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What The Data Says About FDA Responses To FOIA Requests

By **Bradley Thompson** (June 15, 2023, 5:42 PM EDT)

Information is important, and thus so is access to it. Our democracy needs to know what is going on in our government, and businesses trying to navigate regulatory processes such as the ones at the U.S. Food and Drug Administration likewise need to understand the regulatory process. For both purposes, the Freedom of Information Act, or FOIA, process should be fair and efficient.



Bradley Thompson

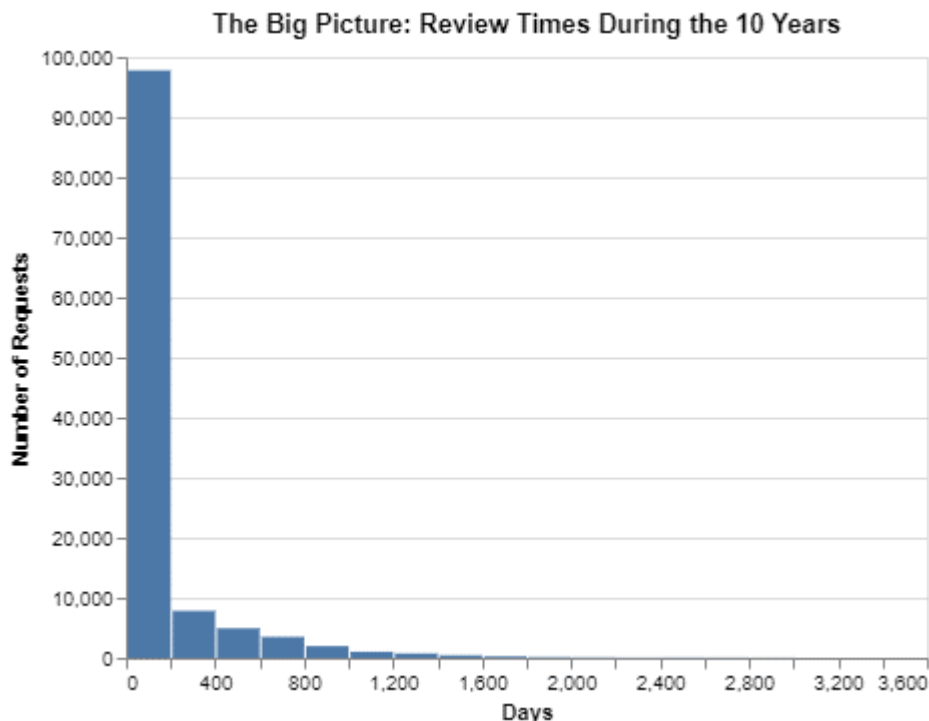
On Dec. 21, 2022, I submitted a FOIA request to the FDA seeking data on all the requests made over a 10-year period, and I received the data less than a month later.

With over 118,000 requests during the 10-year period, there is a lot of data to analyze. This article focuses on a high-level analysis of the response times.

Exploring the Data at a High Level

The FDA tracks the number of requests year to year and presents them online.[1] Spoiler alert: The volume does not really seem to change a lot.

The first thing I wanted to see was review times. Using the raw data, I simply compared the date the request was resolved with the date it was made and plotted them here.



These data are from the time between Jan. 1, 2013, and Jan. 1, 2023.

The chart may be hard to read because of the two extremes. The first extreme is the height of the first column, dwarfing the other columns. The second extreme is the length of the tail on the x-axis that goes all the way out to 3,600 days, or nearly 10 years. But the chart does at least make two points:

1. About 80% of requests are completed within 200 days.
2. But equally interesting, there are material numbers that appear to go on forever.

Zoomed-In Picture

I was interested in getting rid of the two extremes to focus more granularly on what is going on in the lower left-hand corner.

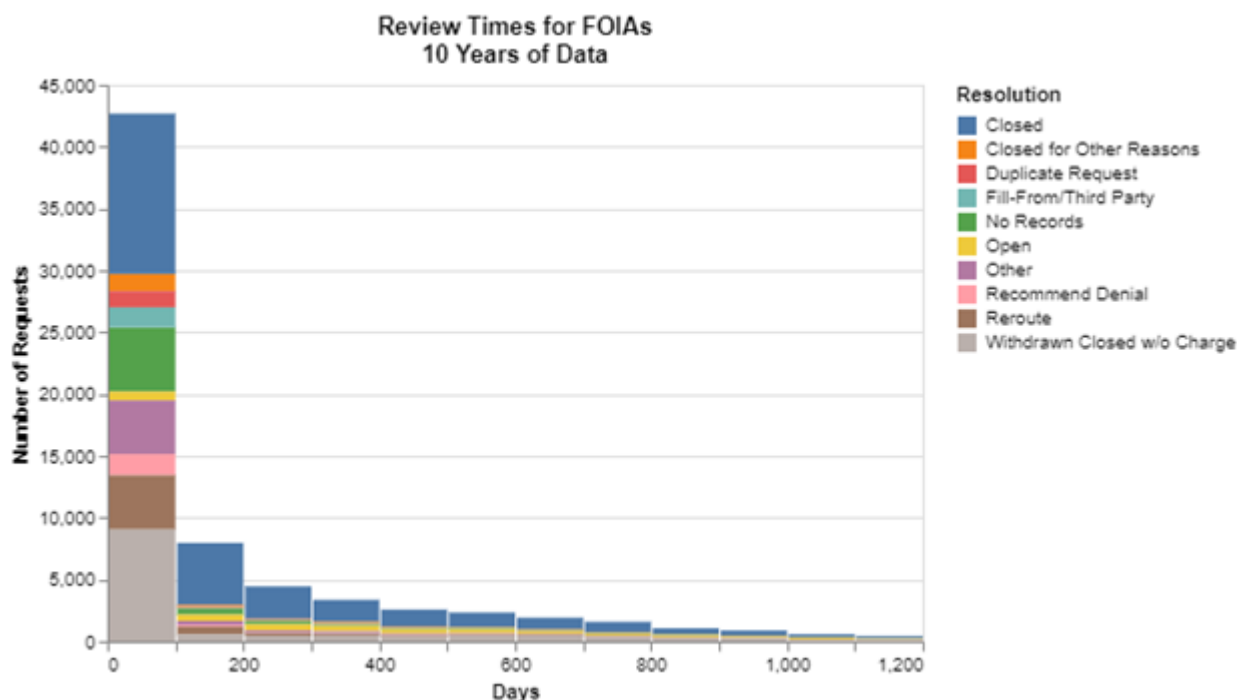
To do that, I first got rid of all those requests that were closed within the first 30 days. As you will see in a bit, the word "closed" has a specific meaning that records were found and produced, as opposed to other ways in which a request might end, for example in a declaration that there were no responsive records.

I picked 30 days because that is roughly equivalent to the time the FDA has under the regulations — Title 21 of the Code of Federal Regulations, Section 20.41 — to provide at least an initial response. It turns out, setting these parameters removes over 46,000 records, so it trims that first column nicely.

Then, to prune the extremely long tail, I picked 1,200 days as the maximum I would display, which is just over three years. No particular magic to that selection because the tail trails off pretty gradually. But that did remove about 1,800 outlier requests.

The next step was to layer on how cases are disposed of. The FDA has 24 different categories of resolution, most of which look rather similar, and quite a few of which are rarely used. Thus, I created a miscellaneous category, and kept the top 10 categories.

With those changes, here is what I came up with.



It may look strange that a large chunk is shown as "open," despite also showing as being resolved within 100 days. Open is a special category and includes those that remained open as of Jan. 1, 2023. This chart says that many of those that are open as of that date, were less than 100 days old.

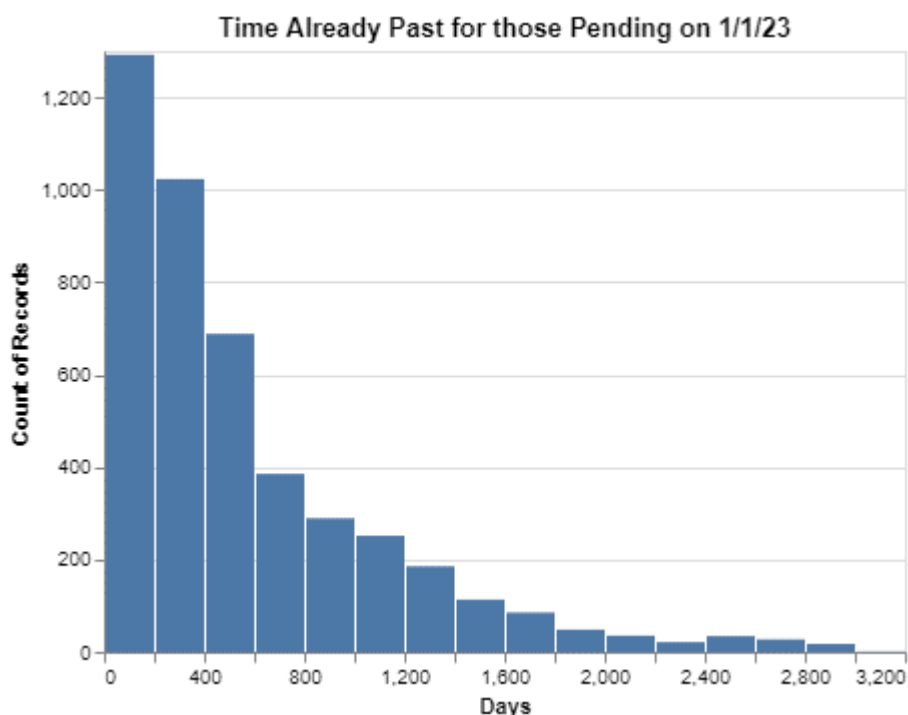
Closed, meaning fulfilled, was the most popular category. Withdrawn without charge, another big category at almost 10,000 records in the first 100 days, probably includes those who made a request, were informed that it would be expensive to pursue, and decided against spending the money. There is also a very large bar, about 5,000 in that first 100 days, where it appears there were no responsive records.

Many of these resolutions that involve something other than "closed" come in the first 100 days. But clearly there are also many people who do not get the records even though it takes more than 100 days to reach a resolution.

In other words, having to wait a long time doesn't guarantee an affirmative response. My assumption going in was that if the FDA was going to say no, they would say it relatively promptly. But that is not always true.

Open FOIAs

Regarding the FOIAs that were still open as of Jan. 1, I wondered, given that some in the 10-year data set had been under FDA review for many years, would the open ones include mostly the difficult ones that were also associated with longer reviews to that point? As it turns out, there is a bit of truth to that.



There are, of course, a bunch that are in their first 200 days. But notice that it does not drop off abruptly after that first 200 days like the larger chart above does. This chart shows that there are quite a few that have already been under review for quite some time and are still sitting there, open and unresolved. Indeed, there are a few that have been open for over eight years.

I myself have been in the position where I submitted a FOIA request because a client needed the information, we did not get it, and eventually we made do with whatever we had. And I would then frankly forget about the request. Then, years and years later, I would get contacted by the FOIA office to ask me if I still wanted the information.

Interpretation of Timing Data

I would say that the FDA does a good job about 80% of the time. Being a data scientist, I am not just making that number up. The agency seems to have addressed about 97,000 out of 119,000 requests in the first 200 days over the course of 10 years.

That includes many that are resolved immediately, some that take maybe 40 days, while others take longer. But getting the various types of requests done in the first 200 days I would say is good.

The FDA handles the next 8% of requests acceptably, in that the requests are resolved in the next roughly 200 days, meaning fewer than 400 days total. That is really pushing it, but the FDA understandably has competing needs for its time and attention.

But that leaves about 12% of the time when resolution requires more than 400 days. More than that, the tail is extremely long in that some requests go on for many years, up to about 10 years.

At that point, I think you have to say the system is broken because for nearly anyone, whether media, commercial or academic, waiting over a year, let alone 10 years, often renders the information useless. There must be some way that we can keep requests from going past a year. However, I imagine fixing that will require not just the FDA, but Congress.

While the extraordinarily long tail in the response times is troubling, I also found one's success in receiving information from the FDA is not only tied to the topic requested but also many other factors that include who you are and how well written your request is.

Overall, there are simply too many requesters to do a detailed review of all of them. But I was comforted to find that, overall, the system is working as intended reasonably well.

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[1] <https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oc-administrative&id=OC-Admin-OES-Number-of-FOIA-requests-received>. See also <https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-office-executive-secretariat>.

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