FDA Rule Analysis Quarto

Intro

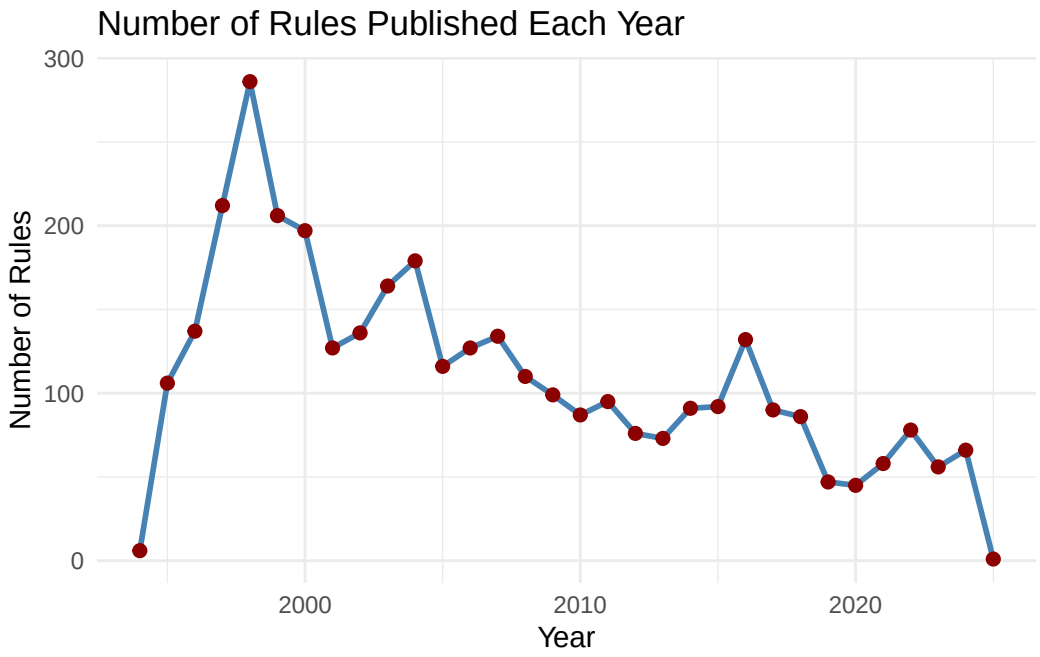
In the summer of 2024, the Supreme Court issued two landmark rulings – *Ohio v. EPA* on June 27, 2024, and *Loper Bright Enterprises v. Raimondo* on June 28, 2024 – that transformed the regulatory landscape for federal agencies. In *Ohio v. EPA*, the Court held that an agency's failure to adequately 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* likely discourage rulemaking. 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 and interrupted time series analyses—using the period following the release of Loper Bright Enterprises v. Raimondo (starting June 29, 2024) as a cutoff, complemented by a longitudinal analysis of rulemaking trends dating back to 2000. This study aims to empirically assess how these Supreme Court rulings, in tandem with broader administrative shifts, have impacted agency rulemaking behavior.

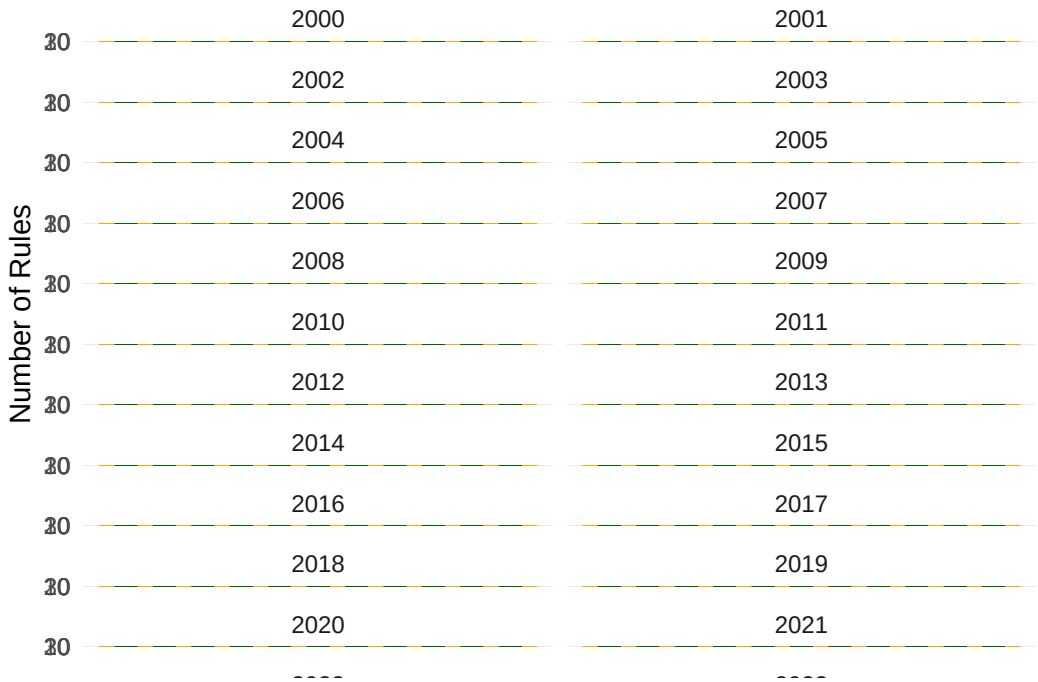
Running Code

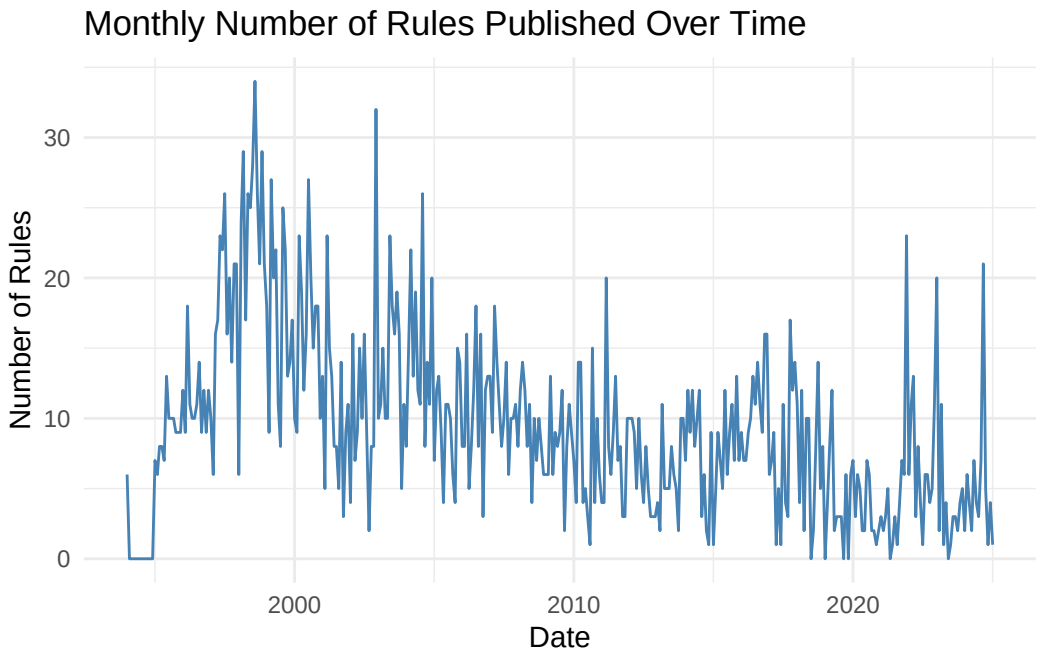
Now, create plots from df data frame



Next, let's analyze the data broken into its constituent months (the first visualization doesn't work yet)

```
`geom_line()`: Each group consists of only one observation.
i Do you need to adjust the group aesthetic?
```

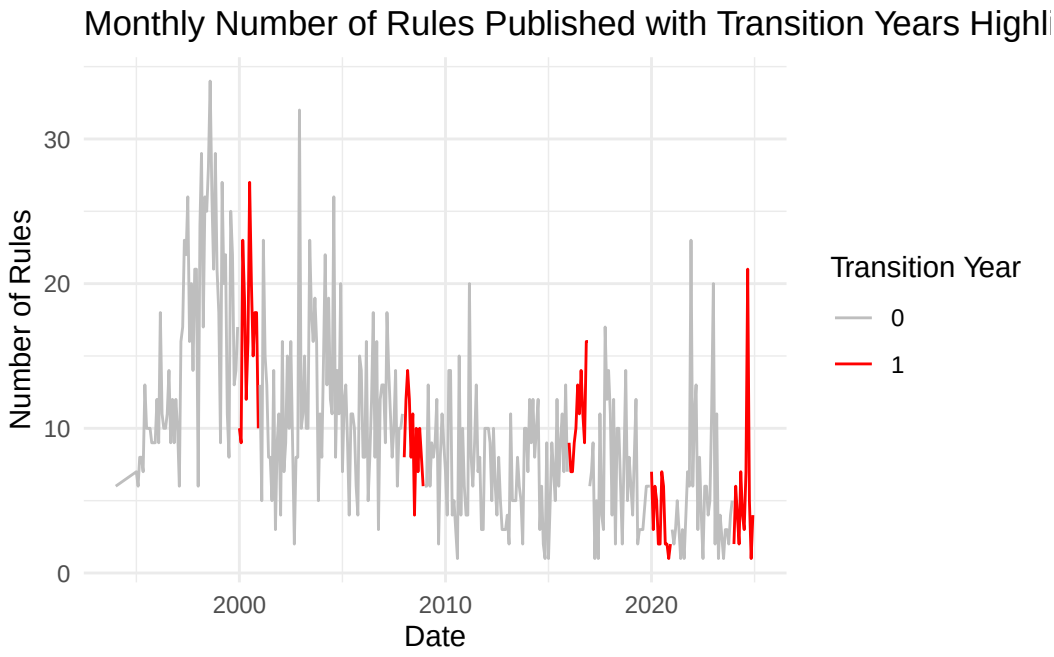




The following graph depicts the data broken into constituent months and highlights Presidential transition years.

```
`summarise()` has grouped output by 'year'. You can override using the
```

`.groups` argument.



Regression Discontinuity Analysis

$$Y_i = \alpha + \tau D_i + \beta X_i + \gamma X_i^2 + \sum_{m=1}^{11} \delta_m M_{im} + \theta T_i + \epsilon_i$$

Where:

- (Y_i): Number of Rules 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

- (X_i^2): Quadratic Term to capture potential non-linear trends in the data.
- (M_{im}): Monthly Dummy Variables for each month (m, January to December), excluding one month to avoid multicollinearity (January 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 (T_i): T_i =1 for 2008, 2016, 2020, or 2024 and 0 otherwise.
- (θ): Coefficient capturing the effect associated with presidential transition years.
- (ϵ_i): Error Term capturing unobserved factors affecting (Y_i).

```
# A tibble: 6 x 4
   year month    rules guidance
  <dbl> <chr>    <int>    <int>
1  2000 January     10        4
2  2000 February     9        2
3  2000 March       23        5
4  2000 April       19        3
5  2000 May         12        0
6  2000 June        16        1
```

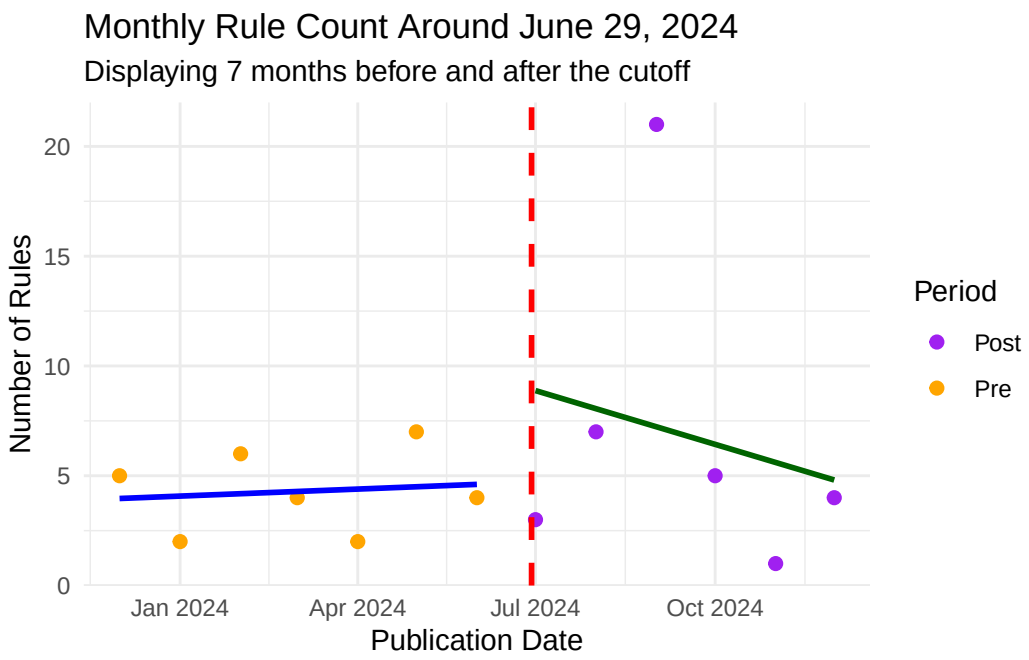
```
Call:
lm(formula = rules ~ treatment * distance + month + transition,
    data = rd_data_all)

Residuals:
    Min      1Q  Median      3Q     Max
-9.6733 -2.9071 -0.5818  2.2703 17.4854

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)         3.524881   0.547545   6.438 5.13e-10 ***
treatment           5.622432   4.010943   1.402  0.16207
distance           -0.032746   0.003122 -10.490  < 2e-16 ***
month.L             0.683134   0.907327   0.753  0.45213
month.Q             0.735963   0.916250   0.803  0.42251
month.C             2.978612   0.907329   3.283  0.00116 **
month^4            -0.062377   0.905578  -0.069  0.94513
month^5             1.779356   0.909297   1.957  0.05134 .
```

```
month^6             1.119657   0.907425   1.234  0.21826
month^7            -2.233488   0.908183  -2.459  0.01452 *
month^8             2.052115   0.907428   2.261  0.02448 *
month^9            -1.587479   0.908290  -1.748  0.08158 .
month^10            0.534394   0.907461   0.589  0.55640
month^11           -0.347802   0.908496  -0.383  0.70213
transition          1.363058   0.680451   2.003  0.04611 *
treatment:distance -1.010874   0.878174  -1.151  0.25065
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 4.537 on 285 degrees of freedom
Multiple R-squared:  0.3422,    Adjusted R-squared:  0.3076
F-statistic: 9.883 on 15 and 285 DF,  p-value: < 2.2e-16



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

Residuals:
    Min      1Q  Median      3Q     Max
 -9.650  -2.611  -0.677   1.718 101.692

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)         8.343186   0.853611   9.774  < 2e-16 ***
treatment           4.185854   6.252975   0.669  0.50377
distance            0.017403   0.004867   3.576  0.00041 ***
month.L             3.057850   1.414503   2.162  0.03147 *
month.Q             0.175262   1.428414   0.123  0.90243
month.C            -0.105815   1.414507  -0.075  0.94042
month^4            -1.794588   1.411776  -1.271  0.20471
month^5            -1.841802   1.417575  -1.299  0.19490
month^6            -0.923469   1.414656  -0.653  0.51442
month^7            -1.902585   1.415838  -1.344  0.18009
month^8             0.233432   1.414661   0.165  0.86905
month^9            -1.385906   1.416005  -0.979  0.32854
month^10           -0.474372   1.414712  -0.335  0.73764
month^11           -0.518115   1.416326  -0.366  0.71477
transition         -0.370870   1.060809  -0.350  0.72689
treatment:distance -0.317373   1.369054  -0.232  0.81684
```

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

Residual standard error: 7.074 on 285 degrees of freedom
Multiple R-squared:  0.0924,    Adjusted R-squared:  0.04463
F-statistic: 1.934 on 15 and 285 DF,  p-value: 0.02003


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

Residuals:
    Min      1Q  Median      3Q     Max
-14.250  -4.221  -1.040   3.306 106.356

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)       11.868067   1.068392  11.108   <2e-16 ***
treatment          9.808287   7.826317   1.253   0.2111
distance          -0.015343   0.006091  -2.519   0.0123 *
month.L            3.740985   1.770413   2.113   0.0355 *
month.Q            0.911225   1.787824   0.510   0.6107
month.C            2.872797   1.770418   1.623   0.1058
month^4           -1.856965   1.767001  -1.051   0.2942
month^5           -0.062445   1.774258  -0.035   0.9719
month^6            0.196187   1.770605   0.111   0.9119
month^7           -4.136074   1.772084  -2.334   0.0203 *
month^8            2.285547   1.770611   1.291   0.1978
month^9           -2.973385   1.772293  -1.678   0.0945 .
month^10           0.060021   1.770674   0.034   0.9730
month^11          -0.865917   1.772695  -0.488   0.6256
transition         0.992188   1.327725   0.747   0.4555
treatment:distance -1.328247   1.713529  -0.775   0.4389
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 8.853 on 285 degrees of freedom
Multiple R-squared:  0.08617,   Adjusted R-squared:  0.03807
F-statistic: 1.792 on 15 and 285 DF,  p-value: 0.03539
```

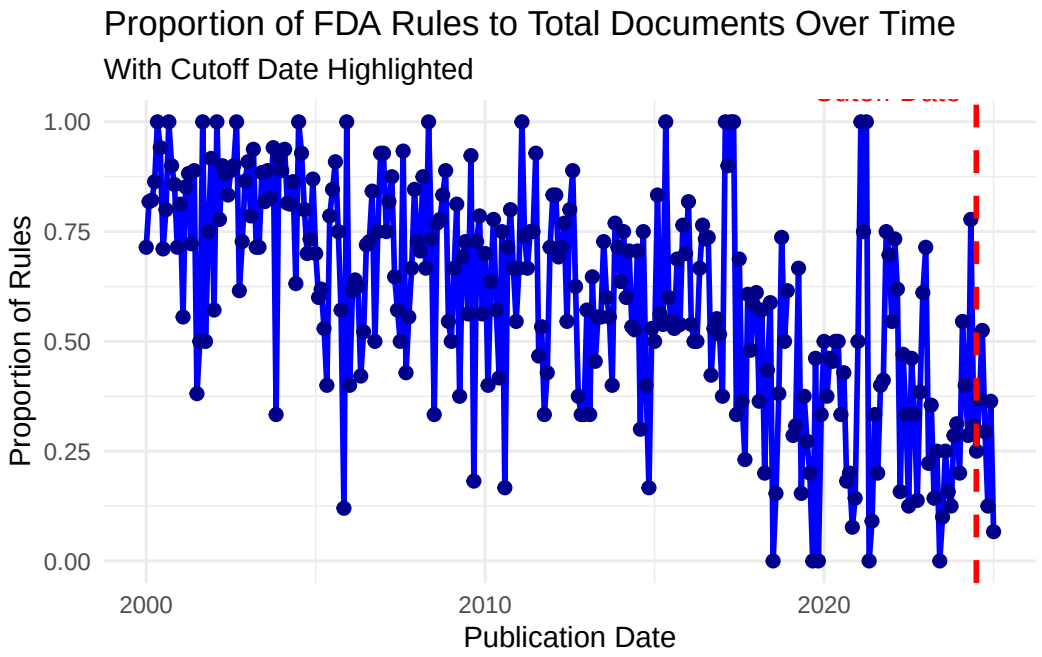
Now, let's visualize the RD regression, displaying the number of rules published in the 7 months before and after the cutoff date

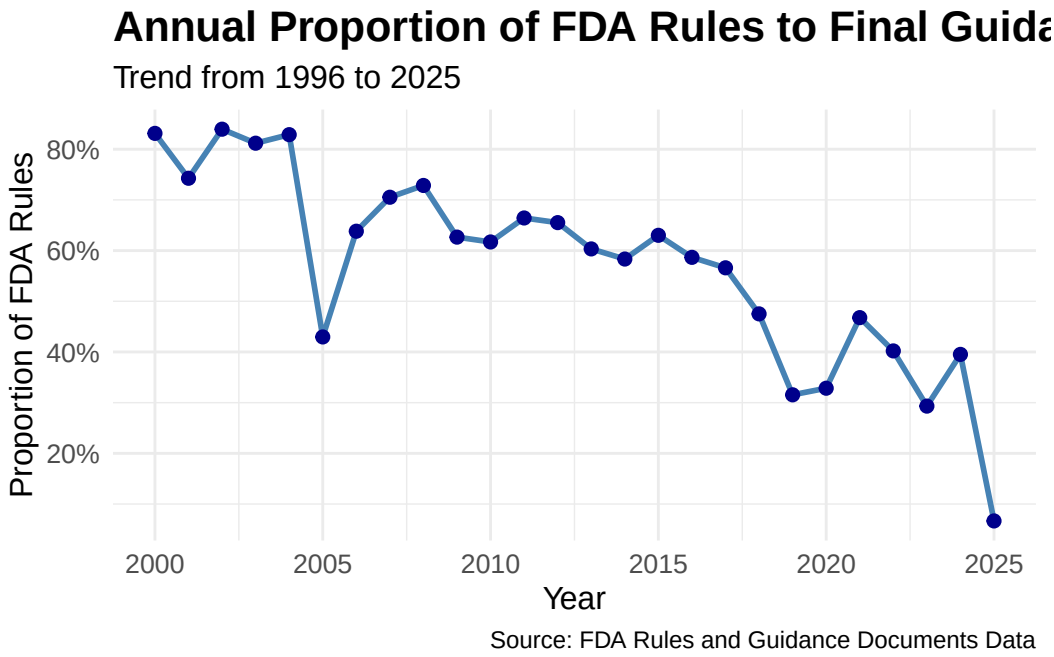
```
`geom_smooth()` using formula = 'y ~ x'
`geom_smooth()` using formula = 'y ~ x'
```



Now we'll try an ITS model.

```
Series: ts_rules
Regression with ARIMA(1,1,1)(0,0,2)[12] errors

Coefficients:
          ar1      ma1    sma1    sma2  Intervention  TimeAfterIntervention
      -0.0250  -0.7833  0.0634  0.1128        5.9283                -1.3589
s.e.   0.0677   0.0442  0.0522  0.0519        3.7620                 0.9109

sigma^2 = 23.73:  log likelihood = -1114.53
AIC=2243.05   AICc=2243.36   BIC=2270.48

Training set error measures:
                     ME     RMSE      MAE  MPE MAPE      MASE         ACF1
Training set 0.002791429 4.825765 3.629884 -Inf  Inf 0.6842757 0.0003992911


Warning: Removed 1 row containing missing values or values outside the scale range
(`geom_point()`).
```





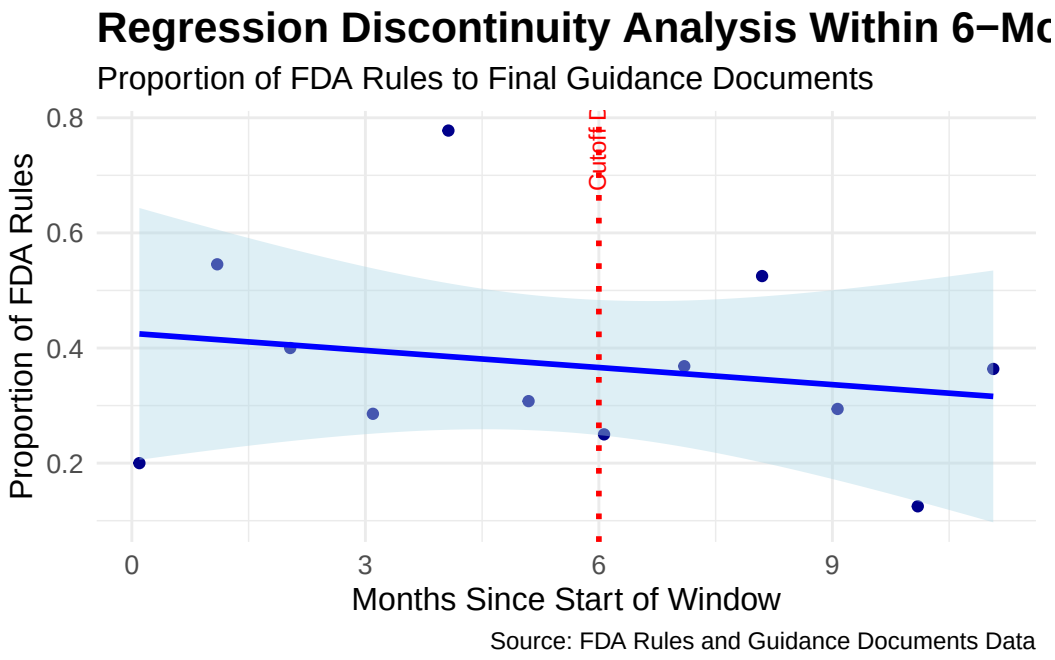
RD model for proportion of guidance docs to total documents with only 6 mos before and after cutoff

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

Residuals:
     Min       1Q   Median       3Q      Max
-0.19106 -0.14332 -0.01185  0.09594  0.31151

Coefficients:
                   Estimate Std. Error t value Pr(>|t|)
(Intercept)         0.33805    0.14179   2.384   0.0443 *
treatment           0.07867    0.42529   0.185   0.8578
distance            0.03153    0.04582   0.688   0.5108
treatment:distance -0.04268    0.06480  -0.659   0.5286
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 0.1915 on 8 degrees of freedom
Multiple R-squared:  0.1421,    Adjusted R-squared:  -0.1797
F-statistic: 0.4416 on 3 and 8 DF,  p-value: 0.7297
```

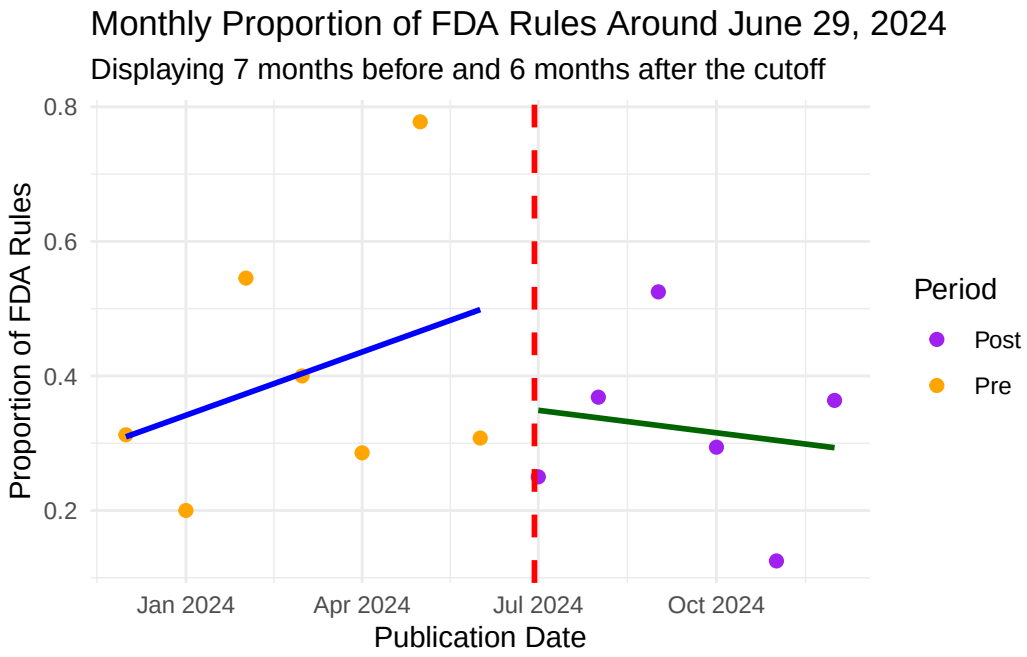
RD model for proportion of guidance docs to total documents with all data (does not include Jan 2025).

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

Residuals:
     Min       1Q   Median       3Q      Max
-0.53664 -0.12497  0.01234  0.11296  0.56897

Coefficients:
                    Estimate Std. Error t value Pr(>|t|)
(Intercept)         0.3458669  0.0238869  14.479   <2e-16 ***
treatment           0.0268312  0.1508588   0.178   0.8590
distance           -0.0017115  0.0001353 -12.654   <2e-16 ***
month.L            -0.0930523  0.0398610  -2.334   0.0203 *
month.Q             0.0543076  0.0398338   1.363   0.1739
month.C             0.0843200  0.0396159   2.128   0.0342 *
month^4             0.0126976  0.0393752   0.322   0.7473
month^5             0.0582927  0.0393846   1.480   0.1400
```

```
month^6              0.0344916  0.0392709   0.878   0.3805
month^7              0.0104279  0.0393028   0.265   0.7910
month^8             -0.0117084  0.0392479  -0.298   0.7657
month^9             -0.0159263  0.0392855  -0.405   0.6855
month^10             0.0262113  0.0392457   0.668   0.5048
month^11            -0.0141505  0.0392973  -0.360   0.7190
transition           0.0224673  0.0296287   0.758   0.4489
treatment:distance -0.0161162  0.0478745  -0.337   0.7366
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 0.1962 on 283 degrees of freedom
  (1 observation deleted due to missingness)
Multiple R-squared:  0.4005,    Adjusted R-squared:  0.3687
F-statistic:  12.6 on 15 and 283 DF,  p-value: < 2.2e-16
```




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




```
Call:
lm(formula = proportion_rules ~ time + intervention + time_after,
    data = combined_counts)

Residuals:
     Min       1Q   Median       3Q      Max
-0.61351 -0.12564  0.01424  0.12761  0.58256

Coefficients:
              Estimate Std. Error t value Pr(>|t|)
(Intercept)  0.8531517  0.0230012  37.092   <2e-16 ***
time        -0.0017089  0.0001361 -12.560   <2e-16 ***
intervention 0.0390056  0.1390001   0.281    0.779
time_after  -0.0323138  0.0371518  -0.870    0.385
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Residual standard error: 0.1977 on 296 degrees of freedom
  (1 observation deleted due to missingness)
Multiple R-squared:  0.3734,    Adjusted R-squared:  0.367
F-statistic: 58.79 on 3 and 296 DF,  p-value: < 2.2e-16
```