TITLE: Let's Use the Federal Debt Crisis to Reduce America's Medicalization.
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DESCRIPTION: Despite a dysfunctional Congress and a pro-corporate-advertising Judiciary, consumers can find ways to improve our nation's drug marketing system. We will need new strategies that use the government's financial crisis, postmarket safety study legal authorities, and activist state governments to achieve needed reforms. This session will discuss those strategies.

The fiscal crisis is real, and will be long-lasting, given human nature and Washington's habit of 'kicking the can down the road.'

Let's use this budget war to sell our ideas—jujitsu the budget crisis to our favor.

Let's wrap our ideas for fighting disease mongering in budgetary money-saving robes.

PhRMA wins when it convinces Congress—and the public-- that if they'll just defang the FDA, if the FDA just stops asking questions, industry will soon find the cure for death.

We can win if we can convince the public and Congress that we can save money by buying drugs smarter, an idea which will be much more popular than

--raising Medicare's age or

--forcing every senior into a barebones, crappy HMO.

And we can win if we can convince people to quit picking on just Medicare/Medicaid—it is TOTAL health care cost and inflation that is the problem-- and that we'd all benefit from a less expensive health care system.

And I'd like to make another point, I believe that a major reason there is so much

unscientific,

unethical medicalization of America, is because the sale of drugs and devices is so insanely, grossly profitable. If we paid less for these products, perhaps, perhaps there would be less gold rush lust, ethics-be-damned mentality.

Following is a romp-thru of some ideas for savings, some general, others specific to the issue of stopping disease mongering.

I would urge that we should refine a list sort of like this into a platform and use in the budget battles of the next several years.

USE FEDS' NEED FOR SAVINGS TO FIGHT DISEASE MONGERING

Part D price negotiating

Importation, especially of generic biologics already proven safe overseas

Reference or value pricing: pay no more than for best available drug

Stop all pay-for-delay of generics

Medicare/Medicaid Rebates equal to increased-use costs attributable to DTC

Rebates from health plans/insurers with below average use of generics

Get rebates from insurers and plans that have COIs on formulary committees,

Get rebates from hospitals that allow internal drug lobbying

Prohibit COI on guideline panels, and lobbying in med schools

Reduce patent/exclusivity windfalls to biologics

Use low or zero copays to encourage use of generics

Decision aids to help patients pick best product

Increase false claims act penalties—so they quit treating it as a cost of doing business

Future FDA clinical trials should test against best practice

> Show comparative effectiveness results of trials in a Woloshin-Schwartz-type drug fact box

Concentrate PCORI research on our areas of interest, e.g., ineffective, overuse of antibiotics

In DTC ads of new products, tell public how few people/little time tests used

Go beyond Sunshine Act, to outright prohibition on gifts

Move faster to determine whether a drug is safe or effective: Adopt IOM 2012 recommendations on when to conduct Phase IV studies

Stop paying for things that science shows don't work!

Note the point about rebates equal to estimated increased utilization due to advertising.

I'm not a lawyer, but it sure seems like the Federal courts are moving against my dream of no drug/device advertising. December's US v Caronia case, as I understand it, shifts burden of proof onto an already budget-strapped FDA and makes more aggressive OL cases more difficult.

If it gets to the Supremes….well, a Citizens United court willing to turn our democracy into an oligarchic plutocracy will probably have no trouble letting companies lie about deadly pills.

We need to think of new ways to discourage the gross advertising waves engulfing us.

--like get rebates on the increased utilization caused by the ads or telling people how few people these drugs are actually tested on and for what a short time…..

And off-label—OL-- use, which is so much a part of the medicalization problem, would it be reduced if we could get clinical trials on the OL use to prove, once and for all, whether the stuff works?

The following slide describes a novel approach that we might consider:

LOSING THE WAR ON OFF-LABEL ADVERTISING? A NEW HOPE??

Current law defines adverse event as, among other things, "any failure of expected pharmacological action of the drug" 21 USC355-1(b)(1)(E)

OL use is, per se, something that hasn't proven an 'expected [beneficial] pharmacological action'.

Why not petition FDA to require postmarket safety studies of drugs that we know have some serious adverse events, but have not proven any effectiveness in OL use??

Such studies may help us publicize the dangers of OL—or equally importantly, their possible value.

Another line of attack: Congress is talking about tax reform that lowers rates by broadening the base. Let's suggest reforms in our areas of concern….Sure, a tough battle… probably won't win, but would educate a lot of Members and public about some issues. As a group, let's propose a tax reform platform, like some of the following, to open a new battlefront in this war!

EDUCATE CONGRESS—AGITATE ON TAX REFORM

Limit R&D tax credits to FDA-designated breakthrus, NMEs

Profits tax on population-adjusted drug price increases above rate of general inflation

No business tax deductions for clinical trials where ALL data not released; where results not fully posted at ClinicalTrials.gov

No tax exemption for journals/medical practice-setting association panels with COIs

Tax on increased drug/device utilization attributed to advertising

Of course, cutting what we pay for drugs, industry will fight back saying they will quit doing research and won't be able to cure death. They will scare the public away from us.

We need—we should develop-- a campaign that the industry currently does NOT do enough real research…that so much of what they do is me-too, wasted research, and we should suggest new ways of truly bringing good drugs to market. Some examples

FIND BETTER WAYS TO RESEARCH—TRUMP THE INDUSTRY AT ITS OWN GAME

Eliminate R&D tax credit, but double it on designated breakthrough drugs

Prizes for breakthroughs which are then sold at a fair price

Public funding of clinical trials in exchange for fair pricing

Collect rebates on drug inflation, except on new breakthrough drugs

In conclusion, these are some ideas to take the poor Federal hand we've been dealt and turn it into a silk purse—or at least a good cloth handbag.

ACTION PROPOSALS—NOW

PDUFA V A DISAPPOINTMENT. PROPOSE A MODEL PDUFA VI THIS YEAR—TO AGITATE AND BUILD PUBLIC SUPPORT ON—when people ask us what's missing from FDA, what's wrong, we have a platform to point to

DEVELOP A PLATFORM OF SAVINGS TO PROPOSE IN BUDGET-FIGHT ARENAS

JOIN THE TAX REFORM DEBATE: PROPOSE A REFORM AGENDA

SINCE CONGRESS UNFRIENDLY—SUE MORE OFTEN TO HIGHLIGHT FDA FAILURES

See Public Citizen v. FDA re Aricept dosage. A model of using Citizens Petitions as basis for suing FDA to do its duty?

Sue for Phase IV studies on OL uses?

IOM'S 2012 RECOMMENDATIONS FOR WHEN TO DO PHASE 4 TRIALS: PETITION FDA TO IMPLEMENT

Not national legislation, but how about some national campaigns? JOIN PETITIONS (see UK's NICE) TO JOURNALS, INDUSTRY FOR FULL RELEASE OF DATA If PhRMA and Glaxo are arguing about level of disclosure, let's chime in!!