


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

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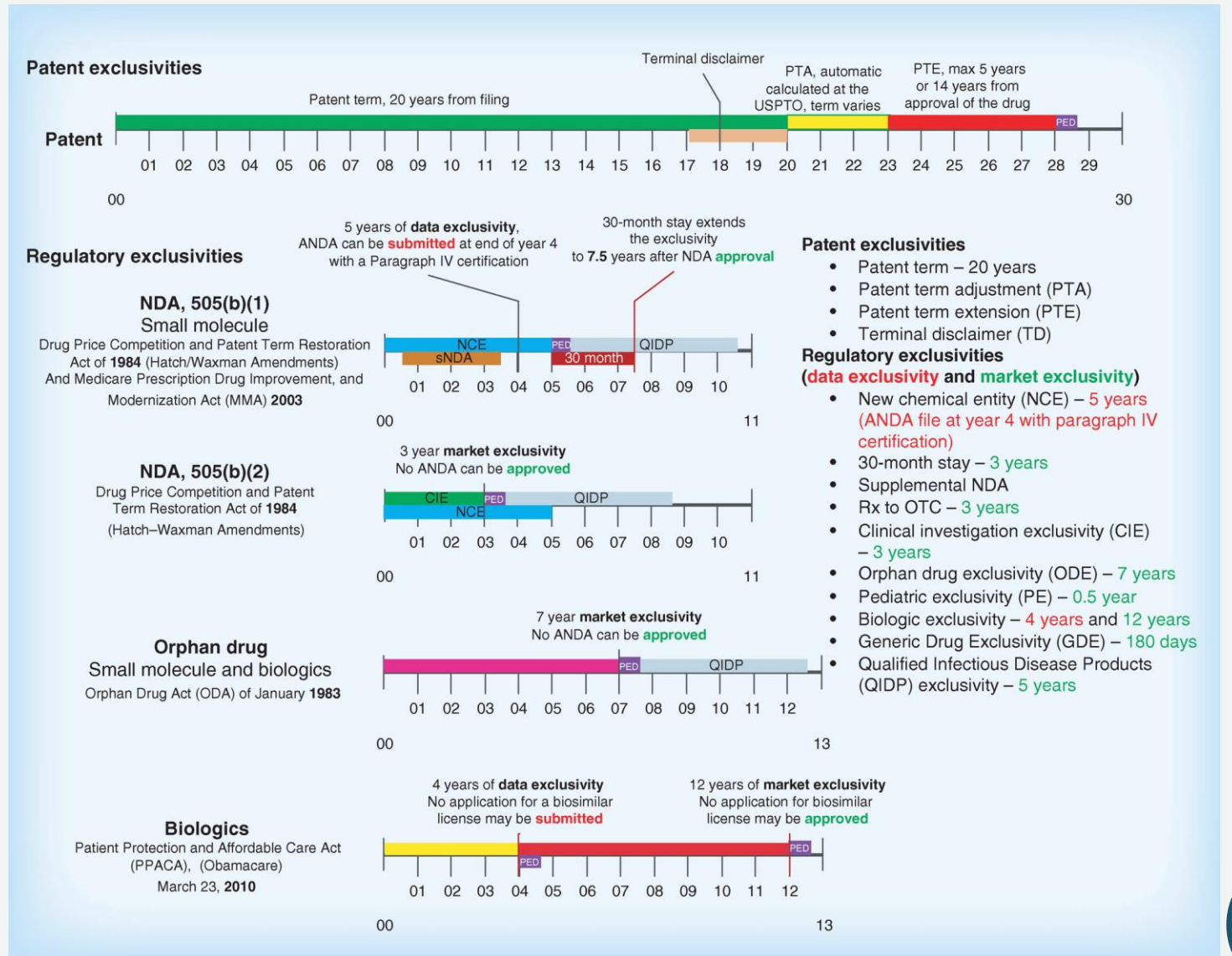
How we got here.

- 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 have these rules 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.
 - \$41 billion National Institutes of Health Budget in 2020.
 - 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 & establishing fair prices
 - Medicare Negotiation and Competitive Licensing Act
 - Title I of H.R. 3
 - Prescription Drug Price Relief Act
 - Prescription Drug Affordability and Access Act
 - Stopping price spikes
 - Stop Price Gouging Act
 - Senate Finance Committee Package / Title II of H.R. 3
 - Curbing monopoly abuses
 - Affordable Prescriptions for Patients Act
 - Preserve Access to Affordable Generics and Biosimilars Act
 - PRICED Act
- Other notable proposals
 - Affordable Drug Manufacturing Act
 - We PAID Act
 - Transparent Drug Pricing Act

*Increasing
negotiating
power &
establishing
fair prices*

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.

Medicare Negotiation and Competitive Licensing Act

*Rep. Doggett & Sen.
Brown*

- Require HHS to negotiate prices for Medicare Part D (world's largest purchaser of drugs)
- If fail to reach agreement on appropriate price, HHS can issue "competitive licenses" (CLs)
 - In the interim period between generic authorization and generic launch, require international reference pricing from rich countries
- Appropriate price based on R&D spending, federal subsidies for R&D, affordability and therapeutic value
- 127 co-sponsors in the House


Lower Drug Costs Now Act (H.R. 3), Title I

*House Democratic
Leadership – Passed by
the House*


- Secretary required to negotiate at least 50 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
- Limitations:
 - Failure to cover uninsured
 - Limitations on what drugs are negotiation-eligible

Prescription Drug Price Relief Act


*Sen. Sanders & Rep.
Khanna*

- HHS required to review prices, identify “excessively priced drugs” based on a series of factors
 - Automatically excessive if U.S. price exceeds median in five other rich countries
 - If excessive, HHS required to issue CLs
 - Notwithstanding international reference price standard, price may otherwise be deemed excessive
 - Any person in U.S. can petition Secretary to make an excessive price determination
 - Co-sponsors in Senate include Booker, Blumenthal, Gillibrand, Harris, Warren & Klobuchar (notice anything?)
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*Prescription
Drug
Affordability
and Access
Act
Sen. Booker*


- Establishes Bureau of Prescription Drug Affordability and Access
 - Drugs already on the market subject to international reference pricing standard and potentially subject to further review
 - Bureau required to review prices of drugs generating high cumulative revenues to determine appropriate price and drugs with sharp price spikes, may review prices of other drugs at will
 - Enforcement of interim international reference price through steep civil money penalty
 - Licenses competition if drug company fails to sell product at appropriate price established by the Bureau
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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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Stop Price Gouging Act


*Sen. Brown & Rep.
Pocan*

- Bill imposes an excise tax on companies that sell prescription drugs that are subject to price spikes that exceed inflation
 - For each taxable prescription drug, the excise tax ranges from 50% to 100% of price spike revenue received by the company
 - Depending on the size of the price spike and including an adjustment for revenue that is due solely to an increase in the cost of the inputs necessary to manufacture the drug.
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*Lower Drug
Costs Now
Act (H.R. 3),
Title II &
Senate
Finance
Committee
Package*

- Inflation-based rebate for Part B and Part D drugs
 - H.R. 3 includes language calling on government to establish regs to provide inflationary rebates for group health plans, as well
- Level of rebate based on Average Sales Price (ASP) & Average Manufacturer Price (AMP)
 - Likely to modestly mitigate some private sector price spikes, depending on composition of market

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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Affordable Prescriptions for Patients Act


*Sens. Cornyn &
Blumenthal, Reps.
Cicilline & Collins*

- Affordable Prescriptions for Patients Act (Cornyn-Blumenthal)
 - Strong, unique language defining patent thickets as anti-competitive was replaced by weakened language aimed at biologic patent dance
 - Still effectively targets product hopping, in which companies switch to a new product before end of exclusivity to stymie generic market
 - Penalty of disgorgement of unjust enrichment

*Preserve
Access to
Affordable
Generics and
Biosimilars
Act*
*Sens. Klobuchar &
Grassley*

- Pay-for-delay patent settlements presumptively anticompetitive
 - Violators face damages up to three times the value gained through the anticompetitive behavior
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PRICED
Act
Reps. Schakowsky &
Westerman

- Reduce biologics exclusivity from 12 years to 5 years (comparable to small-molecule NCEs)
 - New study in Nature Biotechnology by Beall et al., shows that biologics have similar development times to small-molecule drugs
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*Other
notable
proposals*




*Affordable
Drug
Manufacturing
Act*
Sen. Warren & Rep.
Schakowsky

- Establishes an Office of Drug Manufacturing within HHS
- Authorizes the Office to manufacture **generic drugs** under three key conditions
 - No company is manufacturing the drug
 - Only one or two companies produce the drug, and the price has spiked or the drug is in shortage,
 - Only one or two companies produce the drug, the price is a barrier to patient access, and the drug is listed as an “essential medicine” by the World Health Organization
- Authorizes the Office to manufacture any drug that the federal government has licensed, including under existing compulsory licensing authorities


We PAID

Act


*Sens. Van Hollen &
Scott*

- Directs National Academy of Medicine to complete study on how to define reasonable pricing, based on various factors
 - Establishes an independent Drug Affordability and Access Committee to determine a reasonable price for each applicable drug
 - Applies to all drugs in which Bayh-Dole rights attach to at least one patent (~10%)
 - If companies refuse to lower price, does *not use* licensing as a remedy (?) but instead voids exclusivities and bans future licensing arrangements
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*Transparent
Drug
Pricing Act*
Sens. Hawley & Scott

- Includes a provision requires companies to sell at the lowest price among five other rich countries
 - No real enforcement mechanism
 - Sunsets after five years
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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

