

Sentinel and the Media: **An Old Challenge, A New Opportunity**

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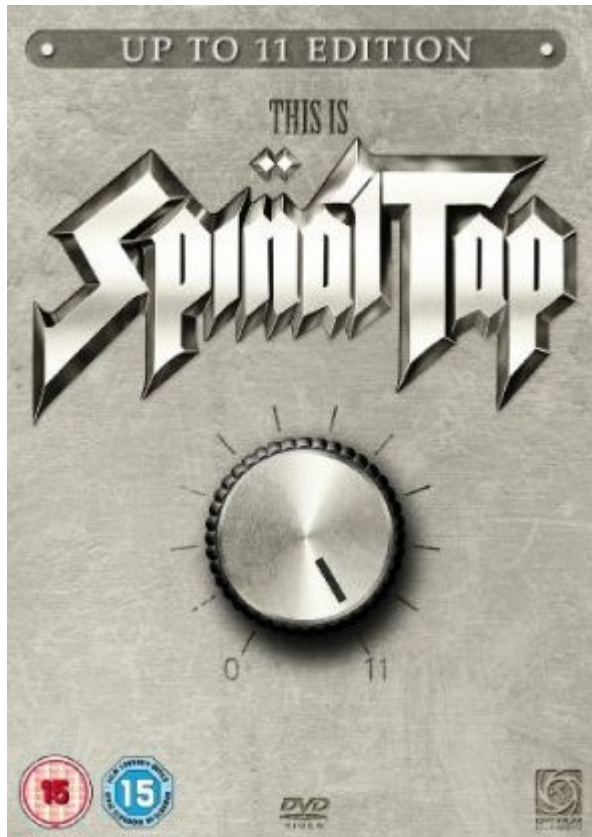
Founding Member, Prevision Policy

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- **What Makes “News?”**
 - **Public Health Impact Is One Factor...**
 - ...And Journalists WILL Play a Role
 - **But Many Other Factors Count—Often For More**
 - Deadlines and Space Considerations
 - Individual Interests (Stories Beget Stories)
 - Business Impact
 - Public Policy Impact
 - Desire for “Scoops”
 - Selling Subscriptions, Driving Ratings, Pleasing Funders

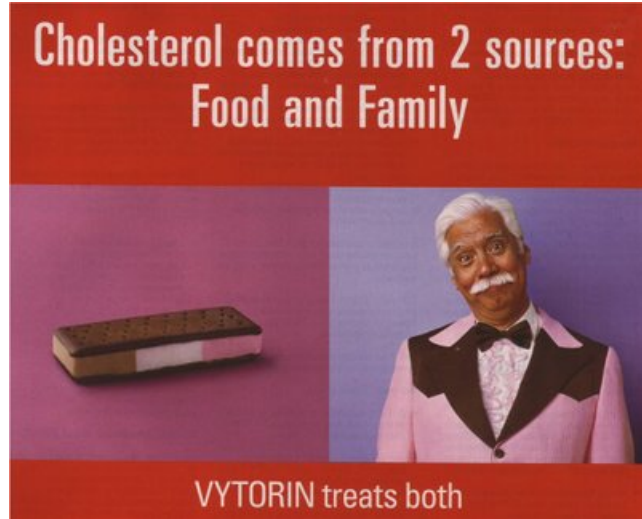
Secrecy Increases News Value

Health Headlines Aren't All About Health



News Amplifiers

- Investor Impact
 - Consider *Byetta* & Pancreatitis
- Product Liability Issues
 - *Avandia* vs. *Meridia*
- Political/Policy Agendas
 - Epidemiology vs. Clinical Trialists
- Score-Settling
- Publicity-Seeking
- Sheer Luck

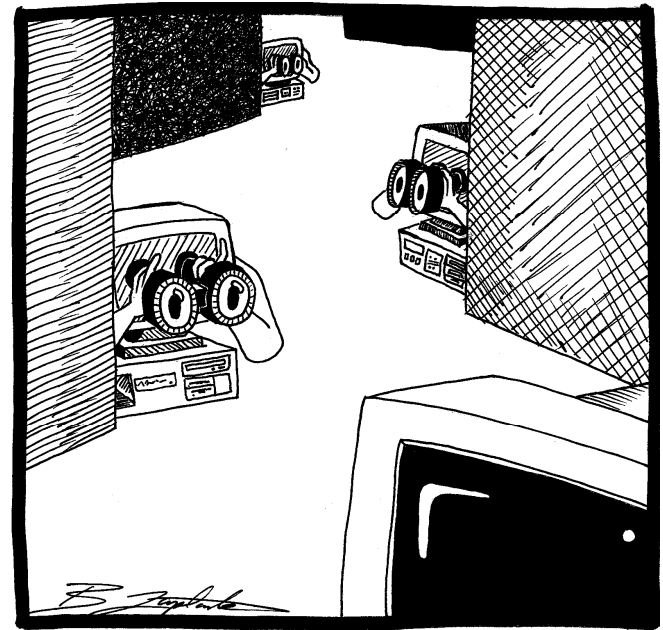


Katie Couric & Steve Nissen

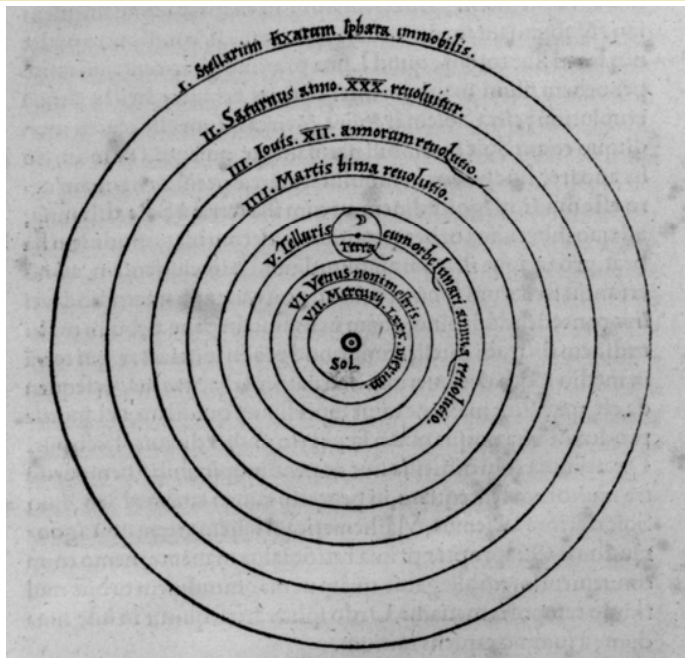
The *Vytorin* Experience

- Issue Was Handling of Failed Trial
- Brand Awareness Amplified News Value of the Story
- Compare to *Lopid* Helsinki II Study

- It's A Computer...
 - So It Must Be Right
- It's The Government...
 - I Must Fear It
- It's My Data...
 - Leave it Alone



What About The Sponsor?



Pharma Sponsor No Longer at Center of Information Flow About Medicine

- Do They Get “Privileged” Access To Emerging Signals?
 - If So, THAT’S A Story
 - If Not, They Are Still My First Call
- What if There are Multiple Affected Sponsors?

What if There is NO Center?



TripTik for Reporters

- “Dollars for Docs” database
- Look on State Medical Board sites
- Look for FDA Warning Letters, disqualifications
- County Courthouse for malpractice suits
- Interview docs: they often work for different companies: don’t know how much they receive; on IRS filings

Follow-up Stories

First Story

Lawsuits

Investigation

Source: Alicia Mundy

- **Remember the Broader Context**
 - Risk Communication Challenges Overall
 - New Regulatory Model (REMS, PMCs, etc.)
- **Disclose EVERYTHING**
 - Eliminates “Secrecy” As Headline Driver—and Exhausts Interest
 - Disclose Does NOT = Publicize
- **Iterative Process is a Plus**
 - As Long as There is a Conclusion

***The Drug Approval Process Works:
Public Uncertainty Precedes FDA Conclusion***

Questions?

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