

# Abuse of the FDA Regulatory Process And Possible Solutions

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COALITION TO PROTECT PATIENT CHOICE

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# My Background

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Served as Policy Director of the Bureau of Competition of the Federal Trade Commission

Helped create FTC's pharmaceutical enforcement program and worked on several groundbreaking FTC enforcement actions in generic drug markets, including pay for delay, monopolization, and product hopping cases

Advised several Congressional committees on generic drug competition

As Senior Fellow at Center for American Progress authored a 2009 study "[Removing Obstacles to Generic Drug Competition](#)" that became the template for generic drug enforcement in the Obama administration

Helped consumer groups provide testimony and advocacy before Congress on generic drug competition

# Further Background

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Authored over 20 amicus briefs before the Supreme Court and several appellate courts for consumer groups on major generic antitrust cases, and represented consumer groups and generic drug firms in FTC generic drug investigations

The consumer groups include Families USA, AARP, Consumers Union, Consumer Federation of America, Consumer Action, and US PIRG

Represented several consumer groups and generic drug firms in FTC generic drug investigations

Led the consumer opposition to the Mylan/Teva merger before the FTC

As part of the Coalition to Protect Patient Choice, led the consumer opposition to the Aetna/Humana and Anthem/Cigna mergers before DOJ

# Underlying Problem

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Hatch-Waxman and patent laws balance incentives to innovate and patient access to affordable drugs

Once patent ends, brand-name company faces “patent cliff”

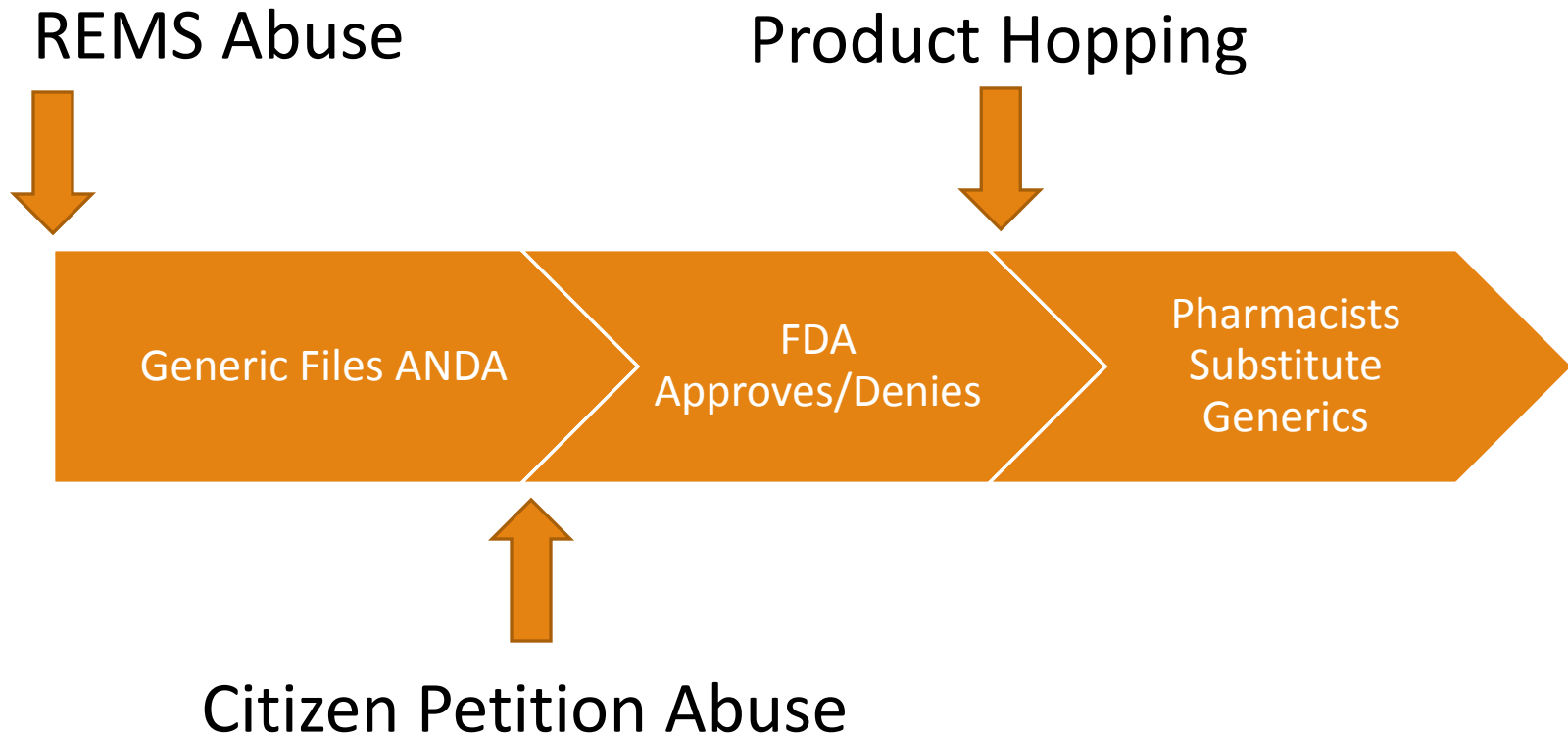
Brand-name companies are extremely motivated to use any means possible to keep generics off the market

FDA Official David Gaugh - brands “feel it’s their duty to their stockholders to delay competition as long as possible.”

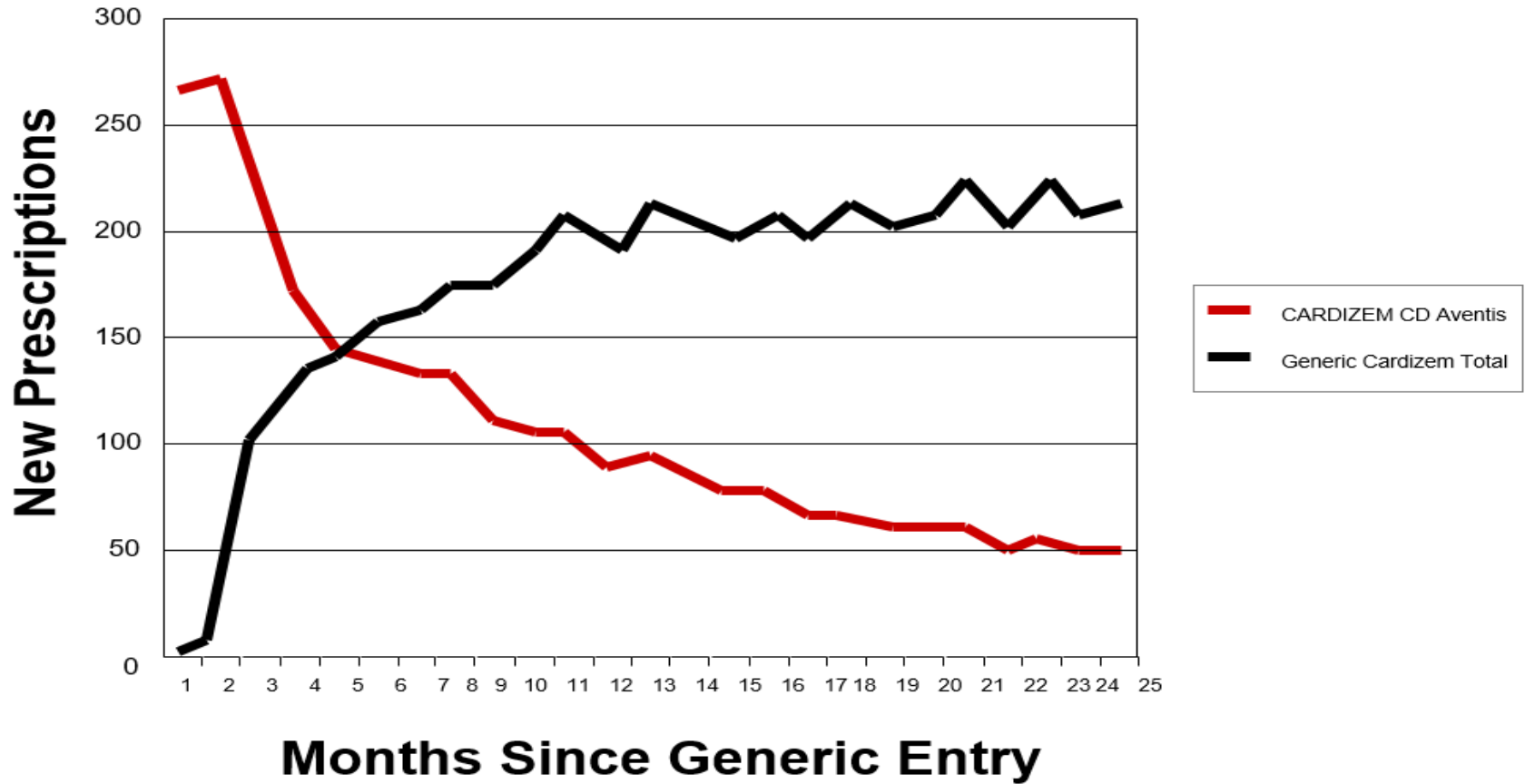
These actions have nothing to do with innovation—purely intended to game the system

# Regulations Are Being Abused to Block Access to Generic Drugs

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# Generic Cardizem Entry



The “patent cliff”

“Predation by abuse of governmental procedures, including administrative and judicial procedures, presents an increasingly dangerous threat to competition.” – Robert Bork

# Problems With Regulatory Abuse

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Dominance in the marketplace can be solved; competitors will likely arise and compete with them

Dominance acquired through manipulation of regulations cannot be solved through competition

Regulatory approval is needed to enter drug markets—this market is vulnerable to abuse

Market forces can't discipline the market

Need to fix the regulations to fully address the problem



# Main Areas of Focus

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Three major areas of abuse that block generic drugs from coming to market

- REMS (Risk Evaluation and Mitigation Strategies)
- Abuse of citizen petitions
- Reformulations/product hopping

# Guiding Principles

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FDA is best situated to stop bad behaviors in their incipiency; antitrust litigation is after the fact, costly and time consuming, and may provide very limited relief

Regulatory modesty is critical – are regulations necessary and narrowly focused

If the behavior makes “no economic sense” except to harm generics, then it needs appropriate remedy

Be careful of unintended consequences, and readjust policy that becomes an avenue for abuse

# REMS Abuses

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DELAY, DELAY, DELAY: HOW COMPANIES STALL OUT  
THE CLOCK

# What Is A REMS?

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REMS (Risk Evaluation and Mitigation Strategy)

A distribution safety protocol that is required for many products of brand-name manufacturers

Can include

- Medication Guide, Communication Plan, Elements To Assure Safe Use, Implementation System

If brand drugs are subject to REMS, any abbreviated new drug application (ANDA) is too

# REMS Are Increasingly Important

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There is an increasing prevalence of REMS drugs

- FDA website lists 72 active Individual REMS programs and 6 Shared programs
- FDA approved 199 REMS 2008-2011
- Nearly 40% of all new FDA approvals are subject to REMS, and increasingly more REMS include distribution restrictions

REMS vary in complexity and burden

- May range from medication guide or insert to a comprehensive plan for managing distribution
- FDA has unilateral authority to determine 1) if a REMS program is necessary, and 2) the parameters of the REMS program
- ANDAs for RLD subject to REMS must comply with REMS terms
  - Includes Single Shared REMS (“SSRS”) – FDA-mandated collaboration between brand and generics for REMS program

# Manipulating Regulations

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Brand-name companies prevent potential generic competitors from getting samples of branded drugs

Generic companies cannot perform testing needed to show their drugs are equivalent and get FDA approval

Companies justify this behavior by citing REMS, claiming they cannot share samples

# Bi-Partisan Concern

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Senator Charles Grassley (R-IA) –

- “tactics that appeared to frustrate the intent of the Hatch-Waxman Act,” as brand firms “were misusing their . . . REMS to withhold access to drug samples for bioequivalence testing and generic drug development in violation of FDA regulations and the Hatch Waxman Act.”

Senator Patrick Leahy (D-VT) –

- “[t]his simple delay tactic uses regulatory safeguards as a weapon to block competition.”

# Effects of These Delays

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Competitors must ask their rivals for permission to compete!

Generic competitors cannot participate in the safety protocols

They have few if any options for legal remedies—antitrust suits take too long

According to a July 2014 study by Matrix Global Advisors, this costs \$5.4 billion per year in lost savings and \$1.8 billion to the federal government





Martin Shkreli pursued a similar strategy of denying access to samples

# Daraprim's Price Hike

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Daraprim's price hike by Turing is an example of this

Drug went off-patent about 40 years ago and used to be recently available on ordinary distribution channels

Turing now only distributes Daraprim through a closed pharmacy system

Getting samples of Daraprim to make and market lower cost alternatives is very difficult

# Dubious antitrust solution

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Revlimid – FTC investigation from 2006-2013

Actelion v Apotex – from 2012-2014. Actelion reached settlement with generic drug makers to ensure it did not have to supply samples of blood pressure drugs

Accord Healthcare v Acorda – from 2013-2016. Accord stated that Acorda refused to provide samples of Ampyra in violation of antitrust laws and that Ampyra was an essential facility

No enforcement action

No successful private cases

# FDA's Previous Solution Is Also Ineffective

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The FDA developed a process to review generic companies' bioequivalence protocols and determine whether or not they were consistent with REMS

- This process is not required and was designed solely to aid generics in their attempts to acquire brand samples

Generic manufacturers have employed this process and have received agency approval of their bioequivalence protocols

However, this process has not solved the problem

- The FDA cannot compel a company to sell drug product
- The FDA cannot impose monetary fines on a company for anticompetitive behavior
- FDA has suggested that FTC address the problem

# Solution Put Forward In Congress

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## The CREATES Act: A Helpful Alternative

- REMS refusals are a big problem and current FDA measures are insufficient
- CREATES Act would correct these abuses
- Generic drug companies could file suit in federal court to get samples
- Judges could levy damages to discourage delays
- FDA could approve alternative safety protocols

# Potential FDA Solutions

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FDA should use its authority to allow generics to do their own shared REMS program

FDA should also be given greater authority to require brands to cooperate in a timely way

The FDA's draft guidance is helpful, but has given branded manufacturers another avenue to hold up drugs. This needs to be corrected

# Sham “Citizen” Petitions

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OR, ESTABLISHING A MONOPOLY THROUGH  
EXPLOITATION OF THE REGULATORY SYSTEM



# Gumming Up the Works

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Individuals can use citizen petitions to express concerns about and challenge drug products before they enter the market

But companies can file frivolous petitions to delay generic drug approval—and they do

Brand manufacturers often file petitions after FDA has determined generics are safe and effective

Competition is blocked for several months while FDA reviews the petition



# The First Amendment and Citizen Petitions

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Individual or company First Amendment rights can't be infringed by antitrust law

However, First Amendment does not allow petitioners to use the citizen petition process as a sham to interfere with competitors

A petition is considered a sham when it is both objectively and subjectively baseless

- Objectively baseless: the plaintiff has to demonstrate that no reasonable party could reasonably expect the petition to succeed on the merits
- Subjectively baseless: the plaintiff has to demonstrate that the petitioning party intends to inhibit competition instead of petitioning the government for redress of grievances

# How the Petition is Handled Matters

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Courts and agencies consider four factors when determining if citizen petitions are shams

- **Suspect Timing**—if a petition are filed on the eve of generic entry, the court may incline toward finding the petition to be a fraud
- **Relief Requested Contrary to FDA Regulations and Practice**—Brand companies have strong regulatory departments and are familiar with FDA actions. If a petition asks for relief that is against normal FDA practice, a court may see that as a potential sign of a sham
- **Tone of FDA Rejection**—if the FDA says a petition lacked any basis or convincing evidence, a court may weight that factor as a sign of a baseless petition
- **Petition Actually Cause Delay**—if the approval of a generic drug applicant was delayed for reasons other than the filing of a citizen petition, a court may decide that a citizen petition, although baseless, did not cause any antitrust injury

# Authorities Recognize The Problem

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Qualified generic drugs are kept off-market for no good reason

Congress amended law in 2007 to expedite the citizen-petition process and combat abuse

FDA now has to make a decision on petitions within 180 days of submission

Antitrust challenges have been brought against brand companies for misusing petitions

# Dubious Benefits

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Carrier and Minniti study found that brand firms file 92% of citizen petitions and only 8% of the petitions are granted

39% of the petitions are filed within 6 months of patent expiration or end of FDA exclusivity

Average number of petitions being filed per year is trending upward while success rate is trending downward

# FTC Complaint Against ViroPharma

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## Allegations –

- ViroPharma violated the antitrust laws by abusing government processes to delay generic competition to its branded prescription drug, Vancocin HCl Capsule
- ViroPharma waged a campaign of serial, repetitive, and unsupported filings with the U.S. Food and Drug Administration and courts to delay the FDA's approval of generic Vancocin Capsules.
- ViroPharma submitted 43 filings with the FDA and filed three lawsuits against the FDA between 2006 and 2012.
- ViroPharma failed to provide any clinical data to support its arguments. Even after a panel of 16 independent scientific and medical experts considered ViroPharma's unsupported arguments and then voted unanimously in favor of the FDA's guidance for generic Vancocin Capsules, ViroPharma continued to repeat its rejected arguments.

The FTC believes that consumers and other purchasers paid hundreds of millions of dollars more for their medication.

# ViroPharma Moves To Dismiss

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ViroPharma filed a motion to dismiss arguing:

- FTC engaged in an “exaggerated counting exercise” to portray ViroPharma as engaging in a pattern of forty-three regulatory actions and three legal proceedings
- ViroPharma only filed its citizen petition in response to the FDA’s decision to create new bioequivalence standards without first seeking public input
- The fact that it took the FDA over six years to come to a decision on ViroPharma’s March 2006 petition is evidence that there was merit

Oral argument was requested by ViroPharma on June 28, 2017.

# The Solutions

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Conduct a study on the continued usefulness of citizen petitions

Greatly scale back the citizen petition program

Public disclosure of real party in interest

# Reformulations Product Hopping

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HOW BRAND NAME COMPANIES OBSTRUCT  
GENERIC COMPETITORS AND PRESERVE MONOPOLY  
PROFITS



# Minor Drug Product Changes to Extend Profits

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Brand-name companies make trivial changes to drugs to secure longer patents and periods of exclusivity

Usually happens close to end of the patent's life and has nothing to do with real innovation

Brand induces a switch of all or part of the demand for drug from the old version to the new

Informally known as “product hopping”

# Strategy Enhancement Actions

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Raise price of original product shortly before launch of new product

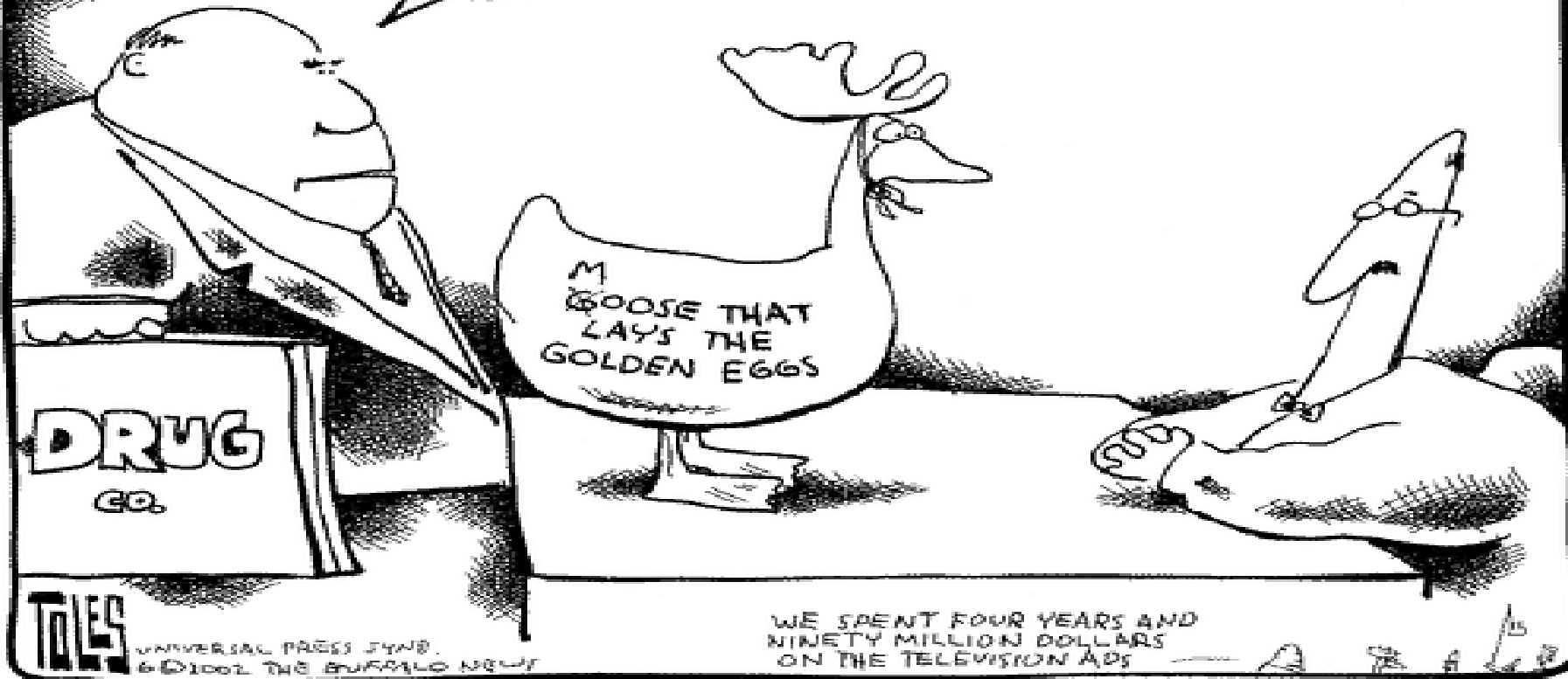
Withdraw original product from the market

Buy back inventory of original product

Destroy inventory of original product

Delete “National Drug Code” from “National Drug Data File”

WE'VE MODIFIED IT SIGNIFICANTLY  
SINCE OUR PATENT EXPIRED,  
SO NOW WE WANT A NEW PATENT.



6-4-02

# The Washington Post

June 5, 2002, p. A 22

# Effects of Product Hopping

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This switch decreases consumer welfare and impairs competition from generic drugs

Occurs in uniquely complicated markets

Pharmacists can't substitute a generic version

Higher prices for consumers and less competition are the results

Inconsistent with Hatch-Waxman Act, which is intended to promote generic competition

“[P]roduct-hopping seems clearly to be an effort to game the rather intricate FDA rules . . . . The patentee is making a product change with no technological benefit solely in order to delay competition. . . . [S]uch a change could qualify as a predatory product change if it lacks substantial medical benefits.”

Hovenkamp & Lemley, IP and Antitrust,  
2006 Supplement, § 12.5 at 12-45 – 12-46.

# Antitrust Has Provided Uncertain Results

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## Compare Namenda

- “Hard switch” from Namenda IR twice a day formulation to Namenda XR once a day formulation
- Namenda had sales of \$1.5 billion, was one of their best-selling drugs
- Second Circuit granted preliminary injunction requiring defendants to make Namenda IR available
- Found the switch made no economic sense “in the absence of the benefit derived from eliminating generic competition.”

## With Doryx

- “Hard switch” from Doryx capsules to Doryx tablets, then other additional changes to tablets.
- Four critical changes to Doryx, all of which required generics to apply for AB-rating if they wanted to continue to benefit from state substitution laws.
- Third Circuit found no violation to antitrust laws.
- The Court in part relied on the innovation claims of the defendant.

# Antitrust is a Poor Answer

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OR, HOW TO SPEND A LOT OF TIME AND MONEY  
AND NOT GET VERY MUCH



# The Problems with Antitrust

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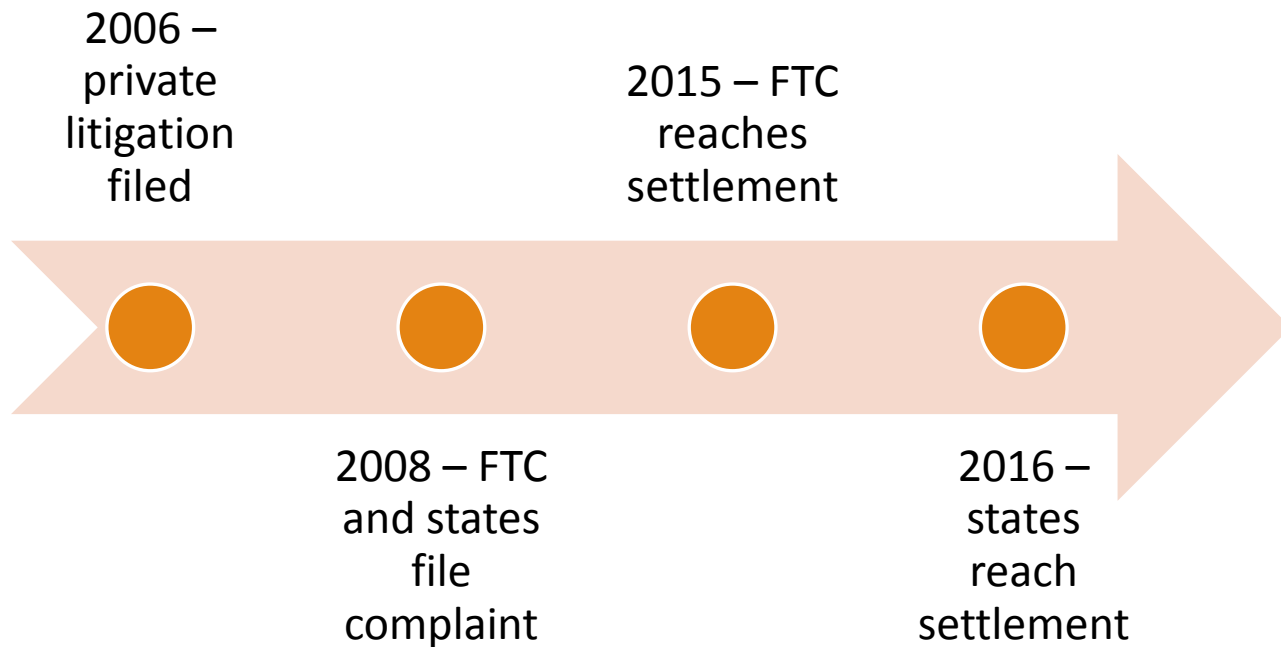
1. Enforcement agencies have limited resources
2. Antitrust litigation is time consuming and expensive
3. It is unclear how much the results actually benefit consumers

*The FTC has brought no product hopping or REMS cases, they have only participated in cases by filing amicus briefs.*



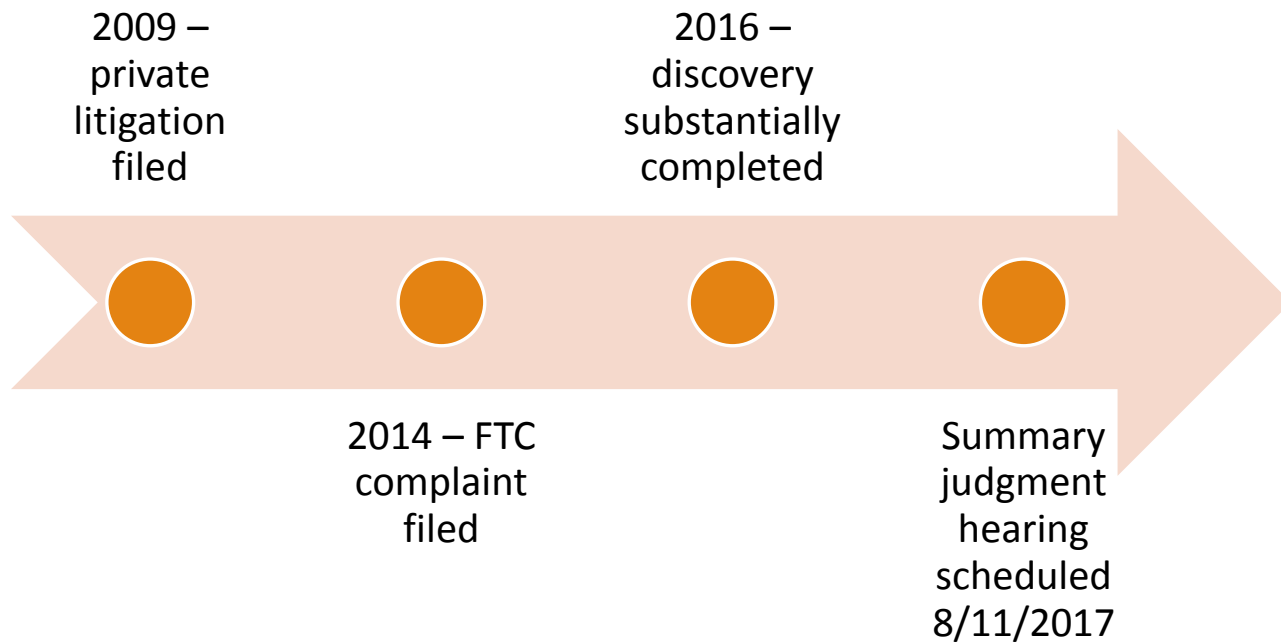
# FTC v. Cephalon, Inc. (Provigil)

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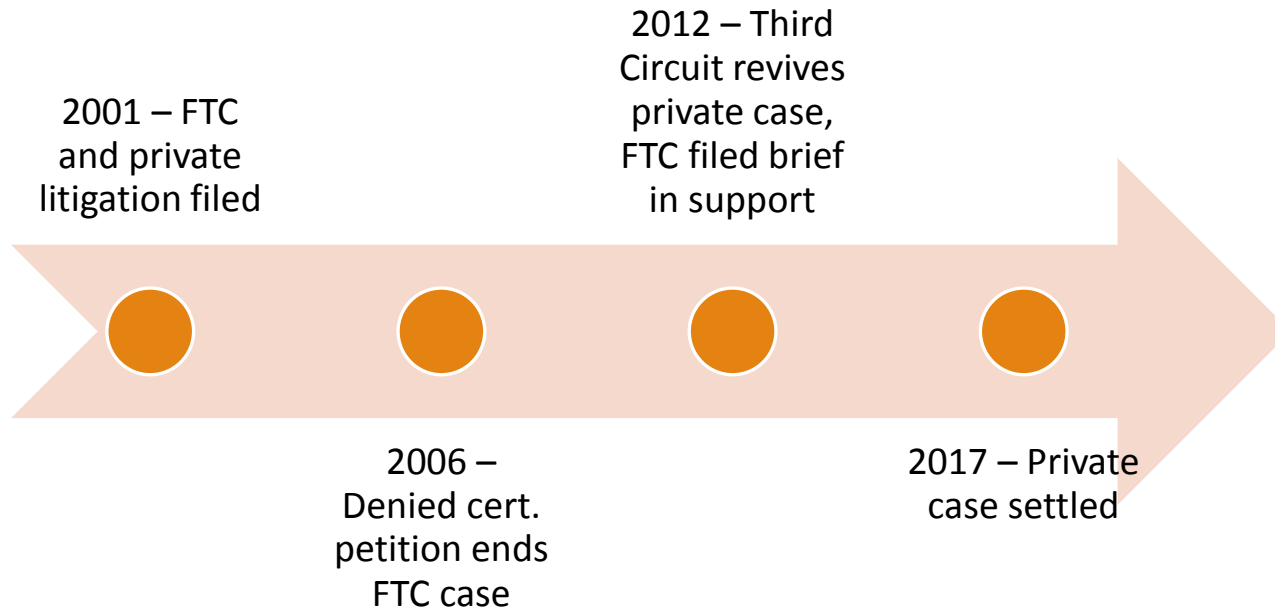
# FTC v. Abbvie Inc. (Androgel)

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# In re K-Dur Litigation

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# Conclusions

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Companies abuse the regulatory system to block generic drugs

Again, these abuses promote no innovation or progress

Regulatory problems must be fixed: antitrust enforcement is not enough

# Recommendations

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Work with the FTC to provide transparency

Conduct a study of these abuses to provide Congress with the empirical evidence needed for reforms

Don't rely on antitrust – the underlying regulatory problems must be fixed

The FDA should recommend that the CREATES Act be passed

# Contact Information

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