Twitter Thread by Alexander Gaffney



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Alright, folks. You may have seen that the FDA was in a fight with distilleries last week.

Let's unpack what happened, why it happened, and why it's now resulting in some extremely unusual behavior by HHS.

Thread below. Follow if you're interested.

If you're like most people, you might have stumbled across a few news items in this past week talking about how the big-bad-FDA was deciding to screw over distilleries with a $14,060 fee.

https://t.co/JSNC0mN7h2

It should be noted that the only reason distilleries were being charged this fee was because they had been permitted by the FDA to make hand sanitizer.

It basically sounded like "no good deed goes unpunished by the government." Reddit's take:

https://t.co/N75y14ZSvb

The problem is that this is a wildly incomplete picture of what happened and why it happened.

So let's look at what did happen, and you can decide for yourself where the blame lies.

Let's start with some regulatory background here.

Hand sanitizer is regulated as an over-the-counter (OTC) product. Under that regulatory approach, entities which adhere to an FDA "monograph" may market an OTC drug without obtaining explicit FDA approval.

(Think of a monograph as a standard, or a recipe, for drug companies. Follow the standard/recipe, and your product is fine).

Here's the sanitizer monograph: https://t.co/OicqzGEhvF

Now, early on in the pandemic, public health officials had a problem: There was massive demand for hand sanitizer, which was leading to huge shortages.

So on March 20, 2020, FDA released a new policy intended to help alleviate those shortages.

https://t.co/MobkmU2g5F

That policy allowed non-drug manufacturers that register with the FDA to manufacture and sell hand sanitizer without falling afoul of federal requirements.

This policy was commonly understood to primarily target distillers of alcohol.

The policy required that companies follow the WHO recipe for hand sanitizer and keep “a simple record … to document key steps and controls.” Distillers also had to verify the alcohol content in their hand sanitizer and label it in accordance with the FDA’s sanitizer monograph.

Critically, the FDA’s policy also required that any entity making hand sanitizer must register with the FDA using its FDA Drug Registration and Listing System.

This requirement is longstanding and typically applies to traditional drug manufacturers.

Registration serves a whole bunch of purposes, but three in particular:

- it allows the FDA to know the identities of all companies that make drugs
- Helps FDA conduct inspections and safety surveillance
- Indicates which companies owe fees to FDA

Now, there are lots of fees that companies much pay to the FDA, but most are because of something called "user fee" programs.

These fees are used to help fund the FDA, and make up more than half of its overall budget.

But there are generally two types of user fees:

- Application fees, assessed each time a company wants FDA to review a new drug or medical product, and
- Facility fees, assessed on an annual basis and used to offset the costs of inspections and routine regulatory work.

These fees have traditionally been assessed on lots of products. Drugs, biologics, medical devices, generic drugs, biosimilars, compounding pharmacies, etc.

But never for nonprescription (OTC) drugs.

As a result, OTC companies had to register, but didn't have to pay fees.

Now, think back to the last date I told you:

March 20, 2020. That's when FDA released its guidance document.

A week later, on March 27th, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

This is where things get interesting.

The CARES Act is remembered mostly for economic stimulus checks, but it also contained about 100 pages overhauling how the FDA regulates OTC drugs.

It also established a user fee program called the OTC Monograph Drug User Fee Program (OMUFA). https://t.co/A6ued6pmRo

Among other things, the law established that FDA had the right to collect fees from registered facilities, known as “OTC monograph drug facility.”

Here's the relevant explanation from my writeup for AgencyIQ:

According to the text of the CARES Act: “Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility.” Fees were to be due 45 days after publication of the annual fee amounts in the Federal Register. The fee amounts were expected to be calculated by the FDA based on a formula which took into account an amount to be collected ($8 million in FY2021, divided by the anticipated number of facilities).

While the law passed in March 2020, the FDA hadn't actually released (or calculated) these fees yet.

That changed on December 29, when FDA announced the OMUFA fees for FY2021: https://t.co/zkcfavN8xs

By the FDA's calculation, each registered producer of OTC drugs would owe it $14,060 within 45 days.

And because distilleries had been required to register, that would now include distilleries, too.

This resulted in distillers being (understandably) upset. They felt they had stepped up during a public health emergency, and now the government was slapping them with a penalty for having done so.

Some had even donated these supplies, meaning they would have lost even more $.

Here's a statement from @DistilledSpirit, which seemed pretty indicative of the broader sentiment of the industry:

https://t.co/ekIkzjs3lf

> Phil McDaniel, CEO of St. Augustine Distillery and Chair of the DISCUS Craft Advisory Council, added, “Everyone was totally blindsided by FDA’s announcement and as a result, craft distillers across the country are scrambling to understand and respond. Given all that’s happened in 2020, the timing of this news could not be worse. The $14,000 fee being assessed could certainly put many of these small family owned businesses out of business.”

So you might be thinking: If FDA's March policy exempted distilleries from regulatory enforcement, why couldn't it just be exempted from the user fees, too?

This actually has a pretty simple answer: Congress.

Fee calculations are set by statute, rather than FDA’s discretion.

Basically: Congress gives FDA a formula, and tells it to use the formula to determine the fees. (This formula is usually signed off by industry groups prior to passage, as it was here).

OMUFA fees also don’t include a small business fee exemption or any sort of special fee waivers meant to allow development.

Those *do* exist for other user fee programs.

According to a statement provided by FDA to USA Today, it was hoping to work with Congress to fix this oversight.

Given that it had 45 days to do so, that seemed like a possible timeline.

https://t.co/jM5Ox8BjVr

> The FDA confirmed to USA TODAY that "the statute does not provide any waiver provisions for any specific category of manufacturer” or for the deadline for assessing those fees for that matter. “We stand ready to work with Congress on ways this can be addressed," said an FDA spokesperson.

But then HHS got involved. And this is where things get EXTREMELY unusual.

On Dec. 31, HHS spokesperson Brian Harrison put out a statement saying that FDA's user fee notification "was not cleared by HHS leadership, who only learned of it through media reports late yesterday."

Full HHS Statement:

Good Afternoon – early in the COVID-19 pandemic many small businesses across the country joined the fight to combat the virus and keep Americans safe – that included distilleries that augmented their operations to produce hand sanitizer, an important asset in the battle to deter the spread of COVID. In March, the Food and Drug Administration (FDA) issued a guidance document – the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) – which provides flexibility for those entities capable of producing hand sanitizer to rapidly enter the market. In the guidance, the FDA stated it "does not intend to take action against firms that" produce hand sanitizer products – which are classified as over-the-counter drugs – during the COVID-19 Public Health Emergency, provided the firm's activities are consistent with the guidance. Importantly, the guidance contains no discussion regarding user fees or any indication such fees would be due by these entities, many of which would be entering the drug manufacturing business for the first time. Nevertheless, on December 29, the FDA posted an over-the-counter drugs user fee notice that imposes a significant financial burden on these small businesses.

This action was not cleared by HHS leadership, who only learned of it through media reports late yesterday. HHS leadership convened an emergency meeting late last night to discuss the matter and requested an immediate legal review. The HHS Office of the General Counsel (OGC) has reviewed the matter and determined that the manner in which the fees were announced and issued has the force and effect of a legislative rule. Only the HHS Secretary has the authority to issue legislative rules, and he would never have authorized such an action during a time in which the Department is maximizing its regulatory flexibility to empower Americans to confront and defeat COVID-19. Because HHS OGC has determined the notice is really a legislative rule and that no one at FDA has been delegated authority to issue such a rule, the notice is void. HHS leadership, based on this legal opinion, has ordered the Federal Register Notice to be withdrawn from the Federal Register, meaning these surprise user fees will not need to be paid.

"Small businesses who stepped up to fight COVID-19 should be applauded by their government, not taxed for doing so. I'm pleased to announce we have directed FDA to cease enforcement of these arbitrary, surprise user fees. Happy New Year, distilleries, and cheers to you for helping keep us safe!" – Brian Harrison, HHS Chief of Staff

Harrison said the FDA user fee notice would be withdrawn in its entirety after HHS found that it constituted a "legislative rule and that no one at FDA has been delegated authority to issue such a rule."

If that language sound kind of weird to you, it's because it's relatively new. In fact, it comes from a December 2020 final rule in which HHS said any "significant" guidance would need to go through notice-and-comment rulemaking.

https://t.co/F1mqF1zZ07

I should note that every user fee notice in the Federal Register (going back to the *original* notices) has been published as a normal "notice," and not a rule. So this is a big change by itself.

Proof: https://t.co/ZflKfKtS6J

There are a bunch of other odd things to unpack here, too. First, HHS didn't just order FDA to rescind the facility fee part of this. It ordered FDA to rescind the ENTIRE notice. That leaves a lot of nonprescription drug companies in limbo.

The order: https://t.co/TWIsTB3F8n

It also means FDA is unable to collect *any* OMUFA fees (for now, at least), which could hamstring its ability to hire new staff, delaying its ability to enact Congressional reforms.

OTC groups I spoke with are... not pleased.

I should also note that the user fee notice itself is pretty basic.

It applies a basic formula to determine what the annual fee should be by taking a base amount mandated by Congress and then dividing by the number of active facilities.

So if that notice is “significant” then… arguably everything is significant.

Alternatively, anything that HHS doesn’t like is “significant” and therefore a “legislative rule.”

I’ll also note that HHS’s notice about this wasn’t (initially) published in the Federal Register, or on HHS’ website. It was an emailed statement.

The only online version I could find was here: https://t.co/DpaKdsQp24

Now FDA has finally (as of late yesterday) announced that it will formally rescind the notice.

You can read it here: https://t.co/TWIsTB3F8n

This statement is extraordinary. “The Notice was issued without approval of the Secretary.” “FDA has also been ordered to crease collections…”

Folks, this is not how government normally works. Now, this isn’t the first time that FDA and HHS have been at odds in recent weeks…

SUPPLEMENTARY INFORMATION:

On December 29, 2020, FDA published a Notice in the **Federal Register** entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021*. 85 FR 85646. The Notice purports to implement certain user fee provisions contained in the in the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Pub. L. No. 116-136, 134 Stat. 281 (March 27, 2020). The Notice was issued without approval of the Secretary. For this

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reason, the Notice, Docket No. FDA-2020-N-2246, as published in the **Federal Register** on December 29, 2020, (85 FR 85646), is hereby withdrawn.

FDA has also been ordered to cease collections activities related to the Over-the-Counter Monograph User Fee Program ("OMUFA") until, with the approval of the Secretary, the Department issues further direction concerning FDA's administration of OMUFA which provides the public with notice and opportunity for comment.

One related example: After FDA was deemed too slow at regulating Lab Developed Tests, HHS (Harrison, specifically) determined that FDA actually didn't have regulatory authority over them.

See my colleagues @DanDiamond and @DavidALim's story: https://t.co/bf3E3oRAOc

In the meantime, it's not actually clear that HHS's actions actually… solved anything. FDA's position is that it doesn't have the authority NOT to collect these fees.

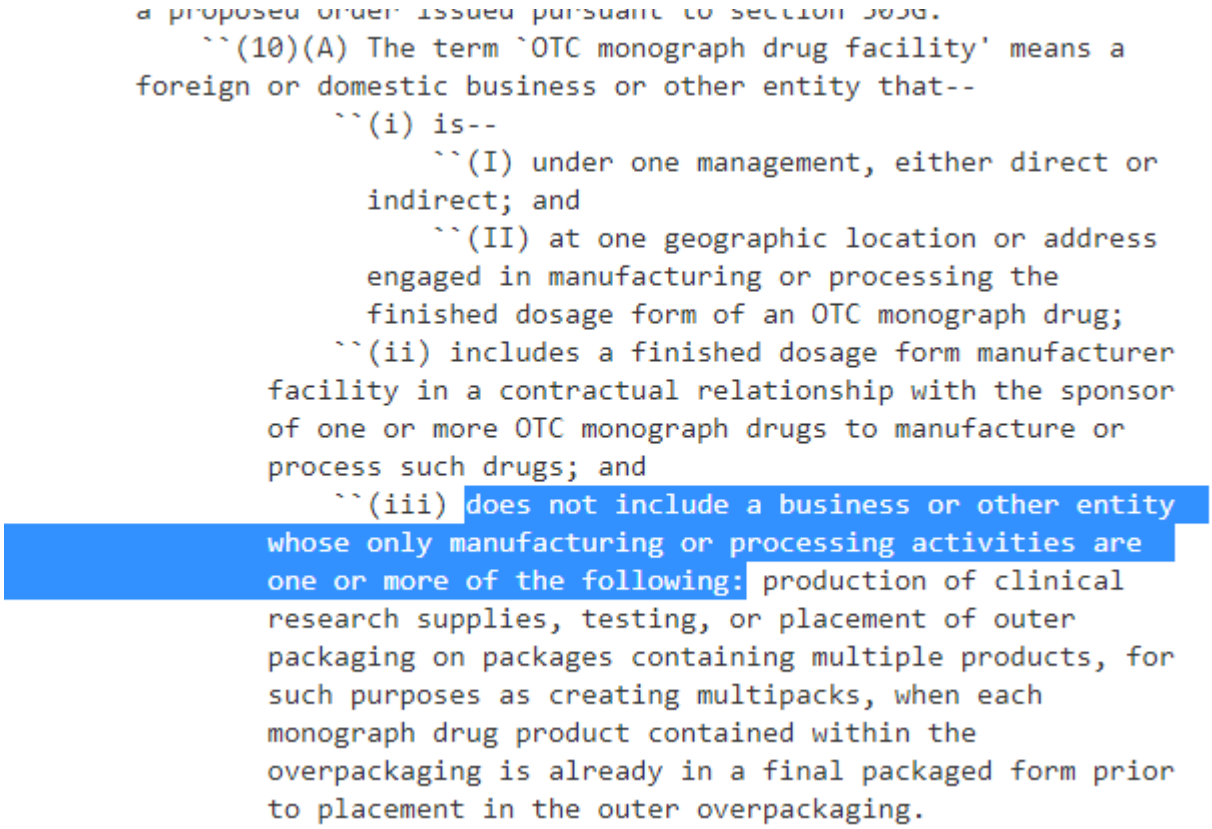
So withdrawing them just punts the issue down the road.

Ultimately, it's probably up to Congress to fix this. I can think of a few potential approaches:

- Public Health Emergency waiver
- First-time-filer waiver
- Small business waiver

Easy fixes that wouldn't be difficult to implement and are common to other programs.

Like, the OMUFA statute could literally be fixed by adding some language here:



```
a proposed order issued pursuant to section 505G.
    ``(10)(A) The term `OTC monograph drug facility' means a
foreign or domestic business or other entity that--
            ``(i) is--
                ``(I) under one management, either direct or
              indirect; and
                ``(II) at one geographic location or address
              engaged in manufacturing or processing the
              finished dosage form of an OTC monograph drug;
            ``(ii) includes a finished dosage form manufacturer
          facility in a contractual relationship with the sponsor
          of one or more OTC monograph drugs to manufacture or
          process such drugs; and
            ``(iii) does not include a business or other entity
          whose only manufacturing or processing activities are
          one or more of the following: production of clinical
          research supplies, testing, or placement of outer
          packaging on packages containing multiple products, for
          such purposes as creating multipacks, when each
          monograph drug product contained within the
          overpackaging is already in a final packaged form prior
          to placement in the outer overpackaging.
```

So let’s think back to my original point: Who do you think is at fault here?

My personal take: Every big piece of legislation has drafting anomalies or oversights. It’s just not often that new laws are tested first in the middle of a pandemic.

Let’s wrap this (way too long) thread here. Do you have more questions? Let me know.

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