FDA's OTC Monograph User Fees Public Meeting

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The Washington Post

The Drug Approval Pendulum

By Anne Applebaum
Wednesday, April 13, 2005;

"It just breaks my heart when I think of American citizens having to go to Switzerland or Mexico to get the drugs and devices they need to stay alive because the Washington bureaucracy won't approve them."

Rep. Thomas Bliley (R-Va.), 1995

"When the FDA approves a drug, it should be a Good Housekeeping seal of approval. . . . Consumers shouldn't have to second-guess the safety of what's in their medicine cabinet."

Sen. Chuck Grassley (R-Iowa), 2005

http://www.washingtonpost.com/wp-dyn/articles/A48135-2005Apr12.html

Vox SCIENCE & HEALTH

2 new studies show the FDA is rushing more drugs to market based on shoddy evidence

Updated by Julia Belluz on September 24, 2015, 5:39 p.m. ET

There was a time when the Food and Drug Administration was so sluggish and conservative in approving new drugs that people who desperately needed access to medicines would die waiting. …

Today, the FDA is now considered the fastest regulatory agency in the world. But there's some concern that these expedited pathways are being used by drug companies to speed through medicines that *aren't* actually helping patients with unmet medical needs — and that often aren't any improvement over what's already on the market.

In two new studies, published on Wednesday in the ***BMJ***, a group of researchers from Brigham and Women's Hospital and Harvard Medical School, find that while more drugs are indeed getting to patients more quickly, there's good reason to question their novelty, safety, and effectiveness.

http://www.vox.com/2015/9/24/9387987/fda-expedited-drug-approvals

USA TODAY

FDA's slow process hurts innovation

February 15, 2014

Deb Fischer and Angus King

U.S. Sens. Deb Fischer, R-Neb., and Angus King, I-Maine.

… As the gatekeeper for new health information technologies trying to enter the marketplace, the Food and Drug Administration is tasked with keeping Americans safe. The FDA's work is important, but its processes are often painstakingly slow and based on outdated assumptions. This halting regulatory pace, along with a lack of bureaucratic incentives to embrace disruptive technological change, has often held back progress.

The FDA's regulatory footprint is growing beyond its statutory shoe size. The overreach comes in various forms, including sub-regulatory proceedings and selective regulation. Companies — including those who have already invested and deployed their technology — are left on uncertain footing given the FDA's regulatory discretion.

Such heavy-handed moves have caused legitimate concern that the FDA could slow down the development of low-risk health technology, including mobile-wellness applications and electronic health records.

http://www.usatoday.com/story/opinion/2014/02/15/fischer-king-health-information-technology/5464693/

Cruz Calls for Major Overhaul of FDA

Posted 11 December 2015
By Zachary Brennan

Republican presidential candidate Sen. Ted Cruz (TX) and Sen. Mike Lee (R-Utah) on Friday introduced a bill that would completely overhaul the way the US Food and Drug Administration (FDA) operates.

More specifically, the "Reciprocity Ensures Streamlined Use of Lifesaving Treatments Act (S. 2388), or the RESULT Act," would:

- allow for reciprocal approval of drugs, devices and biologics from foreign sponsors in EU member countries, Israel, Australia, Canada and Japan
- require FDA to make a decision on "life-saving" drug and device applications within 30 days
- allow Congress to override FDA denials of certain applications for life-saving drugs with a majority vote via a joint resolution

"Our legislation will unleash life-saving drugs and devices in the United States, help mitigate critical drug shortages in the US, and put downward pressure on the prices of medical devices and drugs as well," Cruz said in a statement.

http://www.raps.org/Regulatory-Focus/News/2015/12/11/23763/Cruz-Calls-for-Major-Overhaul-of-FDA/#sthash.ANkQso4y.dpuf

The OTC Drug Review 1972 - ????

- Ingredient (~700) review vs. product (~400,000) review
- 17 expert panels, 513 meetings, 10 years
- OTC drug category Monographs
- Completion date = 20??

The OTC Drug Review

- 1972 Hexachlorophene
- 1975 Zirconium
- 1975 Tribromsalan
- 1975 Antacid testing procedures
- 1976 Theophylline

The OTC Drug Review

- 1976 Chloroform
- 1977 Chlorofluorocarbons
- 1979 Daytime sedatives
- 19xx Methapyrilene
- 1978 Sun protection factor (SPF) rating system

The OTC Drug Review

- 19xx Phenacetin
- 19xx Accidental ingestion warnings
- 1982 Camphorated oil
- 1982 Pregnant or nursing women warning
- 1982 Tamper-resistant packaging

The OTC Drug Review

- 1983 Abrasiveness index - fluoride anticaries products
- 19xx Internal insect repellents, over-indulgence remedies, anti-cholinergics and hair restorers removed from the market
- 1986 Aspirin - Reye's syndrome warning

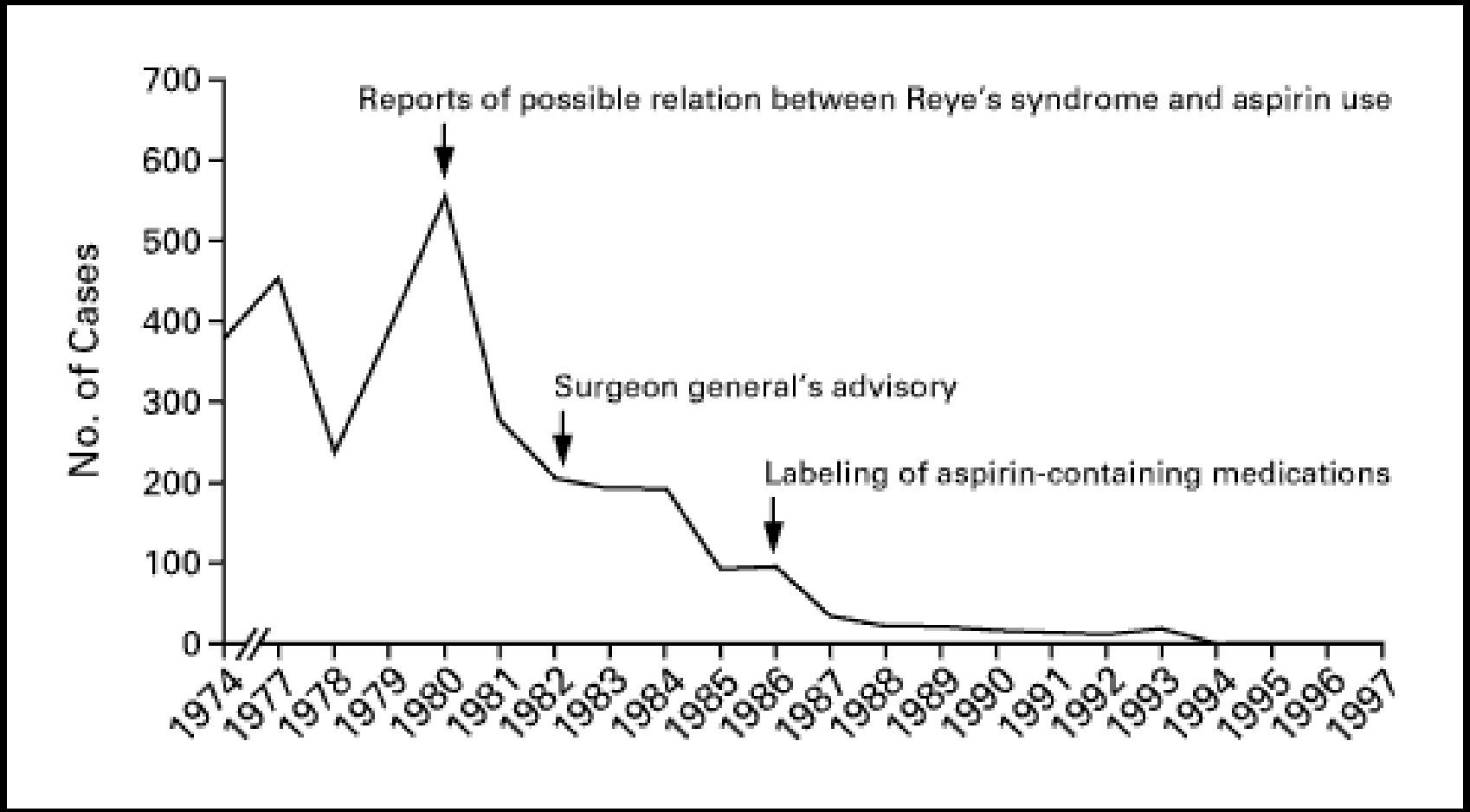

Figure 1. Number of Reported Cases of Reye's Syndrome in Relation to the Timing of Public Announcements of the Epidemiologic Association of Reye's Syndrome with Aspirin Ingestion and the Labeling of Aspirin-Containing Medications.

N Engl J Med. 1999 May 6;340(18):1377-82.

ConsumerReports July 2016

CAN YOU TRUST THE SPF?

THE SORRY STATE OF SUNSCREENS

All sunscreens should live up to the SPF claim on their labels–the Food and Drug Administration requires it. But for four years straight, we found that many sunscreens in our tests fall short.

We crunched the data from four ye
testing—104 products in all—to se
in general protect you against the
findings were troubling, especially
products—those that contain only
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The FDA doesn't routinely test s
the manufacturers to test their pr

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of protection
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equirements

In our tests almost half of the products failed to meet their SPF claim after water immersion—despite the fact that all featured claims of water resistance.

Met their SPF claim

Did not meet their SPF claim

"All sunscreens should live up to the SPF claim on their labels … but for four straight years we found that many sunscreens in our tests fall short."


The End
Metro Goldwyn Mayer