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Dark Days Ahead for "Big Pharma" and You

By ACSH Staff — March 12, 2009

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When all three branches of the federal government target an industry, you know it's in big trouble. The hapless companies under the gun are our pharmaceutical manufacturers, but we will all be victims in this crusade.

The Obama administration has taken up the cause of encouraging drug importation. No one in the administration seems to know -- or care -- that importing cheaper drugs will not only expose Americans to sub-standard, counterfeit, and toxic copies of American-made brand name drugs, but will simultaneously import foreign price controls (if Congress really wanted to conserve healthcare dollars, they would pass tort reform and reduce the insidious costs of defensive medicine).

Such artificial price-fixing was a major factor in the decline of European pharmaceutical research and the concomitant revival of our own. But that was then, this is now: a bipartisan coalition of Senators is trying to poke holes in the dike that the FDA had erected against cheap, but unreliable, imported drugs. The dual threats of counterfeits and price controls are coming to a pharmacy near you.

The Obama health plan also includes over $1 billion to institute "comparative effectiveness" criteria for new drug approvals. This means drug trials will have to show that a new drug is not merely effective and safe, but somehow better than its older competitors. Currently, getting a new drug approved for marketing consumes over a billion dollars and ten to fifteen years. To show superiority to drugs already on the market will take longer and be more expensive. This will exert a chilling effect on drug companies that are considering testing new drugs without clear blockbuster potential, since failure to attain FDA approval leads to massive financial losses. Recently, Pfizer scrapped testing of two new drugs in late-stage clinical trials. Were these drugs effective? We'll never know: the world's largest drug maker stated that there was insufficient evidence that they were better than currently marketed drugs, and thus they feared investing millions more in a dead-end trial.

Another front in the anti-pharma crusade is the Medicare drug program. Those now in charge of revamping our health care system plan to make drug companies "negotiate" with Medicare to determine drug prices, due to Medicare's recent expansion into prescription drug coverage. Official and patients agree that this expansion -- Medicare part D -- has been working out even better than predicted. However, drug formulary managers will soon have to accept the prices Medicare dictates: you cannot "negotiate" with an adversary who controls the terms of the discussion. This amounts to another foray into price-fixing. Perhaps Congressional Democrats perceive that this program is working well for seniors and want to put their thumbprint on it before Republicans claim

all the credit.

Now, the unkindest cut of all: federal pre-emption of state tort action against drug-makers is off the table. The U.S. Supreme Court ruled 6-3 that Wyeth is indeed responsible for an adverse reaction to one of its injectable drugs -- even though the negligent physician-assistant did not follow the FDA-approved labeling instructions. Wyeth had argued, in *Wyeth v. Levine*, that the FDA-mandated label pre-empted state tort law. The Justices disagreed, and the pharmaceutical industry is now more susceptible to state actions for negligence and inadequate warning labels -- even though they are legally required to adhere to the FDA's dictates on what should, and should not, be included in the label. Anti-business media headlined, "High court finds against Wyeth." In fact, this decision is against all of us, as pharmaceutical companies brace for the onslaught of litigation and new drug development stalls. Forget about new vaccines against HIV or bird flu, as well as new cancer treatments, despite the President's alleged commitment to a new "war on cancer."

Taken together, these various assaults foretell the decline of the American pharmaceutical industry -- which had been one of our major growth engines over the past twenty years. I believe it may take a wake-up call in the form of an American drug company being taken over by a foreign entity to bring the real costs of pharma-bashing home to our leaders.

The regulatory and legal strictures impeding new drug development will redound to our detriment, as our pharmacopoeia stagnates. Even before this crescendo of bad news, the last two years saw a historically low number of new drug approvals. Do we really want our children and grandchildren to accept 2009 drug choices in 2020 and beyond?
