Editorial

The best medicine that money can buy?

Paul G. King, PhD
PhD Analytical Chemist, MS Inorganic Chemist
FAME Systems
33A Hoffman Avenue
Lake Hiawatha, NJ 07034 USA
Phone: +1 973 263 4843
Email: drking@gti.net Website: http://www.dr-king.com

Abstract

This essay discusses government and industry control and coercion in the development, regulation, and prescription of the "treatment centric" medicines available today in the United States. It recommends a course of action to restore a truly "cure centered" system to the nation's people.

Problems with today's medicines are identified, and several concrete examples are given that establish the validity of the essay's premises. The inordinate societal influence wielded by the pharmaceutical industry is discussed, exposing the industry's methods of increasing greed-driven profits while using government to revise our laws and statutes, excusing any liability for past, current, and future egregious "public health and safety be damned" decisions.

In closing, a set of actions are defined that are necessary to restore our medicine system to the "cure centered" approach to which the purchasing public is entitled.

Keywords: pharmaceutical industry, medicine, treatment, cure

Medicine Today

Americans pay the highest prices for the medicines available to us.

Yet, we do not even get the quality of medicines our laws demand.

The pharmaceutical industry knows the medicines sold in America do not meet our minimum standards.

Today, the American pharmaceutical and healthcare industries have little interest in finding cures.

Provided there is sufficient profit, their focus is on treating ever more of us with increasingly costly products and protocols.

More and more, their practices maximize their profits at our expense.

Today's flood of direct-to-consumer pharmaceutical ads is designed to sell, or increase consumer demand for, their increasingly expensive products.

To do this, they sell the benefits and minimize the risks.

They do this without caring that the people's health costs increase while access to healthcare declines.

Worse, when cures are found, these industries resist implementing them.

The Delayed Cure for Stomach Ulcers

For example, in 1982 an Australian doctor proved that a bacterium, Heliobacter pylori (H. Pylori), was the cause of most peptic ulcers.

The medical profession should have begun treating the causative H. pylori with large doses of an antibiotic and curing their patients' ulcers.

Had they done this, almost all their patients would have experienced rapid cures of their gastric and duodenal ulcers.

In 1994, 12 years later, the NIH finally strongly recommends that antibiotics be used to treat ulcers.

However, in 1995, the NIH still found that about 75% of ulcer patients are treated with antisecretory medications; only 5 % receive the curative antibiotic therapy.

That same year, consumer research by the American Digestive Health Foundation finds that nearly 90% of ulcer sufferers are unaware that H. pylori causes ulcers.

In 1997, 15 years after the cause was discovered, the CDC finally undertakes a program to "educate" the public that most ulcers are caused by a bacterium, H. pylori, and can be cured with antibiotics.

The pharmaceutical and healthcare industries delayed public access to this cure for more than a decade.

Their excuse was they "could not agree on a 'standard' treatment regimen."

More than ten years of increasing profit for both the pharmaceutical and healthcare industries from ongoing treatments for stomach ulcers with antisecretory drugs and surgery that only treated, migrated or removed the ulcer, but did not cure it.

Faced with loss of a significant portion of the market for their antisecretory drugs, the pharmaceutical industry simply converted them into over-the-counter "antacid" remedies and began hawking them to that market.

Moreover, though the most effective treatment regimen was a three-drug set (Carafate®, an acid-stable antibiotic and an antisecretory compound) the current favored pre-packaged treatments omit the Carafate component.

Was the Carafate omitted because, as the "cure rate" statistics indicate, removing it lowers the cure rate from 95+% to about 80+%?

Furthermore, though more than one (1) generic Carafate (sucralfate) has been approved, the analytical tests accepted by the FDA and provided by the United States Pharmacopeia do not

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guarantee that the structure of the sucralfate is the same as that of the Carafate. [Note: In a clinical trial, "sucralfate" with proven structural equivalence to Carafate was found to give clinically equivalent results while a structurally non-equivalent was ineffective.]

The As-Yet-Unavailable Cure for Cervical Cancer And?

Or consider their handling of the disease cervical cancer.

Cervical cancer kills about 4,800 American women each year.

About 13,000 are annually diagnosed with cervical cancer.

It is the second most deadly cancer in women and has been implicated in prostate cancer in men.

Having one or two of the known 90+ strains of the human papilloma virus (HPV) is a known "risk" factor for cervical cancer.

At least 70 % of those with cervical cancer have significant levels of HVP-16 and HVP-18, and traces of HVP are found in 99.7 % of all cervical cancers.

Lest men feel safe, HPV-16 was present at significant levels, in one German study, in 10 of 47 samples of prostate-tumor tissue versus a 1 in 37 rate in tissue samples from men with benign prostate hyperplasia.

Another study found that 42 per cent of the men with prostate cancer had antibodies to HPV-16.

Compared to 13,000 diagnosed cervical cancers annually, over 1 million American men have prostate cancer and there are about 200,000 new cases each year (more than 15 times the annual incidence of cervical cancer).

Currently, one in three American men have or will develop prostate cancer.

Clinical trials have shown some vaccine candidates developed outside of the US to be effective against HPV and have no significant immune system or other risks.

One of the most promising is based on a vaccine (protective against HPV-6, -11, -16, and -18) developed in Australia.

Merck claimed that the vaccine was 100% successful in a British clinical trial it conducted in 2000-2001.

In the UK, a "5 year" availability date was projected; yet, their 2002 projections are that a vaccine for the American public is "10 years away."

I wonder how long, if ever, it will be before a truly effective HPV vaccine is offered as a standard, or even an optional, preventive measure for cervical and prostate cancers in America.

In the US, cervical cancer in women and prostate cancer in men are detected and treated.

Moreover, the system of screening, detection and treatment is a big and highly profitable business.

In women, the focus is on early detection, annual PAP smears for all women, better (more expensive) PAP tests, and better drug, surgical and other treatments for those who have or may have the "disease."

In men, the approach is similar

Both industries stand to lose a lot of that money if a late childhood preventive vaccination program were to be adopted and the ongoing risk of "cervical cancer" were to be, in effect, almost completely eliminated.

The Current Record on Medical Progress in Curing and Preventing Disease

Modern science has had more than a decade to develop effective cures for HIV ("known" in America since 1984), Lyme disease ("known" since 1975), the Hantaviruses that cause an often-fatal human pulmonary syndrome (HPS hantaviruses, "known" since 1994), and Malaria (known elsewhere for centuries but recently found in America).

Yet all that has been developed in some cases are "better," ever more expensive treatments.

In other cases, where the number of American deaths and injuries is small, like St. Louis encephalitis, the virulent strains of Ebola and, until recently, West Nile virus, there has been little or no real improvement.

Not enough profit for the drug industry; let healthcare make the money.

Some Illustrative Examples

A Safe and Effective Lyme-Disease Vaccine?

Oh, I forgot about the "Lyme disease" vaccine, LYMErix ™, that the developers, SmithKline Beecham Pharma, managed to get licensed in a little over a year after their submission.

Starting in January of 1999, they released and sold LYMErix to the public.

They did this until, in the face of strong evidence that it caused more harm than good, they "voluntarily" stopped marketing LYMErix in February 2002.

This vaccine and a like vaccine, ImmuLyme ™, developed by Aventis, were developed and released by those who knew, or should have known, that the potential damage and concomitant increased treatment needs for some receiving such a limited-duration and potentially dangerous vaccine outweighed the "protective benefits" to those vaccinated.

Though their literature suggested long-term protection, the reality was that the three-shot regimen only provided, at best, limited-duration protection coupled with a hidden, but real, risk of the vaccine's triggering chronic autoimmune disease in those vaccinated.

Moreover, when the vaccine became available, the "industry educated" medical profession obligingly stopped using the effective "treatment on exposure" antibiotic regimen previously used.

So far, their actions have been a win-win situation for the pharmaceutical and healthcare industries.

Some of those treated with the vaccine have been irreversibly damaged and will require significant healthcare for the rest of their lives.

Of course, a "better," "effective" vaccine is in the works – but not for several years and at what cost?

Baycol® and Other "Safe" Cholesterol-Lowering "Statin" Drugs?

Take the case of the cholesterol-lowering "statin" drugs.

What about the increasing pressure being applied by both industries to raise the percentage of Americans "needing" cholesterol-lowering drugs?

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They want many of us to take a daily "statin" for the rest of our lives.

What about Bayer's now withdrawn, Baycol, Cerivastatin, that just happened to kill a hundred plus of the 700,000+ who took it, maimed hundreds, and apparently damaged thousands?

Yes, in 2001 Bayer withdrew the drug, approved in 1987, and may pay sizeable amounts in sealed settlements with the hundreds injured or the families of the 100+ people it killed. [Note: As of October 2004, Bayer has spent more than two billion dollars ($ 2,000,000,000.00 and still has tens of thousands of claims left to settle.]

Though their actions or inactions killed more than a few American citizens and injured hundreds of others, no one in Bayer is being prosecuted for the deaths and injuries that Bayer's action or inaction caused.

If your or my deliberate actions or inactions kill or injure others, the law will prosecute us.

Yet, if someone knowingly lets a drug stay on the market though the people taking it are dying and being injured, no one prosecutes him or her for the deaths and injuries that his or her actions or inactions have caused.

After all, taking any drug is a risk – yours – and the monetary benefit is theirs.

Of course the dead were informed of and understood the risk, and chose to take the drug anyway – didn't they?

Do you really believe the 100+ who died from taking Baycol were suicidal?

Though the dollars paid out for Baycol may be significant, they are small compared to what Bayer and both industries have made, are making and will make.

Moreover, those "responsible" Bayer officials who concealed or minimized the rhabdomyolysis risk have, to date, avoided prosecution and the risk of conviction.

Further, that "side effect" (severe muscle and kidney damage), while less common in the "statin" drugs remaining on the market, is a real risk for those taking the five remaining "statin" drugs – Lipitor ®, Zocor ®, Pravachol ®, Lescol ® XL and Mevacor ®.

Of course, unlike the 772+ injured by statin drugs, or the 31+ Americans killed by Baycol and the 29+ other Americans who died taking the other statin drugs, current prescriptionees are now fully informed of the risks and their warning signs, or are they?

What about impaired brain function? Increased hemorrhagic stroke risk? The risk of increased aggression, depression, and suicide? And?

The present goal of the pharmaceutical and healthcare industries is prescriptions for 50 % of us (about 100 million scripts [for more than 18 million of us] were written in 2000).

In contrast, those who look at overall risk project that 5 % of the current number really benefit from taking this class of drugs.

Accutane ®, A Safe Acne-Curing Drug?

Consider the ongoing saga of Accutane (Isotretinoin), an acne drug originally approved in the mid-1980s.

Since this drug is just as teratogenic as Thalidomide ™, it was approved only for the worst form of acne with a strong "causes birth defects" warning.

It was approved because its revealed benefits outweighed its revealed risks.

However, Hoffman-LaRoche (Roche), the applicant, knowingly omitted a problematic study from their submission.

That study showed that the drug had significant negative effects on the central nervous system (CNS) in mice – however, it took until 2002 for that study to be "rediscovered" and given to the FDA.

In 1982, the FDA rewarded Roche's willful omission by approving Accutane.

Having fraudulently obtained FDA approval of Accutane as a "last resort" acne treatment, Roche set about "educating" doctors and the public about this drug.

Their efforts over the past two decades have been very successful and highly profitable.

For more than 20 years, Roche has "focused" on the teratogenic effects on the unborn and their "responsible" efforts to stop those prescribed Accutane from getting pregnant.

Moreover, whenever the firm's efforts increased their costs they were more than happy to pass them along and then some to the consumer.

What about the extra abortions and adversely affected babies?

Well, that is the risk that the patient and society took to get the benefit.

Has Roche behaved responsibly?

According to the information presented in a recent Congressional hearing (11 December 2002):

- In 2001, more than 2,000,000 prescriptions for Accutane were filled.
- There were still 79 pregnancies reported to Roche – about 70 % resulted in some physical or mental defect in the children carried to term.
- In 2002, the head of Roche's regulatory affairs department celebrated because Roche had again dodged:
  - The restricted distribution of Accutane. (They agreed to an "improved" voluntary program aimed at minimizing pregnancies [the teratogenic effects]).
  - Having to keep a registry aimed at identifying adverse psychiatric effects.
- Roche's President for North America is only responsible for the US and Canada – not Mexico, the major source for the illegal Accutane available in the US.
- Even a "best practice" dermatologist admitted to a "2 % to 5 % off label" prescribing practice.
- The FDA projected a general "off label" use rate of more than 90 %.
- Based on a "30 % drop" in doctor-written scripts in 2002, it was obvious that "off label" prescribing of this drug has been more than 50 %.

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- Finally, when the subject of adverse CNS effects in humans was brought up, Roche said their recent patient label warnings were just precautionary because "there is no scientific proof that taking Accutane caused the 'reported' depressions, attempted suicides and suicides."

- In 1997, the French (reviewing their reported instances linking Isotretinoin to depression, attempted suicide, and suicide) made Roche include patient label warnings of these as serious risks – not "a precautionary measure."

- Roche purposely did not inform the FDA of the label change mandated in France, though the regulations required them to do so.

Thus, Roche continues profiting from the "off label" use that its "educational" advertising to the teenage public has generated.

Conservatively, that "off label" usage is greater than half of the more than 20,000,000 prescriptions written since approval.

In addition, they have, to date, avoided any legal responsibility for the abortions and damaged children born – it's solely the women's fault.

Moreover, they have avoided responsibility for any adverse CNS-related effects including suicide and attempted suicide.

In the hearings, their latest version of the "asbestos mantra" was "there is no scientific proof that taking Accutane causes depression, attempted suicide and suicide."

They take this position in spite of the fact that their own developmental work on an "improved" formulation showed an increase in negative CNS effects.

Much of what has come out would still be hidden had it not been for the suicide death of a seemingly well-adjusted son of a member of Congress who was prescribed Accutane.

Though his mild acne disqualified him from being prescribed Accutane, his doctor gave it to him anyway.

Like all hidden risks, this risk is no respecter of persons or status or innocence.

For Accutane, and the recently approved generic drugs (Amnesteem from, Bertek Pharmaceuticals [Mylan Laboratories], and Isotrentinoin from GenPharm, Inc.) the medical profession benefits from and we pay for:

- The required monthly visits and counseling.

- All the extra testing (baseline blood work, two pregnancy tests before start, monthly pregnancy tests, and follow-up blood work).

- The extra abortions.

- The medical procedures to keep damaged babies alive and repair them.

- The long-term care costs borne by those women who have those abortions or bear those damaged babies.

- The long-term care costs for those children born with mental retardation.

- The "unproven" adverse CNS effects related to depression, attempted suicide and suicide.

Today, Roche remains free to advertise this product to all physicians, to "educate" the public to look for a better acne-treatment alternative, and to profit from all of the ongoing unregulated black- and gray- market usage.

Their blatant direct-to-consumer "educational materials" (ads) targeted at pre-teens and teenagers encourages those with even mild acne to seek a better treatment.

They can't directly advertise this dangerous drug – that is illegal.

However, by marketing the curative power of Accutane to dermatologists and other doctors and downplaying the risks, who are they really fooling?

Similarly, direct-to-consumer ads tout the benefits of each drug or suggest that the consumer should seek a "better" treatment option.

At most, they only briefly mention the major contraindications and risks but not the rare ones and certainly not the suspected but, as yet, "unproven" ones.

Taking any drug is a risk and finding about your risk is your job – not theirs.

Moreover, no matter what drug you take and what your benefits and risks are – both the pharmaceutical and healthcare industries profit – the public pays them.

Schering-Plough's Shipping of "Empty" Inhalers

Look at Schering-Plough's shipping batches of asthma inhalers that they knew, or should have known, did not provide therapeutic levels of Albuterol and/or the related drugs they were supposed to contain.

Though their actions cost some adults and children their lives, all it has cost Schering Plough so far is a fine, a consent decree, and some civil lawsuits.

Normally, we send premeditated murderers to jail for life or execute them – but drug companies get off by paying typically less than 10 cents on the dollar in what they make and no one in the company is prosecuted for the deaths and injuries that their actions or inactions cause.

We really are hard on white-collar crime, aren't we?

We now make the CEOs and Presidents of our largest corporations sign their financial statements because the greed of some of them has cost some Americans money and their jobs, don't we?

But, we don't prosecute those CEOs and Presidents in the pharmaceutical industry for the deaths and injuries that their greed-based actions or inactions have caused.

Is the loss of money or job more important than the loss of health or life?

If corporations have the same rights as people, they and those who run them should be prosecuted just as people are, shouldn't they?

Is not shipping dangerous or defective drug products a criminal activity?

If not criminal, then what is it?

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Industry Seeking to Evade Its Liability for the Apparent Mercury Poisoning of Our Young

Or consider the recent case, where Senator Frist of Tennessee, beholden to healthcare and pharmaceutical industries, convinced his fellow Senators to accept amendments he helped add to the "Homeland Security Act of 2002" (HSA 2002) after the November elections.

The amendments are a blatant quid pro quo for the millions of dollars and hundreds of employees that Eli Lilly and the pharmaceutical and healthcare industries gave in the 2002 Congressional elections to get people favorable to their interests elected.

The last of these amendments, § 1717, voided all the pending lawsuits.

The other three blocked all future lawsuits by redefining the terms "vaccine manufacturer" (§ 1714) "vaccine-related injury or death" (§ 1715) and "vaccine" (§ 1716).

As the amended HSA 2002 was becoming law, Attorney General John D. Ashcroft and HHS Secretary Tommy Thompson moved to seal government records related to the potential links between Thimerosal, and autism and other neurological disorders. [Because a lot of people (including influential members of both parties) protested, the Justice Department withdrew its attempt to seal the records and, in a budget resolution (House Joint Resolution 2) passed in February 2003, these amendments were stricken. However that same resolution contained (pages 1241 to 1242) a mandate for the 108th Congress to revisit the issue of adequately protecting "vaccine manufacturers," "manufacturers of vaccine components or ingredients of vaccines," and "physicians and other administrators of vaccines" within "6 months of the date of enactment of this Act."]

By attempting to seal the records and suppressing other documents and information, our government is trying to force us, the people, to accept the government's assertion that there is no causative link between the alarming increase in childhood neurological disorders (autism, ADD, etc.) and Thimerosal in vaccines without being able to examine the underlying data and its biases.

The government's actions remind me of the patient who told his doctor that he needed a second opinion about the doctor's diagnosis and wanted to review the test results.

His doctor simply said, "For the second time, you need this operation – as for the test results, trust me, you wouldn't understand them."

What information has the current administration hidden from the people to:

- Make it harder for the parents of the more than 1,000,000 neurologically damaged children to establish a causal link between their child's injury and the vaccine that child was given and

- Protect the interests of the vaccine manufacturers?

Perhaps, like tobacco, we, the people, will one day find out what the vaccine industry knows and when it first knew about whatever has caused an American autism rate of "1 autistic child in every 250 children" (with "1 autistic child in every 150 male children" for children born in the 1980s, 1990s, and 2000 to 20xx?

To put the preceding autism rates into perspective, in 1999, 2000 and 2001, more than 12,000,000 children were born.

A "1 in 250 rate" means that in those three years alone, more than 48,000 autistic children were added to our population (about 40,000 of these were male).

Those four (4) amendments were a "Get out of jail free card."

These amendments allowed the Thimerosal and vaccine manufacturers to escape all punitive damage award risk and most liability for damages for their willful and profit-driven actions (continuing to provide Thimerosal-preserved multi-dose vials of vaccines when alternatives were available).

Eli Lilly and the vaccine firms minimized or eliminated their litigation costs related to the hundreds of thousands of autistic children whose condition may have been triggered or caused by the Thimerosal in the vaccines they received.

Fortunately, their initial attempt, orchestrated (according to the now-retired Congressman Dick Army) by the White House, failed.

However, Congress has promised the Eli Lilly and the other firms in the vaccines business another chance to get "indulgences" that they seem to have been promised in return for the campaign contributions and other campaign support they provided in 2002.

At least the risk to future children may have, for the moment, been "reduced."

Only "trace" levels of Thimerosal remain in most of the unit-dose vaccines now available for the "common" childhood diseases.

Hopefully, it is the Thimerosal and not the nature of the recombinant genetic material in some of the childhood vaccines or some other factor or factors.

If so, the late twentieth/early twenty-first century detection rate of "1 in 250 children" ("1 in 150 male children") will drop.

Of course, if a child is vaccinated for some other disease with a Thimerosal-containing vaccine, the risk may remain.

Moreover, adults, including some pregnant women, continue to get vaccines and other drugs that contain significant levels of the known cumulative neuropoison Thimerosal.

Even some in Congress seem to be a little concerned about this.

The "There IS No Proof" Defense

For more than 15 years, a growing body of evidence, much hidden from the general public, has shown that Thimerosal has adverse effects on the brains of children and adults.

The defense they and the FDA are using is their version of the tried and true "asbestos defense" – "there is no proof of a direct causal link."

Perhaps the unchallenged gross non-uniformity reported for vaccines (0.5 to 3 times the labeled level) has something to do with this.

If not, why did they seek to seal the records from the evidence collected?

What are they hiding?

In this 15-year-plus period, the industry has continued enlarging a long-term patient pool of millions needing, who knows, what future medications and treatments.

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The pharmaceutical and healthcare industries will be glad to provide the needed drugs and treatments as long as they profit. [Note: According to the CDC's 2004 Autism A.L.A.R.M., the current level of neurodevelopmental disorders is "1 in 6 children" or about 670,000 children per year or about 10,000,000 damaged children over 15 years.]

The hundreds of thousands of autistic children (currently, greater than 150,000) that Thimerosal may have created or helped create are just an added bonus.

Those children, the parents of those children, the states and the federal government get to pay for that bonus.

We, the people, get to pay.

The pharmaceutical and healthcare industries are, if paid, more than happy to provide the long-term medications and care that these damaged children and adults, if any, need for the rest of their lives.

Had they been ethical, the industry would have: a) switched to unit-dose vials for all vaccines and b) totally removed Thimerosal from their manufacturing processes as soon as there was any evidence of a risk link.

But they did neither.

After all, an ounce of prevention is worth a pound of cure; or is it?

Instead, these firms have resisted for more than a decade and still resist making global changes to remove Thimerosal from all drug formulations.

They hide behind their version of the "asbestos mantra," – there is no conclusive proof that Thimerosal causes autism.

After all, changing all vaccines to unit-dose vaccine vials is costly – so is changing to a different non-mercury preservative when such is required.

The costs are difficult to recover in the short-term.

Changing to unit-dose vaccine vials containing only a trace level of Thimerasol may also reduce their potential long-term customer pool, and removing it most certainly will.

None of the preceding realities are in these industries' profit interest.

Their position sort of reminds me of the similar behavior of the now-defunct asbestos industry and the recently exposed tobacco industry.

The Asbestos Industry Behavioral Model

In about 1918, life-insurance companies stopped insuring asbestos workers.

Their actions were not based on a proven causal link.

Their actuarial data showed them that insuring asbestos workers was an unacceptable risk – they simply acted on that actuarial data.

The asbestos companies simply stepped in, became life insurers, and provided small life-insurance policies to their employees.

The companies deliberately ignored the actuarial reality that working with asbestos shortened their worker's life expectancy.

Moreover, the asbestos industry continued for decades hiding behind a "there is no proof of a direct causal link" assertion.

The preceding is the "asbestos mantra."

Until the causal link is proven, they claimed the right to continue their business as they saw fit.

When the proof finally came in the 1980s, some in the industry declared Chapter 11 bankruptcies to minimize their dollar costs.

Moreover, they or their successor firms, and other firms continue to fight to escape much of the dollar costs – hoping to outlast their victims.

The litigation to "settle" claims is, in many cases, still an ongoing rearguard action for the surviving firms.

Further, neither they nor their executives were prosecuted though their decisions resulted in the early deaths and decreased quality of life that their workers and others suffered.

The Tobacco Industry Behavioral Model

Perhaps the pharmaceutical industry idolizes the more successful tobacco industry – another industry that uses denial and obfuscation to hide their craven activities.

They employed law firms and lobbyists to protect their interests and hide the reality that nicotine is addictive – the public be damned.

They continued to get away with doing this until someone finally, at great personal monetary cost, revealed the truth.

Then, the tobacco industry chose to "settle" the claims against them by buying off the states for "less than 10 cents on the dollar" and no criminal prosecutions.

The tobacco industry is still in business and able to advertise its products.

Those addicted to its product are paying the cost of the settlements.

Society continues to underwrite the long-term human quality of life and healthcare costs.

We continue to subsidize the growing of tobacco – in some cases, ironically, with tobacco settlement funds.

The Pharmaceutical Industry Behavioral Model

Given their settlement tactics and their political lobbying efforts, the pharmaceutical industry seems to be patterning its tactics after those successfully used by the tobacco industry to avoid being held fully culpable for its actions.

Moreover, as with the injuries caused by their releasing off-spec polio vaccine, the industry seeks to buy (by influencing the elections to elect Senators and Congressman who "owe" them) or blackmail (by reducing the number of firms in the vaccine business from 5 to 3, creating medicine shortages or the threat of shortages, and other similar tactics) the federal government into protecting their venal activities.

Using any means, the pharmaceutical industry seeks to subvert the regulatory process and control the legislative process.

They have learned the lessons taught by the asbestos and tobacco industries, legislative, executive and judicial influence is not enough.

Using the power of their advertising dollars, the pharmaceutical industry is now engaged in managing the media so that the media cooperates in protecting the interests of the pharmaceutical industry – after all, the failure of the asbestos and tobacco industries to control the "fourth estate" strongly contributed to the exposure of the harm they were knowingly causing.

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Realizing the importance of media management, the advertising budgets of the drug companies now exceed their total research and development budgets – after all, direct advertising not only allows the industry to promote its products but also provides the industry with considerable leverage over the "news" media, the issues it covers, and the manner in which the media presents those issues.

In addition, to further their greed, they seek to control the legislative, executive and judicial branches of the federal government.

In 2002, the pharmaceutical industry bought another piece of the "soul" of our President and Congress.

In their haste to wrest control of government from the Democrats, the Republicans sold their soul to the pharmaceutical and healthcare industries in exchange for their monetary, materiel, and personnel support.

For their efforts, the industry has gotten a quid pro quo in some of the amendments cravenly added to the "Homeland Security" bill after the elections.

Having failed to "get out from under" the threat of Thimerasol lawsuits, the pharmaceutical industry's current goal is protective liability legislation.

They want to be protected from full liability and/or punitive damage awards for any damage caused by their products provided said products are approved or licensed by the FDA.

Though they have, so far been unsuccessful, the Republicans have continued to place such legislation near the top of their legislative agenda under the guise of "reducing the cost of healthcare to the public."

Based on where we stand in 2004, the pharmaceutical industry continues to be very successful – the people and their health be damned.

Given the damage their willful actions have caused in the cited instances and others, the pharmaceutical industry knows, or should know, their actions warrant severe punitive damage awards.

Today's Reality

To the Republican party, you would have not won the Senate and perhaps the House without the millions the drug companies provided and the hundreds of their employees who helped turn out the "Republican" vote.

Now, you have won.

I'm sure the public will see more of your "compassion" as you continue to try to vote to "permanently" reduce the taxes on the rich and corporations at the expense of the middle class and the poor.

No child shall be left behind if the over-budget states find a way to foot the bill.

The current administration keeps talking about children and our future but provide no more than a pittance to back up their "wonderful" rhetoric.

"No child shall be left behind" – a slogan; not a promise.

Such compassion I have not seen – no, not in all of America.

Given what I know, the reality is even darker.

The pharmaceutical industry is engaged in an ongoing conspiracy to willfully violate the laws of America governing the manufacture of drugs and drug products.

Their unchecked greed drives their actions.

Given their actions, today's pharmaceutical industry is a very lucrative racket that controls our drug and biological products, including vaccines, while flouting both the letter and the spirit of the laws governing their manufacture and distribution.

Yet, the government and those in the FDA who "oversee" the industry seemingly do little or nothing to stop them.

At times, they do what they can to help by ignoring the pharmaceutical industry's willful law breaking in several areas.

In some cases, the FDA even provides the industry with detailed guidance on how to adjust their violative practices so that they comply with the letter of the law.

In others, the FDA simply states it will not comply with some legal requirement – like biannual general inspections – or enforce some legal requirement – like requiring that electronic records be stamped with the correct local time at the time they are generated.

Recently, in an attempt to further conceal their actions from public scrutiny, the FDA has quietly moved, in the name of "Homeland Security," to further restrict (FDA Docket 2004N-0214) the people's currently limited access to FDA records under the Freedom of Information Act while simultaneously touting the Agency's "openness and transparency" to the public.

A Call To Arms – Change The Paradigm

Since the federal government has been and is being corrupted by the pharmaceutical and other industries, what can we, the people do?

If you feel as I do, let us take back our government and prosecute the pharmaceutical industry and its executives to the full extent of the law.

People, let us find those people among us who believe in this republic and the ideals for which it stands as well as genuinely care about all of the people.

Elect those people – throw out the rest.

Have the government revoke the legal license that lets corporations have the same rights as we, the people, – corporations have no soul.

Have the government ban the buying of office by big money – be it individual wealth or corporate wealth – put caps on all spending.

Let the people amend the Constitution so that we, the people, elect the President and Vice President.

Money is not speech – money is not free – money is power.

As Paul the Apostle said, greed – the love of money – is the root of all evil.

Right now, those whose interests are served by "soft money" and the power it buys are seeking to have the courts overturn the recent legislation placing some limits on "soft money."

As usual, they argue that controlling the money interferes with their "free speech" – speech that their money buys.

By letter, FAX and e-mail, let us tell the every federal court, appeals court and the Supreme Court:

- Money is neither free nor speech – money is power.
- The current limits on spending are both legal and not enough.

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- No politician, party, or political action group has the right to drown out the opposition by the volume of their spending as they are doing now.
- Government by the rich and powerful is not government by the people – give the people back their government.

Justice Department – Do Your Job

In the meantime, Mr. Ashcroft, I call upon you to seize all of the assets of the pharmaceutical industry under the criminal RICO statutes.

Force them to operate in a not-for-profit mode until all Americans born or living today have died, or the pharmaceutical industry can prove it:

- Is operating in a manner that provides biologics, devices, drugs and drug products that comply with all federal laws,
- Markets new treatments if and only if they have been proven to be more cost effective and/or less risky than the ones currently available,
- Seeks effective cures ahead of incrementally better treatments that carry higher prices, and
- Will continue to do so.

Our Current National Realities

The United States does have the best of everything that money can buy.

However, when it comes to healthcare, many of us cannot afford the price.

Today, more than 45 million have no health insurance.

Perhaps 150 million more have, at best, marginally adequate coverage provided they or someone in their family does not suffer a "catastrophic" illness.

We, the American people, are becoming increasingly health poor.

In contrast, the pharmaceutical and healthcare industries are becoming increasingly profitable.

In government, the golden rule that we learned as children has been corrupted into "he who has the gold rules" – and there is no outrage at this.

What happened to government of the people, by the people and for the people?

Obviously, the rich and powerful, including the pharmaceutical and healthcare industries, are buying or stealing it.

A Call To Arms – Rise Up And Bring Back American Government

How long will we, the people, tolerate the current government of the rich and powerful, for the rich and powerful, and, increasingly, by the rich and powerful?

Hopefully, we will remember our history, rise up, and take back our government by the force of the vote.

I call on every citizen who can – register to vote – it doesn't hurt.

I call upon all registered voters to find and vote for candidates who will put the interests of the people first.

I call upon all registered voters to write, FAX and/or e-mail both their Senators (www.senate.gov) and their Member of the House of Representatives (www.house.gov).

Put them on notice.

If they do not start putting the interests of the people first, they will not receive your vote in the next election or in any election should they choose to run.

I call upon you to do this even if you like the current office holder – whether you or he or she is a Republican, Democrat, or an Independent – whether or not they belong to your party or to another party.

Remember, each of us is but a single straw in the wind.

Together, we are a strong people.

We are Americans – let us act like Americans.

Let us fight for a federal government that truly is of the people, by the people and for the people.

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