky Mountain News

Colorado is joining other Western states in raising its speed limit, and that left Domingo Martinez with some new signs to tend to at the state Department of Transportation last month. He had to make 280 of them.

and prudent," a driver last week could sail down Interstate 94, though the flat, empty eastern half of the state, with the cruise control set at 85 m.p.h. and not worry about a speeding ticket.

Critics, including Advocates for Highway and Auto Safety, a group based in Washington, note that of the 10 Western states with 75-m.p.h. limits, eight, including Montana, were on a Federal Department of Transportation list of the 10 states with the highest number of fatal crashes per hundred million miles traveled from 1990 to 1994. The high number of fatalities was attributed largely to high speeds, low use of seat belts, and alcohol.

Reflecting a regional undercurrent of apprehension, The Arizona Republic contributed to the state debate with a cartoon that depicted a smoking car wreck, overshadowed by a sign that read, "75 — the age

you probably won't reach once they raise the speed limit."

But, after six months of higher speed limits, there is little sign of increased highway carnage in the West's three pioneering states, Wyoming, Montana and California.

In Wyoming there were 26 traffic fatalities in the first four months of this year, compared with 34 in the same period last year.

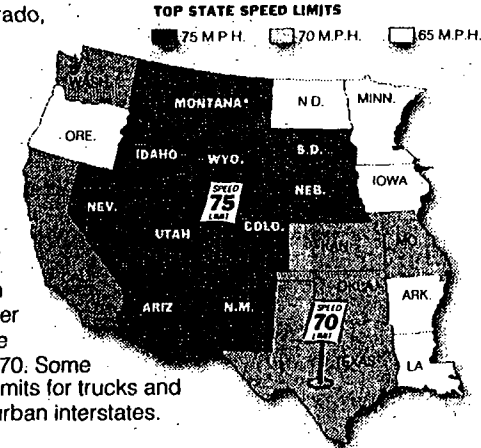
In Montana during the same period, there were 50 traffic fatalities this year and 49 last year. But in the first three months of this year, the Montana Highway Patrol investigated 2,703 accidents, 25 percent more than in the same period last year.

California increased speed limits on some highway sections to 65 m.p.h. on Dec. 17, and on other sections to 70 m.p.h. on Jan. 7. The total number of collisions increased 3 percent and fatal crashes increased 13 percent from Dec. 17 through the end

UPDATE

The Speed Belt

Five states — Colorado, Idaho, Nebraska, New Mexico and Utah — are expected to phase in a 75-mile-an-hour speed limit on rural interstates over the next month, creating a solid block of 10 Western states with the higher limit; other western states have raised their limit to 70. Some states have lower limits for trucks and for all vehicles on urban interstates.



*Montana's top daytime limit is defined only as that which is "reasonable and prudent."

The New York Times

of March, compared with the same period a year earlier, according to the California Highway Patrol.

But analysis of the fatal accidents showed that alcohol-related crashes had increased by 44 percent, while crashes where unsafe speed was the primary factor had dropped by 15 percent.

Independent and government safety experts say results are too preliminary and too subject to seasonal weather fluctuations to draw definitive conclusions.

Still, said Albert E. Goke, safety director for Montana's traffic department, "the doom and gloom that was predicted is not occurring."

Votes in state legislatures this spring were lopsided in favor of higher limits.

Fighting a rear-guard action in Colorado, safety advocates noted that 37 of Colorado's 100 state legislators had received speeding tickets. The driver's license of Ray Powers, the Senate sponsor of the new speed limit bill, was revoked in the 1970's because he had an excessive number of speeding tickets.

The bill easily swept through both houses of the Colorado Legislature. Gov. Roy Romer signed it on April 25 before television cameras in the sign

shop of the state Department of Transportation. Then he took off his coat and hand-stenciled Colorado's first 75-m.p.h. speed limit sign.

In Nebraska, only 22 percent of people polled last December supported raising the speed limit to 75 miles an hour. Nevertheless, the Legislature overwhelmingly approved the new limit, which will go into effect on June 1.

Preparing for an influx of summer tourists, state officials in the West are stressing common sense and individual responsibility in advertising campaigns.

In Montana, "reasonable and prudent" speeds depend on a number of factors, like traffic conditions, road conditions, the car and the driver, said Mr. Goke, who stressed that Montana did not want to attract tourists addicted to speeding.

And two weeks ago in Colorado, as Governor Romer washed the black ink from his hands at the sign shop, Capt. Larry Tolar, spokesman for the state Highway Patrol, warned reporters, "If you are traveling faster than 75 miles an hour, the face you see in your rearview mirror won't be a friendly one."