DataWatch

Deck

The U.S. Food and Drug Administration (FDA) has experienced significant shifts in its regulatory approach over the past two decades. This study examines trends in regulatory output from 2000 to 2024 by analyzing two key data sources: formal rules published in the Federal Register and guidance documents available on the FDA website. Formal rules represent the traditional, legally binding regulatory actions, whereas guidance documents offer more flexible policy direction without undergoing the complete notice-and-comment process. By merging these datasets into a unified monthly series and applying regression discontinuity and interrupted time series analyses, we explore how judicial decisions and administrative changes have reshaped the FDA's reliance on formal versus informal regulatory mechanisms. Our investigation provides insights into evolving regulatory strategies and their implications for policy implementation and transparency. Our regression analyses indicate that for each month away from the cutoff, formal FDA rules decline by about 0.033 units and the proportion of rules among all regulatory documents decreases by roughly 0.2 percentage points. Although guidance documents increase by approximately 0.02 units per month, this modest rise does not fully counterbalance the falling trend in formal rulemaking, resulting in a net decline in overall regulatory output.

Intro

Our analysis reveals four key findings about FDA regulatory output over the past twenty-four years. First, there is a striking decrease in the proportion of formal rules relative to total regulatory documents, suggesting a significant strategic shift away from traditional rulemaking. Second, the annual count of formal FDA rules has steadily declined, highlighting a reduced reliance on conventional regulatory processes. Third, there has been a notable increase in the issuance of guidance documents, indicating a growing preference for more flexible regulatory tools. Finally, despite the rise in guidance documents, the net total of regulatory documents has declined, implying that the increase in guidance has not fully offset the reduction in formal rulemaking. These trends underscore a complex evolution in FDA regulatory practices.

Data Sources and Methods

The analysis draws on two primary data sources. Data on formal rules were obtained from the Federal Register, which is the official publication for federal agency rulemaking. This source provides a comprehensive record of all rules and regulations published by federal agencies. In parallel, information on FDA guidance documents was extracted from the FDA webpage's guidance document database. These complementary databases enable a comparison between formal rulemaking and the alternative, less formal guidance approach.

For the period spanning 2000 to 2024, the rule and guidance datasets were cleaned and merged into a unified monthly dataset. This dataset includes counts of rules and guidance documents, the total number of documents, and the calculated proportion of rules to total documents for each month. Missing data points were filled with zeros to ensure a complete and consistent time series. This unified dataset served as the basis for further analysis, including regression discontinuity (RD) and interrupted time series (ITS) models, which assess the impact of key policy changes—specifically the FDA guidance and rulemaking adjustments following landmark judicial decisions in 2024.

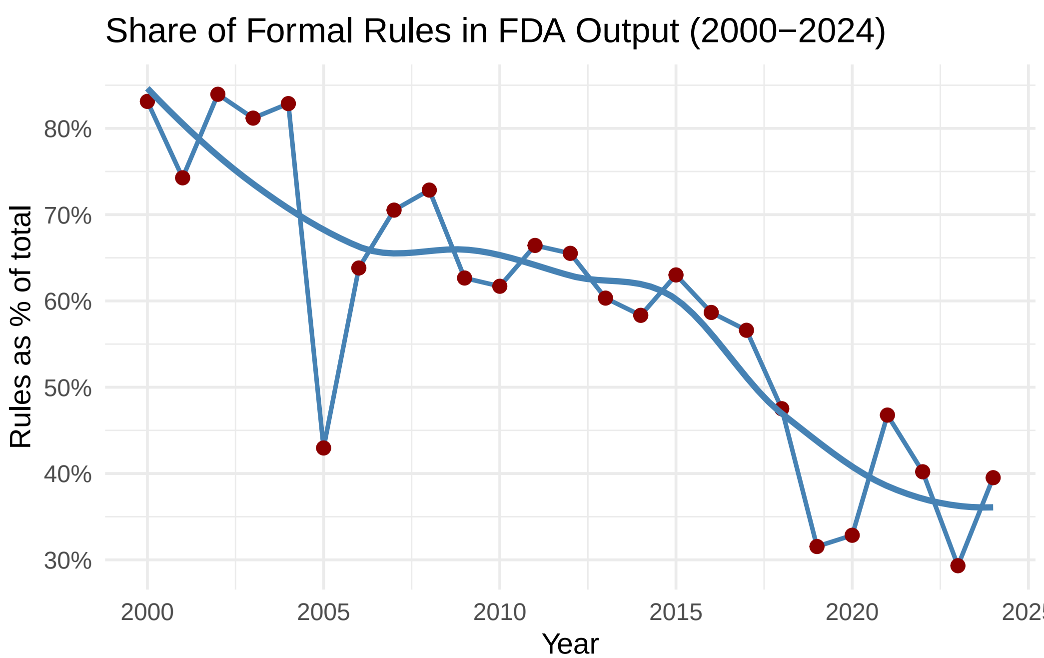
Running Code

```
## Compute slopes from the unified_yearly data for each outcome

# Slope for Total Rules
slope_rules <- round(coef(lm(total_rules ~ year, data = unified_yearly))[2], 3)

# Slope for Total Guidance Documents
slope_guidance <- round(coef(lm(total_guidance ~ year, data = unified_yearly))[2], 3)

# Slope for Total Documents
slope_total <- round(coef(lm(total_documents ~ year, data = unified_yearly))[2], 3)

# Slope for Proportion of FDA Rules
slope_prop <- round(coef(lm(proportion_rules ~ year, data = unified_yearly))[2], 3)

loess_span <- .6            # 0.8 is Stata's default; smaller = wigglier curve
loess_cols <- c("steelblue", "darkred")   # raw line + points colours
smooth_col <- "steelblue"       # colour for the lowess curve
pt_col     <- "darkred"
smooth_col <- "steelblue"

trend_col  <- "black"
trend_lt   <- "dotted"   # line type for the global trend
ann_x      <- min(unified_yearly$year) + 10   # x-position for slope label
```

Graph 1: Striking Decrease in the Proportion of FDA Rules to Total Documents Over Time

Graph 1 demonstrates a clear, steady decline in the proportion of FDA rules relative to the total regulatory documents (rules plus guidance) from 2000 to 2024. This downward trend highlights a marked shift in regulatory practice, with the FDA increasingly favoring less formal instruments over traditional rulemaking. These findings underscore the possibility that legal, administrative, and political factors are driving the agency toward more flexible, expedient regulatory approaches.

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




```
# ggplot(unified_yearly, aes(x = year, y = proportion_rules)) +
#   geom_point(colour = pt_col, size = 2) +
#   geom_smooth(method = "loess", span = loess_span,
#               se = FALSE, colour = smooth_col, linewidth = 1.2) +
#   scale_y_continuous(labels = scales::percent) +
#   labs(title = "Share of Formal Rules in FDA Output (2000-2024)",
#        x = "Year", y = "Rules as % of total") +
#   theme_minimal()
```

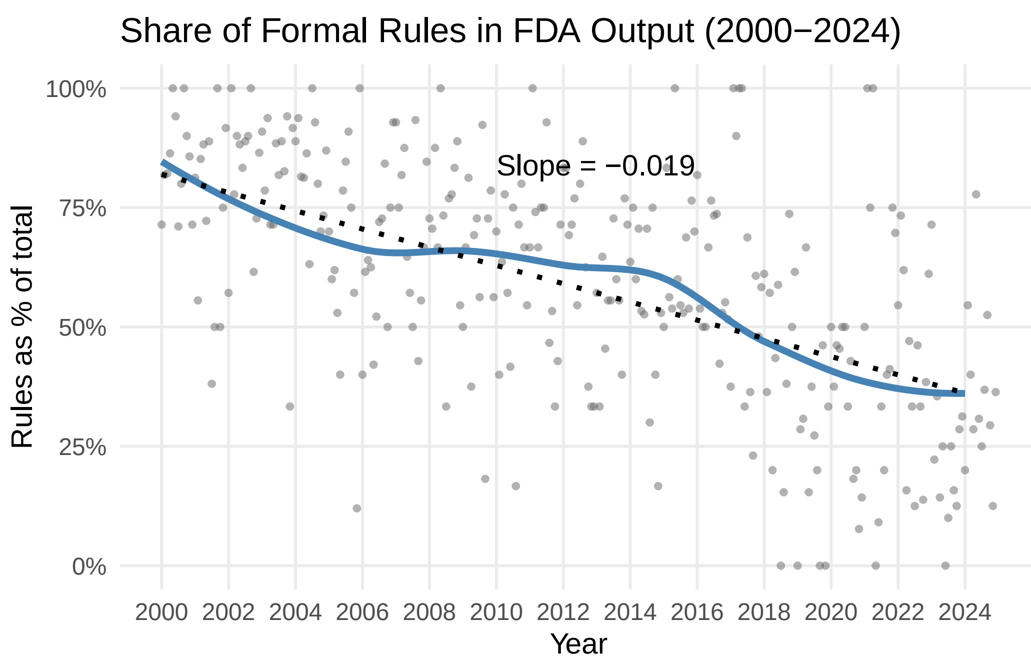
```r
# make_plot <- function(df, yvar, ylab, title) {
#   # compute OLS yearly trend
#   form <- reformulate("year", yvar)          # e.g. total_rules ~ year
#   slope <- coef(lm(form, df))[2]
#   slope_lbl <- paste0("Slope = ", round(slope, 3))
#
#   ggplot(df, aes(x = year, y = .data[[yvar]])) +
#     geom_point(colour = pt_col, size = 2) +
#     geom_smooth(method = "loess", span = loess_span,
#                 se = FALSE, colour = smooth_col, linewidth = 1.2) +
#     geom_smooth(method = "lm",   se = FALSE, colour = trend_col,
#                 linetype = trend_lt, linewidth = 0.9) +
#     annotate("text", x = ann_x,
#              y = max(df[[yvar]]), hjust = 0,
#              label = slope_lbl, colour = trend_col) +
#     labs(title = title, x = "Year", y = ylab) +
#     theme_minimal()
# }
#
# plot_prop  <- make_plot(unified_yearly,
#                           yvar  = "proportion_rules",
#                           ylab  = "Rules as % of total",
#                           title = "Share of Formal Rules in FDA Output (2000-2024)"
# ) +
#                scale_y_continuous(labels = scales::percent) +
#                labs(title = "Share of Formal Rules in FDA Output (2000-2024)")
#
# print(plot_prop)
```

```r
make_plot <- function(df_yearly, df_monthly, yvar, ylab, title) {
  # compute OLS yearly trend for the yearly data
  form <- reformulate("year", yvar)          # e.g. total_rules ~ year
  slope <- coef(lm(form, df_yearly))[2]
  slope_lbl <- paste0("Slope = ", round(slope, 3))

  # Create the plot with both yearly trend and monthly data points
  ggplot() +
    # Add small dots for monthly data
    geom_point(data = df_monthly,
               aes(x = as.numeric(year) + (month_num-1)/12,
                   y = .data[[yvar]]),
```

```r
                color = "gray40", size = 0.8, alpha = 0.5) +
    # Add the yearly smoothed trend
    geom_smooth(data = df_yearly,
                aes(x = year, y = .data[[yvar]]),
                method = "loess", span = loess_span,
                se = FALSE, colour = smooth_col, linewidth = 1.2) +
    # Add the linear trend line
    geom_smooth(data = df_yearly,
                aes(x = year, y = .data[[yvar]]),
                method = "lm", se = FALSE, colour = trend_col,
                linetype = trend_lt, linewidth = 0.9) +
    # Add the slope annotation
    annotate("text", x = ann_x,
             y = max(df_yearly[[yvar]]), hjust = 0,
             label = slope_lbl, colour = trend_col) +
    # Add axis labels and title
    labs(title = title, x = "Year", y = ylab) +
    theme_minimal() +
    theme(
      axis.text.x = element_text(angle = 0, hjust = 0.5),
      panel.grid.minor = element_blank()
    )
}

# Ensure the unified_data has month_num calculated
unified_data <- unified_data %>%
  mutate(month_num = match(month, month.name))

# Create the proportion_rules column in unified_data if it doesn't exist
if (!"proportion_rules" %in% names(unified_data)) {
  unified_data <- unified_data %>%
    mutate(proportion_rules = ifelse(total_documents > 0,
                                     rules / total_documents, 0))
}

# Create the plot
plot_prop <- make_plot(
  df_yearly = unified_yearly,
  df_monthly = unified_data,
  yvar = "proportion_rules",
  ylab = "Rules as % of total",
```

```r
    title = "Share of Formal Rules in FDA Output (2000-2024)"
  ) +
    scale_y_continuous(labels = scales::percent) +
    scale_x_continuous(breaks = seq(2000, 2024, by = 2))

  print(plot_prop)
```

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




```r
  # make_plot_with_cutoff <- function(df_yearly, df_monthly, yvar, ylab, title, cutoff_date
  #   # Convert cutoff_date to numeric year for plotting
  #   cutoff_year_numeric <- as.numeric(format(as.Date(cutoff_date), "%Y")) +
  #                          as.numeric(format(as.Date(cutoff_date), "%m"))/12
  #
  #   # Calculate slopes for before and after cutoff
  #   df_monthly_before <- df_monthly %>%
  #     filter(date <= as.Date(cutoff_date))
  #
  #   df_monthly_after <- df_monthly %>%
```

```
#     filter(date > as.Date(cutoff_date))
#
#   # Calculate slopes (if there's enough data on both sides)
#   if(nrow(df_monthly_before) > 0) {
#     before_model <- lm(reformulate("as.numeric(date)", yvar), df_monthly_before)
#     before_slope <- round(coef(before_model)[2] * 365, 3)  # Convert daily to yearly slo
#     before_slope_lbl <- paste0("Pre-cutoff slope = ", before_slope)
#   } else {
#     before_slope_lbl <- "Insufficient data before cutoff"
#   }
#
#   if(nrow(df_monthly_after) > 0) {
#     after_model <- lm(reformulate("as.numeric(date)", yvar), df_monthly_after)
#     after_slope <- round(coef(after_model)[2] * 365, 3)  # Convert daily to yearly slope
#     after_slope_lbl <- paste0("Post-cutoff slope = ", after_slope)
#   } else {
#     after_slope_lbl <- "Insufficient data after cutoff"
#   }
#
#   # Overall model for reference
#   overall_model <- lm(reformulate("year", yvar), df_yearly)
#   overall_slope <- round(coef(overall_model)[2], 3)
#   overall_slope_lbl <- paste0("Overall slope = ", overall_slope)
#
#   # Create the plot
#   p <- ggplot() +
#     # Add small dots for monthly data
#     geom_point(data = df_monthly,
#                aes(x = as.numeric(year) + (month_num-1)/12,
#                    y = .data[[yvar]],
#                    color = date > as.Date(cutoff_date)),
#                size = 1, alpha = 0.7) +
#
#     # Add vertical line at cutoff
#     geom_vline(xintercept = cutoff_year_numeric,
#                linetype = "dashed", color = "red", linewidth = 0.8) +
#
#     # Add separate trend lines before and after cutoff
#     geom_smooth(data = df_monthly_before,
#                 aes(x = as.numeric(year) + (month_num-1)/12, y = .data[[yvar]]),
#                 method = "lm", se = FALSE, color = "blue", linewidth = 1.2) +
```

```
#
#     geom_smooth(data = df_monthly_after,
#                 aes(x = as.numeric(year) + (month_num-1)/12, y = .data[[yvar]]),
#                 method = "lm", se = FALSE, color = "darkgreen", linewidth = 1.2) +
#
#     # Add overall trend line (optional)
#     geom_smooth(data = df_yearly,
#                 aes(x = year, y = .data[[yvar]]),
#                 method = "lm", se = FALSE, colour = "gray30",
#                 linetype = "dotted", linewidth = 0.9) +
#
#     # Add annotations for slopes
#     annotate("text", x = 2002, y = max(df_monthly[[yvar]]) * 0.95,
#              label = before_slope_lbl, hjust = 0, color = "blue", size = 3.2) +
#
#     annotate("text", x = 2002, y = max(df_monthly[[yvar]]) * 0.9,
#              label = after_slope_lbl, hjust = 0, color = "darkgreen", size = 3.2) +
#
#     annotate("text", x = 2002, y = max(df_monthly[[yvar]]) * 0.85,
#              label = overall_slope_lbl, hjust = 0, color = "gray30", size = 3.2) +
#
#     # Add text to mark the cutoff
#     annotate("text", x = cutoff_year_numeric, y = min(df_monthly[[yvar]]),
#              label = "June 30, 2024", angle = 90, hjust = 0, vjust = 1.5,
#              color = "red", size = 3.2) +
#
#     # Customize colors and labels
#     scale_color_manual(values = c("TRUE" = "darkgreen", "FALSE" = "blue"),
#                        labels = c("TRUE" = "After cutoff", "FALSE" = "Before cutoff"),
#                        name = "") +
#
#     labs(title = title, x = "Year", y = ylab) +
#     theme_minimal() +
#     theme(
#       legend.position = "bottom",
#       axis.text.x = element_text(angle = 0, hjust = 0.5),
#       panel.grid.minor = element_blank()
#     )
#
#   return(p)
# }
#
```

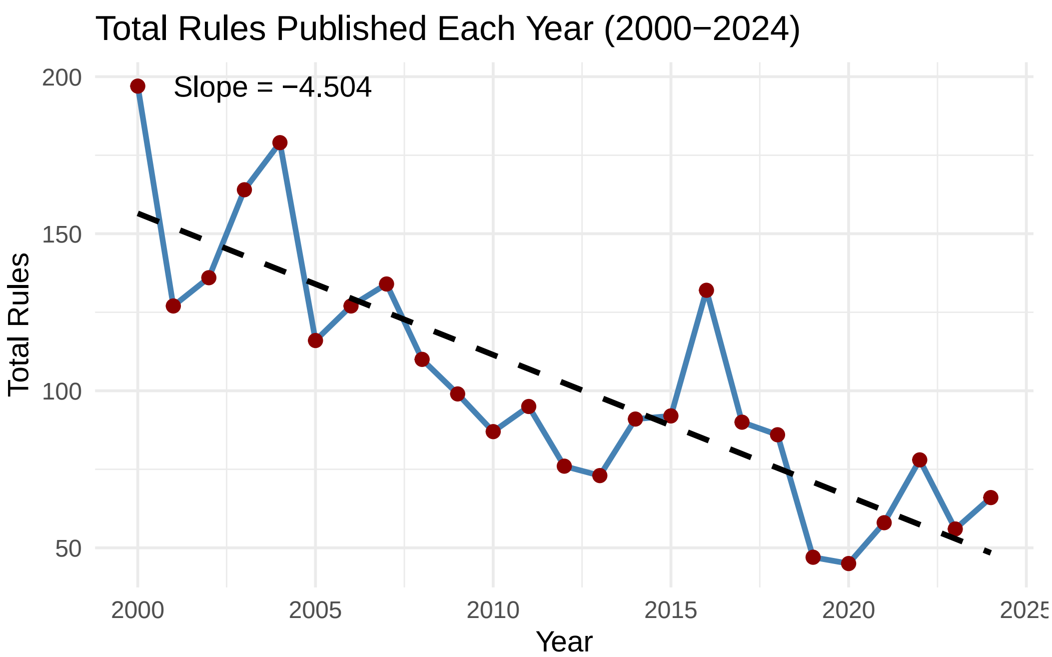
```r
# # Make sure unified_data includes dates through December 2024
# # If you're using the data from the document, it should already include this
#
# # Create the plot with cutoff
# plot_prop_cutoff <- make_plot_with_cutoff(
#   df_yearly = unified_yearly,
#   df_monthly = unified_data,
#   yvar = "proportion_rules",
#   ylab = "Rules as % of total",
#   title = "Share of Formal Rules in FDA Output (2000-2024)\nwith June 30, 2024 Cutoff"
# ) +
#   scale_y_continuous(labels = scales::percent) +
#   scale_x_continuous(breaks = seq(2000, 2024, by = 2))
#
# print(plot_prop_cutoff)
```

Graph 2: Decrease in Total FDA Rules Published Each Year

Graph 2 depicts a persistent decline in the number of formal FDA rules issued annually from 2000 to 2024. This consistent reduction in rule output suggests that the agency is steadily moving away from the traditional, formal rulemaking process. Contributing factors may include increasing administrative burdens, greater legal scrutiny, and a strategic pivot toward alternative regulatory mechanisms such as guidance documents. As the number of formal rules falls, *the overall impact of traditional regulatory measures may be reduced, potentially affecting regulatory consistency and transparency*.

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

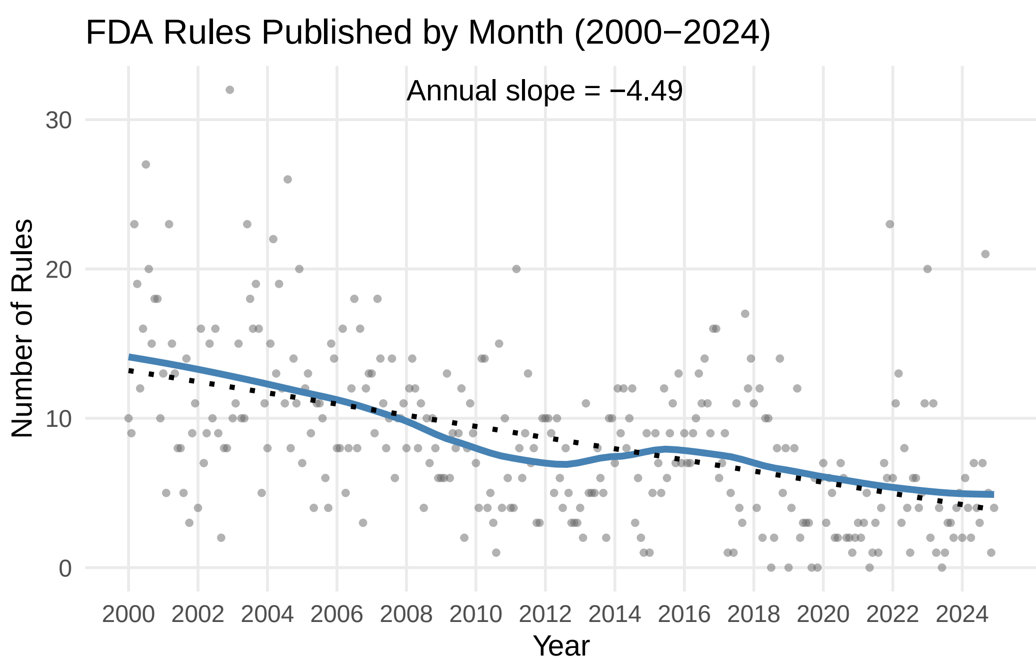
```
`geom_smooth()` using formula = 'y ~ x'
```




```
make_plot_monthly <- function(df_monthly, yvar, ylab, title) {
  # Ensure df_monthly has proper date format for x-axis
  df_monthly <- df_monthly %>%
    mutate(date_decimal = as.numeric(year) + (month_num-1)/12)

  # Compute monthly trend
  form <- reformulate("date_decimal", yvar)
  model <- lm(form, df_monthly)
  slope <- coef(model)[2]
  slope_lbl <- paste0("Annual slope = ", round(slope*12, 3))  # Annualized for easier inte

  ggplot(df_monthly, aes(x = date_decimal, y = .data[[yvar]])) +
    geom_point(colour = "gray40", size = 0.8, alpha = 0.5) +  # Smaller points with some t
    geom_smooth(method = "loess", span = loess_span,
                se = FALSE, colour = smooth_col, linewidth = 1.2) +
    geom_smooth(method = "lm", se = FALSE, colour = trend_col,
                linetype = trend_lt, linewidth = 0.9) +
    annotate("text", x = min(df_monthly$date_decimal) + 8,  # Adjust position of labels
             y = max(df_monthly[[yvar]]), hjust = 0,
             label = slope_lbl, colour = trend_col) +
    scale_x_continuous(breaks = seq(2000, 2024, by = 2)) +  # Set x-axis breaks every 2 ye
    labs(title = title, x = "Year", y = ylab) +
```

```r
    theme_minimal() +
    theme(panel.grid.minor = element_blank())  # Remove minor grid lines for clarity
}

# Create the plot using monthly data
plot_rules_monthly <- make_plot_monthly(
  df_monthly = unified_data,  # Use the monthly dataset
  yvar = "rules",             # Use the "rules" column for monthly counts
  ylab = "Number of Rules",
  title = "FDA Rules Published by Month (2000-2024)"
)

# Print the plot
print(plot_rules_monthly)
```

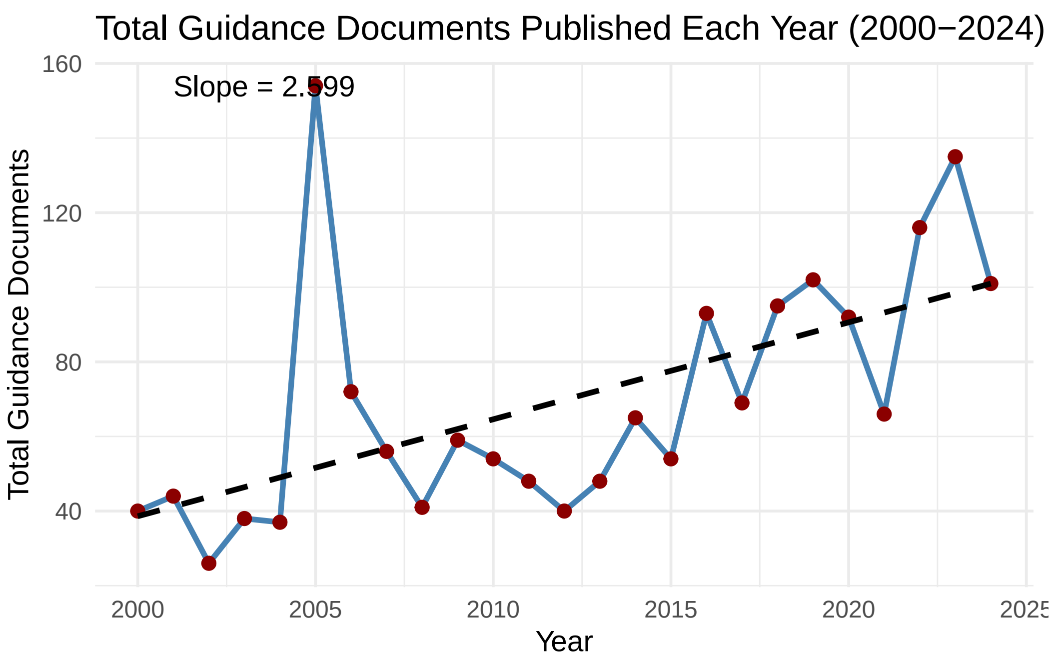
```
`geom_smooth()` using formula = 'y ~ x'
`geom_smooth()` using formula = 'y ~ x'
```



Graph 3: Increase in the Number of FDA Guidance Documents Published Each Year

Graph 3 illustrates a marked upward trend in the publication of FDA guidance documents from 2000 to 2024. As formal rulemaking has declined, the FDA appears to be increasingly relying on guidance documents to communicate policy and regulatory expectations. These documents offer a more flexible and less cumbersome alternative to formal rules, allowing the agency to respond more swiftly to emerging challenges. The graph highlights a strategic shift towards alternative regulatory instruments and suggests that the FDA is adapting its regulatory toolkit to better meet contemporary challenges.

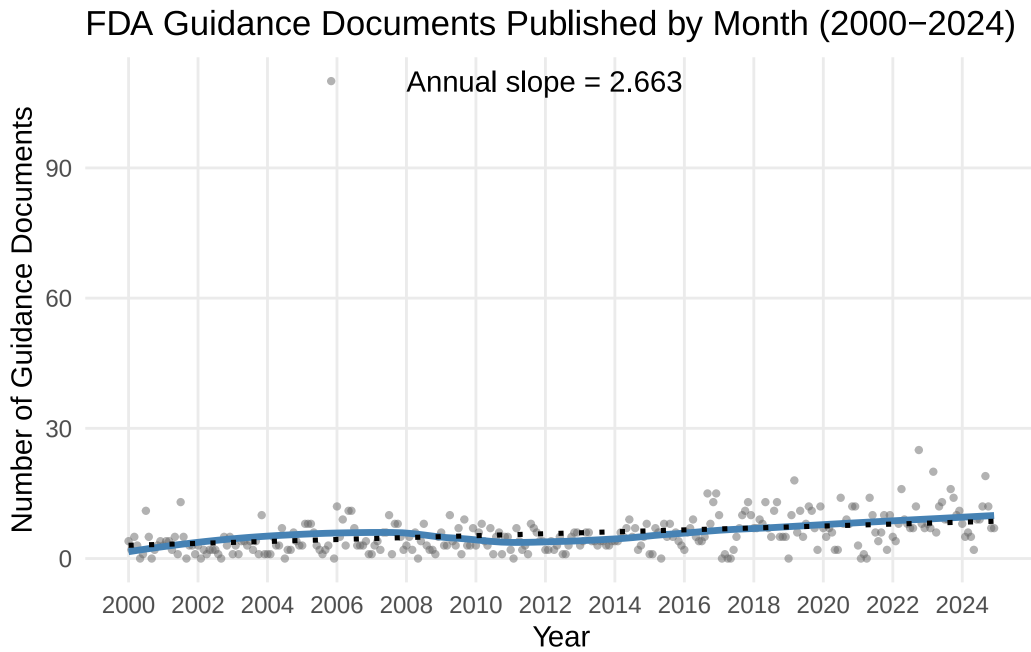
```
`geom_smooth()` using formula = 'y ~ x'
```




```
# Ensure 'month_num' exists in unified_data (if not already added, though previous block m
if (!"month_num" %in% names(unified_data)) {
  unified_data <- unified_data %>%
    mutate(month_num = match(month, month.name)) # Assumes 'month' is like "January"
}

# Define y-variable from unified_data (for monthly guidance counts)
yvar_guidance <- "guidance" # This column should exist in your 'unified_data'

# Define y-axis label
ylab_guidance <- "Number of Guidance Documents"

# Define base for the plot title
```

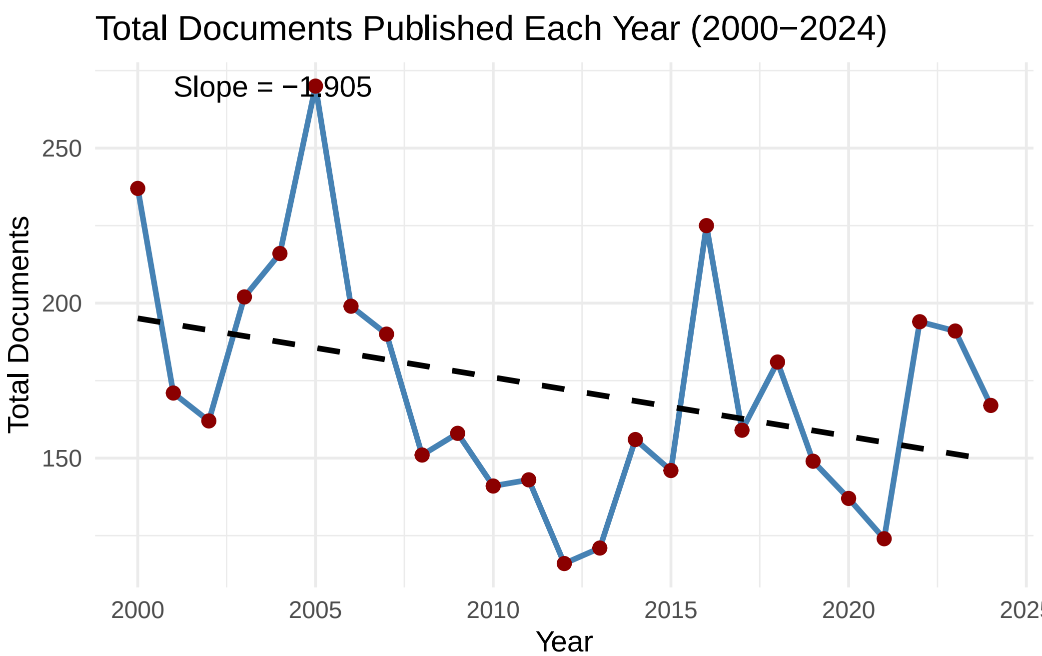
```r
base_title_guidance <- "FDA Guidance Documents Published by Month"

# Dynamically create the full title
# Option 1: Fixed start year for the title (e.g., 2000)
title_start_year_g <- 2000
# Option 2: Dynamic start year for the title (uncomment if preferred)
# title_start_year_g <- min(unified_data$year, na.rm = TRUE)

title_end_year_g <- max(unified_data$year, na.rm = TRUE)

dynamic_title_guidance <- paste0(base_title_guidance, " (", title_start_year_g, "-", title
if (title_start_year_g == title_end_year_g) {
  dynamic_title_guidance <- paste0(base_title_guidance, " (", title_start_year_g, ")")
}

# Create the plot for guidance documents
plot_guidance_monthly <- make_plot_monthly(
  df_monthly = unified_data,
  yvar = yvar_guidance,
  ylab = ylab_guidance,
  title = dynamic_title_guidance
)

# Print the plot
print(plot_guidance_monthly)
```

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



Graph 4: Net Decline in Total FDA Regulatory Documents Published Each Year Graph 4 presents the combined total of FDA regulatory documents, including both formal rules and guidance documents, from 2000 to 2024. Despite the increase in guidance documents, the overall output has declined, indicating that the reduction in formal rulemaking has not been completely offset. This net decline reflects a more restrained overall approach to regulation by the FDA, possibly driven by heightened legal constraints and evolving administrative priorities. The downward trend in total regulatory output raises important questions about the effectiveness of policy implementation in a changing legal and political environment. It highlights the complex interplay between judicial pressures and agency strategy in the modern regulatory landscape.

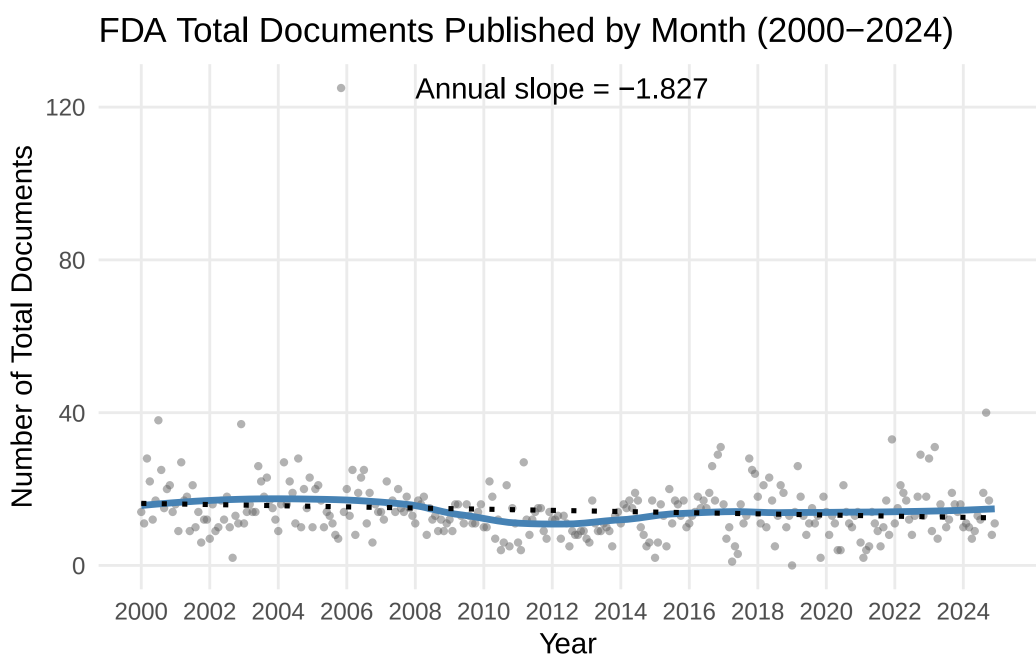
```
`geom_smooth()` using formula = 'y ~ x'
```




```
# Ensure 'month_num' exists in unified_data (if not already added)
if (!"month_num" %in% names(unified_data)) {
  unified_data <- unified_data %>%
    mutate(month_num = match(month, month.name)) # Assumes 'month' is like "January"
}

# Define y-variable from unified_data
yvar_total_docs <- "total_documents"

# Define y-axis label
ylab_total_docs <- "Number of Total Documents"

# Define base for the plot title
base_title_total_docs <- "FDA Total Documents Published by Month"

# Dynamically create the full title
# Option 1: Fixed start year for the title (e.g., 2000)
title_start_year_td <- 2000
# Option 2: Dynamic start year for the title (uncomment if preferred)
# title_start_year_td <- min(unified_data$year, na.rm = TRUE)

title_end_year_td <- max(unified_data$year, na.rm = TRUE)
```

```r
dynamic_title_total_docs <- paste0(base_title_total_docs, " (", title_start_year_td, "-",
if (title_start_year_td == title_end_year_td) {
  dynamic_title_total_docs <- paste0(base_title_total_docs, " (", title_start_year_td, ")"
}

# Create the plot for total documents
plot_total_docs_monthly <- make_plot_monthly(
  df_monthly = unified_data,
  yvar = yvar_total_docs,
  ylab = ylab_total_docs,
  title = dynamic_title_total_docs
)

# Print the plot (or assign it to a list, display in R Markdown, etc.)
print(plot_total_docs_monthly)
```

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



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).

Interrupted Time Series Results

Notes:

Look at another dataset or report that verifies report

- This is extenal inconsistency, also look at internal inconsistency.
- Change to monthly and then smooth the series

If the monthly process were perfectly linear and seasonality were flat, you **would** expect _year 12 × _month.

```
Please cite as:

 Hlavac, Marek (2022). stargazer: Well-Formatted Regression and Summary Statistics Tables.

 R package version 5.2.3. https://CRAN.R-project.org/package=stargazer
```

RD Models for FDA Rules

	Dependent variable:		
	Rules		
	Dist. Only	Dist. + Crtls	Treatment x Dist + Ctrls)
	(1)	(2)	(3)
treatment			7.018
			(4.377)
distance	-0.031***	-0.032***	-0.033***
	(0.003)	(0.003)	(0.003)
month.L		0.530	0.500
		(0.939)	(0.940)
month.Q		0.386	0.570
		(0.940)	(0.945)
month.C		3.002***	3.129***
		(0.925)	(0.929)
month4		-0.009	-0.047
		(0.917)	(0.916)
month5		1.938**	1.829**
		(0.920)	(0.920)

	(1)	(2)	(3)
month6		1.022	1.049
		(0.920)	(0.919)
month7		-2.337**	-2.255**
		(0.918)	(0.918)
month8		2.046**	2.040**
		(0.917)	(0.916)
month9		-1.479	-1.555*
		(0.918)	(0.918)
month10		0.590	0.584
		(0.918)	(0.917)
month11		-0.376	-0.305
		(0.917)	(0.917)
transition		1.138	0.956
		(1.044)	(1.111)
D		0.321	0.284
		(0.572)	(0.572)
treatment:distance			-1.288
			(1.137)
Constant	4.063***	3.662***	3.523***
	(0.529)	(0.707)	(0.713)
Observations	300	300	300
R2	0.247	0.324	0.331
Adjusted R2	0.244	0.291	0.293
Note:			*p<0.1; **p<0.05; ***p<0.01

RD Models for FDA Guidance Documents

	Dependent variable:		
	Guidance		
	Dist. Only	Dist. + Crtls	Treatment x Dist + Ctrls)
	(1)	(2)	(3)
treatment			6.933
			(6.753)
distance	0.018***	0.021***	0.020***
	(0.005)	(0.005)	(0.005)
month.L		3.164**	3.155**
		(1.445)	(1.450)

month.Q		-0.077	0.100
		(1.445)	(1.457)
month.C		-0.039	0.100
		(1.423)	(1.434)
month4		-1.842	-1.880
		(1.411)	(1.414)
month5		-1.689	-1.787
		(1.414)	(1.420)
month6		-1.003	-0.984
		(1.415)	(1.418)
month7		-1.956	-1.880
		(1.411)	(1.416)
month8		0.221	0.213
		(1.410)	(1.412)
month9		-1.312	-1.380
		(1.412)	(1.416)
month10		-0.446	-0.444
		(1.412)	(1.415)
month11		-0.549	-0.476
		(1.411)	(1.415)
transition		0.589	0.541
		(1.605)	(1.714)
D		-1.202	-1.230
		(0.880)	(0.883)
treatment:distance			-1.455
			(1.754)
Constant	8.470***	9.346***	9.236***
	(0.789)	(1.087)	(1.099)
Observations	300	300	300
R2	0.049	0.095	0.098
Adjusted R2	0.046	0.050	0.047
Note:			*p<0.1; **p<0.05; ***p<0.01

RD Models for Total Documents

	Dependent variable:		
	Total Documents		
	Dist. Only	Dist. + Crtls	Treatment x Dist + Ctrls)

	(1)	(2)	(3)
treatment			13.950
			(8.478)
distance	-0.013**	-0.012*	-0.013**
	(0.006)	(0.006)	(0.007)
month.L		3.694**	3.655**
		(1.819)	(1.821)
month.Q		0.309	0.670
		(1.820)	(1.830)
month.C		2.963*	3.230*
		(1.792)	(1.800)
month4		-1.851	-1.927
		(1.777)	(1.775)
month5		0.250	0.043
		(1.781)	(1.783)
month6		0.018	0.065
		(1.782)	(1.780)
month7		-4.293**	-4.135**
		(1.778)	(1.777)
month8		2.266	2.253
		(1.776)	(1.773)
month9		-2.791	-2.934*
		(1.778)	(1.778)
month10		0.144	0.140
		(1.779)	(1.777)
month11		-0.926	-0.781
		(1.777)	(1.776)
transition		1.727	1.496
		(2.022)	(2.152)
D		-0.881	-0.946
		(1.108)	(1.108)
treatment:distance			-2.743
			(2.201)
Constant	12.533***	13.008***	12.759***
	(1.004)	(1.369)	(1.380)
Observations	300	300	300
R2	0.015	0.081	0.090
Adjusted R2	0.012	0.036	0.039

Note: *p<0.1; **p<0.05; ***p<0.01

RD Models for Proportion of FDA Rules

	Dependent variable:		
	Proportion		
	Dist. Only	Dist. + Crtls	Treatment x Dist + Ctrls)
	(1)	(2)	(3)
treatment			0.052
			(0.189)
distance	-0.002***	-0.002***	-0.002***
	(0.0001)	(0.0001)	(0.0001)
month.L		-0.081**	-0.080**
		(0.040)	(0.040)
month.Q		0.047	0.048
		(0.040)	(0.041)
month.C		0.090**	0.091**
		(0.040)	(0.040)
month4		0.005	0.005
		(0.039)	(0.039)
month5		0.062	0.062
		(0.039)	(0.040)
month6		0.033	0.033
		(0.039)	(0.040)
month7		0.013	0.013
		(0.039)	(0.040)
month8		-0.012	-0.012
		(0.039)	(0.039)
month9		-0.016	-0.017
		(0.039)	(0.040)
month10		0.025	0.025
		(0.039)	(0.040)
month11		-0.015	-0.015
		(0.039)	(0.040)
transition		-0.021	-0.020
		(0.045)	(0.048)
D		0.047*	0.047*
		(0.025)	(0.025)
treatment:distance			-0.012
			(0.049)
Constant	0.347***	0.311***	0.311***
	(0.022)	(0.030)	(0.031)

Observations	300	300	300
R2	0.365	0.406	0.406
Adjusted R2	0.363	0.377	0.373
Note:			*p<0.1; **p<0.05; ***p<0.01

Interrupted Time Series Analysis Results

	Dependent variable:			
	Rules	Guidance	Total	Proportion
	(1)	(2)	(3)	(4)
treatment	7.018	6.933	13.950	0.052
	(4.377)	(6.753)	(8.478)	(0.189)
distance	-0.033***	0.020***	-0.013**	-0.002***
	(0.003)	(0.005)	(0.007)	(0.0001)
transition	0.956	0.541	1.496	-0.020
	(1.111)	(1.714)	(2.152)	(0.048)
D	0.284	-1.230	-0.946	0.047*
	(0.572)	(0.883)	(1.108)	(0.025)
treatment:distance	-1.288	-1.455	-2.743	-0.012
	(1.137)	(1.754)	(2.201)	(0.049)
Observations	300	300	300	300
R2	0.331	0.098	0.090	0.406
Adjusted R2	0.293	0.047	0.039	0.373
Note:				*p<0.1; **p<0.05; ***p<0.01
				Standard errors are reported in parentheses below the estimates.

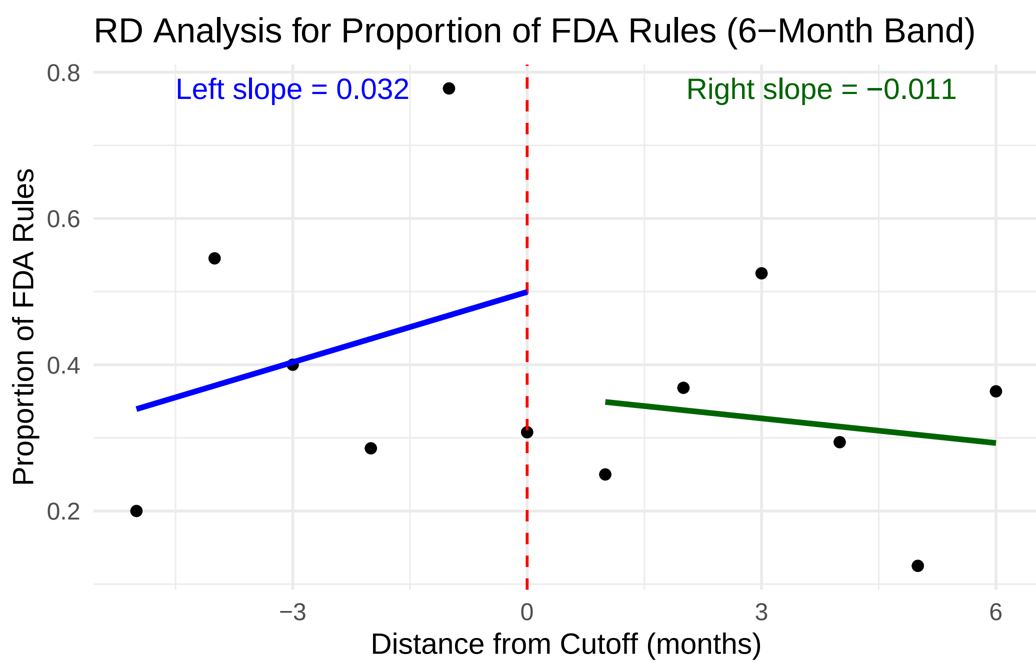
The results show clear and contrasting trends across the four dependent variables. In the model for formal FDA rules, the distance variable is significantly negative (–0.033, p<0.01), indicating that for each additional month from the cutoff, the average number of published rules declines. In contrast, the guidance documents model features a significantly positive distance effect (0.020, p<0.01), suggesting that as time from the cutoff increases, the issuance of guidance documents rises. For the total number of documents (the sum of rules and guidance), the distance effect remains negative but is smaller in magnitude (–0.013, p<0.05). The proportion model further confirms that the share of formal rules falls over time, with a significant decrease of 0.002 (p<0.01) per month. The constant estimates in all models are highly significant, and the models for rules and proportion explain a moderate share of the variance (adjusted R^2 of 0.293 and 0.373, respectively), while those for guidance and total documents show more modest explanatory power.

The analysis also controls for broader contextual factors. The presidential transition indicator is not statistically significant in any specification, suggesting that the designated transition months do not, by themselves, account for the observed trends. However, the Democratic party indicator (D) is significant in the proportion model (0.047, $p<0.1$), implying that during years under a Democratic president, the proportion of formal rules is modestly higher. Additionally, the interaction term between treatment and distance is consistently negative, though not statistically significant across the models, hinting at some attenuation of the distance effect in the treatment period. Overall, the findings point to a clear shift away from formal rulemaking over time, with an increase in guidance documents that, however, does not fully offset the decline in total regulatory output.

Appendix - RD of Proportion of rules

We ran an RD regression but saw no significant short-term effects of *Loper Bright* and *Ohio v. EPA* on rulemaking output.

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



```r
#reality check

# ‘Year’ model (annual totals)
beta_year <- coef(lm(total_rules ~ year, data = unified_yearly))[2]
beta_year
```

```
     year
-4.503846
```

```r
# [1] -4.50  (  rules per *calendar* year)

# Make an "average-monthly" outcome for the same regression
unified_yearly <- unified_yearly %>%
  mutate(avg_monthly_rules = total_rules / 12)
coef(lm(avg_monthly_rules ~ year, unified_yearly))[2]
```

```
      year
-0.3753205
```

```r
#   -0.375   (-0.375   -4.50 / 12)

# Now create a pure month-index that rises 1,2,3,… from Jan-2000 to Dec-2024
unified_data  <- unified_data %>%
  mutate(month_index = 1:n())

coef(lm(rules ~ month_index, unified_data))[2]
```

```
month_index
-0.03117835
```

```r
#   -0.375   (matches the annualised decline)
```