

FDA Rule Analysis Quarto

Intro

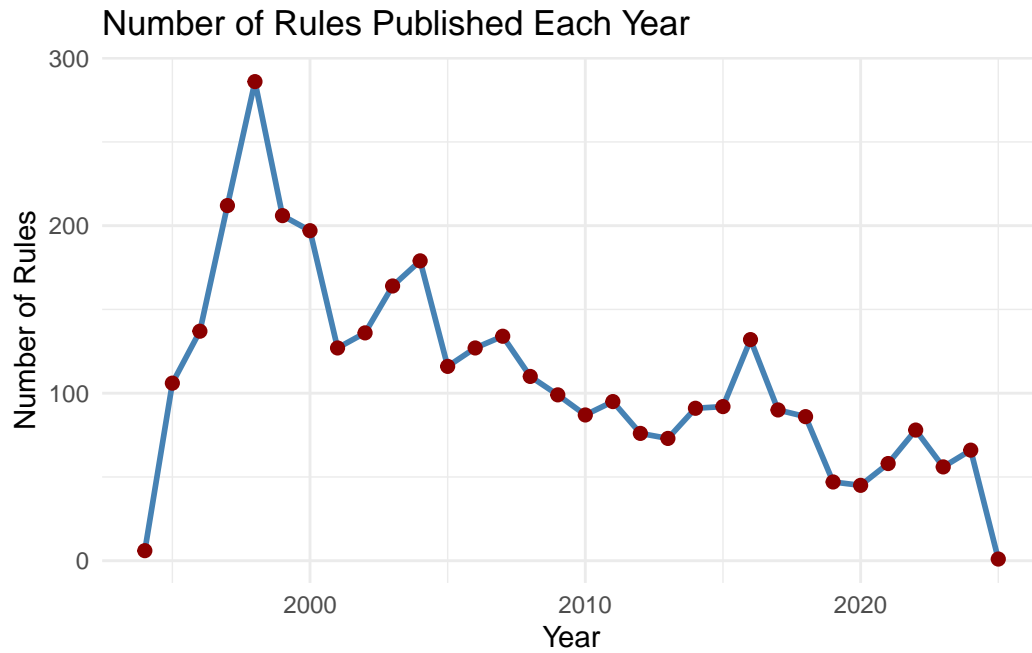
In the summer of 2024, the Supreme Court issued two landmark rulings – *Ohio v. EPA* on June 27, 2024, and *Loper Bright Enterprises v. Raimondo* on June 28, 2024 – that transformed the regulatory landscape for federal agencies. In *Ohio v. EPA*, the Court held that an agency’s failure to adequately 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.

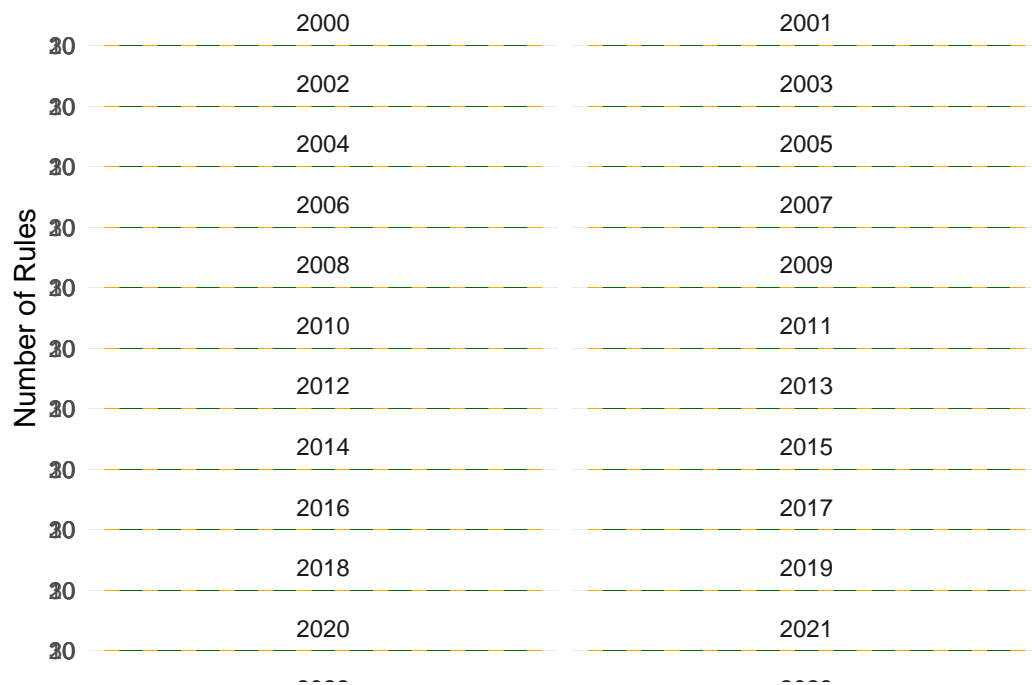
Running Code

Now, create plots from df data frame

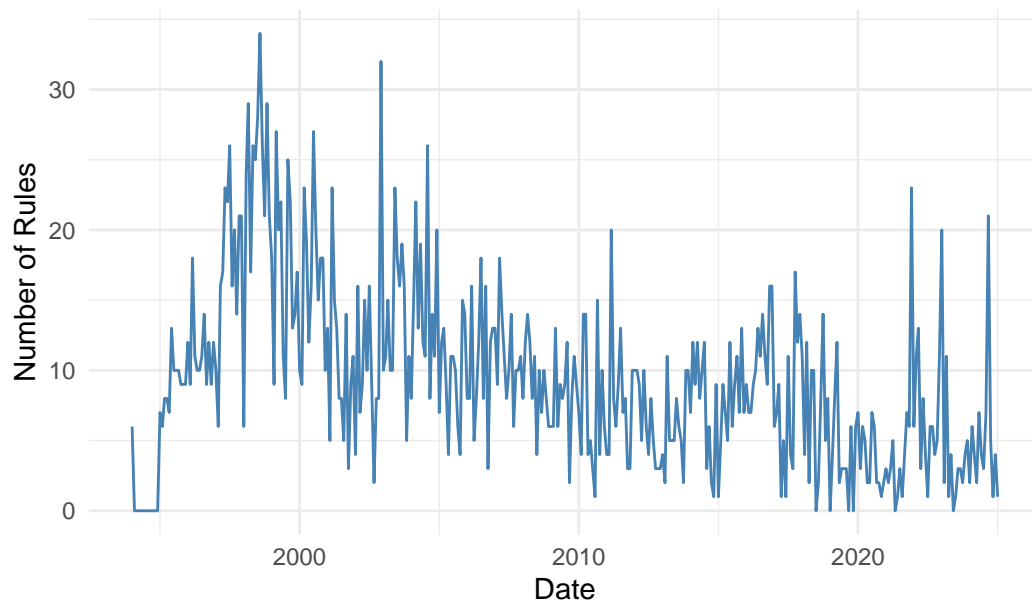


Next, let's analyze the data broken into its constituent months (the first visualization doesn't work yet)

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



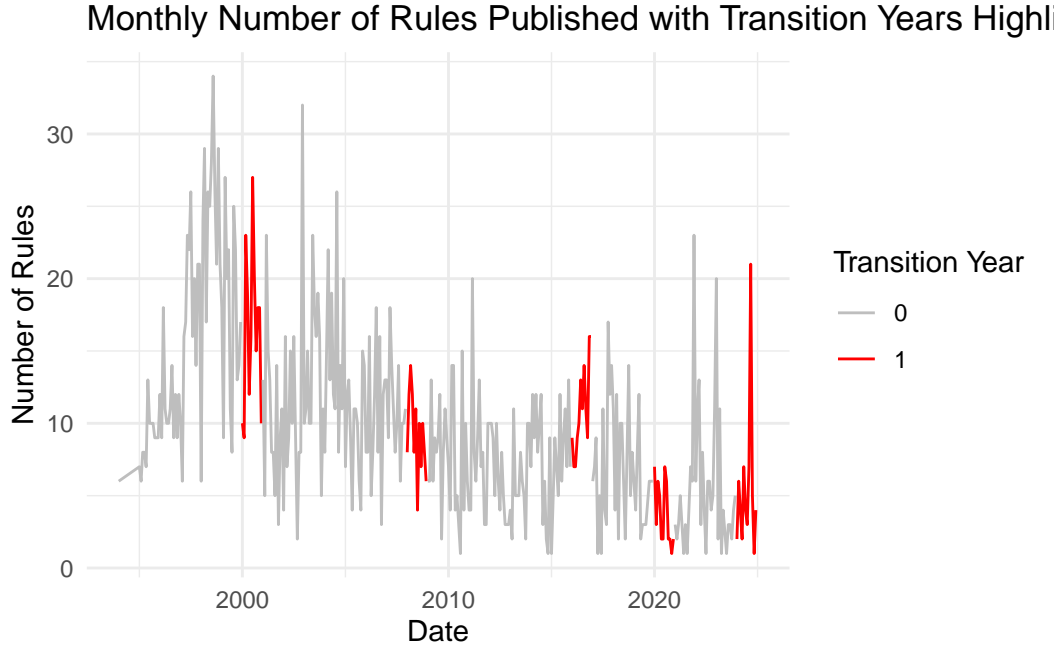
Monthly Number of Rules Published Over Time



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: $X_i = \text{Number of months since June 2024}$
 - $(X_i > 0)$: 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) .

Call:

```
lm(formula = count ~ treatment + distance + I(distance^2) + month +
    transition, data = rules_per_month_year)
```

Residuals:

Min	1Q	Median	3Q	Max
-15.9969	-3.4676	-0.7539	2.8550	21.0793

Coefficients:

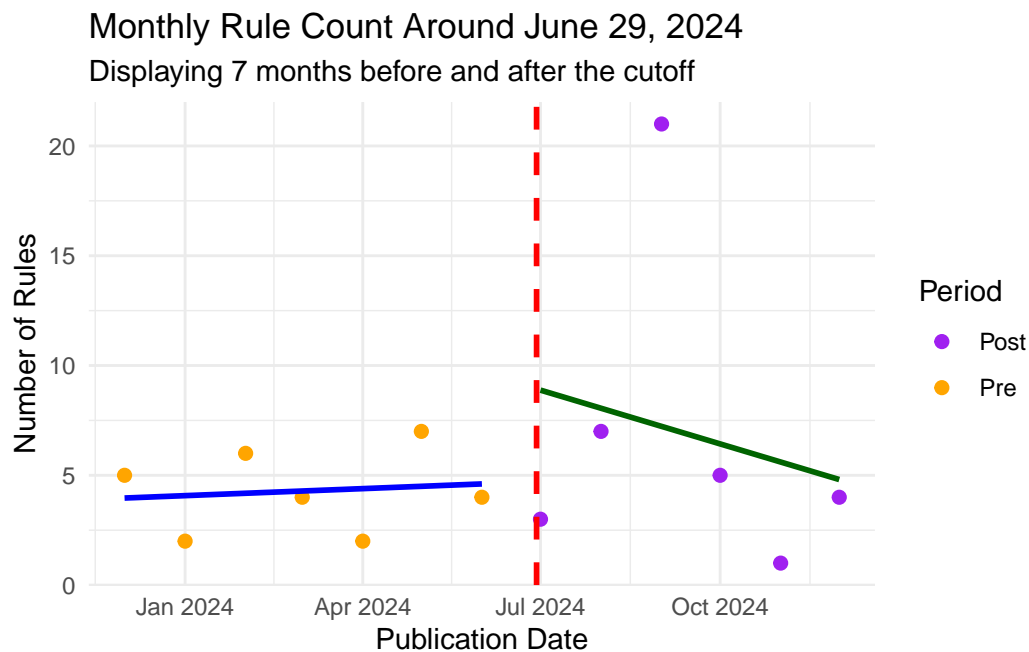
	Estimate	Std. Error	t value	Pr(> t)	
(Intercept)	2.442e+00	9.451e-01	2.584	0.01016	*
treatment	3.441e+00	2.428e+00	1.417	0.15732	
distance	-6.039e-02	1.139e-02	-5.303	2.01e-07	***
I(distance^2)	-9.115e-05	2.991e-05	-3.047	0.00248	**
month.L	1.017e+00	1.025e+00	0.992	0.32191	
month.Q	-3.346e-01	1.022e+00	-0.328	0.74346	
month.C	2.708e+00	1.025e+00	2.643	0.00859	**
month^4	-1.013e-02	1.023e+00	-0.010	0.99210	
month^5	1.645e+00	1.024e+00	1.606	0.10905	
month^6	1.175e+00	1.025e+00	1.147	0.25231	
month^7	-2.539e+00	1.025e+00	-2.477	0.01372	*
month^8	1.699e+00	1.025e+00	1.658	0.09827	.
month^9	-1.833e+00	1.025e+00	-1.788	0.07466	.
month^10	9.035e-01	1.025e+00	0.881	0.37868	
month^11	-3.537e-01	1.025e+00	-0.345	0.73034	
transition	4.935e-01	9.685e-01	0.510	0.61070	

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

Residual standard error: 5.707 on 357 degrees of freedom
 Multiple R-squared: 0.2594, Adjusted R-squared: 0.2283
 F-statistic: 8.338 on 15 and 357 DF, p-value: 2.379e-16

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.

Warning: package 'forecast' was built under R version 4.3.3

Registered S3 method overwritten by 'quantmod':

	method	from
	as.zoo.data.frame	zoo

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1994	6	0	0	0	0	0	0	0	0	0	0	0
1995	7	6	8	8	7	13	10	10	10	9	9	9

1996	12	9	18	11	10	10	11	14	9	12	9	12
1997	10	6	16	17	23	22	26	16	20	14	21	21
1998	6	24	29	17	26	25	28	34	26	21	29	21
1999	18	9	27	20	22	11	8	25	22	13	14	17
2000	10	9	23	19	12	16	27	20	15	18	18	10
2001	13	5	23	15	13	8	8	5	14	3	9	11
2002	4	16	7	9	15	10	16	9	2	8	8	32
2003	10	11	15	10	10	23	18	16	19	16	5	11
2004	8	15	22	13	19	12	11	26	8	14	11	20
2005	7	12	13	9	4	11	11	10	6	4	15	14
2006	8	8	16	5	8	12	18	8	16	3	12	13
2007	13	9	18	14	11	8	10	14	6	10	10	11
2008	8	12	14	12	8	11	4	10	7	10	8	6
2009	6	6	13	6	9	8	9	12	2	8	11	9
2010	7	4	14	14	4	5	3	1	15	4	10	6
2011	4	4	20	8	6	9	13	7	8	3	3	10
2012	10	10	9	5	10	6	4	8	5	3	3	3
2013	4	2	11	5	5	5	8	6	5	2	10	10
2014	7	12	9	12	8	10	12	3	6	2	1	9
2015	1	5	9	7	5	12	6	9	11	7	13	7
2016	9	7	7	9	10	13	11	14	11	9	16	16
2017	6	7	9	1	5	1	11	4	3	17	12	14
2018	11	4	12	2	10	10	0	2	8	14	5	8
2019	0	4	8	12	2	3	3	3	0	6	0	6
2020	7	3	6	5	2	2	7	6	2	2	1	2
2021	3	2	3	5	0	1	3	1	4	7	6	23
2022	6	11	13	3	8	4	1	6	6	4	5	11
2023	20	2	11	1	4	0	1	3	3	2	4	5
2024	2	6	4	2	7	4	3	7	21	5	1	4
2025	1											

Series: ts_rules

Regression with ARIMA(1,1,1)(0,0,2)[12] errors

Coefficients:

	ar1	ma1	sma1	sma2	Intervention	TimeAfterIntervention
	-0.0252	-0.7832	0.0634	0.1128	7.2282	-1.3801
s.e.	0.0677	0.0442	0.0522	0.0519	4.3234	0.9158

sigma^2 = 23.73: log likelihood = -1114.51

AIC=2243.02 AICc=2243.32 BIC=2270.45

Training set error measures:

	ME	RMSE	MAE	MPE	MAPE	MASE	ACF1
Training set	0.003090028	4.825542	3.629745	-Inf	Inf	0.6842496	0.0004223061

A tibble: 6 x 4

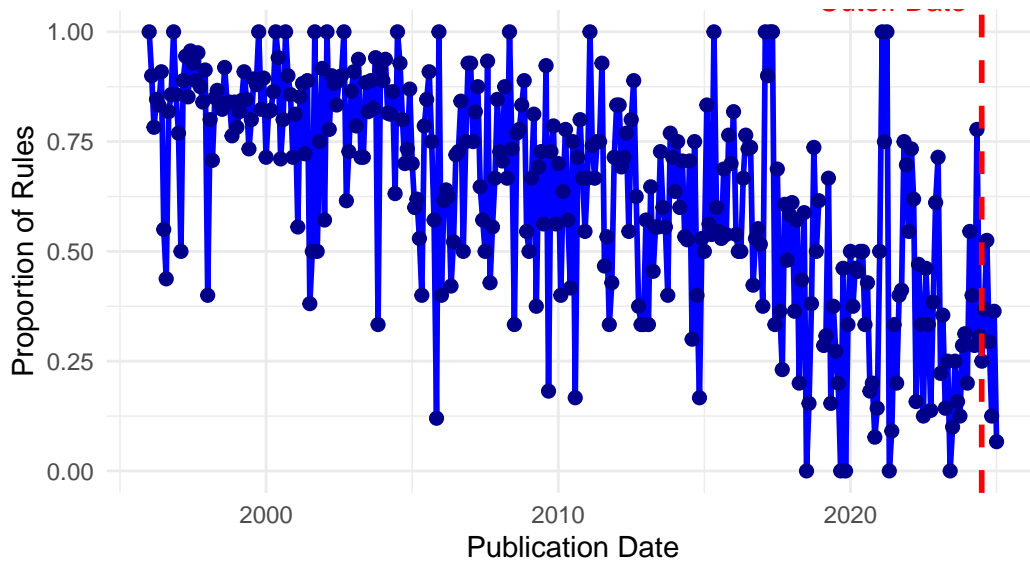
	year	month	rules	guidance
	<dbl>	<chr>	<int>	<int>
1	1996	January	12	0
2	1996	February	9	1
3	1996	March	18	5
4	1996	April	11	2
5	1996	May	10	2
6	1996	June	10	1

A tibble: 6 x 5

	year	month	rules	guidance	date
	<dbl>	<chr>	<int>	<int>	<date>
1	2025	January	1	14	2025-01-01
2	2024	December	4	7	2024-12-01
3	2024	November	1	7	2024-11-01
4	2024	October	5	12	2024-10-01
5	2024	September	21	19	2024-09-01
6	2024	August	7	12	2024-08-01

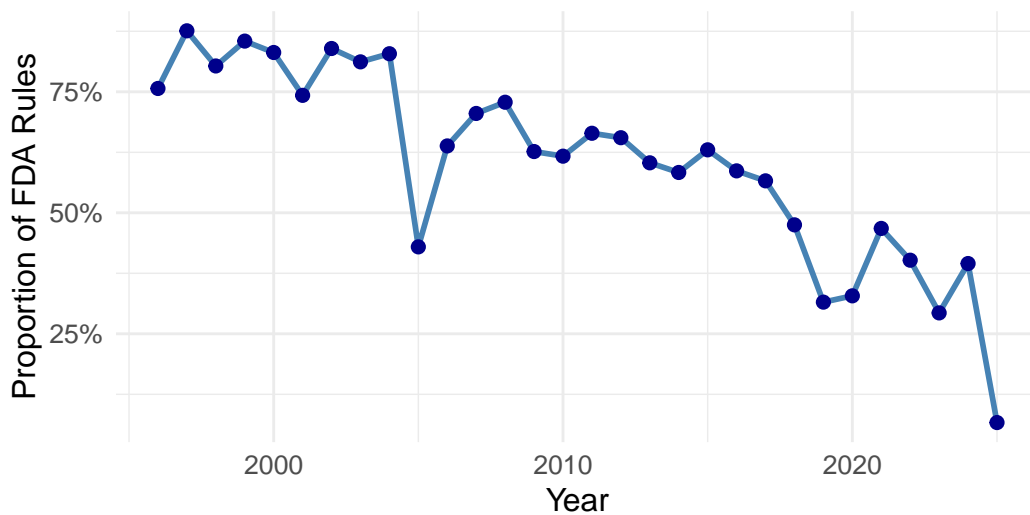
Warning: Removed 1 row containing missing values or values outside the scale range (``geom_point()``).

Proportion of FDA Rules to Total Documents Over Time
With Cutoff Date Highlighted



Warning: package 'scales' was built under R version 4.3.3

Annual Proportion of FDA Rules to Final Guidance
Trend from 1996 to 2025



Source: FDA Rules and Guidance Documents Data

RD model with only 6 mos before and after cutoff

```
Call:
lm(formula = proportion_rules ~ treatment + distance + I(distance^2),
    data = rd_data_filtered)
```

Residuals:

	Min	1Q	Median	3Q	Max
	-0.19046	-0.12494	-0.02081	0.11941	0.29950

Coefficients:

	Estimate	Std. Error	t value	Pr(> t)
(Intercept)	0.305717	0.149981	2.038	0.0759 .
treatment	-0.159702	0.219308	-0.728	0.4872
distance	0.060898	0.065858	0.925	0.3822
I(distance^2)	-0.004540	0.005166	-0.879	0.4051

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

Residual standard error: 0.1878 on 8 degrees of freedom

Multiple R-squared: 0.1752, Adjusted R-squared: -0.1341

F-statistic: 0.5664 on 3 and 8 DF, p-value: 0.6524

RD Model with all data (does not include Jan 2025).

```
Call:
lm(formula = proportion_rules ~ treatment + distance + I(distance^2) +
    month + transition, data = rd_data_proportion_filtered)
```

Residuals:

	Min	1Q	Median	3Q	Max
	-0.55578	-0.11627	0.01163	0.11055	0.58206

Coefficients:

	Estimate	Std. Error	t value	Pr(> t)
(Intercept)	2.924e-01	3.179e-02	9.198	< 2e-16 ***
treatment	2.553e-02	8.606e-02	0.297	0.76690
distance	-2.728e-03	4.144e-04	-6.584	1.79e-10 ***
I(distance^2)	-3.350e-06	1.167e-06	-2.870	0.00437 **
month.L	-6.578e-02	3.528e-02	-1.865	0.06311 .
month.Q	4.036e-02	3.502e-02	1.152	0.24998
month.C	8.167e-02	3.504e-02	2.331	0.02037 *

month ⁴	5.185e-03	3.495e-02	0.148	0.88215
month ⁵	4.173e-02	3.492e-02	1.195	0.23301
month ⁶	3.844e-02	3.488e-02	1.102	0.27117
month ⁷	1.579e-02	3.488e-02	0.453	0.65098
month ⁸	-9.683e-03	3.486e-02	-0.278	0.78139
month ⁹	-1.496e-02	3.487e-02	-0.429	0.66822
month ¹⁰	1.731e-02	3.486e-02	0.497	0.61982
month ¹¹	-8.504e-03	3.487e-02	-0.244	0.80749
transition	3.299e-02	2.820e-02	1.169	0.24305

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

Residual standard error: 0.1877 on 331 degrees of freedom

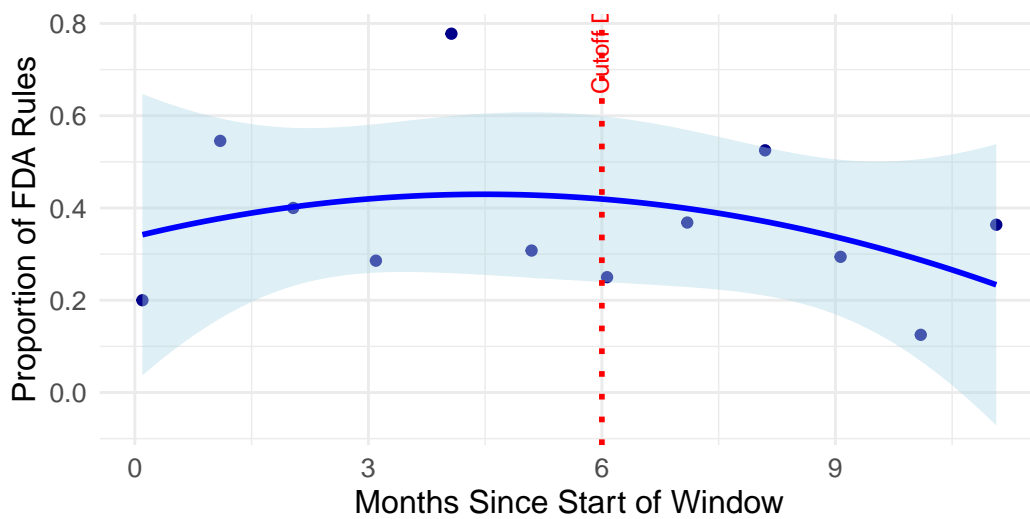
(1 observation deleted due to missingness)

Multiple R-squared: 0.4486, Adjusted R-squared: 0.4236

F-statistic: 17.95 on 15 and 331 DF, p-value: < 2.2e-16

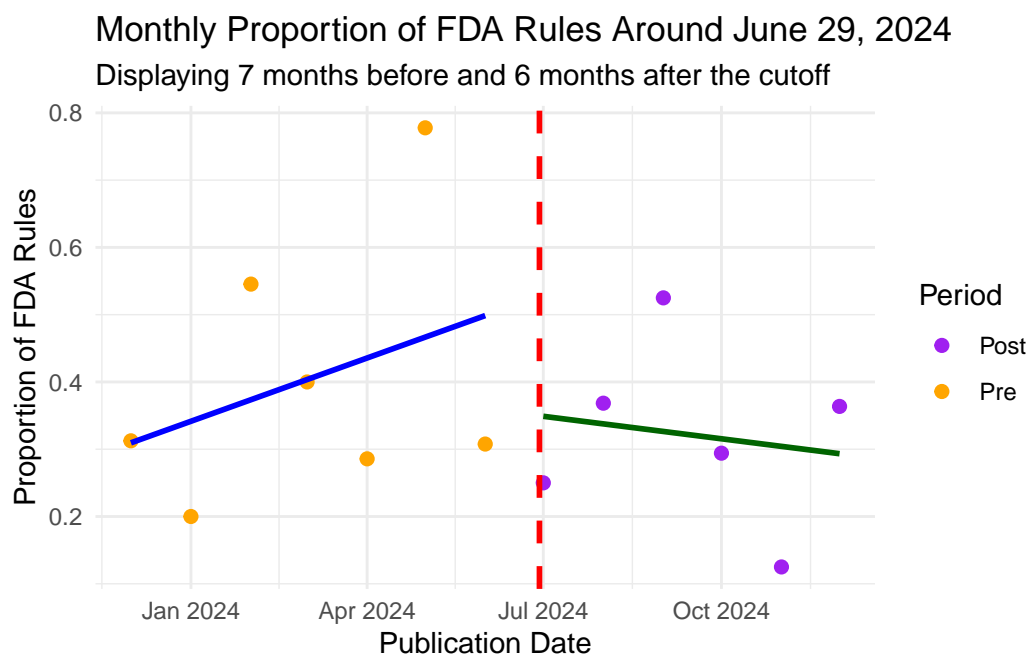
Regression Discontinuity Analysis Within 6-Mc

Proportion of FDA Rules to Final Guidance Documents



Source: FDA Rules and Guidance Documents Data

```
`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
-0.59661	-0.11051	0.00793	0.12260	0.57236

Coefficients:

	Estimate	Std. Error	t value	Pr(> t)
(Intercept)	0.9009803	0.0205667	43.808	<2e-16 ***
time	-0.0015611	0.0001045	-14.944	<2e-16 ***
intervention	0.0209604	0.1317879	0.159	0.874
time_after	-0.0324337	0.0357838	-0.906	0.365

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

Residual standard error: 0.1905 on 344 degrees of freedom

(1 observation deleted due to missingness)

Multiple R-squared: 0.4184, Adjusted R-squared: 0.4133

F-statistic: 82.47 on 3 and 344 DF, p-value: < 2.2e-16