

*U.S. DRUG PRICING
LANDSCAPE AND
PROPOSALS TO MAKE
MEDICINES AFFORDABLE*

*Steve Knievel
Access to Medicines Advocate
Public Citizen*

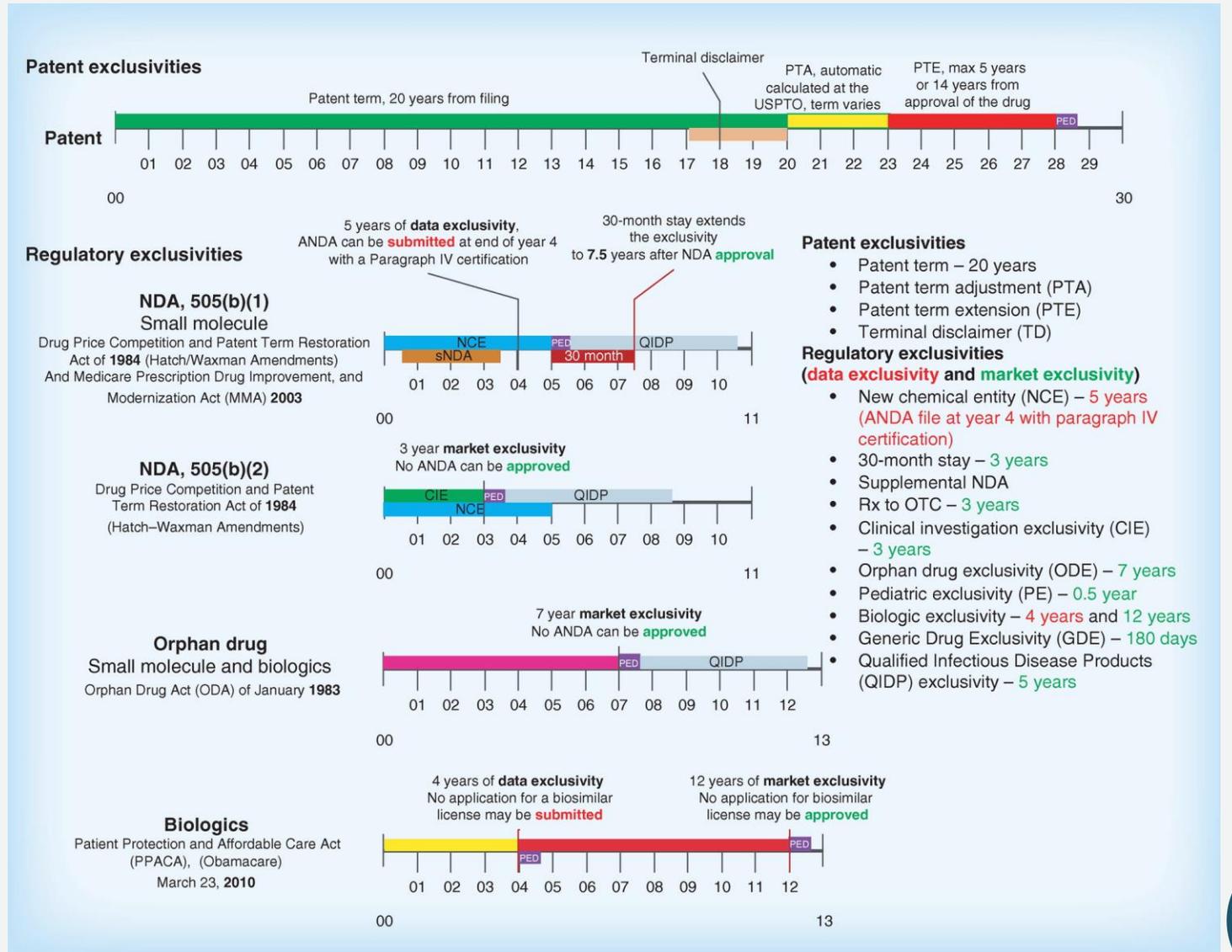
How we got here.

- 1789: U.S. Constitution
 - Congress empowered “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”
 - 1952: Patent Act
 - Patents generally available for any patentable subject matter that is 1) new, 2) non-obvious and 3) useful
 - Later amended to provide 20 year patent term
 - 1980: Patent and Trademark Law Amendments Act (Bayh-Dole)
 - Individuals allowed to take title to patents on publicly-funded inventions
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How we got here (continued).

- 1983: Orphan Drug Act
 - New incentives for development of drugs indicated for fewer than 200,000 patients in the United States
 - Seven years marketing exclusivity; orphan drug tax credit
 - 1984: Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman)
 - New pathway for generic drug approval
 - New FDA-granted marketing exclusivities; patent term extensions
 - 2003: Medicare Modernization Act
 - Medicare Part D created; includes non-interference clause
 - 2010: Biologics Price Competition and Innovation Act
 - New pathway for biosimilar product approval
 - 12 years marketing exclusivity for biologic medicines
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Rules governing pharma monopolies.



Where these rules have brought us?

- Drug corporations have expansive monopoly power to charge whatever prices maximize their profits
 - Public, taxpayer funding de-risks drug research and development, while private companies reap the benefits of biopharmaceutical technologies developed with government funding
 - Under Medicare Part D the government has an obligation to purchase prescription drugs under monopoly conditions, but its hands are tied by the prohibition on direct price negotiations
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*The
industry is
a behemoth.*

- The global market for pharmaceuticals reached **\$1.2 trillion in 2018**.
 - The U.S. accounts for more than **40 percent of the market (\$485 billion)**.
 - Brand-name drugs represent just **10 percent of U.S. prescriptions but nearly 80 percent of spending**.
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Exorbitant prices and high spending.

- The U.S. spends [\\$1,443 per person](#) on prescription drugs, compared to the average of \$749 among other rich countries.
 - That's more than twice as much France, Germany, Canada and Australia.
- The average price of new cancer medicines is [\\$149,000](#).
- This May, Novartis launched a [\\$2.1 million](#) treatment.
- Americans will spend [\\$38.3 billion](#) on just five drugs by 2024.
 - That's more than [Nike](#) earned globally in all of 2018.

*Exorbitant
prices and
high
spending
(continued).*

- For top 45 top-selling drugs, more than half of all sales growth in past three years due to price increases.
 - \$39 billion National Institutes of Health Budget in 2019.
 - Medicare spent more than \$128 billion on prescription drugs in 2016, nearly 20% of overall Medicare spending.
 - Prescription drug costs account for up to 25% of spending by commercial health plans.
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People are suffering.

- Three-in-ten Americans report [rationing their medicine](#) due to its cost. Eight-in-ten think medicine prices are [unreasonable](#).
 - [Nine-in-ten Americans](#) want Medicare Part D, the world's largest purchaser of medicines, to negotiate prices.
 - Nearly [eight-in-ten](#) believe that competitively licensing patents to authorize generic competition will reduce drug prices.
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*There are
many, many
proposals
(80+).*

- Notable Proposals
 - Increasing negotiating power
 - Medicare Negotiation and Competitive Licensing Act
 - Title I of H.R. 3
 - Stopping price spikes
 - Stop Price Gouging Act
 - CURE High Drug Prices Act
 - Senate Finance Committee Package / Title II of H.R. 3
 - Curbing monopoly abuses and taking on monopoly power
 - Prescription Drug Price Relief Act
 - Affordable Prescriptions for Patients Act
 - PRICED Act
 - Preserve Access to Affordable Generics and Biosimilars Act
 - CREATES Act
- Other notable proposals
 - Affordable Drug Manufacturing Act
 - We PAID Act
 - Transparent Drug Pricing Act

Increasing negotiating power

Drug companies can price gouge because of government-granted monopolies.

- Patents and regulatory exclusivities give companies the unilateral ability to set prices, which the U.S. does not by and large negotiate or regulate.
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Price spikes

- Drug companies regularly jack-up prices on existing medicines far beyond inflation.
 - Prescription drug corporations typically increase the price of products in their portfolios twice per year, with specialty drugs averaging an annual price increase of seven percent—or more than three times inflation.
 - For the 45 top-selling drugs, more than half of all sales growth in the past three years was due to price increases.
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Curbing monopoly abuses

- Drug companies can price gouge because of government-granted monopolies.
 - Companies try to preserve this monopoly by any means necessary, including by amassing dozens of patents, and paying off competitors.
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Lower Drug Costs Now Act (H.R. 3)

*House Democratic
Leadership*

- Secretary empowered to negotiate up to 250 drugs per year, based on high spending
 - Maximum price is 1.2 * AIM (average international market price)
 - Minimum price is lowest offered in reference country
 - Negotiated price available to private sector plans
 - Factors considered in negotiation: R&D costs, manf. costs, comparison to alternatives, market data
 - Escalating tax penalties for failure to negotiate; civil penalties for not offering negotiated price
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*Lower Drug
Costs Now
Act (H.R. 3)*
*House Democratic
Leadership*

- Inflation-based rebates for Medicare Part B and Part D
 - Medicare Part D redesign & \$2,000 out-of-pocket cap
 - Transparency measures
 - Other Medicare and public health improvements
 - CBO estimates \$456 billion in savings from Title 1 alone
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Lower Drug Costs Now Act (H.R. 3)

*House Democratic
Leadership*

- Limitations:
 - Failure to cover uninsured
 - Limitations on what drugs are negotiation-eligible
 - Negotiations unduly restricted by floor prices HHS must accept
 - Weak on launch prices
 - Weak claw-back for excessive prices prior to negotiation
 - Does not take on monopoly power
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Lower Drug Costs Now Act (H.R. 3)

*House Democratic
Leadership*

- Improvements extracted by progressives:
 - Increase in number of drugs required for negotiation
 - Incorporation of ability to negotiate prices soon after launch
 - Expansion of inflation-based rebates to group health plans
 - Negotiated drugs remain under price control until there are at least two competitors
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*Senate
Finance
Committee
Package*
*Sens. Grassley &
Wyden**

- Inflation-based rebate for Part B and Part D drugs
 - Likely to modestly mitigate some private sector price spikes, depending on composition of market
 - Part D redesign & \$3,100 out-of-pocket cap
 - Numerous smaller fixes
 - Rebates to Medicare for discounted amounts from vials of infusion drugs
 - Increased manufacturer rebates to Medicaid
 - CBO estimates ~\$100 billion in savings over ten years
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*Looking
ahead to the
117th
Congress*

- Further strengthening H.R. 3?
 - Future of the Senate Finance package?
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Executive Remedies

- The President and executive branch agencies have existing authorities to lower drug prices without Congress passing legislation
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March-in Rights

- The government retains rights over patented inventions developed with government funding
 - One such right allows the government to “march-in” to license patents if the product is not being made available on reasonable terms or to alleviate health or safety needs not being reasonably satisfied
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Government Use

- Government may make use of any patented invention, so long as—
 - The use is by and for the U.S. government
 - The government provides the patent holder with reasonable and entire compensation for such use
 - Not limited to drugs developed with government funding
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Questions

