

Re: Concerns about this month's Vyvanse prescription**Lacey, Michael** <lacey@math.gatech.edu>

Thu 4/1/2021 3:20 PM

To: Schmidt, Maxie D <mschmidt34@gatech.edu>

Maxie, see you at 11:30

Michael Lacey
School of Mathematics
Georgia Institute of Technology

From: Schmidt, Maxie D <mschmidt34@gatech.edu>
Sent: Thursday, April 1, 2021 3:01:32 PM
To: Lacey, Michael <lacey@math.gatech.edu>
Subject: Re: Concerns about this month's Vyvanse prescription

Michael,

If we can go later tomorrow morning, I could use the diversion at TJ's. Very much appreciated. There is also something I need to pick up from CVS or Publix. How about if we meet in the parking lot with masks on at 11:30AM tomorrow (Friday).

I talked with Dr. Dinh this afternoon. It turns out that she or my current doctor at Stamps will be the one that helps me report this to the FDA. Whatever was in my generic Vyvanse (from China, which leads my sister to suggest fentanyl poisoning, though she is no MD either) this month is particularly heinous stuff. They at the FDA need to be aware of it, if not just point blank take it off the legal market as a possibility. Some 20 year old kid at a frat party could die on this stuff at GA Tech!

FYI, Vyvanse is considered safer by some doctors to prescribe because it comes manufactured (in the US, by Shire) with a shell that has to be metabolized, after which point the meds turn into the chemical equivalent of an Adderall XR. It's more than just some organic chemist replicating the chemical molecule. There is a sacred manufacturing procedure under extensive patents (in the US) that has to be preserved. It's scary that Stamps outsourced a generic for this medication I have been taking for 15 years and packaged it with the Shire manufacturer's drug facts sheet and original warnings.

Maxie

From: Lacey, Michael <lacey@math.gatech.edu>
Sent: Thursday, April 1, 2021 2:24 PM
To: Schmidt, Maxie D <mschmidt34@gatech.edu>
Subject: Re: Concerns about this month's Vyvanse prescription

Backseat, I am so sorry that you had this scary visit to the ER.

I suggested picking it up and taking to Trader Joe's as away that might be a good diversion for you.

But if you just wanna send me a list and I'll be dropping off before I can certainly do that it sounds like you're very comfortable at the moment I may not really want to get out.

Or maybe you do. Just let me know.

Michael Lacey
School of Mathematics
Georgia Institute of Technology

From: Schmidt, Maxie D <mschmidt34@gatech.edu>
Sent: Thursday, April 1, 2021 1:39:28 PM
To: Lacey, Michael <lacey@math.gatech.edu>; Yu, Josephine T <jyu@math.gatech.edu>
Subject: Fwd: Concerns about this month's Vyvanse prescription

Michael,

I am sending you the same email chain I sent to Josephine before I went over to the ER on Monday night. Your Gmail rejected it over large attachment sizes.

They discharged me from the ER at around 2pm on Tuesday morning with unexplained chest pain from Saturday. They said no heart attack nor stroke was evident from the tests they ran. I have bruises all over my arms and hands from the repeated ivs and straight sticks by nurses that night.

Do not fill anything from Stamps pharmacy in the future! It is well worth the copay on student insurance at Walgreens where they do not cut costs on generics made out of the US.

The dean of students didn't even respond to me. Alyssa and my doctor are already very concerned at Stamps from outside of the pharmacy department.

This a really fucked up situation (pardon my language). The new Vyvanse I filled at Walgreens this week works well, looks and feels like the actual non generic medication I have been taking to manage adhd for nearly 15 years. I'm going be ok.

Maxie

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From: Schmidt, Maxie D <mschmidt34@gatech.edu>
Sent: Monday, March 29, 2021, 6:08 PM
To: Yu, Josephine T; michael lacey
Subject: Fwd: Concerns about this month's Vyvanse prescription

Images reattached. I am pissed, because I could have died. Enough said about the demeanor with which I communicated my disposition.

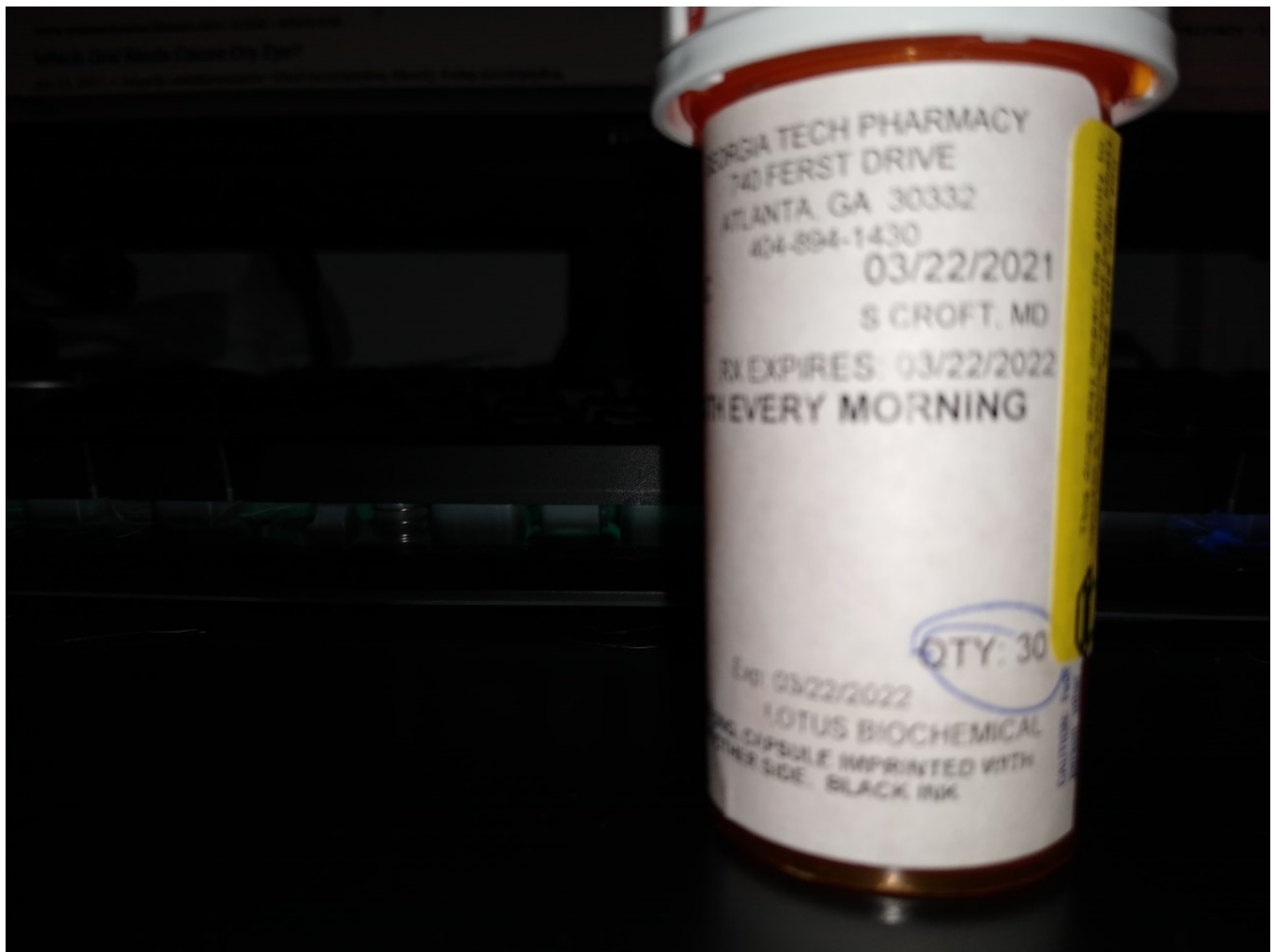
Maxie Image

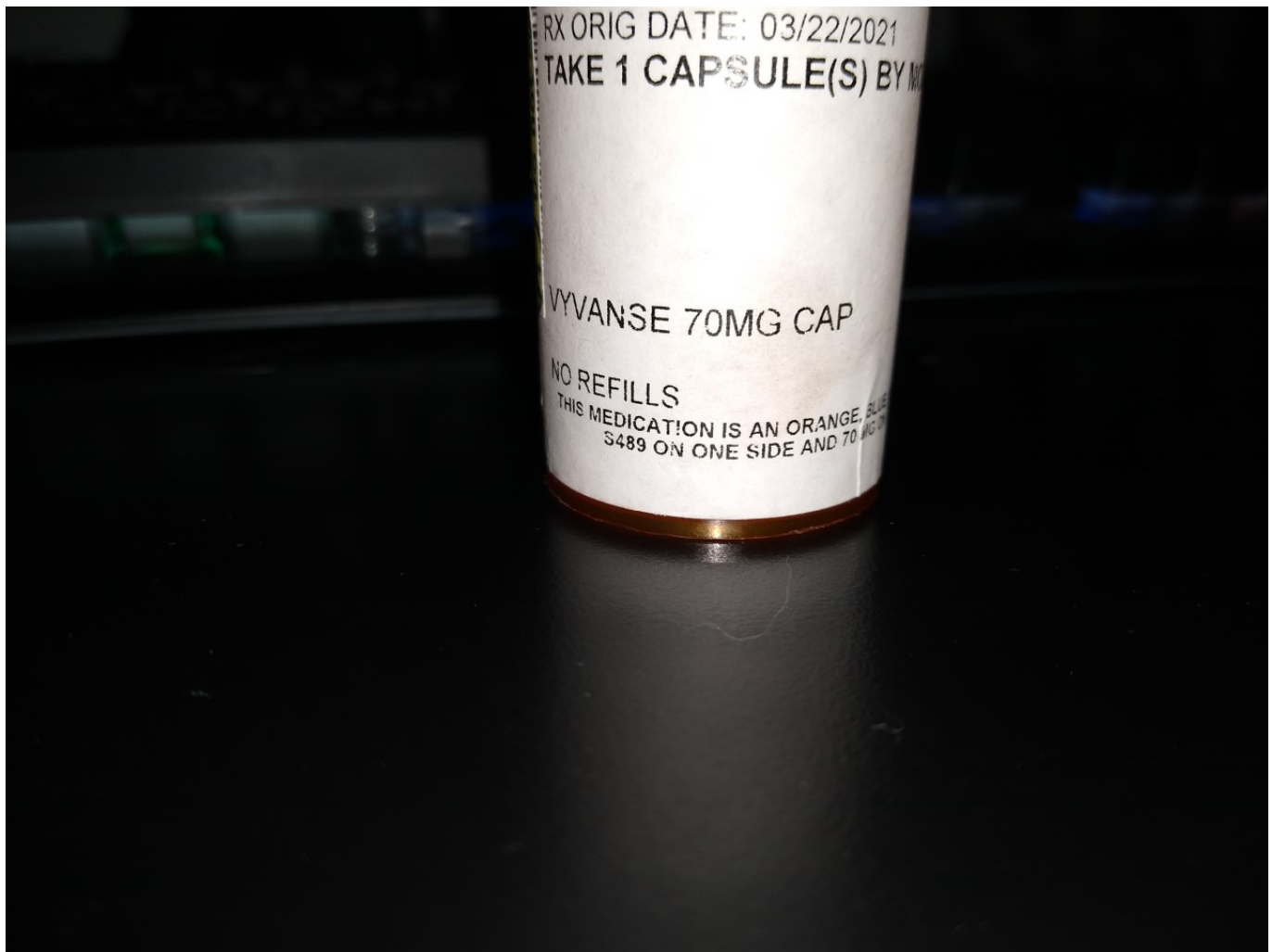
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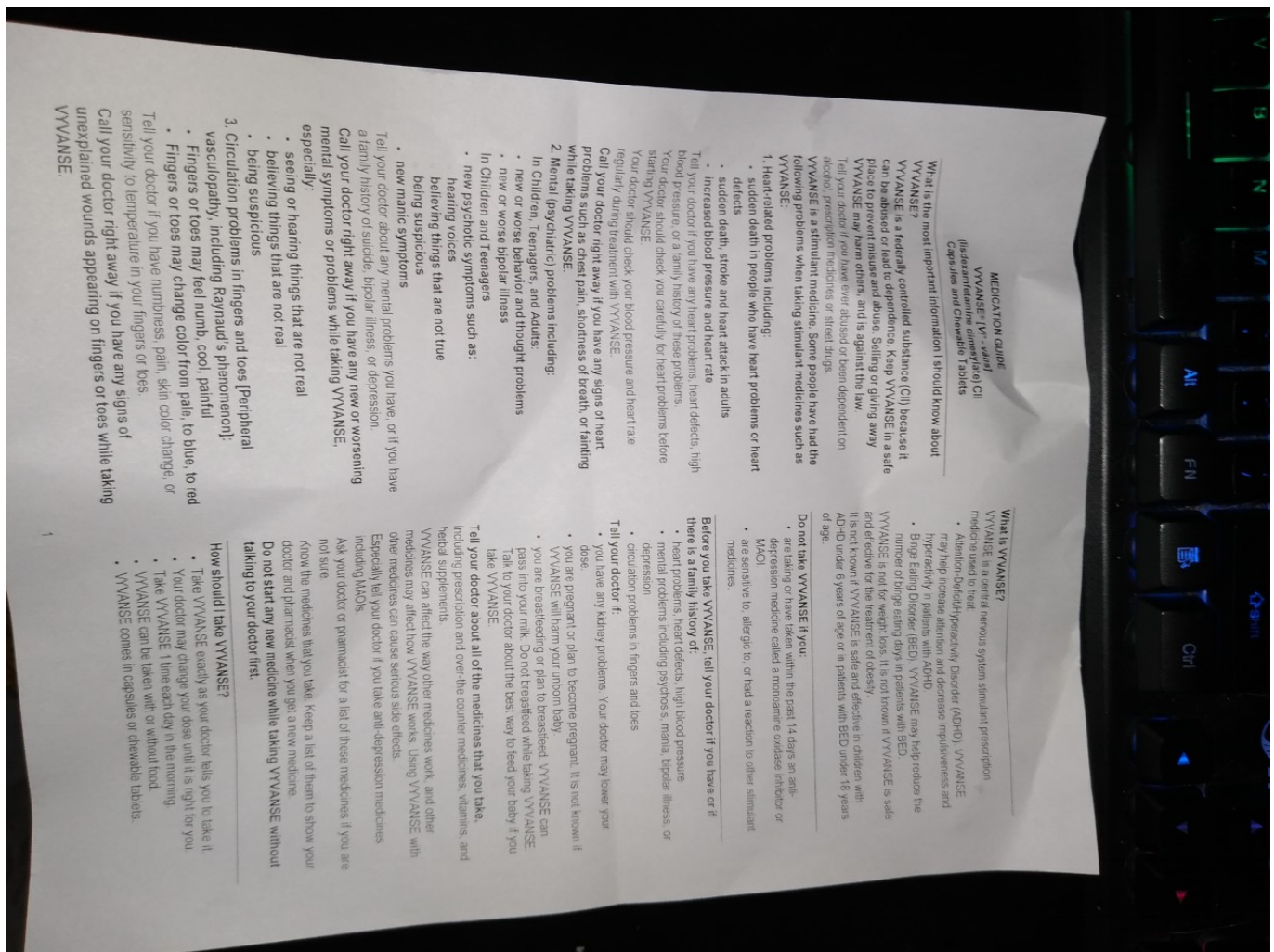
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MEDICATION GUIDE

VYVANSE® [V^r - Vans] (lisdexamfetamine dimesylate) CII Capsules and Chewable Tablets

What is the most important information I should know about VYVANSE?

VYVANSE is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep VYVANSE in a safe place to prevent misuse and abuse. Selling or giving away VYVANSE may harm others, and is against the law.

Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

VYVANSE is a stimulant medicine. Some people have had the following problems when taking stimulant medicines such as VYVANSE:

1. Heart-related problems including:
 - sudden death in people who have heart problems or heart defects

- sudden death, stroke and heart attack in adults
- increased blood pressure and heart rate

Tell your doctor if you have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you carefully for heart problems before starting VYVANSE.

Your doctor should check your blood pressure and heart rate regularly during treatment with VYVANSE.

Call your doctor right away if you have any signs of heart problems such as chest pain, shortness of breath, or fainting while taking VYVANSE.

2. Mental (psychiatric) problems including:

In Children, Teenagers, and Adults:

- new or worse behavior and thought problems

- new or worse bipolar illness

In Children and Teenagers

- new psychotic symptoms such as:

- hearing voices
- believing things that are not true
- being suspicious

- new manic symptoms

Tell your doctor about any mental problems you have, or if you have a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you have any new or worsening mental symptoms or problems while taking VYVANSE, especially:

- seeing or hearing things that are not real
- believing things that are not real
- being suspicious

3. Circulation problems in fingers and toes (Peripheral vasculopathy, including Raynaud's phenomenon):

- Fingers or toes may feel numb, cool, painful

- Fingers or toes may change color from pale, to blue, to red

Tell your doctor if you have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your doctor right away if you have any signs of unexplained wounds appearing on fingers or toes while taking VYVANSE.

What is VYVANSE?

VYVANSE is a central nervous system stimulant prescription medicine used to treat:

- Attention-Deficit/Hyperactivity Disorder (ADHD). VYVANSE may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

- Binge Eating Disorder (BED). VYVANSE may help reduce the number of binge eating days in patients with BED.

VYVANSE is not for weight loss. It is not known if VYVANSE is safe and effective for the treatment of obesity.

It is not known if VYVANSE is safe and effective in children with ADHD under 6 years of age or in patients with BED under 18 years of age.

Do not take VYVANSE if you:

- are taking or have taken within the past 14 days an anti-depressant medicine called a monoamine oxidase inhibitor or MAOI.
- are sensitive to, allergic to, or had a reaction to other stimulant medicines.

Before you take VYVANSE, tell your doctor if you have or if there is a family history of:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers and toes

Tell your doctor if:

- you have any kidney problems. Your doctor may lower your dose.
- you are pregnant or plan to become pregnant. It is not known if VYVANSE may harm your unborn baby.
- you are breastfeeding or plan to breastfeed. VYVANSE can pass into your milk. Do not breastfeed while taking VYVANSE. Talk to your doctor about the best way to feed your baby if you take VYVANSE.

Tell your doctor about all of the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

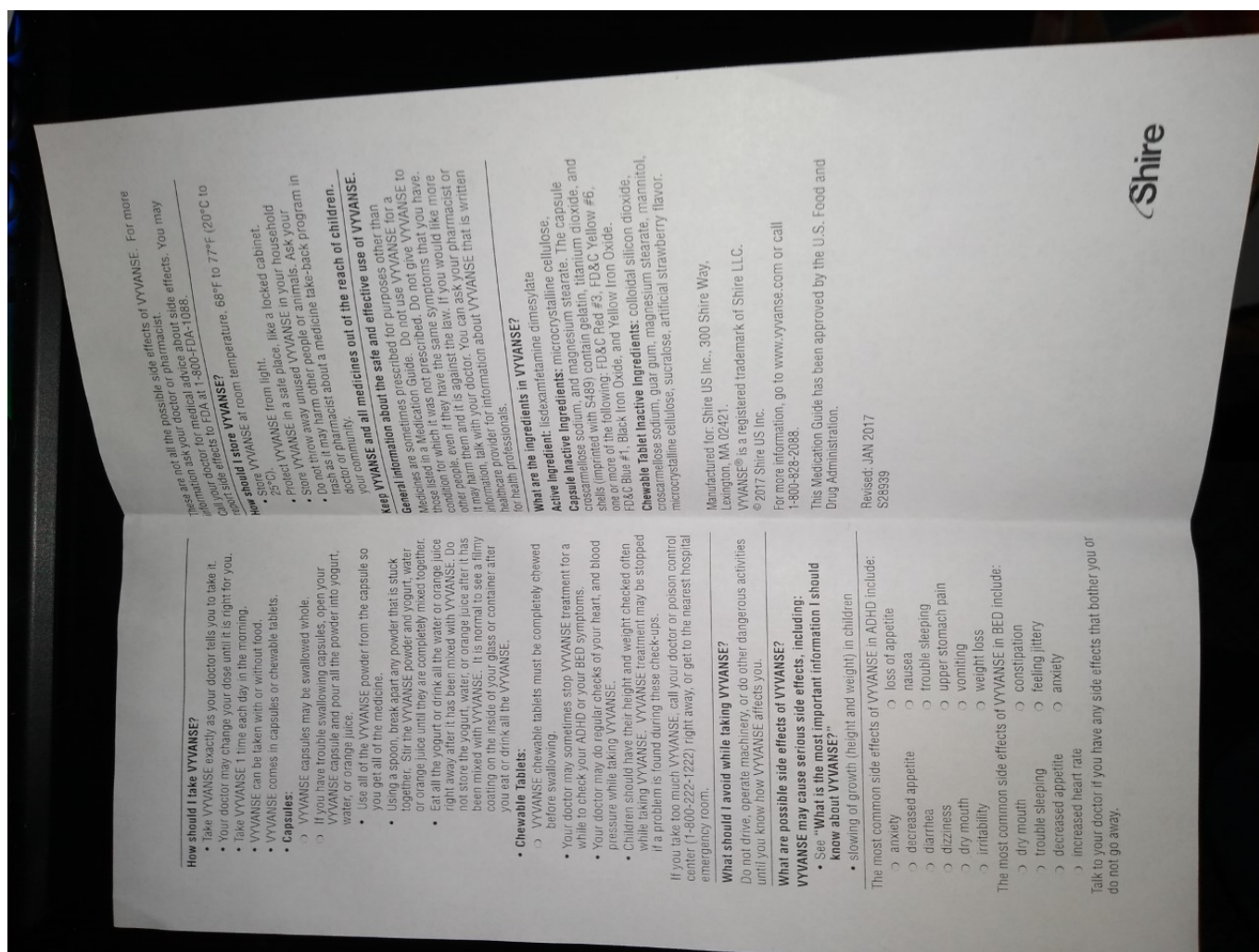
VYVANSE can affect the way other medicines work, and other medicines may affect how VYVANSE works. Using VYVANSE with other medicines can cause serious side effects.

Especially tell your doctor if you take anti-depression medicines including MAOIs.

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

Do not start any new medicine while taking VYVANSE without talking to your doctor first.



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From: Schmidt, Maxie D <mschmidt34@gatech.edu>

Sent: Monday, March 29, 2021 5:17:59 PM

To: Jannarone, Anne L <anne.jannarone@studentlife.gatech.edu>; Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>; John M. Stein, Vice President of Student Life and Dean of Students <studentlife@studentlife.gatech.edu>

Subject: Re: Concerns about this month's Vyvanse prescription

Additionally, see these records. Are they making a profit at the expense of students health, what? This is unfair, disgusting, and makes me a very, very angry hulk in the room. I am, however, powerless right now.

MDS  Image

 Image

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From: Schmidt, Maxie D <mschmidt34@gatech.edu>

Sent: Monday, March 29, 2021 5:14:28 PM

To: Jannarone, Anne L <anne.jannarone@studentlife.gatech.edu>; Mellor, Alyssa J

<studentlife@studentlife.gatech.edu>

Subject: Re: Concerns about this month's Vyvanse prescription



<https://outlook.office.com/mail/inbox>

These are not all the possible side effects of VYVANSE. For more information ask your doctor or pharmacist about side effects. You may call your doctor for FDA at 1-800-FDA-1088.

How should I take VYVANSE?

- Take VYVANSE exactly as your doctor tells you to take it.
- Your doctor may change your dose until it is right for you.
- Take VYVANSE 1 time each day in the morning.
- VYVANSE can be taken with or without food.
- VYVANSE comes in capsules or chewable tablets.
- **Capsules:**
 - VYVANSE capsules may be swallowed whole.
 - If you have trouble swallowing capsules, open your VYVANSE capsule and pour all the powder into yogurt, water, or orange juice.
 - Use all of the VYVANSE powder from the capsule so you get all of the medicine.
- Using a spoon, break apart any powder that is stuck together. Stir the VYVANSE powder and yogurt, water, or orange juice until they are completely mixed together.
- Eat all the yogurt or drink all the water or orange juice right away after it has been mixed with VYVANSE. Do not store the yogurt, water, or orange juice after it has been mixed with VYVANSE. It is normal to see a filmy coating on the inside of your glass or container after you eat or drink all the VYVANSE.

Chewable Tablets:

- VYVANSE chewable tablets must be completely chewed before swallowing.
- Your doctor may sometimes stop VYVANSE treatment for a while to check your ADHD or your BED symptoms.
- Your doctor may do regular checks of your heart, and blood pressure while taking VYVANSE.
- Children should have their height and weight checked often while taking VYVANSE. VYVANSE treatment may be stopped if a problem is found during these check-ups.

If you take too much VYVANSE, call your doctor or poison control center (1-800-222-1222) right away, or get to the nearest hospital emergency room.

What should I avoid while taking VYVANSE?

Do not drive, operate machinery, or do other dangerous activities until you know how VYVANSE affects you.

What are possible side effects of VYVANSE?

VYVANSE may cause serious side effects, including:

• See "What is the most important information I should know about VYVANSE?"

• slowing of growth (height and weight) in children

The most common side effects of VYVANSE in ADHD include:

- anxiety
- decreased appetite
- diarrhea
- dizziness
- dry mouth
- irritability

The most common side effects of VYVANSE in BED include:

- dry mouth
- trouble sleeping
- decreased appetite
- increased heart rate

Talk to your doctor if you have any side effects that bother you or do not go away.

What are the ingredients in VYVANSE?

Active ingredient: lisdexamfetamine dimesylate

Capsule inactive ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells (imprinted with S489) contain gelatin, titanium dioxide, and one or more of the following: FD&C Red #3, FD&C Yellow #6, FD&C Blue #1, Black Iron Oxide, and Yellow Iron Oxide.

Chewable Tablet inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, guar gum, magnesium stearate, mannitol, microcrystalline cellulose, sucralose, artificial strawberry flavor.

Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

VYVANSE® is a registered trademark of Shire LLC.

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For more information, go to www.vyvanse.com or call 1-800-828-2088.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: JAN 2017

S28399

Shire

MEDICATION GUIDE

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Especially tell your doctor if you take anti-depression medicines including MAOIs.

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

Do not start any new medicine while taking VYVANSE without talking to your doctor first.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VYVANSE?

- Store VYVANSE at room temperature, 68°F to 77°F (20°C to 25°C).
- Protect VYVANSE from light.
- Do not store VYVANSE in a safe place, like a locked cabinet.
- Do not store VYVANSE in your household trash.
- Do not throw away VYVANSE as it may harm other people or animals. Ask your doctor or pharmacist about a medicine take-back program in your community.

Keep VYVANSE and all medicines out of the reach of children.

General information about the safe and effective use of VYVANSE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VYVANSE for a condition for which it was not prescribed. Do not give VYVANSE to other people, even if they have the same symptoms as you have. It may harm them and it is against the law. If you ask for more information, talk with your doctor. If you ask for more information, healthcare provider or information about VYVANSE that is written for healthcare professionals.

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Capsule Inactive Ingredients: microcrystalline cellulose, croscarmellose sodium, and magnesium stearate. The capsule shells (imprinted with S488) contain gelatin, titanium dioxide, and one or more of the following: FD&C Red #3, FD&C Yellow #6, FD&C Blue #1, Black Iron Oxide, and Yellow Iron Oxide.

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Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: JAN 2017

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- Use all of the VYVANSE powder from the capsule so you get all of the medicine.
- Using a spoon, break apart any powder that is stuck together. Stir the VYVANSE powder and yogurt, water, or orange juice until they are completely mixed together.
- Eat all the yogurt or drink all the water or orange juice right away after it has been mixed with VYVANSE. Do not store the yogurt, water, or orange juice after it has been mixed with VYVANSE. It is normal to see a filmy coating on the inside of your glass or container after you eat or drink all the VYVANSE.

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- See "What is the most important information I should know about VYVANSE?"
- slowing of growth (height and weight) in children

The most common side effects of VYVANSE in ADHD include:

- anxiety
- decreased appetite
- nausea
- diarrhea
- dizziness
- dry mouth
- irritability
- loss of appetite
- trouble sleeping
- upper stomach pain
- vomiting
- weight loss

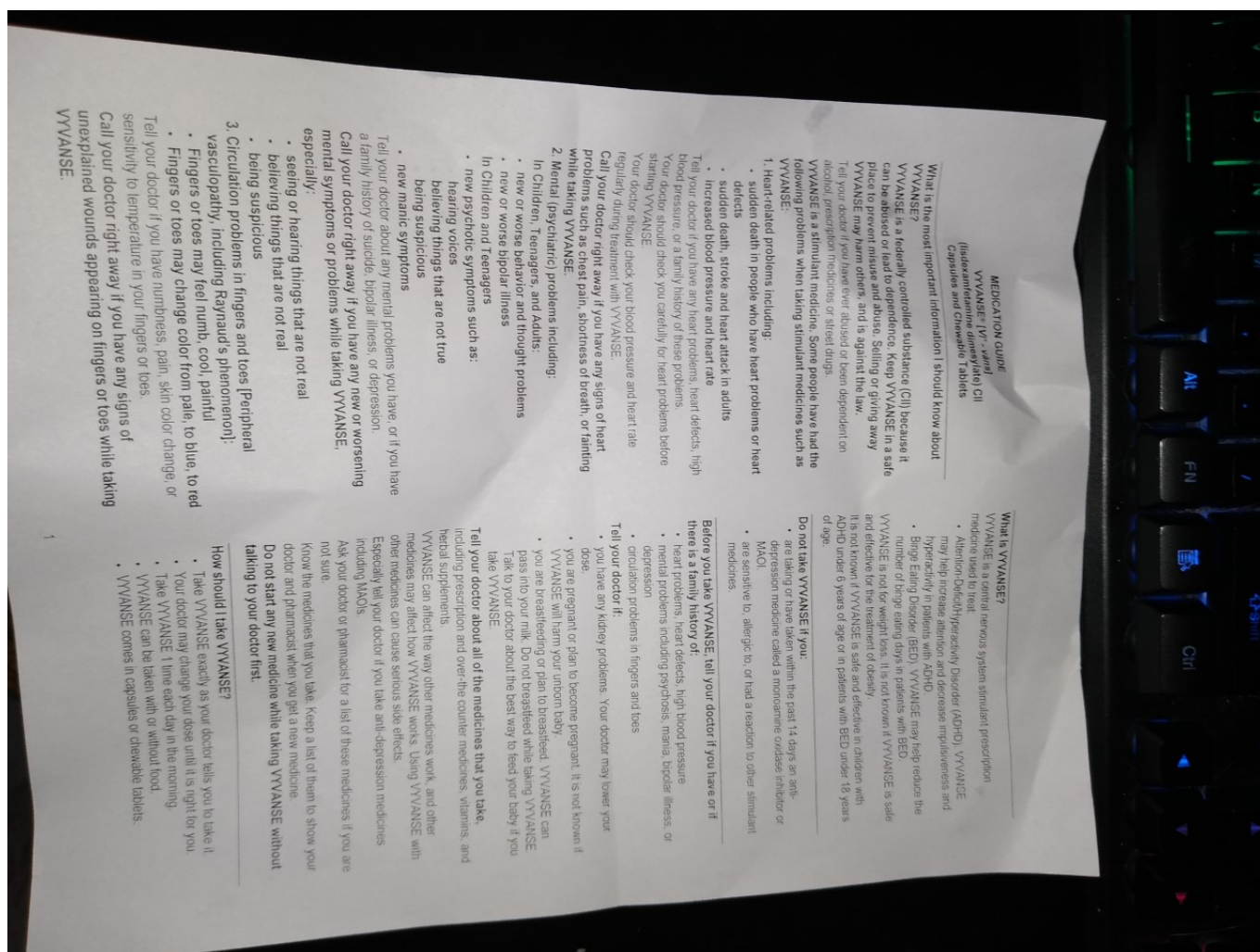
The most common side effects of VYVANSE in BED include:

- dry mouth
- trouble sleeping
- decreased appetite
- increased heart rate
- constipation
- feeling jittery
- anxiety

Tell to your doctor if you have any side effects that bother you or do not go away.

These are not all the possible side effects of VYVANSE. For more information ask your doctor or pharmacist.

Shire



Annie and John,

I have attached images of the actual facts sheet (from Walgreens), the one dispensed at Stamps last week, and a reminder of the authentic Shire vendors endorsement on my newly filled prescription. The chain of command needs to make sure that the active Stamps pharmacist Nina understands the difference first thing in the morning! She has previously made snide remarks to me, the patient, and hassled my doctor about writing too many controlled substances on her campus for months after I reported consistent, but less severe symptoms on their cheap Chinese Vyvanse. Please deliver her the documentation with a smile attached to my middle finger ASAP so she can READ THE F-ING MANUAL, as we computer people are fond of saying about our Unix, ASSHOLE. The facts sheets are identical and use the authoritative endorsement of the Shire Corp manufacturer. N.b.

It has been a very long day already. And I am extremely upset about this. Do you need more of an explanation of my attitude and why this is necessary?

Thank you.

(Try to check in tomorrow over blue jeans)

MDS

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From: Schmidt, Maxie D <mschmidt34@gatech.edu>

Sent: Monday, March 29, 2021 4:20:28 PM

To: Jannarone, Anne L <anne.jannarone@studentlife.gatech.edu>; Mellor, Alyssa J

<alyssa.mellor@health.gatech.edu>; John M. Stein, Vice President of Student Life and Dean of Students
<studentlife@studentlife.gatech.edu>

Subject: Fwd: Concerns about this month's Vyvanse prescription

Annie,

Last message that wasn't originally attached, I believe. I will follow up on this when I get home.

Maxie

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From: Schmidt, Maxie D <mschmidt34@gatech.edu>

Sent: Monday, March 29, 2021, 3:42 PM

To: Mellor, Alyssa J

Subject: Re: Concerns about this month's Vyvanse prescription

Alyssa,

Thank you. I am now at Walgreens waiting for the electronic script to come in as promised. They will write me a two week prescription for Vyvanse until my next appointment with Dr. Croft on the 12th. I have confirmed that Walgreens stocks the Shire medication manufactured as I would have expected in the US. In the future, I will have most of my scripts filled here, not at Stamps.

Out of my concern for the side effects I went through with the generic from China, I will cc you on my message to the dean of students. Please do your best to ensure that correct meds get dispensed at Stamps over this! I don't want any grieving parents who sent their bright engineer off to school with a "safe" adhd medication at \$0 copay. The psychiatry department has no control over the pharmacy.

Maxie

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From: Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>

Sent: Monday, March 29, 2021 8:21:22 AM

To: Schmidt, Maxie D <mschmidt34@gatech.edu>

Subject: RE: Concerns about this month's Vyvanse prescription

Hi Maxie,

Thank you for sending these to me. I am so sorry that you have been having these reactions to your Vyvanse. I am unfortunately out sick today. I am going to have my colleague Kristen call you today to discuss these concerns and figure out what to do about the medication. I am anticipating feeling better to be back in the office tomorrow. Dr. Croft is out all of this week, but we have other psychiatrists who are covering for him this week that Kristen/I can speak with.

Talk to you soon,

Alyssa

From: Schmidt, Maxie D <mschmidt34@gatech.edu>

Sent: Sunday, March 28, 2021 4:41 PM

To: Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>

Subject: Re: Concerns about this month's Vyvanse prescription

Alyssa,

I am actually very concerned about the off-shore branded meds that I have discovered in my locked box this weekend. The Vyvanse this month (and for a while) has caused me very severe and abnormal side-effects that are interfering with my life and ability to function as a grad student at GA Tech. Therefore, I am requesting that all of my meds so far filled at the Stamps pharmacy on campus be re-written and approved for an early refill so I can fill them at a more reliable Walgreens source (except for the Abilify, which is \$2000 a month for generic, and I cannot afford there).

If Dr. Croft ends up being an asshole to me about this request getting approved on Monday so I can get reliable meds in my system over an absurd and overbearing university policy on the controlled substances, then I will need to have another MD write and approve these prescriptions for me. My off-campus GP physician has for a long time offered to write these prescriptions for me in the event of another bad experience with a psychiatrist.

Please convey my sentiment to Dr. Croft ASAP in the morning tomorrow. It is an urgent situation! You do not have to use my precise verbal gesturing at him unless you feel it is appropriate too.

Thank you. Sincerely,

Maxie

From: Schmidt, Maxie D <mschmidt34@gatech.edu>
Sent: Saturday, March 27, 2021 7:46 PM
To: Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>
Subject: Re: Concerns about this month's Vyvanse prescription

Sorry. One more time.

My suggestion is that minimally you all have a skilled chemist at the FDA run an analysis on these capsule samples to figure out what is actually contained in them! I am, however, not a MD nor a chemist, IMHO.

In the meantime, I do not think it is safe for me to take these until a good cause can be found for the side effects, and an appropriate replacement is issued. This is going to interfere with my assignment due Monday afternoon. Please get back to me ASAP about this. My ADD is intense for school work this month.

Maxie

From: Schmidt, Maxie D <mschmidt34@gatech.edu>
Sent: Saturday, March 27, 2021 7:22 PM
To: Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>
Subject: Re: Concerns about this month's Vyvanse prescription

Also, I have termed the phenomenon to which my mind is currently attuned on this daily substance a "Vyvansula", as in, a "Vyvansula" bit me again. This happens roughly every other month for the last 4-6 months. This month's batch is particularly disorienting.

I have asked Nina before at the pharmacy what it means when a Vyvanse makes me dizzy, and in particular, what could have actually gotten slipped into it. She responded dehydration and to eat more regularly after examining the pills by visual inspection.

I am really convinced and concerned about the veracity of the labelled capsules. It is definitely NOT Vyvanse. WTF!?!

Maxie

From: Schmidt, Maxie D <mschmidt34@gatech.edu>
Sent: Saturday, March 27, 2021 6:45 PM
To: Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>
Subject: Re: Concerns about this month's Vyvanse prescription

P.S., the reason I took two was to see if perhaps the wrong dosage had been assigned and test to see if conditions improve. They did not (as confirmed).

Maxie

From: Schmidt, Maxie D
Sent: Saturday, March 27, 2021 6:43 PM
To: Mellor, Alyssa J <alyssa.mellor@health.gatech.edu>
Subject: Concerns about this month's Vyvanse prescription

Alyssa,

I have some concerns about "mind fuck" type symptoms that arise when I take this month's batch of 70mg Vyvanse filled at the Stamps Pharmacy this last Monday (images below). This drug is non-generic (still) and only manufactured by Shire Phramecuticals in the US. The manufacturer listed on my pill bottle is LOTUS BIOCHEMICAL. I am concerned that the pharmacy stocked a non-US manufactured capsule. Can we please make sure this doesn't happen again!?! The quantity was also not initialed by the pharmacist (as usual), but instead circled.

Every day I take this, I get very mentally clouded and unable to function. I can barely work on my assignments and research under these conditions. I am actually going to go so far as to admit that I have taken two in ~1.5 days and only had worse mental clouding (e.g., mind fuck) symptoms. I would like to ask you to have Dr. Croft give me approval to exchange those that remain on the prescription for a new round that have been manufactured by the legitimate US-based pharmaceutical company. Can we arrange to have that happen this week, please?

Maxie