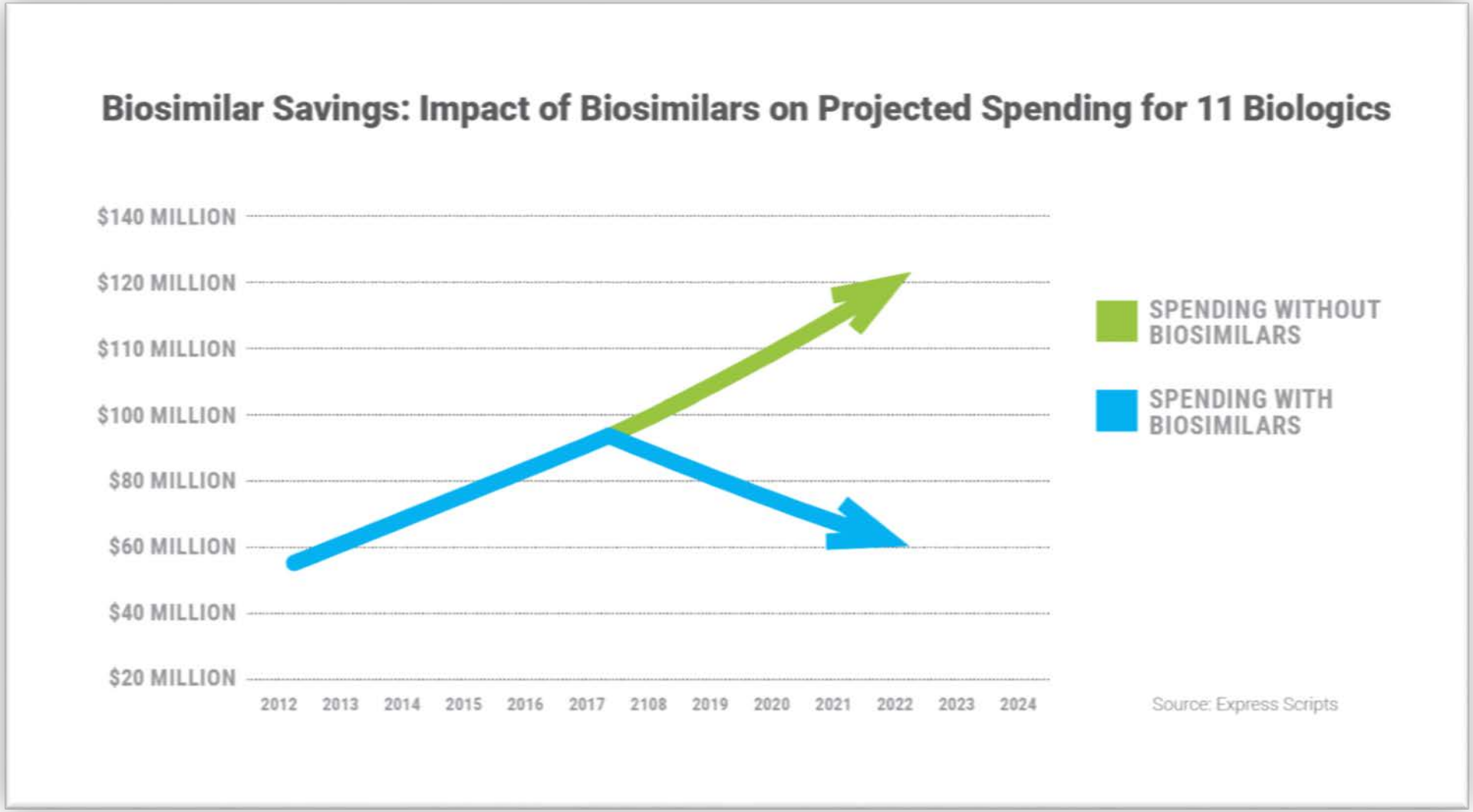
Your Generics & Biosimilars Industry

Market Access,
Market Success

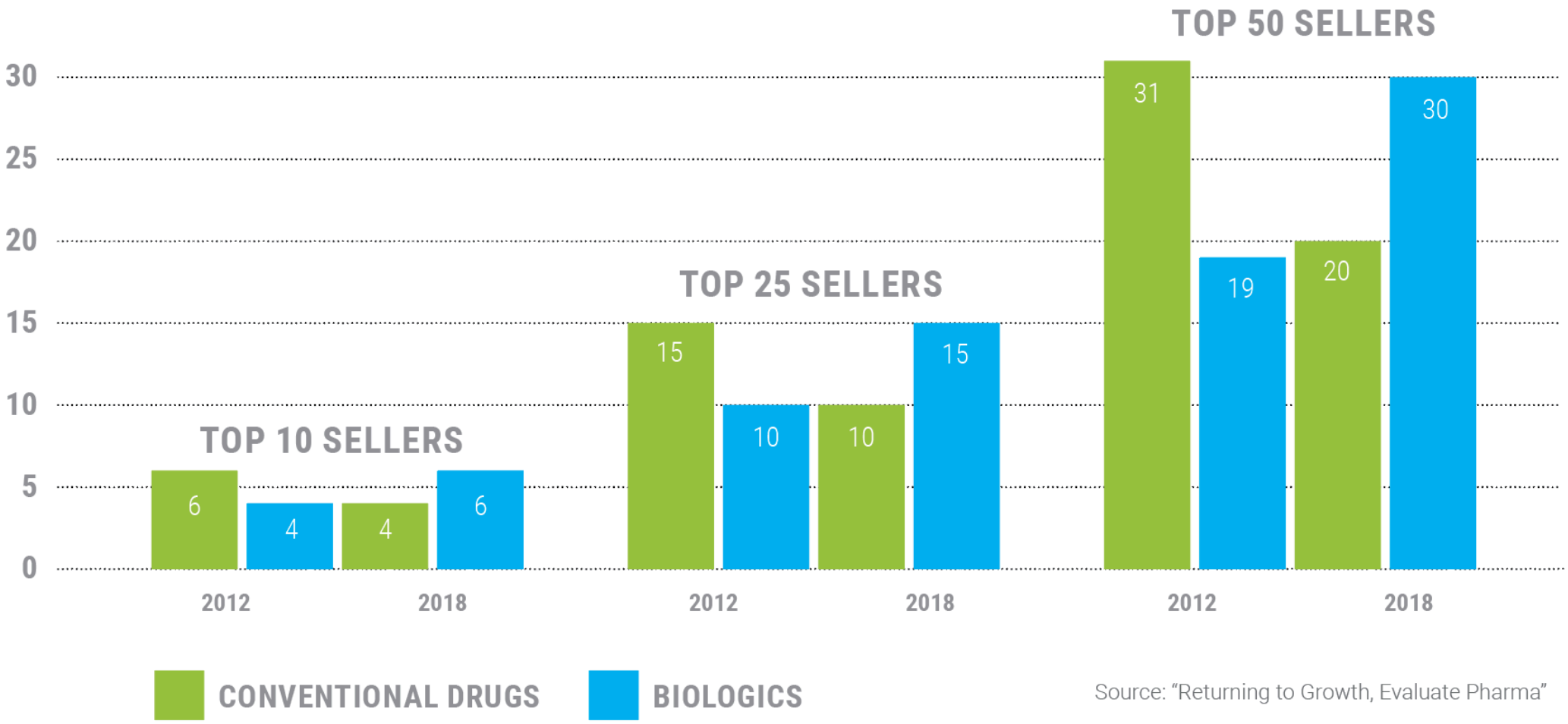
Agenda

- The Current Biosimilars Market
- The Challenges
  - Abuse of FDA-mandated safety programs (and voluntarily imposed “safety programs”)
  - Prolonged negotiations around single shared system REMS
  - Attack on the IPR system
- The Impact: Inadequate Competition in Defiance of Congressional Intent
- The Solution: Earlier Access to Market and Better Competition
- Recent FDA Actions

Solutions: Biosimilars Present Significant Opportunities for Savings



The Rising Cost of Biologics



Source: "Returning to Growth, Evaluate Pharma"

The Challenges

Access to Samples

- Some brand manufacturers refuse to sell their product to generic or biosimilar developers.
- Brand product is necessary for generic and biosimilar developers to conduct the necessary testing under rigid FDA oversight to gain marketing approval.
- By refusing to sell their product, they prevent or delay an application being filed at FDA and thus, the approval of a more accessible alternative.
- This occurs for drugs for which the brand company voluntarily imposes a REMS-like program even though the FDA has not identified them as having a higher risk profile.

Single Shared System

- For REMS drugs, the law presumes patients and providers benefit from a common REMS protocol shared by the brand and generic or biosimilar.
- Negotiations over these shared systems have proven another opportunity for delay.

The Impact: Inadequate Competition in Defiance of Congressional Intent

- Through these delay tactics, brand companies are able to recoup additional revenues at monopoly prices.
- During the delay they can pursue other strategies like patent evergreening or product hopping, blunting the deflationary impact of generic entry.
- A 2014 study concluded these abuses cost the U.S. healthcare system $5.4 billion annually - $1.8 billion to the federal government.
- $140 Million lost savings for every $1 Billion in biologics sales
- A recent analysis concluded that the market of products subject to competitive access restrictions is more than $22 billion.

The CREATES Act offers a solution

- The CREATES Act (H.R. 2212, S. 974) offers a clear solution to the problem.
- As it does today, FDA would have to certify that generic or biosimilar developers can handle the brand product safely.
- After receiving this certification, if a contract of sale is not finalized within 31 days, the generic or biosimilar developer can seek injunctive relief through the courts.
- The bill also gives FDA greater authority to waive the law's requirement that the brand and generic or biosimilar developer share a common safety protocol.
- This allows a generic or biosimilar to establish their own program – approved by FDA – that provides the same safety protections as the brands.
- By giving FDA expanded waiver authority, the bill encourages shared programs by removing the incentive for delay.

FDA has made solving this problem a priority

- “We know that branded companies are using our rules that are intended to protect consumers, or meant to make the regulatory process more predictable, and taking advantage of these rules in order to deliberately forestall the entry of expected generic drug competition. In other words, they are 'gaming' our system.“ – Dr. Scott Gottlieb, M.D., Commissioner of Food and Drugs

- Dr. Gottlieb recently announced a Drug Competition Action Plan and has spoken extensively about the challenges REMS and Restricted Access programs present.

- AAM appreciates FDA’s attention to the problem. FDA should take strong enforcement action using the no-delay provision in current law. FDA should also address shared REMS through clear deadlines and intent to exercise its waiver authority

- FDA’s authorities are limited to REMS-drug, and has no authority to compel sale of the brand’s product.

- Expansion of these principles to biosimilars is critical. FDA needs to hear your input.

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Inter Partes Review

- Some advocates for the brand manufacturers have called to exempt pharmaceutical patents from the IPR process.
- This exemption is unnecessary, and would ultimately cost patients and payers more by delaying competition and increasing the cost to develop a competitor:
  - Only a small fraction of IPRs instituted are for pharmaceutical patents, around 8%;
  - There is no evidence that pharmaceutical patents are overturned at IPR more often than any others;
  - The IPR process has been proven to be a more efficient process for the review of patents than traditional district court litigation, and is subject to judicial review after a decision has been rendered.
- The need for IPR in the biologics arena is even greater: biologics have more patents (e.g., Humira) erecting higher barriers to entry

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Thank you.

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