TOP FIVE FLAWS WITH *THE BLOCKING ACT*:
How it Would Slow the Availability of More Affordable Generic Medicines

(1) BLOCKING could lead to the loss of a first generic's exclusivity if it is not approved in 30 months – even when FDA data shows a median approval time of 51 months.

- *The BLOCKING Act* relies a 30-month review timeline. *The BLOCKING Act* was drafted based on the average approval time **for all** generic drug applications (ANDAs) in the most recent FDA quarterly report (FY19).

- However, the 180-day exclusivity incentive is only applicable to first-filed ANDAs with Paragraph IV certifications (e.g., with a challenge to a brand-name patent).

- According to FDA data, the median approval time for first-filed ANDAs with Paragraph IV certifications was 51 months over FY16-20. See table below.

- Given these timeframes, generic developers will be severely disincentivized from making Paragraph IV challenges if there is not reasonable certainty that approval is obtainable within 30 months. And, as the data confirms, there is no such reasonable certainty.

Time to AP for FF ANDAs with PIV at time of approval

FY of AP	Months		Number
	Mean	Median	
2016	66.9	66	51
2017	61.3	53.5	42
2018	63.3	54	45
2019	46.5	44	68
2020	53.1	52.5	30
Total	57.6	51	236

Note: Numbers reflect ANDAs with PIV certification at time of approval.

(2) BLOCKING does not require the subsequent applicant to launch – only that the subsequent applicant be eligible for approval.

- The intended goal of *The BLOCKING Act* is to encourage more generic launches. However, nothing in the legislation requires the subsequent applicant to actually launch.

- *The BLOCKING Act* will only lead to additional generic entry if a subsequent applicant triggers a first applicant's exclusivity and immediately launches on day 181.

- Unless the patent landscape is cleared before that subsequent applicant's launch, it is highly unlikely that the subsequent applicant will launch at-risk and potentially incur billions of dollars of damages.

- Therefore, the subsequent applicant may not be able to launch for the exact same reasons the first applicant has not launched. And yet *The BLOCKING Act* would cause the

value of the 180-day exclusivity incentive to be lost.

(3) BLOCKING does not account for COVID-19's impact on FDA's operations and inspections.

- *The BLOCKING Act* was drafted and considered based on pre-COVID approval timelines. Those approval timelines have been drastically impacted by COVID.

- In particular, an application generally cannot be approved until FDA conducts a pre-approval inspection of the facility used to manufacture the generic drug. The COVID-19 pandemic impacted FDA's operations and ability to conduct pre-approval inspections—FDA is not presently conducting in-person inspections of foreign facilities.

- These inspection delays may further complicate a generic manufacturer's ability to gain approval within the 30 months as proposed by *The BLOCKING Act*.

(4) BLOCKING will curtail the development of complex generics.

- The 30-month review timeline will be impossible to meet when it comes to the development of complex generics. Developing complex generics requires a higher level of expertise than is the case in the development of other generic medicines.

- The length of review and approval times have historically exceeded 5+ years due to the issuance of product-specific guidances.

- For example, FDA has not approved generic alternatives to Restasis® in 8 years and recently approved the first generic for ProAir® after approximately 10 years.

- One of the more promising opportunities for new generic competition would become infeasible under *The BLOCKING Act*.

(5) Current FDA authority is sufficient to solve the alleged problem purportedly addressed by BLOCKING.

- FDA's current statutory and regulatory authorities allow the agency to conclude that 180-day exclusivity is forfeited if a first applicant does not diligently pursue approval.

- FDA's regulations state: "If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval."

- In September 2020, FDA issued a guidance stating that the agency may deem an ANDA to be withdrawn—and exclusivity forfeited—if an applicant does not respond in a timely manner to an FDA complete response letter ("CRL").