FDA Rulemaking Memo

Intro

In the summer of 2024, the Supreme Court issued two landmark rulings – *Ohio v. EPA* on June 27, 2024, and *Loper Bright Enterprises v. Raimondo* on June 28, 2024 – that transformed the regulatory landscape for federal agencies. In *Ohio v. EPA*, the Court held that an agency's failure to adequately respond to significant public comments during the notice-and-comment process renders its rules arbitrary and capricious. The following day, in *Loper Bright v. Raimondo*, the Court overruled Chevron deference, directing lower courts to interpret statutory ambiguities independently rather than deferring to agency interpretations. In doing so, the Court substantially reduced agency latitude in interpreting legislative "gray areas".

We hypothesize that these decision created an environment where agencies are less likely to publish formal rules due to the increased logistical burden of addressing public comments post-*Ohio v. EPA* and the heightened risk of litigation over statutory interpretations post-*Loper Bright*. In addition, we propose a broader hypothesis: the overall proportion of formal rules has been decreasing since 2000. This decline is likely driven by a combination of factors. First, evolving expectations for transparency and adaptability have encouraged agencies to favor more flexible, informal governance mechanisms. Second, the cumulative impact of judicial constraints—exemplified by recent rulings—further disincentivizes the proliferation of formal rulemaking.

To investigate these hypotheses, we employ quantitative methods—specifically, regression-discontinuity with 6 month bands and interrupted time series analyses starting at January 2000—using the period following the release of *Loper Bright Enterprises v. Raimondo* (starting June 29, 2024) as a cutoff. This study aims to empirically assess how these Supreme Court rulings, in tandem with broader administrative shifts, have impacted agency rulemaking behavior.

Results

1. **FDA Rules**

- **Decrease Over Time:** There is a highly significant negative relationship with time—indicating that the number of published FDA rules has declined over time.
- **Treatment Effect:**
  - In the full dataset, the treatment effect (post-June 2024) is positive but not statistically significant.
  - In the 6-month (1-year window) model, no significant effects (treatment, distance, or interaction) are detected.

2. **FDA Guidance Documents**

- **Increase Over Time:** There is a significant positive relationship with the running variable, suggesting an increase in guidance documents as time progresses.
- **Treatment Effect:**
  - Overall, the treatment effect and its interaction with time are not statistically significant in the full dataset.
  - The 6-month window model shows a positive treatment effect that borders on significance, hinting at a possible short-term increase.

3. **Total FDA Documents (Rules + Guidance)**

- **Aggregate Decline:** A significant decrease in the total number of documents as time progresses.
- **No Immediate Shift:** The treatment effect and its interaction are not significant, suggesting that the immediate impact of the rulings on total document output is minimal.

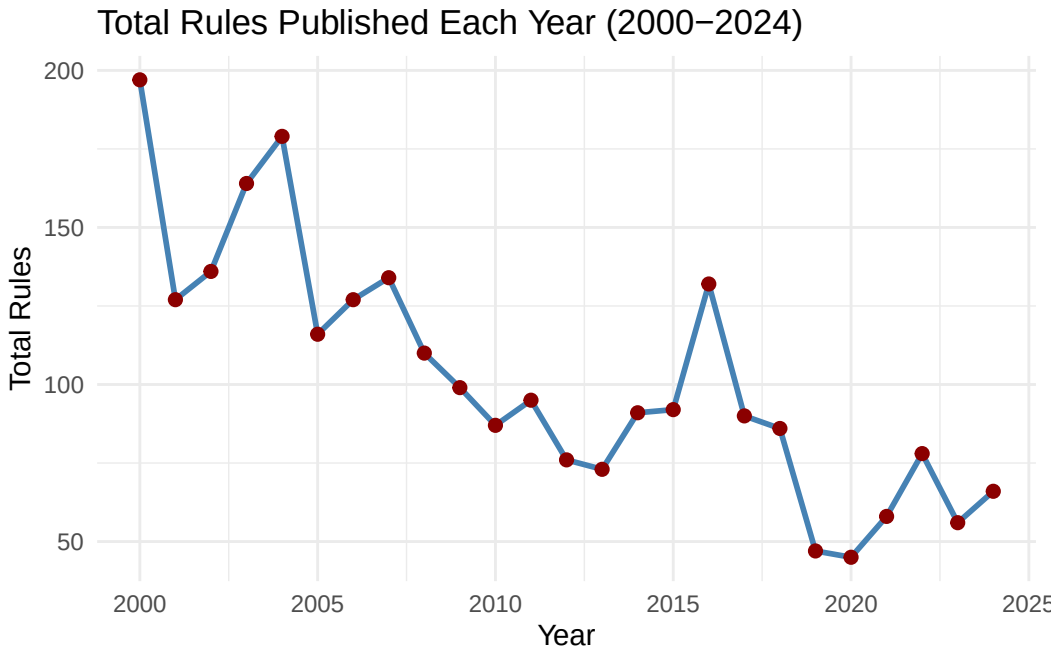
4. **Proportion of FDA Rules to Total Documents**

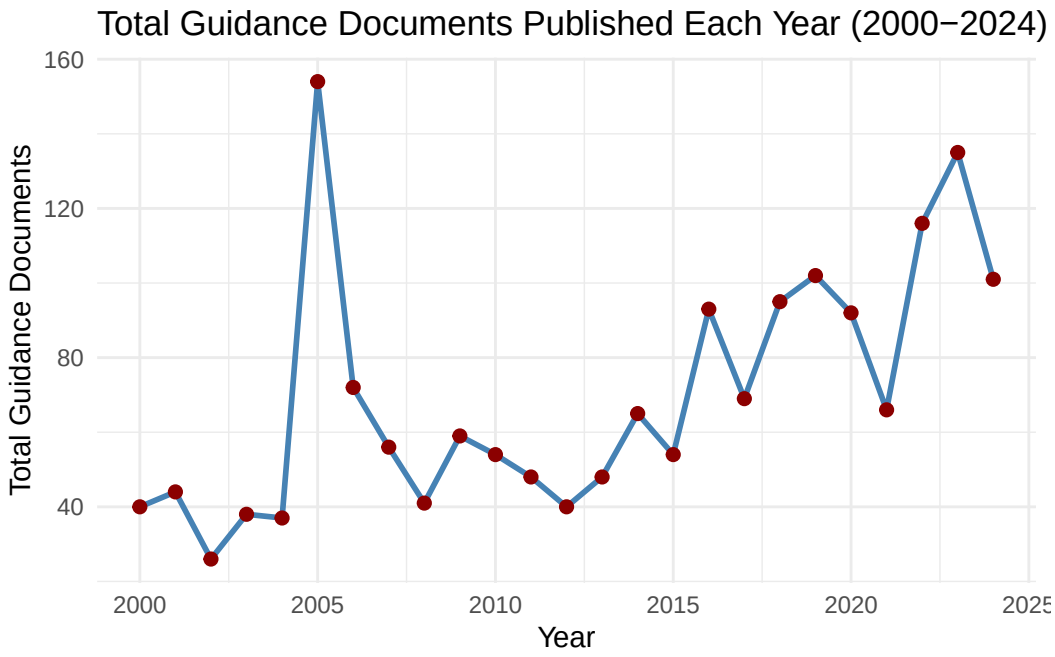
- **Shifting Composition:** There is a highly significant negative effect of time, meaning that as time progresses, the proportion of formal rules relative to total documents declines.
- **Implication:** This supports the broader hypothesis that the FDA is shifting away from formal rule making toward more flexible, informal guidance mechanisms.

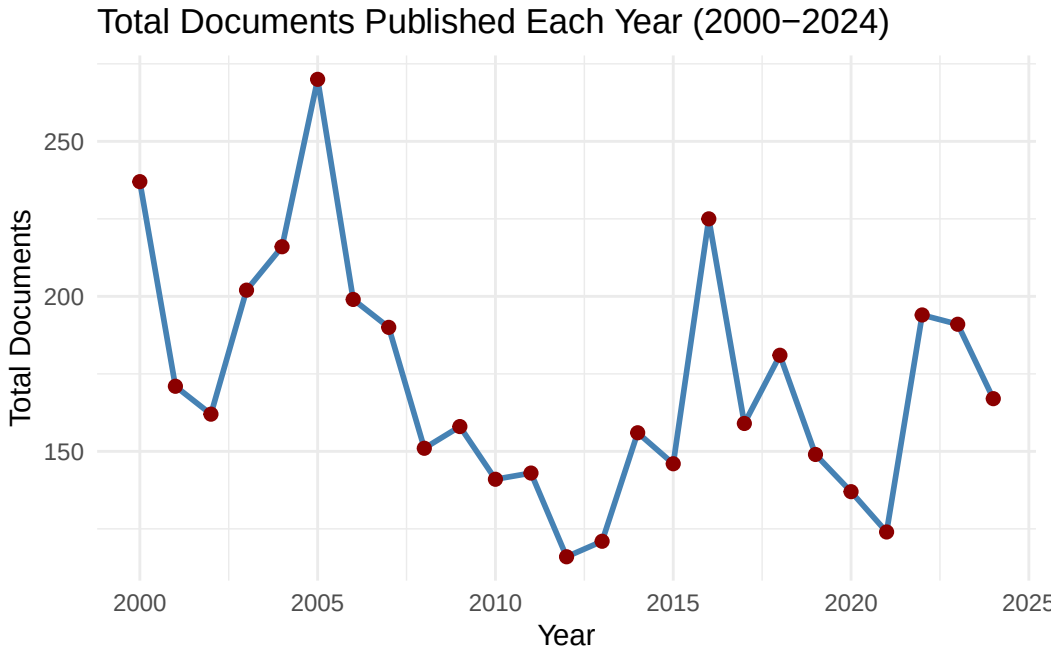
Running Code

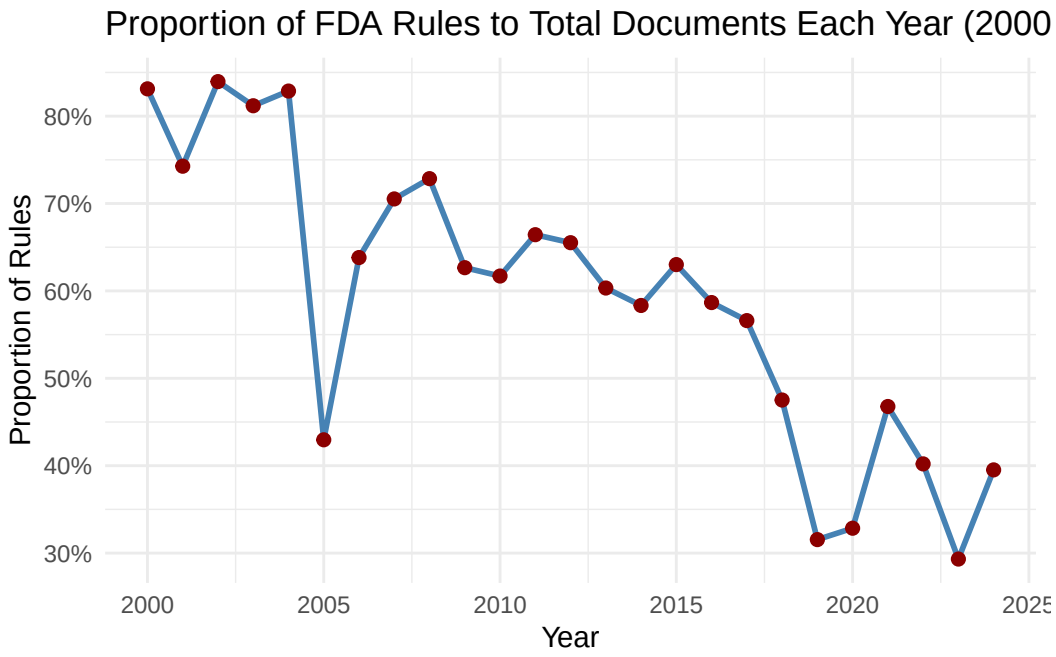
Now, create plots from df data frame

```
Warning: Using `size` aesthetic for lines was deprecated in ggplot2 3.4.0.
i Please use `linewidth` instead.
```




Total Guidance Documents Published Each Year (2000−2024)
Total Guidance Documents
160
120
80
40
2000
2005
2010
2015
2020
2025
Year


Total Documents Published Each Year (2000−2024)
Total Documents
250
200
150
2000
2005
2010
2015
2020
2025
Year



Regression Specifications

$$Y_i = \alpha + \tau D_i + \beta X_i + \gamma(D_i \times X_i) + \sum_{m=1}^{11} \delta_m M_{im} + \theta T_i + \epsilon_i$$

Where:

- (Y_i): The number of rules, guidance documents, total documents, or the proportion of rules to total documents published in month i.
- (α): Intercept term (baseline level of Y).
- (D_i): Treatment Indicator for month (i). $D_i = 1$ if month i is after June 2024 and 0 otherwise.
- (X_i): Running Variable representing the distance from the cutoff (June 2024) for month i). Measured in months: X_i = Number of months since June 2024
  - ($X_i > 0$): Post-June 2024 (treatment group)
  - ($X_i < 0$): Pre-June 2024 (control group)
- (β): The Treatment Effect

- (γ): Coefficient for the interaction between treatment and distance, capturing the change in slope after the cutoff.
- (M_{im}): Monthly Dummy Variables for each month (m, January to December), excluding one month to avoid multicollinearity (December is the reference category).
- (δ_m): Coefficients for each monthly dummy variable, capturing the effect of being in month (m) relative to the reference month.
- (T_i): Presidential Transition Indicator for month (i). $T_i = 1$ if the month is either September–December of an election year or January of the year following an election year, and 0 otherwise.
- (θ): Coefficient capturing the effect associated with presidential transition years.
- (ϵ_i): Error Term capturing unobserved factors affecting (Y_i).

Analysis for FDA Rules

Entire Dataset

The model for FDA Rules shows a strongly significant negative relationship with the running variable (distance, p < 2e-16), suggesting that the number of published FDA rules decreases as time progresses. The treatment effect is positive but not statistically significant (p = 0.1068), and the interaction between treatment and distance is not significant either. Several seasonal components (e.g., month^C, month^5, month^7, and month^8) are significant, while the presidential transition indicator does not have a significant effect.

```
Call:
lm(formula = rules ~ treatment * distance + month + transition,
    data = rd_data_all)

Residuals:
    Min      1Q  Median      3Q     Max
-9.6913 -3.0201 -0.6288  2.6139 17.4341

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)         3.755796   0.536401   7.002 1.83e-11 ***
treatment           7.070208   4.370240   1.618 0.106814
distance           -0.032425   0.003142 -10.319  < 2e-16 ***
month.L             0.489466   0.938527   0.522 0.602407
month.Q             0.569979   0.943413   0.604 0.546215
month.C             3.130836   0.928067   3.374 0.000845 ***
```

```
month^4            -0.046948   0.915088  -0.051 0.959119
month^5             1.828582   0.919144   1.989 0.047612 *
month^6             1.048743   0.917782   1.143 0.254128
month^7            -2.254139   0.916416  -2.460 0.014500 *
month^8             2.040164   0.914325   2.231 0.026439 *
month^9            -1.555138   0.916660  -1.697 0.090882 .
month^10            0.584463   0.916052   0.638 0.523972
month^11           -0.304525   0.915965  -0.332 0.739785
transition          0.957589   1.109688   0.863 0.388901
treatment:distance -1.288350   1.135088  -1.135 0.257323
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 4.571 on 284 degrees of freedom
Multiple R-squared:  0.3304,    Adjusted R-squared:  0.2951
F-statistic: 9.343 on 15 and 284 DF,  p-value: < 2.2e-16
```

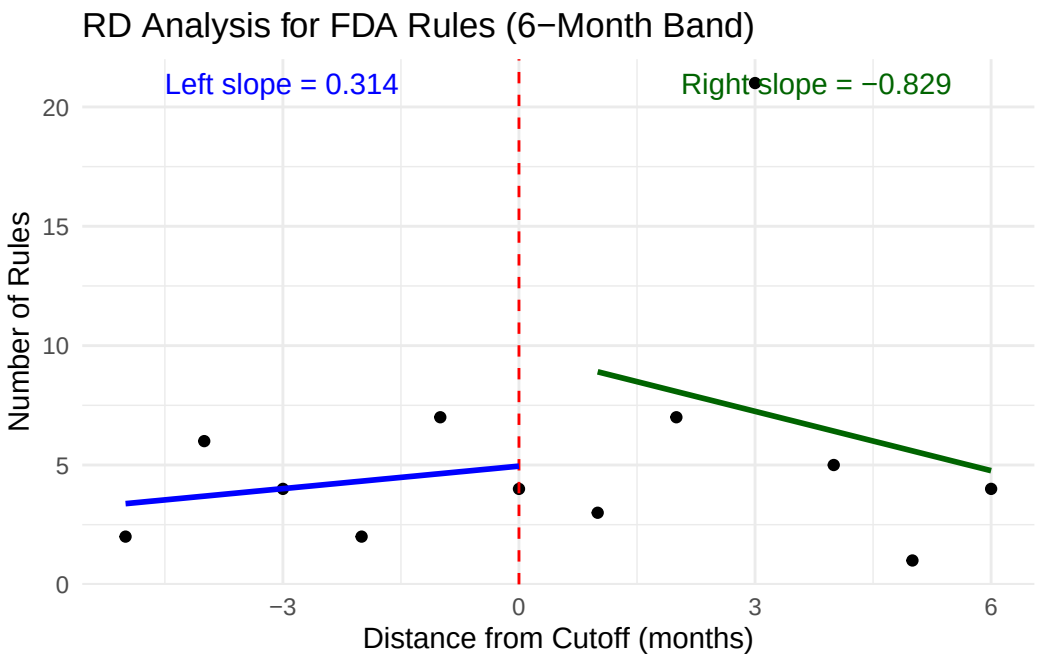
1-Year Window

The FDA Rules model (6-month bandwidth) yields an insignificant treatment, distance coefficient, and interaction between treatment and distance.

```
Call:
lm(formula = rules ~ treatment * distance, data = rd_data_band)

Residuals:
   Min     1Q Median     3Q    Max
-5.905 -1.645 -1.014  0.569 13.752

Coefficients:
                  Estimate Std. Error t value Pr(>|t|)
(Intercept)         4.9524     4.1884   1.182    0.271
treatment           4.7810     6.8241   0.701    0.503
distance            0.3143     1.3834   0.227    0.826
treatment:distance -1.1429     1.9564  -0.584    0.575

Residual standard error: 5.787 on 8 degrees of freedom
Multiple R-squared:  0.1158,    Adjusted R-squared:  -0.2158
F-statistic: 0.3491 on 3 and 8 DF,  p-value: 0.7911
```

```
print(plot_rules)
```

```
`geom_smooth()` using formula = 'y ~ x'
`geom_smooth()` using formula = 'y ~ x'
```



Analysis for FDA Guidance Documents

Entire Dataset

The analysis for Guidance Documents indicates that distance has a significant positive effect ($p = 0.000426$), implying an increase in guidance documents as time increases. However, both the treatment effect and its interaction with distance are not statistically significant. Only one seasonal component (month.L) reaches significance, and the overall explanatory power of the model is low (Adjusted R-squared = 0.04379).

```
Call:
lm(formula = guidance ~ treatment * distance + month + transition,
    data = rd_data_all)
```

```
Residuals:
    Min      1Q  Median      3Q     Max
 -9.589  -2.626  -0.648   1.768 101.740

Coefficients:
                    Estimate Std. Error t value Pr(>|t|)
(Intercept)         8.229625   0.830036   9.915  < 2e-16 ***
treatment           6.705764   6.762581   0.992 0.322238
distance            0.017337   0.004862   3.566 0.000426 ***
month.L             3.201098   1.452292   2.204 0.028314 *
month.Q             0.101349   1.459852   0.069 0.944701
month.C             0.094146   1.436106   0.066 0.947777
month^4            -1.880147   1.416022  -1.328 0.185321
month^5            -1.783766   1.422298  -1.254 0.210821
month^6            -0.983266   1.420191  -0.692 0.489285
month^7            -1.882487   1.418077  -1.327 0.185412
month^8             0.213132   1.414841   0.151 0.880366
month^9            -1.377575   1.418455  -0.971 0.332285
month^10           -0.444590   1.417513  -0.314 0.754024
month^11           -0.479155   1.417379  -0.338 0.735570
transition          0.531885   1.717150   0.310 0.756979
treatment:distance -1.453692   1.756453  -0.828 0.408575
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 7.073 on 284 degrees of freedom
Multiple R-squared:  0.09176,   Adjusted R-squared:  0.04379
F-statistic: 1.913 on 15 and 284 DF,  p-value: 0.02188
```

1-Year Window

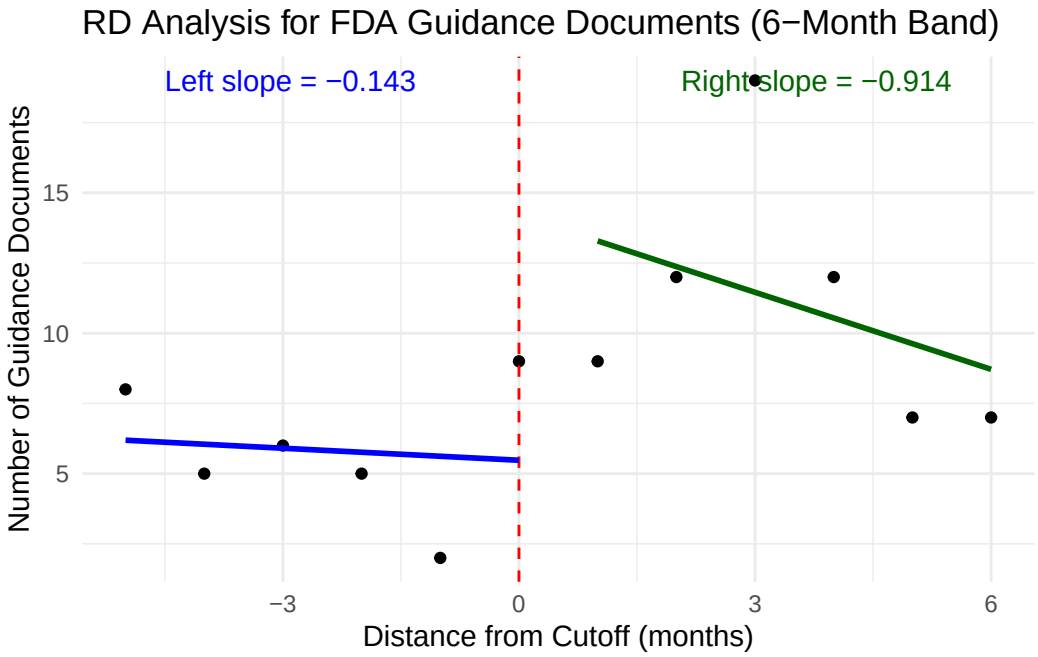
The Guidance Documents model (6-month window) shows a significant positive treatment effect (8.7238, p = 0.0901). The effects of distance and its interaction with treatment are not significant.

```
Call:
lm(formula = guidance ~ treatment * distance, data = rd_data_band)

Residuals:
    Min      1Q  Median      3Q     Max
-4.2857 -1.9429 -0.5667  1.5452  7.5429
```

```
Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)          5.4762     2.7778   1.971   0.0842 .
treatment            8.7238     4.5258   1.928   0.0901 .
distance            -0.1429     0.9175  -0.156   0.8801
treatment:distance  -0.7714     1.2975  -0.595   0.5686
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 3.838 on 8 degrees of freedom
Multiple R-squared:  0.4465,    Adjusted R-squared:  0.2389
F-statistic: 2.151 on 3 and 8 DF,  p-value: 0.1719
```

```
print(plot_guidance)
```

```
`geom_smooth()` using formula = 'y ~ x'
`geom_smooth()` using formula = 'y ~ x'
```



Analysis for Total FDA Documents (Rules + Guidance)

Entire Dataset

In the Total Documents model, the distance variable is significantly negatively related to the total count (p = 0.0138), suggesting a decline in total documents as time progresses. The treatment effect and its interaction with distance are not significant, but some seasonal factors (notably month.L and month^7) are.

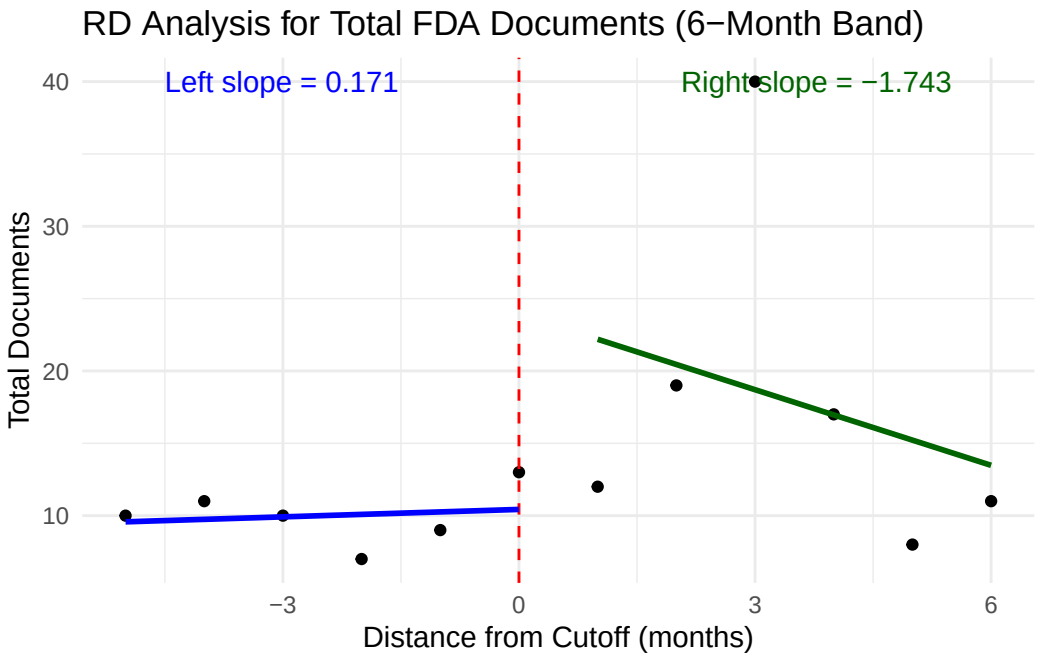
```
Call:
lm(formula = total_documents ~ treatment * distance + month +
    transition, data = rd_data_all)

Residuals:
    Min      1Q  Median      3Q     Max
-14.131  -4.319  -1.042   3.125 106.353

Coefficients:
                    Estimate Std. Error t value Pr(>|t|)
(Intercept)        11.985421   1.039788  11.527   <2e-16 ***
treatment          13.775971   8.471502   1.626   0.1050
distance           -0.015088   0.006091  -2.477   0.0138 *
month.L             3.690564   1.819290   2.029   0.0434 *
month.Q             0.671328   1.828761   0.367   0.7138
month.C             3.224982   1.799014   1.793   0.0741 .
month^4            -1.927095   1.773855  -1.086   0.2782
month^5             0.044816   1.781717   0.025   0.9800
month^6             0.065477   1.779077   0.037   0.9707
month^7            -4.136626   1.776428  -2.329   0.0206 *
month^8             2.253296   1.772375   1.271   0.2046
month^9            -2.932712   1.776903  -1.650   0.1000 .
month^10            0.139874   1.775723   0.079   0.9373
month^11           -0.783679   1.775554  -0.441   0.6593
transition          1.489475   2.151078   0.692   0.4892
treatment:distance -2.742043   2.200314  -1.246   0.2137
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 8.861 on 284 degrees of freedom
Multiple R-squared:  0.0878,    Adjusted R-squared:  0.03962
F-statistic: 1.822 on 15 and 284 DF,  p-value: 0.03137
```

In the Total Documents model (6 month bands), treatment, distance, and their interaction are not significant.

```
Call:
lm(formula = total_documents ~ treatment * distance, data = rd_data_band)

Residuals:
     Min       1Q   Median       3Q      Max
-10.1905  -2.6286  -0.6095   0.6357  21.2952

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)         10.4286     6.4590   1.615    0.145
treatment           13.5048    10.5235   1.283    0.235
distance             0.1714     2.1333   0.080    0.938
treatment:distance  -1.9143     3.0170  -0.634    0.543

Residual standard error: 8.924 on 8 degrees of freedom
Multiple R-squared:  0.2717,    Adjusted R-squared:  -0.00135
F-statistic: 0.9951 on 3 and 8 DF,  p-value: 0.443
```

```
print(plot_total)
```

```
`geom_smooth()` using formula = 'y ~ x'
`geom_smooth()` using formula = 'y ~ x'
```



Analysis for Proportion of FDA Rules to Total Documents

Entire Dataset

The proportion model shows a highly significant negative effect of distance ($p < 2e\text{-}16$), indicating that the proportion of rules declines as one progresses through the time period. The treatment effect and its interaction with distance are not significant, but some seasonal effects (month.L and month.C) are statistically significant. This model has a comparatively higher explanatory power (Adjusted R-squared = 0.367).

```
Call:
lm(formula = proportion_rules ~ treatment * distance + month +
    transition, data = rd_data_all)

Residuals:
     Min       1Q   Median       3Q      Max
-0.54491 -0.12520  0.01316  0.12175  0.56615

Coefficients:
                    Estimate Std. Error t value Pr(>|t|)
(Intercept)         0.3490678  0.0232422  15.019   <2e-16 ***
```

```
treatment           0.0607106  0.1893618   0.321   0.7487
distance           -0.0017270  0.0001362 -12.684   <2e-16 ***
month.L            -0.0822513  0.0406662  -2.023   0.0441 *
month.Q             0.0480820  0.0408779   1.176   0.2405
month.C             0.0913557  0.0402130   2.272   0.0238 *
month^4             0.0050466  0.0396506   0.127   0.8988
month^5             0.0617028  0.0398264   1.549   0.1224
month^6             0.0327470  0.0397674   0.823   0.4109
month^7             0.0132121  0.0397082   0.333   0.7396
month^8            -0.0123213  0.0396175  -0.311   0.7560
month^9            -0.0167641  0.0397188  -0.422   0.6733
month^10            0.0250676  0.0396924   0.632   0.5282
month^11           -0.0144518  0.0396886  -0.364   0.7160
transition         -0.0199279  0.0480826  -0.414   0.6789
treatment:distance -0.0123204  0.0491832  -0.251   0.8024
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 0.1981 on 284 degrees of freedom
Multiple R-squared:  0.3988,    Adjusted R-squared:  0.367
F-statistic: 12.56 on 15 and 284 DF,  p-value: < 2.2e-16
```

1-Year Window

For the proportion model with 6-month bands), treatment, distance, and their interaction are not statistically significant. With an adjusted R-squared of –0.2938, this model has poor explanatory power.

```
Call:
lm(formula = proportion_rules ~ treatment * distance, data = rd_data_band)

Residuals:
     Min       1Q   Median       3Q      Max
-0.19183 -0.14195 -0.01236  0.09652  0.31029

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)         0.49952    0.13848   3.607  0.00691 **
treatment          -0.13920    0.22562  -0.617  0.55442
distance            0.03203    0.04574   0.700  0.50357
treatment:distance -0.04326    0.06468  -0.669  0.52246
```

```
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 0.1913 on 8 degrees of freedom
Multiple R-squared:  0.1439,    Adjusted R-squared:  -0.1772
F-statistic: 0.4481 on 3 and 8 DF,  p-value: 0.7255
```

Now, let's visualize the RD regression, displaying the number of rules published in the 7 months before and after the cutoff date

```
print(plot_prop)
```

```
`geom_smooth()` using formula = 'y ~ x'
`geom_smooth()` using formula = 'y ~ x'
```