

III clinical trials with roughly 550 patients with fourteen different cancer types in 44 cancer facility trial sites around the United States; and is currently conducting additional clinical trials to prepare for its final submission to the FDA for approval. *Id.* at 8–9. In addition to CBT-1®, CBA has also developed a dietary supplement that it markets as Bright Star, though the supplement is also known as nutraceutical. *Id.* at 11.

CBA does not have any venture capital investors, institutional investors, government funding, or pharmaceutical company participation. *Id.* at 10. Instead, the company has relied primarily on investments from its existing shareholders. *Id.* In 2016 and 2017, shareholders Aleta and Barry Shiff invested a total of \$2,000,000 into the company. *Id.* at 11–12. CBA alleges that the Shiffs subsequently grew impatient with the FDA approval process for CBT-1® and, fueled by misinformation that the company was abandoning its CBT-1® efforts to focus on marketing Bright Star, the Shiffs attempted to replace CBA’s president, Mike Putnam. *Id.* at 12–14. CBA further alleges that after the Shiffs’ efforts to gain control of CBA failed, the Shiffs reached out to the Kentucky Public Protection Cabinet, Department of Financial Institutions, Division of Securities, Enforcement Branch (the Department) in September 2020. *Id.* at 17.

On January 12, 2021, Department agent Jeff Jacobs informed CBA that the Department had received a complaint from Aleta Shiff and was initiating an investigation into the company. *Id.* at 19–20. As part of the investigation into CBA, the Department requested certain information, including the following:

- a description of CBA’s business and fund-raising activities since 2015, including the progression and status of the New Drug Application (“NDA”) and the percentage of funds raised that have been used toward the approval of the NDA;
- voting trust agreements for CBA stock;
- balance sheets and general ledgers (for 2015 to 2019);
- stockholder lists (with addresses, amount invested, etc. for the period from 2000 to the present); and
- copies of advertising and promotional materials, including offering circulars, private

placement memoranda used in the period from 2000 to the present time.

Id. The following month, during a Zoom call with company counsel, Mr. Jacob asked such questions as:

- When was the new drug application (“NDA”) filed with the FDA?
- When was the FDA “complete response letter” received?
- How many patients are involved in the latest sarcoma trial?
- Are you still studying 5-year stability (“shelf life”)?
- Have you approached big pharma to buy out the company?

Id. at 22. Mr. Jacob asked similar questions over the next several weeks, some of which CBA answered, and some it did not. *Id.* at 20, 29. CBA also alleges that Mr. Jacob, in an effort to intimidate existing CBA shareholders, sent a document titled “Enforcement Questionnaire” to a small group of shareholders. CBA states that Mr. Jacob is seeking to send the questionnaire out to the rest of the shareholders. [*Id.* at 33; *see also* R. 12 at 7.] CBA charges that the investigation has “an improper and undeniable bias against CBA” and that the investigation mirrors the complaints of Ms. Shiff. [R. 8 at 32; *see also* R. 8 at 4.] The investigation is ongoing, and the Department has yet to initiate any formal action against CBA because the matter is still under review.

On March 24, 2021, CBA Pharma filed a Complaint in this Court against Kerry B. Harvey, in his official capacity as Secretary of the Kentucky Public Protection Cabinet, seeking declaratory judgment that CBA’s stock offerings were covered securities and that the Department “has no control, directly or indirectly, over the registration of, representations about, or merits of any CBA offering of covered securities.” *Id.* at 33–34. CBA also requested injunctive relief and sought damages under 42 U.S.C. § 1983 because the Department’s handling of the investigation violated CBA’s due process rights and violated the “rights, privileges and immunities of citizenship of the United States.” *Id.* at 35, 42.

On April 14, Mr. Harvey filed his first motion to dismiss. [R. 7.] On May 5, CBA filed an Amended Complaint.¹ [R. 8.] On May 19, Mr. Harvey filed a second motion to dismiss and CBA responded to Mr. Harvey’s first motion to dismiss. [R. 11; R. 12.] On June 2, Mr. Harvey replied to CBA’s response to the first motion to dismiss. [R. 13.] One week later, on June 9, CBA filed a response to Mr. Harvey’s second motion to dismiss. [R. 14.] Mr. Harvey replied to CBA’s response on June 22. [R. 15.]

II

In the motion to dismiss, the Department argues that (1) CBA failed to exhaust its administrative remedies and this matter is not ripe, (2) the Commonwealth and Secretary Harvey are protected by sovereign immunity, (3) the Department has the right to enforce its own laws, (4) the Department is not preempted from investigating CBA Pharma, and (5) CBA is not entitled to damages under § 1983. [R. 11-1.] The Department also argues that both the Complaint and Amended Complaint fail to state a claim on which relief can be granted. [R. 11 at 1.]

A

The doctrine of ripeness focuses on the extent of the actions taken by the defendant. “A court lacks jurisdiction over the subject matter if the claim is not yet ripe for judicial review.” *Norton v. Ashcroft*, 298 F.3d 547, 554 (6th Cir. 2002) (citing *Bigelow v. Mich. Dep’t of Nat. Res.*, 970 F.2d 154, 160 (6th Cir. 1992)). To determine whether a matter is ripe, a court considers whether the issues are fit for judicial review and if the parties will suffer hardship if the court withholds consideration. *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967).

¹ With the filing of the Amended Complaint, CBA Pharma’s first motion to dismiss [R. 7] became moot. *Crawford v. Tilley*, 15 F.4th 752, 759 (6th Cir. 2021) (“The general rule is that filing an amended complaint moots pending motions to dismiss.”)

Generally speaking, “[a] claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal citations omitted). Thus, until an administrative agency has taken “some concrete action applying the regulation to the claimant’s situation in a fashion that harms or threatens to harm him,” the matter is not yet ripe for review. *Lujan v. Nat’l Wildlife Fed.*, 497 U.S. 871, 891 (1990).

The ripeness doctrine is designed “to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Nat’l Park Hosp. Ass’n v. Dept. of Interior*, 538 U.S. 803, 807–08 (2003). In evaluating whether a pre-enforcement challenge is ripe, a court must weigh three considerations:

The first two deal with the “fitness of the issues for judicial determination.” One aspect of the “judicial fitness of the issues” is the extent to which the legal analysis would benefit from having a concrete factual context. The second aspect of the “judicial fitness of the issues” is the extent to which the enforcement authority’s legal position is subject to change before enforcement. The third consideration deals with the “hardship to the parties of withholding court consideration.”

Ammex, Inc. v. Cox, 351 F.3d 697, 706 (6th Cir. 2003) (citing *Abbott Labs.*, 387 U.S. at 148–49).

B

Here, the Department is still in the very early stages of investigating alleged fraud in this case, and judicial action would be premature. Pursuant to KRS § 292.460, the Department may conduct investigations into fraud. This fact is not in dispute. [*See, e.g.*, R. 8 at 34.] Once an investigation is completed, the Commissioner may choose to (1) issue a cease and desist order,

with or without a prior hearing,² that is appealable to the Franklin Circuit Court against the persons who are allegedly engaged in the prohibited activities; (2) bring an action “in the Franklin Circuit Court or any other court of competent jurisdiction to enjoin any acts or practices and to enforce compliance with this chapter or any rule or order under this chapter”; or (3) issue a final order, after providing notice and the opportunity for a hearing, that contains findings of fact and conclusions of law. KRS § 292.470. After this has occurred,

[a]ny person aggrieved by a final order of the commissioner may obtain a review of the order by filing in accordance with KRS Chapter 13B in the Franklin Circuit Court, within thirty (30) days after the entry of the order, a written petition praying that the order be modified or set aside in whole or in part.

KRS §292.490.

Here, Mr. Harvey argues that CBA has failed to exhaust its administrative remedies and therefore the constitutional claims in this case are not ripe. [R. 11 at 11.] After review, the Court agrees and finds not only that the constitutional issues are unripe but that all of CBA’s claims in this matter are unripe. *See Bigelow*, 970 F.2d at 157 (finding court may raise ripeness *sua sponte* if it is not raised by the parties). The unripe nature of this matter is evident from CBA’s own admission of why the company filed this lawsuit in the first place: “[t]his lawsuit was filed by CBA to stop or severely curtail an *investigation* by the [Department].” [R. 12 at 1 (emphasis added).] This statement clearly indicates that even CBA understands it is in the midst of an investigation—one in which the Department has made no findings or alleged any wrongdoing on CBA’s part. The investigation in this matter has not concluded, which means that the Department has not even decided whether it will, in fact, take any action against CBA. [R. 11-1 at 19.] There has been no final agency action in this matter.

² The Commissioner may only issue an order without a prior hearing if the commissioner finds “that the delay in issuing a final cease and desist order will cause harm to the public.” KRS § 292.470(1).

In Count I, CBA asks the court to declare that CBA’s stock offerings “all fall within the definition of covered securities” because the Department “has *suggested* that one or more of CBA’s stock offerings was not of ‘covered securities.’” [R. 8 at 33 (emphasis added).] Ripeness is intended “to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Nat’l Park Hosp. Ass’n v.*, 538 U.S. at 807–08. A mere suggestion regarding CBA’s stock offerings does not constitute an administrative decision whose effects could be felt in a concrete way by CBA. It would be inappropriate and premature for the Court to grant CBA’s request on the basis of a suggestion that may not become part of a future administrative decision. *See Texas v. United States*, 523 U.S. 296, 300 (1998) (“A claim is not ripe for adjudication if it rests upon ‘contingent future events that may not occur as anticipated, or indeed may not occur at all.’”) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (1985)). Therefore, the Court finds that this issue is not fit for a judicial decision and that the hardship of withholding court consideration, given the early stage of the investigation, is minimal. *Nat’l Park Hosp. Ass’n*, 538 U.S. at 807–08. Accordingly, the Court will dismiss Count I.

In Count II, CBA seeks a declaratory judgment that the Department’s investigation is preempted by federal law, specifically 15 U.S.C. § 77r, which exempts certain securities offerings from state regulation. *Id.* at 34. However, CBA admits that the Department has the authority to investigate CBA regarding matters of fraud or deceit. [*Id.*; *see also* R. 12 at 8–9.] At this early point in the investigation, this is precisely what the Department has stated it is doing. The investigative scope of this matter is to determine “whether CBA has made any untrue

statements of a material fact or omitted to state a material fact necessary in order to make the statements that have been made, in light of the circumstances under which they were made, not misleading.” [R. 11-1 at 9 (citing R. 8 at 3).] This language mirrors KRS § 292.320, which defines “[f]raudulent and other prohibited practices” in securities cases in Kentucky, and it also mirrors 17 CFR § 240.10b-5, which is the federal definition for fraud in securities cases. CBA argues that the Department relies on an improper definition of fraud and therefore the clause contained in 15 U.S.C. § 77r permitting states to enforce actions for fraud and deceit does not apply to this investigation. [R. 12 at 14.]

The Court finds *Ammex, Inc. v. Cox*, 351 F.3d 697 (6th Cir. 2003), to be persuasive. In *Ammex*, the Michigan Attorney General issued a Notice of Intended Action to Ammex, Inc. “informing it that its advertising might result in the Attorney General filing an enforcement action under the Michigan Consumer Protection Act.” *Id.* at 700. Ammex subsequently sought a declaratory judgment, arguing that the Attorney General could not enforce the Act against it because “(1) federal law preempted the MCPA with respect to Ammex, and (2) any enforcement of the MCPA against Ammex would abrogate the restrictions placed upon states by the Commerce Clause.” *Id.* The district court dismissed the action on mootness grounds, and the Sixth Circuit affirmed on ripeness grounds. *Id.* Specifically, the Sixth Circuit found in part that the issue of whether the MCPA was preempted by federal statutes needed more factual development and “would be significantly benefitted by the concrete context that would be afforded by an enforcement action against a specific action by Ammex.” *Id.* at 706–07.

Here, as in *Ammex*, the preemption issue would benefit from a better understanding of the specific context of this fraud investigation, which the Court does not have because this investigation is still in the early stages. Additional analysis of the effects of KRS § 292.320 and

its relationship to 15 U.S.C. § 77r would be beneficial in this case. Furthermore, the opening of an investigation by the Department “was at most an initiation of proceedings” and did not constitute final agency action. *Id.* at 708. Because the investigation is still ongoing, CBA’s declaratory judgment on the preemption issue is brief and generalized—and also completely irrelevant if the Department ends up not bringing any agency action at all. *Cnty. Mental Health Servs. of Belmont v. Mental Health and Recovery Bd. Serving Belmont, Harrison & Monroe Cntys*, 150 F. App’x 389, 399–400 (6th Cir. 2005) (finding matter not ripe “without knowing what type of action, if any, [the state administrator] plans to take in the future”). Ultimately, the Court finds that the “need for more factual development consideration thus weighs against ripeness in this case.” *Ammex*, 351 F.3d at 707. Accordingly, the motion to dismiss will be granted as to Count II.³

3

In Count III, CBA also requests a “preliminary and permanent injunction against the Defendant from further investigation into actual, credible claims of fraud or deceit.” [R. 8 at 35.] The Court finds that Count III should be denied for the same reasons articulated above, particularly the benefit of additional concrete factual context and the lack of final agency action. *Ammex*, 351 at 706–08.

Furthermore, although the Court must view the Complaint in the light most favorable to CBA and draw all reasonable inferences in its favor, *Gold Village North, LLC v. City of Powell, Ohio*, 14 F. 4th 611, 621 (6th Cir. 2021), issuing an injunction in this matter would likely be

³ To the extent CBA argues that continuing the investigation would be futile because a “hearing officer would not have the legal authority to adjudicate whether a federal statute...pre-empts the [Department’s] investigation,” CBA is mistaken. [R. 12 at 22.] The issue here is that if after the investigation the matter goes away entirely, there would be no preemption issue left to adjudicate. Because this matter is only at the investigation stage, it cannot be said that continuing the investigation would “amount to an exercise in futility.” *Id.*

entirely advisory. This is because at this early stage in the investigation, the Department states that it is investigating an actual, credible claim of fraud or deceit, which all parties agree the Department may do. CBA's evidence to the contrary primarily consists of inquiries from Mr. Jacob that CBA construes as too broad to constitute a fraud investigation. [R. 12 at 5–7.] However, “[e]ven if one were to regard the request for information in this case as caused by nothing more than official curiosity, nevertheless law-enforcing agencies have a legitimate right to satisfy themselves that corporate behavior is consistent with the law and the public interest.” *Dolomite Energy, LLC v. Commonwealth of Ky. Office of Fin. Insts.*, 269 S.W.3d 883, 886 (Ky. App. 2008) (quoting *Commonwealth ex rel Hancock v. Pineur*, 533 S.W.3d 527 (Ky. 1976)). An agency may make inquiries so long as “the demand is not too indefinite and the information sought is reasonably relevant.” *Id.*

After the investigation concludes, the Department may choose to take no further action or continue to take action based upon a credible claim of fraud or deceit, which is precisely what CBA requests in Count III. Essentially, there is not necessarily a conflict between what CBA is requesting and the status quo, and this makes judicial action inappropriate at this point. Therefore, the Court will grant the Department's motion to dismiss as to Count III.

4

Finally, in Count IV, CBA seeks relief for violations of civil rights under 42 U.S.C. § 1983. [R. 8 at 35.] Parties bringing § 1983 claims need not exhaust administrative remedies before seeking relief. [R. 12 at 19 (citing *Patsy v. Board of Regents of State of Florida*, 457 U.S. 496 (1982)).] However, any claim must still “comply with the principles governing ripeness determinations generally.” *Monk v. Huston*, 340 F.3d 279, 282 (5th Cir. 2003). Under § 1983, CBA argues that the Department's handling of the investigation has violated CBA's “rights to

due process, subjects CBA to the type of burdensome regulations from which [federal law] was specifically created to protect it, and is a violation of the rights, privileges and immunities of citizenship of the United States.” [R. 8 at 42.]

However, none of these claims have merit. First, “[t]he constitutional right to due process is not, however, an abstract right to hearings conducted according to fair procedural rules. Rather, it is the right not to be deprived of life, liberty, or property without such procedural protections.” *Monk*, 340 F.3d at 282–83; *see also United States v. Coffman*, 2011 WL 839565, at *3 n.1 (E.D. Ky. Mar. 7, 2011) (rejecting “perfunctory argument” that the defendant’s due process rights were violated given the “[Department’s] authority to conduct private investigations” under KRS § 292.460). At this stage, the mere fact that CBA had a fraud investigation opened against it does not constitute a deprivation of due process. This is especially true given that this matter is still in the early investigative process. *Cf. Bigelow*, 970 F.2d at 160 (finding due process claim unripe when initial decisionmaker had not yet “arrived at a definitive position on the issue that inflicts an actual, concrete, injury”) (quoting *Williamson Cnty. Reg. Planning Comm’n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 193 (1985)).

Furthermore, the record does not reflect that the Department has stepped beyond its regulatory and statutory authority in this matter at this early stage. As discussed above, agencies have a lot of leeway in conducting fraud investigations into corporations under Kentucky law. *Dolomite Energy, LLC*, 269 S.W.3d at 886.

Finally, privileges and immunities do not apply to corporations such as CBA. *See McNeilus Truck and Mfg., Inc. v. Ohio ex rel. Montgomery*, 226 F.3d 429, 439 (6th Cir. 2000) (stating “it is settled law that the Privileges and Immunities Clause does not apply to corporations”); *see also New West, L.P. v. City of Joliet*, 491 F.3d 717, 720 (7th Cir. 2007)

(noting that “a corporation is not a ‘citizen’ for the purpose of the privileges and immunities clause”); *South Macomb Disposal Auth v. Washington Tp.*, 790 F.2d 500, 503–04 (6th Cir. 1986) (finding that corporations “can never assert the denial of privileges and immunities under section 1983”).

As for the hardship CBA may incur if this investigation is permitted to continue, the Court finds that the harms CBA alleges are speculative. CBA states it has incurred and will continue to incur “irreparable harm” in two specific ways: (1) CBA fears that the continuance of this administrative proceeding would equate to continued harassment and intimidation of shareholders, and (2) that the production of certain “sensitive and voluminous financial information” during the investigation would put CBA “at a competitive disadvantage.” [R. 12 at 22–23.] However, CBA’s charges of harassment and intimidation stem from a survey that was sent out to a select few shareholders, and the CBA’s charge that the survey constituted harassment and intimidation is conclusory. “A finding of irreparable harm must be grounded on something more than conjecture, surmise, or a party’s unsubstantiated fears of what the future may have in store.” *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). CBA has failed to demonstrate that any shareholder actually felt bullied by the survey or changed its impression toward CBA because of the survey, or that CBA has been financially harmed directly because of the survey or any other actions taken during the investigation up to this point.

As for the request that CBA produce certain information as part of the investigation, it is not as if CBA is being asked to share proprietary information with the general public or its competitors. The information is being requested in the context of a fraud investigation, and the record is devoid of any allegations that the Department has a track record of failing to protect

secured information or has ever failed to protect such information. In addition, 808 KAR 10:390 provides that “a consumer complaint or other information relative to an investigation or examination shall remain confidential” if the public disclosure would:

- a. Jeopardize the integrity of another active investigation, examination or proceeding;
- b. Reveal the name, address, telephone number, Social Security number, or other identifying number or information of a complainant, customer, or account holder;
- c. Disclose the identity of a confidential source;
- d. Disclose investigative techniques or procedures; or
- e. Reveal a trade secret.

808 KAR 10:390. While CBA cites to this regulation in the Complaint, CBA has failed to allege that the information being provided would not fall within these protections.⁴ Furthermore, notwithstanding CBA’s concerns, agencies “have a legitimate right to satisfy themselves that corporate behavior is consistent with the law and the public interest.” *Dolomite Energy, LLC*, 269 S.W.3d at 886. Accordingly, the Court will grant the motion to dismiss as to Count IV.

III

Because the Court has found that this case is not ripe, it need not evaluate the other arguments contained in Mr. Harvey’s motion to dismiss. *Cnty. Mental Health Servs. of Belmont v. Mental Health and Recovery Bd. Serving Belmont, Harrison & Monroe Cntys*, 150 F. App’x at 399–400 (finding court did not need to address issue of immunity because “the issue is not ripe for adjudication”); *see also Citizens for Preservation of Jessamine Cty, LLC v. Jessamine Cnty-City of Wilmore Joint Planning Comm’n*, 2009 WL 5170164, at *2 n.2 (E.D. Ky. Dec. 18, 2009) (declining to address failure to state a claim arguments because matter is not ripe). Accordingly, and the Court being sufficiently advised, it is hereby **ORDERED** as follows:

⁴ Sensitive information would be protected as a trade secret if it is “information, including a formula, pattern, compilation, program, data, device, method, technique, or process, that: (a) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (b) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.” KRS § 365.880.

1. Kerry B. Harvey's first Motion to Dismiss [R. 7] is **DENIED AS MOOT**;
2. Kerry B. Harvey's second Motion to Dismiss [R. 11] is **GRANTED**; and
3. Judgment shall be entered contemporaneously herewith.

This the 30th day of March, 2022.

The image shows a handwritten signature in black ink, which appears to read "Gregory F. Van Tatenhove". The signature is written over a circular official seal. The seal contains the text "UNITED STATES DISTRICT COURT" at the top and "EASTERN DISTRICT OF KENTUCKY" at the bottom. In the center of the seal is an eagle with its wings spread, perched on a shield.

Gregory F. Van Tatenhove
United States District Judge