

INNOVATION IN HEALTH CARE AND HEALTH SPENDING

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Innovation in health care draws on two quite distinct branches of research:

A. BIOMEDICAL RESEARCH

The development of new pharmaceutical products and medical devices.

B. OPERATIONS RESEARCH

Also called, “health services research,” aimed at enhancing patient safety and economic efficiency in the delivery of health care to patients.

A. BIOMEDICAL RESEARCH

Advances in the development of new drugs and medical devices have been breath-taking in recent decades.

The U.S. can fairly claim to be the world's leader in this field, because

- a. we have great scientists working in the field;**
- b. we have a well developed venture-capital market;**
- c. every year, we spend huge amounts of tax money and private venture capital on R&D in this field.**

I will add a few more remarks to what already has been said about drug prices further on, but first I would like to offer some observations on the second sphere of research – OPERATIONS RESEARCH.

B. OPERATIONS RESEARCH

For reasons that escape me, operations research has long been the neglected step-child of research and innovation in U.S. health care, and it shows.

It has been well documented by now that the U.S. spends twice as much per capita than do most other industrialized nations without producing commensurately superior results.

Congress budgets only a pittance for the operations research required to make our health care delivery system safer for patients and also more efficient.

The private sector also has underinvested in this kind of research, because many of the benefits from it accrues to competitors who do not bear the cost of it.

FEDERAL SPENDING ON HEALTH-RELATED RESEARCH 2011

| | Billions of Dollars | % of U.S. Health Spending |
|-----------------------------|---------------------|---------------------------|
| All health-related research | \$49.8 | 1.800% |
| Health-services research | \$2.0 | 0.074% |
| Budget of AHRQ | \$0.43 | 0.016% |

SOURCE: Estimates provided by *AcademyHealth*, Nov. 6, 2015

The figure 0.074% for total federal spending on health services research means only \$7.4 is spend on operations research per \$10,000 total spending on that large industry.

The federal *Agency for Healthcare Research on Quality (AHRQ)* had a budget of only \$1.6 for every \$10,000 total national health spending in 2011.

That agency has been on the forefront of funding research on ways to enhance patient safety in hospitals and to enhance the quality of U.S. health care over all.

Yet there has been talk recently in Congress to terminate or to cut drastically the funding of the prestigious and highly productive *AHRQ*, which also conducts the large Medical Expenditure Panel Surveys (MEPS producing data on which most estimates of the cost of proposed health insurance legislation is based..

Cutting funds for that agency truly strikes me as truly penny wise and pound foolish – but so it goes!

It seems now widely assumed that the private IT industry will revolutionize health care in the U.S. and make it better and cheaper.

Just this morning Gillian Tett had a highly optimistic column of this sort in *The Financial Times*.

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November 5, 2015 5:42 pm

The start-ups turning healthcare on its head



Gillian Tett

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Companies could transform the medical industry just as Uber has upended our idea of the taxi

After hearing talk of such revolutions on the conference circuit for over three decades now, I would not hold my breath for the arrival of this particular “revolution.”

Our IT companies and sundry start-ups have nibbled at the fringes of US health care for at least a decade now, with only modest success.

There will be progress, to be sure, but it will be very slow in coming – the operative word is here is “evolution,” not “revolution.”

After all, aside from chronic underfunding the operations research required for greater efficiency in US health care, there are other obstacles to rapid innovation in this sphere:

- a) such innovations are often resisted, because they can be highly disruptive of a more comfortable life style to which providers of health care have become accustomed over the years;**
- b) what those who pay for health care call “greater efficiency” usually comes across as “less revenue” to the providers of health care.**

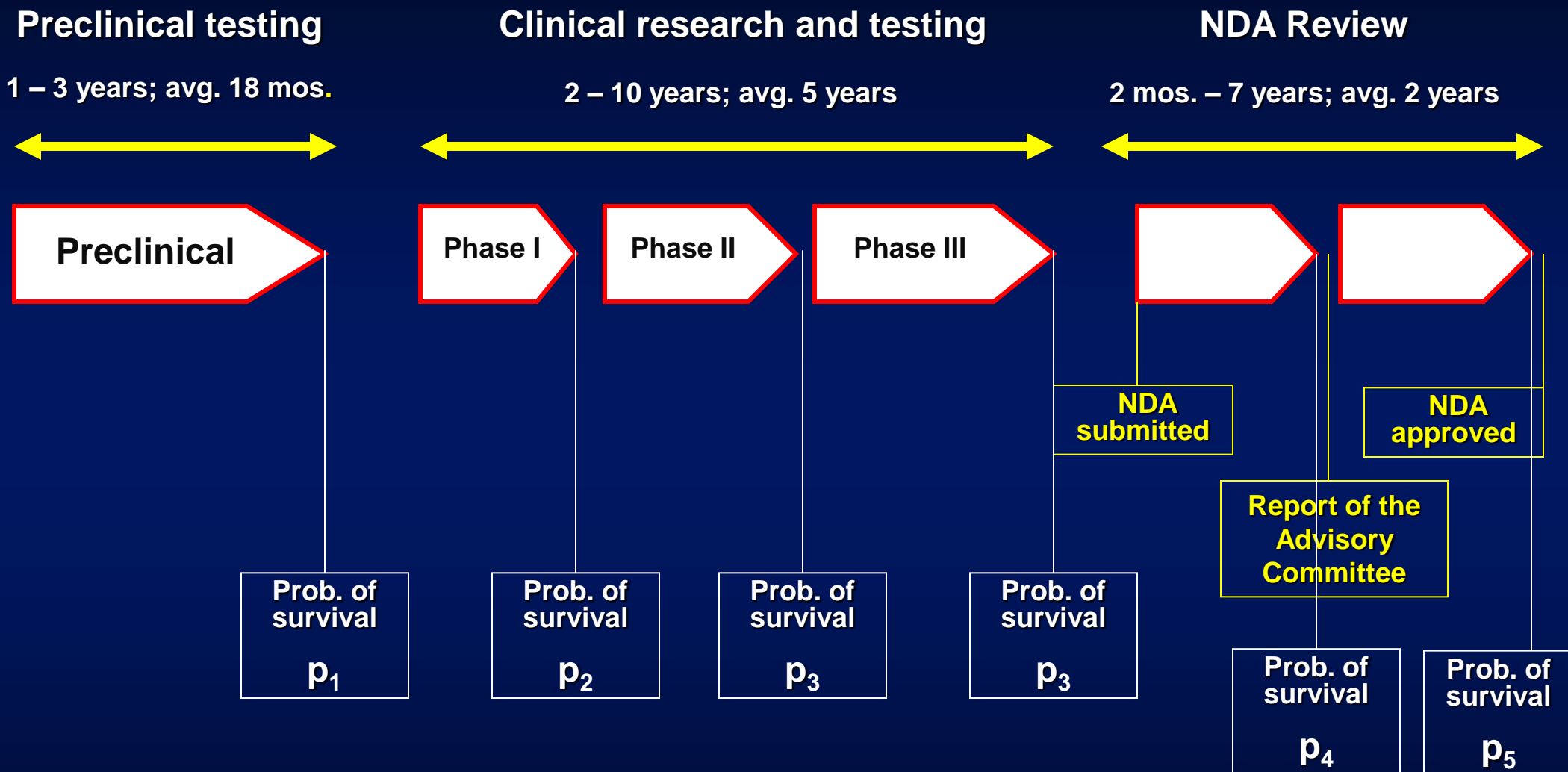
Indeed, I should not wonder if quite a few lobbyists on Washington's fabled K-Street have dedicated their lives to preserving inefficiency in U.S. health care – and the U.S. Congress often has gone along with their pleas.

INNOVATIONS IN BIOMEDICAL PRODUCTS

A. The cost of biomedical innovation

The path from a novel idea to a marketable products in biomedical innovation can be long and arduous, which is not always sufficiently appreciated by critics of R&D based health products manufacturers.

THE DRUG APPROVAL PROCESS IN THE UNITED STATES



SOURCE: Adapted from Michael Dickson and Jean Paul Gagnon, “Key Factors in the Rising Cost of New Drug Discovery and Development,” *Nature Reviews*, Volume 3, May 2004:417-29, Figure 1.

A new compound or biological product, for example, can “die”, so to speak, at every phase in this long process.

It is well known to the cognoscenti that only a few of the new ideas for drugs, once started in research, actually make it to a marketable product.

The rest hit dead ends.

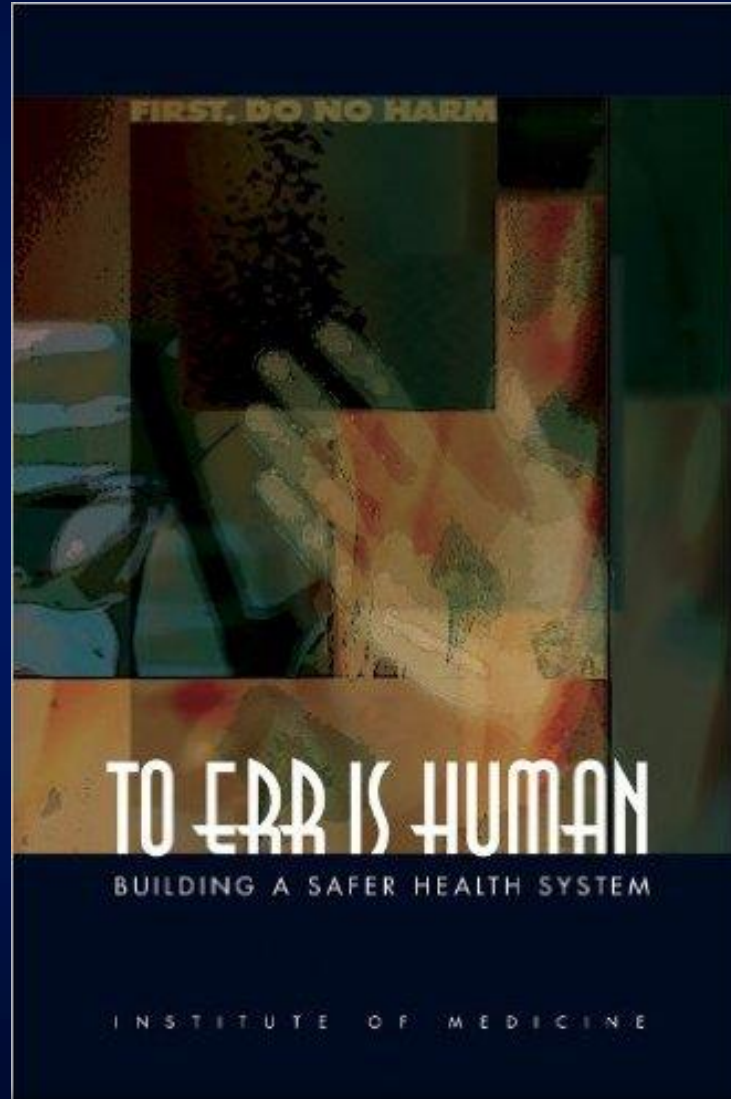
It should also be understood that the future revenues from a products that survives this gauntlet and makes it to market must cover not only its own cost of development, but also the cost of attempts that failed along the way.

If one then adds to it the *opportunity cost* of financial capital devoted to the enterprise, it is quite credible that many new drugs cost more than \$1 billion to develop.

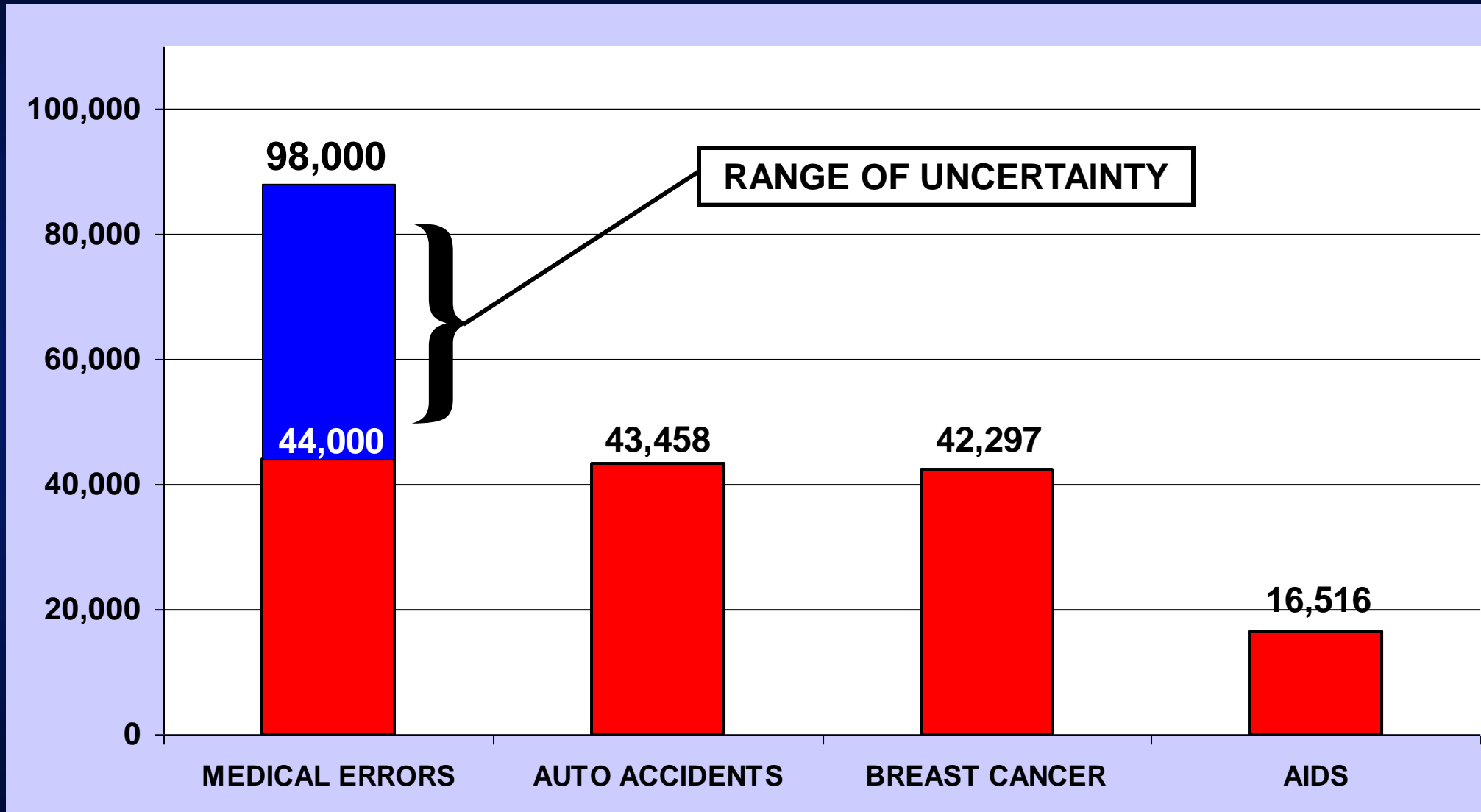
One major cost driver in this area is that we hold the manufacturers of health-care products to very high standards of patient safety, which is as it should be.

What has always amazed me, however, is how much more relaxed we have been about patient safety in other spheres of U.S. health care.

Over a decade and a half ago, the Institute of Medicine published the following highly alarming report.



SELECTED CAUSES OF DEATH, UNITED STATES, 1997



SOURCE: Institute of Medicine, *To Err is Human: Building a Safer Health System*, November, 1999..

According to a more recent analysis published in the *JOURNAL OF PATIENT SAFETY* (Vol. 3, September 2013) an estimated 400,000 patients die prematurely in U.S. hospitals from avoidable errors.

REVIEW ARTICLE

A New, Evidence-based Estimate of Patient Harms
Associated with Hospital Care

John T. James, PhD

Excerpt from the Abstract of the paper:

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

Imagine if the manufacturers of health products caused this kind of mayhem.

Can anyone explain to me why Congress, the media and the public have had these quite different perspectives on patient safety?

INNOVATIONS IN BIOMEDICAL PRODUCTS

A. The cost of biomedical innovation

B. The prices of health-care products

Because the enterprises producing drugs and devices in the US are owned by and operated for private investors – including venture capitalists – it is natural to think of the industry as quintessential examples of free enterprise.

From an economist's perspective, however, the industry evokes a quite different image, as shown on the next slide.



**Drug and device
industries**

Government supports the drug industry not only by generously funding basic research at the NIH. It also protects these firms' market turf through

- a. Patents, granted by the Patent Office**
- b. Market exclusivity (granted by the FDA)**
- c. Data exclusivity (granted by the FDA)**
- d. Prohibition of resale of products among buyers
(prohibiting reimports of US products from Canada)**
- e. Sundry subsidies for R&D**

This naturally raises the question what freedom an industry so protected by government should have to use its government-granted monopoly power in the pricing of its services to the rest of society.

Does not the government have a duty to provide oversight and perhaps countervailing pressure when the privilege of an artificial monopoly it has granted private investors seems to be abused at the expense of consumers (here sick people)?

The industry argues that what may seem as high prices really is nothing other than “value pricing” of the sort every industry tries to practice (but, of course, is severely constrained in truly competitive markets.”

What the industry now calls “value pricing” really amounts to probing how much American society is willing to pay for an added quality-adjusted life year – a very delicate question.

What value do Americans impute to providing another life year to, say, a fellow American on Medicaid?

Government can show countervailing power here not only through outright price controls – a blunt instrument not easily applied.

As economist Len Nichols has noted, bargaining chips in cases of egregious pricing, government could instead take away or clip back the many protections it now affords the industry e.g.,

- a) Shorten market exclusivity;**
- b) Shorten data exclusivity;**
- c) allow more parallel imports from Canada or Europe**

There is, of course, the question of how large the reward for financial risk taking investors in innovative R&D oriented companies should be paid – i. e., the risk premium in the rates of return to their investment.

In theory, it is the premium that is high enough to elicit the socially desired flow of innovations.

In practice it is a hard question to estimate that number, because when over half of health spending is tax financed, this becomes a political question.

For guidance, we might look to the risk premiums we pay other Americans who, on our behalf, take enormous risks not with their finances, but with their limb and life:

- 1. Fire Fighters;**
- 2. Police;**
- 3. Combat personnel in the military**

What do we pay these ones for risking not merely money, but life and limb to do something good for the rest of society?

The next slide shows what a Humvee looks like after it struck a road mine.

What risk premium do we pay a young man or woman to sit in such a vehicle, fighting the good fight on our behalf?

Is risking mere money that much more meritorious in our eyes than is the risk taking by our warriors?



2005.08.04

INNOVATIONS IN BIOMEDICAL PRODUCTS

A. The cost of biomedical innovation

B. The prices of health-care products

C. Drug prices, social spending and taxes

Finally, it is not uncommon to hear people – especially in the halls of Congress –

- **defend the high prices charged for specialty drugs on the ground that it furthers innovation in health care;**
- **argue for even more market protection for the industry, for the same reason;**
- **argue for cutbacks in “social spending” and for lower taxes**

all without connecting the budgetary dots.

These cerebral processes bring to mind a novel theory in astronomy I noticed on the Internet.

NEW THEORY PUBLISHED IN ASTRONOMY

The strongest proof that there is intelligent life
elsewhere in the universe

THE GREAT WALL OF GALAXIES

is the fact that it has never sought to contact us.

Thank you for listening