Notox

THE SHOCKING TRUTH ABOUT

COSMETIC INJECTIONS

2

TABLE OF CONTENTS.

ABOUT THE AUTHOR.

Megan McCue is a speech-language pathologist and writer based in California. She has many static and dynamic lines on her 35-year-old face, and has learned to appreciate each and every one of them.

OTHER BOOKS BY THE AUTHOR:

Me Tox Pretty (2024)

Iatrogenic Botulism 101 (2025)

Conversations and collaborations welcome:

metoxpretty@gmail.com

www.iatrogenicbotulism.com

NOTE FROM THE AUTHOR.

Although the subtitle of this book uses the term "cosmetic injections," you will soon learn that I am speaking solely about botulinum toxin (e.g.: Botox, Dysport, Xeomin, Jeuveaux, etc.) injections.

I have an equal disdain for hyaluronic filler injections, or as I call them, "clown shots," but this book is not the place to air out those grievances.

Obviously, botulinum toxin injections are used for a wide variety of medical conditions, and cosmetic use constitutes less than half of their sales. I understand that these injections can temporarily relieve pain or discomfort associated with certain medical conditions, however, in my opinion the benefits *never* outweigh the risk of botulism.

References are listed at the end of the book by chapter in alphabetical order.

DEDICATION.

For my colleague and botulism historian, J.A. Talkington, PhD:

Thank you for teaching me more about botulism than I ever wanted to know, and encouraging me to write.

And for all of those who have suffered after a cosmetic injection:

Nothing can fully erase the trauma and disability that can be caused by these drugs, but I hope this book helps to bring your suffering to light and expose the world to the dangers of Botox.

Our stories can and do make a difference.

Please know that you are never alone.

INTRODUCTION.

My doctor gave botulism to the wrong girl.

I'm sure she naively assumed that when one of her patients developed severe adverse effects after receiving botulinum toxin (hereafter referred to as "BoNT," and known by the most common brand "Botox") injections from her, they would quietly recover at home without a fuss.

Not me.

Once I became ill, and was left alone to pick up the pieces of my crumbling life without any answers from the medical community, a fire was lit.

I had many questions, and, much to my husband's chagrin, spent the majority of the next year thinking and talking about them.

How did this happen? What was my prognosis? Why were there no readily available treatments for this man-made disease that was at

least 30 years old? Why did exactly zero *doctors I interacted with seem to know anything about BoNT adverse effects or botulism?*

And, given how disabling and long-lasting the adverse effects could be, how was this drug even legal?

Last year when I decided to try BoNT injections, I surprised many people, including myself.

I had always been known as the "natural" girl to my close friends and family. In elementary school, I swore off pizza and soda, declaring that they weren't healthy enough for me (although pretzels and cheese continued to make up the majority of my diet, so that's 10-year-old logic for you). In college, I was a regular at my local farmer's market every Saturday in San Francisco. As an adult, I happily spend my hard earned cash on grass-fed beef, elaborate water filtration systems, and organic cotton,

OEKO-TEX-certified clothes (for me, not my kids; they get whatever's at Goodwill).

The point is, my decision to try cosmetic injections was totally out of character: I wouldn't light a scented candle in my home, but I was going to let someone inject me with the planet's most lethal toxin?

Once I ended up developing systemic toxin spread (i.e.: botulism) due to being (unintentionally) injected in the bloodstream, I spent many months beating myself up for that decision. Life as I knew it had abruptly fallen apart, and I laid in bed night after night wondering if and when it would ever return to normal.

In those early months post-poisoning, I would have given up just about *anything* to travel back in time and cancel my injection appointment. I had lost a normal functioning body and brain, half of my beautiful

salt-and-pepper hair, and even some friendships to the toxin, and I wanted all of those back.

Sitting here today, I'm relieved and grateful to report that I made it through the deepest, darkest lows of my illness with a newfound purpose.

After spending many months living in fatigue, discomfort, uncertainty, crushing depression, and profound grief for my normal life, I slowly healed and re-emerged (keyboard in hand) with curiosity and determination. I still had questions that needed answering, after all.

This book is the result of the quest I embarked upon to feed my over-thinking brain.

With it, I aim to do four things:

- take you through a brief history of botulism and botulinum toxin injections
- discuss some of the early warning signs of harm and legal troubles of these drugs

- detail the exact health risks these injections pose, and lastly,
- convince you, dear reader, to abandon your tox appointments, *stat*.

History is rife with instances in which drugs that were initially praised as "miraculous" and "just what the doctor ordered" (think cigarettes, Fen-Phen, Vioxx, Accutane, and opioids, among many others) eventually became notorious for their harmful and lethal effects. I believe that one day, botulinum toxin injections will be added to this list, and that our descendants will look back at today's carefree and ubiquitous use of them with shock and horror.

I was not given *any* information about the risk of developing botulism when I received my injections last year. When I asked her what the side effects of Botox were, my doctor told me I

might experience pain at the injection site and a slight headache.

Once I began experiencing bizarre and debilitating symptoms (including dizziness, head pressure, neck muscle weakness, panic attacks, severe dry mouth, difficulty swallowing, fatigue, hair loss, insomnia, and ear pressure) in the subsequent hours, days, and weeks, every doctor I interacted with told me that I "looked fine" and was probably just nervous. One actually sneered at me after I told her I suspected I was experiencing adverse effects of the toxin, asking incredulously, "So, what? You think you have *botulism*?"

The gaslighting and the (sometimes willful) ignorance must end. As you are about to learn, for nearly 30 years, these drugs have repeatedly demonstrated their potential to cause symptoms of botulism.

Doctors and nurses (especially those who regularly inject patients) need urgent crash courses on the potential adverse effects of BoNT injections. Iatrogenic botulism (botulism that occurs after injection with botulinum toxin) in mild, moderate, and severe forms can happen, does happen, and will continue to happen as the popularity of these drugs increases.

In my opinion, it is a public health crisis that demands immediate attention and the urgent need for all to reconsider the drug's risk-benefit ratio, particularly when used cosmetically and electively.

We all deserve to know the havoc these drugs can wreak on the body when they spread from the intended injection site. We all deserve the right to make truly informed medical decisions.

My hope is that this book helps you do just that.

HISTORY LESSON.

Imagine the aliens have finally landed on Earth to study our species. One arrives at your front door on a Sunday afternoon and asks if they can observe you going about your day. Sure, why not?

You're watching football, and they have many questions: *Why are overweight men purposefully ramming into each other*? *What's "the griddy*?" *Who's Taylor Swift?* (Just kidding, even the aliens know that one.)

At halftime, a commercial comes on for a drug named "Botox," spouting all its supposed benefits for migraines. We learn that in its clinical trial, the drug was shown to "prevent" 8 to 9 migraines per month, versus the saline placebo, which "prevented" 6 to 7. At the end of the commercial, a lightning-quick voice tells us to seek medical care if we're having difficulty

"swallowing, speaking, or breathing" in the days and weeks after receiving Botox.

"Woah. Sounds scary. What's in that drug?" the alien asks.

"Oh, the main ingredient is the most lethal poison on our planet. Turns out it's really good at disrupting our nervous system and paralyzing our muscles."

(Fine, the alien is definitely at my house.)

"And you're injecting it…near your brains?"

"Yeah, we've been doing it for a little over 30 years now. Originally, we were studying it as a biological weapon of war, then we realized it might have short-lived benefits for some medical conditions. So we brought it to market and began using it off-label for dozens of medical conditions and cosmetic purposes without any testing for long-term adverse effects. Some do it to "freeze" their facial muscles, and others do it

for migraines, muscle spasms, and even excessive sweating. It causes permanent damage to the nerve synapses it reaches, and no one knows exactly how often it's causing harm. There are also no readily available medical tests or treatments if and when it spreads throughout the bloodstream (like every other drug injected into humans). What could possibly go wrong?"

"To use an expression from your language, WTF?!"

WTF, indeed, little alien.

How did we get here, exactly? How is it that botulinum toxin, once known only to a small number of biochemists and military scientists as the "most poisonous poison," has been made into an injectable form and become as commonplace as acrylic nails and aspirin?

Each year, nearly 9 million injections of BoNT are administered (including from the brands Botox, Dysport, Xeomin, Jeuveau, and

Daxxify) globally, for both cosmetic and medical purposes. Yearly BoNT sales were recently valued at over $11 billion, and that number is expected to grow at an annual rate of 9.8%, making it one of the top earning drugs of our time.

No doubt about it, the BoNT industry has hired extremely talented marketers. The deadliest poison on the planet has become an eternal fountain of youth and a remedy for a long, growing list of physical ailments. Its adverse, and at times, deadly, effects are quietly swept under a rug (i.e. buried in lengthy package inserts or on clunky, user-unfriendly government websites), unbeknownst even to most physicians and nurses.

To get the complete picture of just how amazing the rebranding of this little toxin has been, I need to take you (and our new alien friend) back a few hundred years for a little

history lesson. So grab your smores sticks and gather ‘round the campfire, kids.

IST DAS BOTULUS?

Our story begins in western Europe in the late 18th century - an era that was not for the faint of heart. Most humans farmed for survival (rather than for the Instagram likes), and their lives were marred by brutal weather conditions, frequent famines, and a smörgåsbord of deadly illnesses.

One such illness was a mysterious food poisoning that was killing more than 70% of its victims within days to weeks. Researchers in southern Germany named it “botulus,” the Latin word for sausage, after outbreaks of the disease were traced back to sausages and other preserved foods.

For many decades, doctors were perplexed, because the patients that were dying

from “botulus” were not presenting with typical food poisoning symptoms, such as diarrhea, vomiting, fever, and chills. Rather, they reported odd neurological symptoms, including dizziness, blurry vision, and difficulty speaking and swallowing, before eventually succumbing to sudden respiratory failure or cardiac arrest. Over the course of a century, the disease claimed many victims, while doctors and researchers remained clueless about its cause.

Finally, in 1895, the Belgian bacteriologist Emile Pierre van Ermengem discovered and isolated the offending party: *Clostridium botulinum*, an anaerobic bacterium whose spores could multiply and form botulinum toxins in improperly preserved foods.

Even though the *what* behind botulus, which was later renamed “botulism,” had been discovered, researchers at the time still did not

understand *how* the toxin functioned once it entered the body.

What they were beginning to understand, however, was the great variability in the severity of botulism. Accounts of the lucky minority who survived the poisoning proved to be important in understanding the disease fully.

In the book *Recognizing Botulism* by J.A. Talkington, the author notes that "Botulism symptoms unfold at a different pace for each patient, and can also present with different severities for each patient." (p. 30)

The author goes on to highlight notes on botulism patients written by the dean of Stanford University's medical college in 1913, Dr. Ray Wilbur:

> "In the patients seen by me there was a wide variation in the severity of the disease, some having only transient disturbance of vision

> or swallowing, others (complaining of): jaws seemed very tired, apparent inability to chew food, tongue seemed hard to move, sleep all the time, could not walk fast, throat filled up with mucus all the time…legs and arms were almost powerless…throat felt as if there was a shelf in it beyond which food could not pass, but it did not hurt... Throughout you must be constantly reminded that the symptoms may be extremely acute and followed by an early death, or they may be gradually unfolded in their entirety or only one or two characteristic evidences may appear."

These detailed early case studies about botulism patients, written by Dr. Wilbur and

others, helped physicians at the time understand that botulism could occur in mild, moderate, and severe forms.

While some patients experienced a more transient version of the illness, with symptoms like dry mouth, blurry vision, fatigue and weakness eventually subsiding in the months post-poisoning, others were destined for swift and terrifying deaths within hours or days of their last meal.

The fact that botulism could present with drastically different symptoms and severities is historical knowledge that seems to have been lost to time. Many physicians and nurses in the 21st century are unfamiliar with mild and moderate botulism symptoms, assuming that unless descending flaccid paralysis and respiratory failure are occurring, it simply can't be botulism; more on this in later chapters.

As important as these early case studies were in identifying and describing botulism, without understanding the disease's pathophysiology, the medical community remained unable to help desperate patients as the decades ticked by.

WEAPON OF MASS DESTRUCTION

During World War II, the U.S. military began experimenting with different biological war agents at Camp Detrick (later renamed Ft. Detrick) in Maryland.

Botulinum toxin was of obvious interest due to its astonishing lethality. Just one gram of the toxin, if aerosolized, is enough to kill over a million people, making it 100,000 times more deadly than sarin nerve agent.

It was during these years, from around 1943-1946, that American scientists were able to both purify and crystallize botulinum toxin,

making an injectable version of the poison a future possibility.

While our military was hard at work attempting to understand the ins and outs of the toxin, our friends across the pond were the first to figure out exactly *why* botulinum toxin was so deadly.

In 1947, Dr. Arnold Burgen and his colleagues in England, while experimenting on rats, discovered that the toxin could block communication (by blocking the release of the neurotransmitter acetylcholine) between nerves and muscles or other nerves. The toxin, once in the bloodstream, is taken up into nerve synapses (the space between two nerves) within minutes to hours, rapidly damaging cholinergic pathways within the peripheral nervous system (PNS). The PNS includes both the somatic and autonomic nervous systems (ANS), the latter of which regulates respiration, cardiac function,

swallowing, salivating, and digestion, among other processes. Botulinum toxin, Burgen proved, has an affinity for quickly shutting down the chemical communication involved in our body's most critical functions.

Military research on botulinum toxin continued up through the 1960's, with scientists developing a vaccine against the toxin for soldiers. In 1969, when the U.S. military's offensive biological weapon research unit was dismantled by President Nixon, all of the toxic agents held in stockpiles, including BoNT, were ordered to be destroyed.

A biochemist named Edward Schantz, PhD, who was the lead researcher in the biological war unit, found a new job at the University of Wisconsin in Madison, and brought a vial of the military's toxin with him to his new lab.

Schantz's intent was to study how BoNT could be applied to various medical conditions, and his time spent researching the toxin in Wisconsin would soon usher in a new era of experimental medical uses.

OCULINUM - BOTOX BEFORE IT WAS COOL

Dr. Alan B. Scott, an ophthalmologist in California, found out about Schantz's injectable toxin, and was curious to see if it could treat strabismus, a condition where eye muscles don't coordinate properly, resulting in asymmetry of the eyes, known as "crossed eyes" or "lazy eye."

In 1972, Dr. Scott received his first batch of BoNT from Dr. Schantz, and went to work on trialing it on monkeys' eye muscles (fair warning to PETA fans: many animals were harmed in the making of Botox).

It is worth noting that in order to fund his initial drug trials and first registered company,

Oculinum, Inc., Dr. Scott was forced to take out a loan on his house. With that level of investment from his own pocket, it is easy to imagine just how much incentive he had to ensure this drug was successful.

In one of his early studies, Dr. Scott injected eight monkeys in the eye muscles and noted "no systemic effects" of the toxin, although two of the monkeys died of intestinal infections in the weeks after injections.

In his report, he failed to mention that monkeys don't speak English and thus couldn't possibly tell him how they were feeling. Because they are mostly *subjective* experiences that are not measurable via objective testing, mild and moderate botulism symptoms are impossible to rule out in animal studies. (How does one determine if monkeys in a cage are experiencing nausea, headaches, dizziness, blurry vision, dry mouth, or muscle weakness?)

But I digress. He considered these trials a success and was ready to move on to humans.

Before it could be tested on humans, Dr. Scott's product needed to be approved as an "Investigational New Drug" (IND). His IND application sat at the FDA untouched for nearly four years, until an old buddy ophthalmologist of his, David Cogan, MD, who had recently been hired at the NIH, "kindly put in a word" for him. The application was approved days later, greenlighting the way for human trials in 1978.

Before Dr. Scott injected others, he made sure to personally protect himself from the risk of botulism; he received three doses of the BoNT vaccine, in the case that a needle broke his skin during the trials (he didn't want that nasty stuff wreaking havoc in his body!).

He was ready to begin, and at first injected less than a single unit of BoNT into a few dozen patients' eye muscles to test for its safety.

The “unit” measurement for BoNT products is important to understand. A Botox unit is not a converted measurement representing milligrams, micrograms, or the international units that are used to measure drugs like insulin or penicillin. It is a measurement of *lethality* of the toxin. The term “unit” is short for “mouse unit,” and one of these units is the amount of injected toxin that caused half of a batch of test mice to die from botulism within a 3-day window. In toxicology, this amount is called the “LD50,” or lethal dose, 50%. So, when someone gets 34 Units of Botox injected into their face, they can honestly report, “I got 34 times the amount of Botox it took to kill one mouse!” Please pause for a moment to reflect on the wild notion of taking a drug whose measurement is based on its efficiency to kill. Now back to the story.

Dr. Scott soon moved on to larger unit loads, and in his initial human studies, surprisingly noted *no systemic effects whatsoever* in any patients. His remarkable findings go against everything we know to be true about BoNT injections for eye disorders today. Xeomin, the brand of BoNT I received, lists the following as having occurred in 5% *or more* of patients during their double-blind, placebo-controlled clinical trial for blepharospasm (eye spasms): eyelid ptosis, dry eye, dry mouth, diarrhea, headache, visual impairment, dyspnea (difficulty breathing), nasopharyngitis, and respiratory tract infection.

Dr. Scott didn't document any measurement tools that he may have used to gather side effect data from his subjects, nor did he include any placebo controls in his trials, so our only option is taking him at his word.

Interestingly, what was noted in his early studies was that the toxin had the unfortunate ability to migrate to muscles surrounding the injected ones. Research has since confirmed that injected BoNT can unintentionally spread at least 3-4.5 cm away from the intended site.

Nonetheless, Dr. Scott was satisfied with his results, as the toxin did exactly what it had been promised to do: it permanently destroyed affected nerve synapses, thereby paralyzing the patient's eye muscles until their body healed from being poisoned and regrew new synapses.

He published his trials and was eager to find a pharmaceutical company willing to purchase his product. (The guy had a Marin County house to pay off, after all.)

Due to the liability this drug posed, he initially failed to find anyone who was remotely interested. He continued injecting any and all willing patients with his product for nearly 10

years before finally receiving FDA approval in 1989.

In 1991, Dr. Scott sold Oculinum, Inc. for $9 million to the pharmaceutical company Allergan, who gave it the catchy name “Botox.” They got to work cleaning up Dr. Scott’s messy research and conducting their own double-blind placebo-controlled trials of the drug.

DON’T SAY THE “B” WORD

It’s impossible to pinpoint exactly when Allergan realized its newly purchased product had the potential to cause botulism symptoms. Because it is probably proprietary information that has been lost to the pre-internet era, we will never know if they were aware of their new drug’s dirty little secret prior to, or shortly after, its purchase.

I imagine a small group of sweaty businessmen with furrowed brows in a

fluorescently-lit, blue-carpeted conference room sometime in the early 90s, cursing their fate and arguing over the exact verbiage they would use to present the results from their clinical trial.

What one can guess is that at some point, the decision was made to never, under any circumstance, utter the dreaded "B" word (botulism). *Way* too much baggage with that one.

Instead, what you will find written in the 1996 Botox package insert (the earliest I could find) is the following:

> "Other events (besides dysphagia, neck pain, and headache) reported in 2-10% of patients in any one study in decreasing order of incidence include: increased cough, flu syndrome, back pain, rhinitis, dizziness, hypertonia, soreness at

> injection site, asthenia (muscle weakness), oral dryness, speech disorder, fever, nausea, and drowsiness. Stiffness, numbness, diplopia (double vision), ptosis, and dyspnea (difficulty breathing) have been reported rarely."

Please note that the word "rarely" is never actually defined. (Once? A hundred times? A thousand times? More? Nobody knows.) These reported symptoms indicate localized or systemic toxin spread (i.e. botulism), a fact that was hinted at in the next sentence:

> "Dysphagia (difficulty swallowing) and symptomatic general weakness may be attributable to an extension of the pharmacology of BOTOX resulting from the spread of

> the toxin outside the injected muscles."

"The pharmacology of BOTOX." Yes, indeed. I believe there is a word for that. Hmm what is it, again? Let me think, hold on, it's on the tip of my tongue…oh, right: Botulism.

Allergan wasn't the only company dancing around the B word, either. In the UK, a rival BoNT product named "Dysport" had recently been approved for the treatment of eye and neck spasms. I couldn't find any original versions of its package insert (and the Wayback Machine got sick of me trying), but the 2024 package insert (which is based on original clinical trial data from the 1990s) states the following:

> "The most commonly reported adverse reactions (occurring in 5% or more of patients who received 500

> Units of DYSPORT® [equivalent to roughly 166 Botox units] in the placebo-controlled clinical trials) in cervical dystonia patients were: muscular weakness, dysphagia, dry mouth, injection site discomfort, fatigue, headache, musculoskeletal pain, dysphonia, injection site pain and eye disorders (consisting of blurred vision, diplopia, and reduced visual acuity and accommodation)."

Although the word "botulism" is never mentioned explicitly, anyone capable of critical thinking can put two and two together and detect the lack of transparency in these package inserts.

It bears repeating. Per their *own* data and admission, almost 30 years ago, the makers of BoNT drugs reported that *at least* 2-5% of their

clinical trial patients were experiencing botulism symptoms in the days and weeks following injection.

What's more, a drug's package insert typically only reveals the data that is required by the FDA, as warning labels are negotiated documents between the FDA and pharmaceutical companies.

As detailed in the illuminating book *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*, many pharmaceutical companies have an unfortunate long-standing habit of throwing out any and all trial data that isn't palatable, so that they can present the "best" version of their product's safety data to the FDA and consumers.

Of course, luckily for Allergan and Ipsen (the original makers of Dysport), hardly anyone reads clinical trial data on package inserts.

Doctors are *just* too busy.

The font is *just* too small.

Right?

Maybe.

Or, perhaps, the dollar signs that began clouding doctors' eyes were *just* too large.

IATROGENIC BOTULISM.

A NEW CLINICAL TERM EMERGES

At the turn of the 21st century, while Alan Scott was deciding what to do with his newfound wealth, and Allergan was seeking FDA-approval for their Botox Cosmetic line, a new clinical term was slowly beginning to surface in the medical literature: iatrogenic botulism.

The term iatrogenic refers to medical conditions that are (unintentionally) caused by physician errors. The other types of botulism known to affect humans are foodborne (when the toxin is ingested), wound (when the toxin enters the body through an open laceration), inhalation (when the toxin is inhaled), intestinal (when toxin is formed by spores in the intestinal tract), and infant botulism (when any of the above types occurs in children under the age of 1).

By the early 20th century, we knew the most common symptoms of foodborne botulism well:

dizziness, nausea, blurry vision, muscle weakness, dry mouth, and difficulty swallowing and breathing.

And by the mid-1990's, we also knew the potential symptoms following BoNT injections:

dizziness, nausea, blurry vision, muscle weakness, dry mouth, and difficulty swallowing and breathing.

Researchers were beginning to confirm the obvious truth from the front lines: people were getting botulism from BoNT injections.

A 2003 article by Beseler-Soto et al. details one such early (and harrowing) case of iatrogenic botulism that occurred in Spain. Their report involves a 6-year-old girl with cerebral palsy who was regularly receiving BoNT injections for muscle spasticity.

The girl began showing signs of botulism, including fatigue, muscle weakness, and difficulty swallowing, after a round of injections, but her doctor did not know or recognize the signs of the illness and assumed she had bronchitis. Thus, she was re-injected six months later, and within days developed severe botulism requiring mechanical ventilation. She tragically died of septic complications six weeks after her ICU admittance.

Imagine. A 6-year-old child with cerebral palsy, incapable of communicating her symptoms, dying slowly in a hospital in the 21st century from one of the most horrific diseases known to mankind, surrounded by doctors who *could not save her*.

What's even more shocking, however, is that hers is not an outlier case.

Since 1990, the FDA has received reports of over 150 children dying after BoNT injections

in the U.S. alone. (This likely represents a very small percentage of actual deaths due to the problem of underreporting, as well as the fact that the FDA grants pharmaceutical companies *the right to erase their submitted reports*.)

From Botox's early days, many children with cerebral palsy and other movement disorders have received injections for muscle spasticity. Upper and lower limb spasticity resulting from cerebral palsy can be painful, and it is not easily managed via conventional medications. For many children with these conditions, BoNT injections help to temporarily reduce or eliminate spasticity. However, these injections clearly do not come without their risks, and because many of these children already suffer from difficulty speaking and swallowing as a result of their underlying disease, any adverse effects they may develop have a high likelihood of going undetected. Many

children with cerebral palsy have *no reliable way to communicate how they are feeling*, and thus likely suffer in silence when experiencing symptoms, with no one the wiser.

In the early 2000s, these injections were an "off-label" (non-FDA approved) use of Botox, as the FDA did not approve Botox for pediatric patients until 2019.

Off-label use of pharmaceuticals is legal, commonplace, and typically left up to a physician's discretion.

What is not legal, however, is the promotion of such off-label uses by pharmaceutical companies.

By the early 2000s, Allergan had gained FDA-approval for Botox for a limited number of uses in adults (eye disorders and cervical dystonia) and then moved on to promote and distribute it for a wide variety of other purposes and populations not yet approved by the FDA

(e.g. your sweaty uncle Steve and children with cerebral palsy). It was a brilliant strategy, and their shareholders must have been thrilled. Until, of course, they got caught red-handed by the Department of Justice.

In 2010, Allergan was ordered to pay $600 million in fines to the federal government for its illegal off-label promotion of Botox. A press release about the investigation from the DOJ's website includes the following details:

> "In 2003, Allergan doubled the size of its reimbursement team to assist doctors in obtaining payment for off-label Botox® injections. Allergan held workshops to teach doctors and their office staffs how to bill for off-label uses, conducted detailed audits of doctors' billing records to demonstrate how they could make

money by injecting Botox®, and operated the Botox® Reimbursement Hotline, which provided a wide array of free on-demand services to doctors for off-label uses. Allergan also lobbied government health care programs to expand coverage for off-label uses, directed physician workshops and dinners focused on off-label uses, paid doctors to attend "advisory boards" promoting off-label uses, and created a purportedly independent online neurotoxin education organization to stimulate increased use of Botox® for off-label indications."

While Allergan was busy teaching doctors how to quadruple their income via off-label uses of their product, parents who had children with cerebral palsy were being offered a new, cutting-edge solution (that was not yet FDA-approved) for their child's muscle spasticity, potentially without knowing about all the risks involved.

GROWING EVIDENCE OF HARM

When the FDA first approved Botox, and later, Botox Cosmetic for the treatment of glabellar lines (the "11s" that pop up on the forehead when we frown), we as public consumers can only wonder about whether or not they knew the drug was capable of causing systemic illness. Whatever their prior knowledge was, they were quickly inundated with the truth.

In the first 15 years that BoNT injections were on the market, the FDA's Adverse Events

Reporting System, "FAERS," which was established to track drug safety data in the real world, received over 1,300 reports of *serious* adverse effects (serious AEs must be life-threatening, disabling, or result in death) and 60 reports of death occurring after Botox and Myobloc (a rival BoNT injection). (As a quick comparison, the FAERS database received reports of 44 serious adverse events and 1 death related to Allergan's other cosmetic injection, the hyaluronic filler Juvederm, in its first 15 years on the market.)

Symptoms like dysphagia (difficulty swallowing), muscle weakness, fatigue, blurry vision, shortness of breath, anxiety, hair loss, and ear disorders make frequent appearances in reports.

An important note to keep in mind when looking at data from FAERS is that even though it is the best system we have, it is still imperfect.

Data collection relies on doctors, or even patients themselves in the case of unwilling or unbelieving doctors, to not only know a reporting system exists, but also to report adverse effects in full. It can be time-consuming and laborious to submit a report, the FDA's website is not exactly user-friendly. Before the internet, it's a wonder how consumers even knew of this system or how to file a report. Most importantly, as mentioned earlier, the FDA grants pharmaceutical companies *the right to edit and delete their previously submitted reports.*

In the pharmacovigilance world (the industry that aims to ensure that side effects from drugs are accurately documented), it has been estimated by Hazell et al. that data from FAERS only represents 2-10% of actual adverse effects that occur, due to the aforementioned obstacles.

Even so, the reports pouring in related to Botox and Myobloc injuries were not slowing down, and the FDA wasn't the only regulating body receiving these reports, either.

In 2007, the European Medicines Agency (the European equivalent of the FDA), issued a warning to its medical communities about the potential that BoNT products had to induce systemic symptoms of botulism. Allergan placed a "Distant Spread of Toxin Effect" warning on their product labels that were sent out to European countries (but didn't bother including this same warning on their American product inserts until they were forced to two years later).

The FDA, after receiving a Public Citizen petition in 2008 demanding that they issue stricter warnings about the risks of BoNT products, finally followed in their European counterpart's footsteps in June of 2009.

They made it mandatory for doctors to give out a medication guide to patients warning of the potential of toxin spread and required Allergan to include its toxin spread warning in American package inserts for Botox. It states:

> "WARNING: DISTANT SPREAD OF TOXIN EFFECT. The effects of BOTOX and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity

> (underlined by author) but symptoms can also occur in adults, particularly in those patients who have an underlying condition that would predispose them to these symptoms.

Again, with the euphemisms: “symptoms consistent with botulinum toxin effects”…as in, botulism? (Just say the B word!)

That same year, the FDA also wrote a letter directly to Allergan. It included the following:

> “Since Botox/Botox Cosmetic (onabotulinumtoxinA) was approved in 1989, we have become aware of information indicating that the use of botulinum toxin products, including Botox/Botox Cosmetic

(onabotulinumtoxinA), has been associated with spread of toxin effects from the site of injection to distant sites causing generalized weakness, resulting in hospitalization and, in some cases, death. We have also received postmarketing reports of patients who had received botulinum toxin injections in the head, neck and shoulder areas having symptoms of dysphagia, ptosis, and difficulty holding their heads up. These symptoms are consistent with the local spread of botulinum toxin. Respiratory problems after botulinum toxin injections have also been reported."

Even though it probably felt like a breath of fresh air for the thousands of iatrogenic botulism sufferers and their families, this "Black Box Warning," as it's called, did not come soon enough. Thousands, if not hundreds of thousands, of consumers were harmed by these products without adequate warning from 1989-2009.

One of those pre-Black Box Warning victims was a doctor named Sharla Helton who, despite being nearly paralyzed for months after receiving cosmetic Botox injections, decided to take action and fight relentlessly to alert the public about the dangers of the drug.

LEGAL WOES BEGIN

In 2006, Sharla Helton was a 42-year-old practicing OB/GYN and the medical director of Lakeside Women's Hospital, which she had founded with her partners in Oklahoma City.

She had tried Botox a few times, and during her third round of injections, she received 50 units from a licensed nurse practitioner, who at the time was working for Allergan, training other clinicians nationwide on how to administer Botox.

Over the course of the next 24-48 hours, Sharla's health began to rapidly deteriorate. She soon found herself completely bed bound on her back, unable to even turn to her side due to extreme muscle weakness and fatigue. Her abilities to breathe and swallow normally were diminishing with each passing hour, and her limbs began experiencing unrelenting nerve pain that she later described as feeling like someone was continuously electrocuting her.

She spent the next few years fighting an uphill battle to regain her strength and ability to breathe, swallow, and walk properly.

In 2008, she made the decision to seek legal counsel and teamed up with attorney Ray Chester from the McGinnis Lochridge Law office in Austin, TX.

Helton's lawsuit against Allergan took place in May of 2010, and through the discovery process, a Pandora's box of extraordinary and damning evidence against the company was opened. One of these documents was a 1994 Botox toxicity study conducted on cynomolgus monkeys, in which 50% of the females in the "high dose" group (16 units per kilogram) were sacrificed due to being in "moribund" (near-death) condition. Two of the three had died of "foreign body (aspiration) pneumonia," which is a known botulism complication. The study concluded that "...the no observed effect level (the amount of toxin given that resulted in no significant adverse effects) for intramuscular BOTOX® administration to cynomolgus

monkeys every two months for one year under conditions of this study was 4 units per kilogram." (The current recommended dose of Botox for lower limb spasticity in children is 4-8 units per kilogram, and dose limits per kilogram are not used at all in cosmetic applications.)

The McGinnis Lochridge Law office also reported after the trial,

> "One disturbing revelation at trial centered around an Allergan-commissioned study by an independent drug safety company known as Biosoteria, Inc. Biosoteria adjudicated 207 adverse event cases, including Dr. Helton's case, as being due to "spread of toxin" -- an Allergan euphemism for botulism. Allergan then made Biosoteria rewrite the report four times until

> the number of adjudicated cases was reduced to 26. Biosoteria's name did not appear on the final report and the original Biosoteria report was never disclosed to the FDA or the public until the jury in the Helton case considered it as part of the evidence at trial."

The jury voted 10-2 in favor of Helton, agreeing that Allergan had acted with negligence in failing to adequately warn its consumers about its product's potential harmful effects. She was awarded $15 million, as she was unable to return to her medical practice due to her long-lasting injuries.

Allergan's response? Their vice-president, Mitchell Brin, can be seen in a deposition video from the trial obtained by a Canadian investigative news show "16x9," available on

Youtube under the title “Worry Lines: Botox Investigation,” in the following exchange:

“Botox doesn’t cause botulism.” -Brin

“But you would agree that it’s possible that you can get the signs and symptoms of botulism from Botox injections?” -Chester

“I think it’s theoretical, possible that you can get some.” -Brin

After the trial, Allergan’s attorney, Vaughn Crawford told local newspaper *The Oklahoman* that Botox’s 2006 product insert included “every known and even remotely possible side effect,” including the possibility of death.

So, in other words: our product doesn’t cause botulism. But, as we’ve already told you, it might injure and kill you from symptoms that “may be attributable to an extension of the pharmacology of BOTOX.”

Make it make sense.

The truly astonishing outcome from Helton's case didn't come from anything that was discussed during the trial, however, but from what *wasn't* discussed afterward.

Her trial and verdict received exactly zero seconds of airtime on any major news networks in the U.S. (NBC, ABC, CBS, NPR, CNN, FOX, etc.). Might this have had anything to do with the fact that we are one of only two countries in the world that allow direct-to-consumer pharmaceutical marketing via TV commercials? I don't know, but it strikes me as very odd that Helton's trial was mostly met with crickets by the large corporations that had the power to reach and warn millions of potential Botox users.

In the subsequent years after Sharla's trial, Ray Chester represented other Botox-injured victims, winning two more cases against Allergan, and settling about a dozen others outside of court. I was able to find only

one major news network (CBS) that wrote about one of these cases, which involved a veteran in Virginia named Douglas Ray, Jr.

SUPERWOMEN

Current medical literature is full of iatrogenic botulism case studies. You could spend a few weeks reading through them (trust me, I did).

One thing that almost all the recent case studies have in common is that they are written by doctors outside of the U.S.

Researchers in countries like China, India, Turkey, Iran, Egypt, Greece, France, Russia, Spain, Germany, and Switzerland have all published lengthy and vital case studies and literature reviews about IB in the past 5-10 years.

On the flip side, you will find *thousands* of articles from American scientists detailing

exciting new and potential therapeutic and cosmetic uses for botulinum toxin injections.

I wonder if America's meager offerings about the downsides of botulinum toxin (and never-ending supply of positive articles) have anything to do with just how thoroughly pharmaceutical companies have infiltrated our medical research institutions.

Many times, research articles studying new uses for drugs are written by ghostwriters who work for pharmaceutical companies, who then pay doctors to slap their names on the studies to make everything look unbiased and authoritative. (For further reading on this topic, I recommend the books *Bad Pharma* by Ben Goldacre, *The Truth About the Drug Companies* by Marcia Angell, and the website PharmedOut by Georgetown University.)

There aren't billions of dollars to be made in documenting and studying botulinum toxin

adverse effects, thus it would likely be difficult to find someone willing to fund such a study in a country whose healthcare system is profit driven.

The only doctor in the U.S. I could find who independently authored detailed case studies of iatrogenic botulism patients within the past 10 years is Dr. Anna Hristova, who was working in Virginia in the early 2000s.

As a neurologist, she offered Botox to patients for various medical purposes and had received extensive training in administering injections from Columbia University.

In 2007, she began using Botox with one of her patients, a veteran named Douglas Ray Jr., to treat his painful hand cramp. In the subsequent days and weeks after his third injection, he developed severe botulism symptoms that indicated the toxin had spread throughout his body and into his brain. He was

placed on life support, requiring around-the-clock care to survive.

Instead of sweeping her patient under a rug, like so many injectors do today, Dr. Hristova went down a completely different path and ended up testifying as an expert witness in Ray's 2011 trial. A federal judge found Allergan (again) guilty of failing to warn consumers about the potential injuries that can occur after Botox injections.

Dr. Hristova published articles in 2012 and 2016 that documented the various disturbing and debilitating neurological symptoms she was witnessing in patients post-BoNT injections. She named this cluster of symptoms "Impaired Neuronal Communication Syndrome," and was one of the first researchers to discuss the effects botulinum toxin could have on the central nervous system (a.k.a. the brain!). Her work was groundbreaking, as she revealed the many

different bodily systems that can be affected by BoNT, as well as the devastating potential the toxin has to cause long-term damage.

In one of her studies, she followed IB patients for years and found that nearly 80% of them had not recovered to their pre-injection health status at the four-year mark.

The “Dr. Hs” as I call them (Helton and Hristova) are my personal heroines in this story. Both of these courageous and whip-smart women weren’t afraid to speak up, risk their reputations, and expose the dangers of one of the most profitable drugs in the world.

They are both an inspiration to all who care deeply about this topic, as well as the broader topic of medical informed consent. On behalf of myself and all of the victims of botulinum toxin injections, know that we are deeply grateful to you both for your bravery and resolute dedication to the truth.

WHERE ARE WE NOW?

Even though many women and men worked tirelessly in the early 2000s to ensure the public was adequately warned about the potential risks of BoNT products, their efforts went largely ignored by the popular press. Twenty years later, the number of iatrogenic botulism sufferers seems to only be multiplying with each passing month.

Today, from a quick Google search, you will find tens of thousands of people gathered in online support groups who, instead of getting any help from their doctors or injectors, rely on answers and advice from fellow victims.

I spent many months as a member in a few of these groups, and can sum up a typical new member post with this fictional example:

"Hey everyone, a couple
weeks ago I had my usual (20-40)

units of Botox in my forehead and crow's feet…I've been getting it for a few years now without any side effects besides headaches. This time, I got dizzy and nauseous immediately after, and my vision became blurry. I'm really worried. I went to the ER and they told me I was fine and that none of this was possible from Botox; they couldn't get me the antitoxin and gave me a benzodiazepine instead. This week I noticed I'm having difficulty swallowing some foods and my mouth and eyes are really dry. My injector stopped responding to my phone calls and I'm really scared. Help! What can I do to get this toxin out of my system?!"

Every time I see a post like this (which is often, as these groups' memberships tend to grow by the hundreds each month), my heart breaks a little bit more.

I know the answer to their question is "pretty much nothing," and that they're in for a rollercoaster ride of new symptoms for the next 3-6 months, at least. After that, their body will likely take another 6-18 months to fully heal, if they're lucky and have mild or moderate symptoms.

If they are suffering from severe botulism symptoms, which can happen from therapeutic *or* cosmetic doses, they could be in for years or decades of healing.

Recovery from iatrogenic botulism is impossible to predict and likely depends on a wide variety of factors. After combing through thousands of sufferers' stories, I've developed my

own theories about what matters in the recovery process; these are all my own educated guesses:

- How many units of toxin spread into the bloodstream (an impossible number to know for sure - each BoNT unit contains millions of molecules of toxin, all of which are all capable of damaging nerve synapses); people can get mild, moderate, or severe botulism from the same 20 units.
- Which nerves the toxin ends up disrupting
- Exposure to any contraindicated drugs/procedures in the weeks post-poisoning
- Age and overall health of the person (the younger you are, the faster and more likely your nerve synapses are to regenerate)

Many of these men and women suffer for months or years without any answers or support from their doctors. Medical practice usually takes about 15-20 years to catch up with research, and thus it's not surprising that in 2025 we're still waiting for most doctors and injectors to be trained in identifying and responding to these cases. (Although, one could reasonably wonder, who would be training these doctors? And what incentive is there for BoNT injectors to become versed in the consequences of their craft?)

Allergan's reminder to "seek medical attention if you're having difficulty breathing, swallowing, or speaking" doesn't really help anyone when the local hospital is unfamiliar with botulism symptoms.

Even when doctors take patients at their word and suspect iatrogenic botulism, they likely won't be able to get their hands on antitoxin.

Hopefully, though, they can at least provide patients with resources and information about the disease.

There is a growing list of medications and procedures that are well-worth avoiding for botulism patients, including anticholinergic drugs, certain antibiotics, SSRIs, pseudoephedrine, “detox” drugs, massage, chiropractic, acupuncture, and many more, due to the possibility of these drugs/procedures have to further toxin spread. A complete list can be found at www.iatrogenicbotulism.com/post/botulism-don-ts.

The “Things to Avoid” list was compiled based on Dr. Hristova’s research, Botox’s own package insert, and my own and others’ experiences living with botulism.

The stories of iatrogenic botulism sufferers vary greatly; some had been receiving

over 150 units for migraines every three months for over 20 years before getting sick; others (like me) fell ill after receiving just 10-12 units *once*. The number of units that people have reported receiving before developing botulism symptoms ranges from as little as 5 to more than 300.

What almost all iatrogenic botulism sufferers do have in common with each other, though, is that they would give up nearly *anything* to go back in time and cancel their injection appointment. The pain from migraines, muscle spasms, and extensive crow's feet pale in comparison to the horrific experience of surviving botulism.

Almost every single victim will tell you that they were not adequately warned about the risks of developing life-altering symptoms from their injections. Because as it turns out, not too many injectors are willing to spell out these risks for paying customers.

Might be bad for business.

Choosing between “do no harm” and “quadruple your income” requires the ethics of a saint, and after all, doctors and nurses are only human, too.

If your injector has not told you what all is possible following a BoNT injection (or does not even know all of the possibilities, because they learned about botulinum toxin from marketing reps, not U.S. military research articles), I am about to spend an entire chapter spelling it out for you.

RISK:BENEFIT RATIO.

NO SOUP (OR ANTI-TOXIN) FOR YOU!

Every drug (pharmaceutical, herbal, party) has a risk:benefit ratio that must be taken into consideration when determining if the drug is worth taking. As someone who was considering receiving cosmetic injections for the first time last year, I naively believed I had done a pretty thorough job of researching the risks.

I had asked around in my social circle about side effects (none of my friends reported any) and read through at least a dozen websites that discussed expected symptoms. I knew I could possibly experience injection site pain and a slight headache, or, in the worst-case scenario, anaphylaxis. I was ready and willing to take on those risks in exchange for the benefits (freezing my crow's feet for 2-3 months).

What went completely undetected by my radar, because everything I read had assured me

it was impossible with an experienced injector and tiny amount of toxin, was the risk of developing iatrogenic botulism.

And here's the thing: I'll be the first to admit that the chances of someone experiencing no (noticeable) adverse effects from a few cosmetic doses of BoNT are actually pretty high. Russian Roulette doesn't harm most of its players, either.

The more important statistical fact is that iatrogenic botulism can and *will* happen, to varying degrees of severity, and it's entirely impossible to know when it will rear its ugly head and what life will look like if it happens to you.

Will you experience transient anxiety, blurry vision, and dizziness that lasts a few months? Or will you be bed bound, unable to work, care for your children, or breathe and eat normally for the next year?

Remember, in the manufacturers' *own* clinical trials (and it seems safe to assume each company employed "expert injectors"), adverse effects indicative of toxin spread (botulism) occurred 2-5% *or more* of the time. Further research has shown that botulism symptoms can occur after someone's 5th, 10th, 20th, or 30th injection, even when they've previously experienced no adverse effects.

The toxin can and will spread whenever it is given the opportunity. It does not discriminate based on sex, gender, race, age, health, income, zip code, or celebrity status.

Toxin spread happens one of three ways:

- through accidental injection into the bloodstream (which can happen even with the most skilled injectors - this is likely what happened in my case, and my doctor had been injecting others AND herself for many years)

- through localized diffusion of the toxin to adjacent muscles (as proven by Dr. Scott's early work and later confirmed in the medical research)
- through a process called "retrograde axonal transport." BoNT can "travel" backwards along nerve synapses from the site of injection into the CNS.

The amount of toxin that can spread systemically varies greatly and seems to be entirely up to fate.

In a 2018 paper by Bai and colleagues, iatrogenic botulism cases were categorized into three different severity levels: mild, moderate, and severe. Mild cases included symptoms like dizziness, fatigue, blurry vision, anxiety, dry mouth, constipation, insomnia, and mild dysphagia. Moderate cases were those that had the aforementioned characteristics, plus the

need for a feeding tube, while severe cases were those that required mechanical ventilation.

The unlucky folks who end up with iatrogenic botulism following injections are in a dire situation. As we have seen, current medical knowledge about botulism is severely limited, and, again, many "mild" symptoms are *subjective* experiences that do not show up on any diagnostic testing available at hospitals. Most importantly, and I cannot stress this enough, there are *no readily available treatments* for botulism. There is no "botulism remedy" pill or liquid available at your local pharmacy. There is no treatment at your doctor's office or in any hospital's emergency department. The only treatment available is botulism antitoxin, which cannot undo damage that is already inflicted on the body, but can only prevent further damage from occurring. This antidote is guardedly held by the CDC in Atlanta, GA, and stockpiled in just

three other states (California, Colorado, and Alaska). It is government property that is not for sale; it is only distributed at the discretion of the CDC in collaboration with your state's health department. Good luck getting it quickly (or at all) if you're not Kardashian-level famous or suffering from life-threatening respiratory weakness.

"Detox protocols" from holistic practitioners, that include things like chlorella supplementation, liver cleanses, and hyperbaric oxygen treatment have reportedly caused a worsening of symptoms for many people. Unfortunately, well-meaning alternative medicine practitioners have inadvertently harmed botulism patients more while trying to help them.

The only "cure" for iatrogenic botulism is suffering through the (terrifying and debilitating) symptoms while your body does its best to heal

for many months, and possibly, years, from *the most lethal poison on the planet*. In severe cases, botulism can leave its victims with permanent damage.

Lest there be any confusion at this point, adverse effects from BoNT injections are not your average pharmaceutical side effects, such as transient headaches or nausea.

Because botulinum toxin, once in the bloodstream, attacks our most important brain and body functions, it renders many of its victims incapable of participating in life as they knew it for lengthy periods of time.

Iatrogenic botulism *is* botulism. The toxin is agnostic; it does not care how it enters the body, and thus carries the same potential to cause the long-term sequelae and damage seen in foodborne botulism victims.

Because the excruciating details of this disease seem to have been erased from most

medical textbooks sometime in the late 20th century, it is imperative that they are spelled out, for patients and physicians alike.

Consumers (and their injectors) must be aware of what exactly is at risk every time they go under the syringe.

Here are a few things to keep in mind as you read through the below list of known botulism symptoms that can occur after BoNT injections:

- All of the information presented below was obtained from the package inserts across all botulinum toxin brands, as well as post-marketing data via the FDA post-marketing surveillance system FAERS, unless stated otherwise.
- Different injection sites carry different risk profiles (e.g.: the risk of

speaking and swallowing difficulties is much higher when BoNT is injected into the neck vs. the legs or forehead, due to the possibility of localized toxin spread.) The percentages I have laid out reflect this wide range of risk, and they will not be the same for each injection site.

- As you're reading through these symptoms, I want you to imagine suffering from each of them continuously for *months* or *years*. Not hours, not days, not weeks. *24/7 for months and years.* The manufacturers are not required to conduct trials that last beyond 12 weeks and thus can honestly say "we don't know" when asked how long their drug's adverse effects last. We

only have a few studies of long-term outcomes of botulism patients. In one study by Gottlieb et al. that looked at 217 people who were 7-years post foodborne botulism poisoning, the botulism group was much more likely than the placebo group to report fatigue, weakness, dizziness, dry mouth, and difficulty lifting objects. Additionally, in a 1981 study by Jonathan Mann and colleagues, they found that up to 58% of “moderate” botulism patients reported having lingering symptoms at 24 months post-poisoning, including weakness/fatigue, shortness of breath, and dry mouth. Severe cases fared much worse. 69% of respondents in a University College London survey reported

suffering from long-term adverse effects post-BoNT injections.

- In addition to suffering from symptoms for months or years, botulism patients typically suffer from 5, 10, 15, or more symptoms at the same time. I personally had about 10 symptoms total that would come and go for months, and I experienced about 4-5 simultaneously in any given day for the first three months post-poisoning.
- Even the best data we have is likely not accounting for all of the adverse effects being experienced in the real world. Beyond the fact that many doctors and injectors are not aware of Botox's adverse effects, sometimes patients themselves do not even realize that their health issues are

being caused by their injections, especially if they are long-time users of the drug. Which ER doctors are asking “Hey, did you happen to just get Botox?” to heart attack patients? Misdiagnoses and under-diagnosis will likely continue to plague the world of iatrogenic botulism due to the lack of awareness about the condition and readily available, accurate testing.

Okay. (Gets down from soapbox). I’ll let the data speak for itself now.

COMMON BOTULINUM TOXIN

ADVERSE EFFECTS

(1-20% or more of trial participants across all brands and injection locations)

Dizziness and nausea

Both dizziness and nausea are hallmark symptoms of botulism poisoning. These symptoms can last hours, days, weeks, or in some cases, can come and go for many months.

Headache and flu-like symptoms

These symptoms are typically more short-lived and transient; however they can indicate toxin spread. Why would someone experience flu-like symptoms (which typically signal that the body is under attack by a foreign body) after being injected with BoNT around the eye area? I'm no doctor, but to me, the answer seems pretty clear: the body does not like being poisoned.

Vision Impairments

Blurry vision is a hallmark botulism symptom that was first documented in the 1800's and affected nearly 80% of patients in Bai et al.'s

study of 86 iatrogenic botulism cases. It is typically an early sign of botulism poisoning. Vision impairments from BoNT (including double vision, mistiness, and floaters, among others) can last days, weeks, months, or in severe cases, years.

Anxiety and/or panic attacks

Listed as a "very common" side effect on Drugs.com's side effect profile for Botox, anxiety (often described as "panic attacks" or "fight or flight" feelings by sufferers) after toxin spread can last for weeks or months. The attacks can be disabling and unrelenting, and are likely due to parasympathetic nervous system disruption. I personally could not work for two months after my injections while I was experiencing daily anxiety attacks, before they (thankfully) ended abruptly, seemingly out of nowhere.

Muscle weakness

A very common side effect, muscle weakness can also occur anywhere in the body when the toxin spreads. I personally suffered from neck muscle weakness, and subsequent difficulty holding my head up, in the early months of my illness (I was injected around the eyes).

Dysphagia (difficulty swallowing)

In cervical dystonia patients, the chance of developing dysphagia is about 15-25% per injection across all BoNT brands. For all other injection locations, including cosmetic doses, dysphagia risk is around 1-5%, and it indicates toxin spread to the cranial nerves that are involved in swallowing. In addition to pharyngeal muscles becoming weak or paralyzed, saliva production and the muscles of the tongue can also be affected by botulism, making solid food difficult to chew and swallow. Lastly, the

peristaltic muscle movement of the esophagus can be affected, which can result in an uncomfortable feeling of "globus" (food feeling stuck) for hours after eating, a sensation that was first reported by Stanford's Dr. Wilbur in 1913 (see Chapter 1).

Dyspnea (difficulty breathing)

Respiratory distress is a common symptom of botulism, as botulinum toxin can affect the diaphragmatic muscles involved in breathing, and, possibly, the respiratory control signals from the brainstem. In one study, IB sufferers reported the following feelings: "not being able to take a deep breath," "involuntary arrest of breathing for several seconds," and "need(ing) to constantly remind the self to breathe." I personally suffered from the involuntary arrest of breathing for seconds at a time, and the need to remind myself to breathe on a few occasions.

Needless to say, these sensations were absolutely terrifying.

*It is important to note that there is typically *nothing* a hospital can do for people experiencing BoNT-induced respiratory distress. Oxygen levels almost always remain normal (unless there is complete paralysis of the diaphragm) because patients are not suffering from a lung condition that would affect oxygen uptake. In decades past, respiratory failure and death due to paralysis of diaphragmatic muscles from botulism could happen within 30-60 seconds of normal oxygen readings. Breathing difficulties can severely affect a person's quality of life, and last for months or years.

Fatigue

A very common symptom of foodborne and iatrogenic botulism, fatigue can be all-consuming in the initial months

post-poisoning (just 12 units ONCE was enough to keep me on the couch for most of the day for 2 months). Severe botulism typically leaves sufferers with fatigue after moderate exertion for many years.

Dysarthria (slurred speech)

When the muscles of the tongue are weakened or paralyzed due to toxin spread, slurred, imprecise speech articulation can occur alongside swallowing difficulties.

Dry mouth/throat

When the toxin spreads into the autonomic nervous system (which regulates saliva production), one common symptom is a very dry mouth and throat, which can lead to difficulty swallowing solid foods (I was unable to consume solid foods without severe discomfort for 7 weeks due to lack of saliva). In Xeomin's clinical

trials, dry mouth occurred in 16% of the treatment group (vs. 3% of the placebo group) for blepharospasm (eye spasm) injections. Why would 16% of people injected around the eyes suffer from dry mouth? There is only one answer: toxin spread. Dry mouth is a botulism symptom that can last for many months and years.

UTIs and urinary retention

These are more common in patients who are receiving BoNT for an overactive bladder, but they have also been reported in other cases when toxin spread is systemic (24% of respondents in a UCL survey reported UTIs post-BoNT injections). The current clinical trial rates for UTIs after Botox injections for overactive bladder are around 18% (versus 6% in the placebo group).

LESS COMMON ADVERSE EFFECTS

(.1-1% of trial participants)

Dysphonia (hoarse voice)

This symptom can also be a result of the toxin spreading into the vagus nerve (which controls the movements of the larynx/voice box). A hoarse voice can be caused by inflammation or weakness/paralysis of one or both of the vocal cords (the muscles that vibrate when you talk and can be felt by pressing your hand gently against your neck while you vocalize.)

Nerve pain, paresthesia ("pins and needles"), and burning sensations

These uncomfortable sensations can last for months, or come and go for years, making life a living hell. Nerve pain and paresthesia can occur anywhere, but typically occur in the limbs.

Burning sensations have been reported on the head and face, and in the mouth.

Diarrhea and vomiting

'Nuff said.

Insomnia

Another known effect that is likely due to parasympathetic nervous system disruption, insomnia occurred in 38% of IB sufferers in Bai et al.'s study. "Trouble sleeping" is listed on Drugs.com's list of Botox side effects. The insomnia I suffered from for the first three months post-poisoning was like nothing I've ever experienced. I've always been a 10-hours-a-night kinda girl (seriously, it annoys the crap out of my husband). In the three months following my poisoning, I was lucky if I fell asleep by 3 AM, and even then, I only slept for 2-3 hours at the most.

UNKNOWN INCIDENCE OF OCCURENCE

(nobody knows)

Constipation/Gastroparesis

Severe constipation or gastroparesis can occur when the muscles of the intestines that push our food through are weakened or paralyzed by toxin spread.

Ear congestion, tinnitus (ringing in the ears), and other ear disorders and pain

Ear disorders can be present due to disruption of the autonomic nervous system or the cranial nerves that innervate ear muscles. Ear congestion (that feeling of the ears being "clogged" - I personally suffered from this for about 4 months straight) and tinnitus are the most common effects experienced. Sudden

onset of deafness in one or both ears is listed in hundreds of FAERS reports.

Strabismus, Blepharospasm, and other eye disorders

Quelle ironie! Just two of the many examples (others including headache/migraines, nerve pain, and TMJ pain) where BoNT injections can actually cause the same symptoms that they suppsedly "treat". Oy.

Swollen glands

Swollen glands in the neck and near injection sites have been reported after BoNT injections, and indicate that the toxin may have spread into the lymph system.

Heart arrhythmias, chest pain, and cardiac arrest (heart attack)

The potential for arrhythmias and fatal heart attacks are warned about on all BoNT package inserts. We know from past literature that heart attacks (in addition to respiratory distress and aspiration pneumonia) are one of the most frequent causes of death by botulism.

Alopecia (hair loss) and madarosis (loss of eyebrows and eyelashes)

First documented in the medical literature in 2016, hair loss, particularly in the frontal hairline can occur after BoNT injections. In rare cases, loss of eyebrows and eyelashes can occur as well. Sadly, I lost about half of my hair in the first 3-4 months post-injections. This symptom, more than anything else, is probably what kept me going when writing this book. You don't take away half of a silver sister's hair without some kind of backlash.

Pruritus

Itchy skin has been reported as a persistent symptom after toxin spread.

Appetite/weight loss

Many botulism victims ultimately lose a significant amount of weight in the initial months after poisoning. This can sometimes be due to needing to consume an altered diet when the muscles involved in swallowing are impaired, however it can also occur when the parasympathetic nervous system is disrupted, leading to a constant “fight or flight” state in the body. Many IB sufferers report having no appetite for the first few months of their poisoning. I personally lost 20 pounds in the first 2 months after I was poisoned due to a complete lack of appetite and swallowing difficulties.

Psychiatric conditions, including depression, derealization, and suicidal ideation

First described in Hristova's study, IB sufferers have reported severe and persistent psychiatric conditions, including depression, derealization, depersonalization (a frightening mental state where a person feels like they are detached from and floating above their own body), and even suicidal ideation, in the weeks and months post-BoNT injections. Tragically, lives have been lost to suicide.

Cognitive impairments, including brain fog, disorganization, slow processing speed, and short-term memory loss

Just in the past 10 years, researchers have discovered that BoNT can and does cross the blood-brain barrier, with the potential to block other neurotransmitters, such as glutamate, GABA, and dopamine, that are involved in

cognitive processes, such as memory, attention/concentration, organization, and word-finding, among many others.

A video clip that made the rounds on social media last year showed Jean Carruthers, the ophthalmologist who pioneered the use of Botox for cosmetic purposes, at the 2024 American Society for Dermatologic Surgery conference excitedly explaining,

> "It (Botox) has this wonderful side effect that it actually doesn't stay in the skin. We know now that it goes back into the brain. And it goes into the area of the anterior inferior end of the temporal gyrus, which is the area that we deal with pain and discomfort and anxiety. And so what happens two weeks after, if you do a functional MRI (fMRI) of a person

> before you do the neuromodulator (neuromodulator is the industry's shiny new word for neuro*toxin*, a.k.a., Botox) treatment… and then you do this fMRI again a couple of weeks after, you can show it (the inferior temporal gyrus) just turns off."

This is all presented as an amazing new discovery and potential treatment for depression.

And guys, Jean is totally right: attempting to fix mental health issues by having an ophthalmologist or dermatologist inject you in the forehead with the world's most lethal poison in the hopes that it will travel back along your neural pathways into your brain and block essential cognitive functioning IS an excellent idea.

No?

It's not?

Why not?

What's wrong?

C'mon now, you don't want your "anterior inferior" temporal gyrus turned off?? (Your inferior temporal gyrus is only involved in the processes of visual/facial recognition, semantic processing, and emotional regulation…you don't need all that stuff!)

Ugh, you're no fun!

(Side note: if you are struggling with mental health issues, please seek advice from a qualified psychologist or psychiatrist, NOT an ophthalmologist on Allergan's payroll who is pretending to understand neuroscience.)

My list of BoNT adverse effects is (somehow) not a comprehensive one. Because this neurotoxin has the ability to disrupt multiple neurotransmitters and neuromodulators, it can

affect nearly all our bodily functions depending on which nerves it finds and attaches to once it spreads.

Beyond all the risks outlined above, IB sufferers have also reported new onsets of histamine intolerances, autoimmune diseases, thyroid issues, MCAS, POTS, and even neurodegenerative diseases in the weeks following their injections.

If this list was not enough for you, I recommend either accessing the FAERS database, or reading through Dr. Hristova's studies, which are both listed in the References section for this chapter

Okay, now that I've laid out the risks, let's talk about the benefits. Our ratio wouldn't be complete without a bottom number.

BOTULINUM TOXIN BENEFITS

(Occurring in 90-100% of trial patients)

Facial muscles are paralyzed for 2-4 months at a time (although mine were only paralyzed for 6 weeks, so I want my money back!), resulting in smoother skin that must continue to be injected 4 times a year for the desired results to remain.

Okay, so that's a total of 30-something risks and one benefit for cosmetic use, but what about medical uses for BoNT?

With the potential medical uses for BoNT growing rapidly year-by-year (every muscle is a market!), it's worth discussing a few of the most frequent ones.

First, I personally consider BoNT injections for hypersalivation, excessive sweating, and even weight loss, as "cosmetic," not therapeutic, uses. These are all conditions that can be medically managed without risking botulism.

When BoNT injections are used for migraines, TMJ, or other pain mitigation, they are only masking pain temporarily (and according to their own clinical trials, not doing that great of a job at it compared to saline placebo injections).

BoNT (and most of modern medicine) does not look for, find, or treat the root cause of pain, and thus if you use it to "cure" your pain, you will likely need to continue injections every three months ($$$). You will never actually heal from your pain, and you will be risking the chance of developing botulism each time you're injected.

Muscle spasms and dystonias, in my opinion, are some of the only uses of BoNT that carry the potential to truly help people. I personally would never choose to use BoNT therapeutically, but I have also never walked in the shoes of someone with cerebral palsy,

multiple sclerosis, or any other neurological condition that causes uncomfortable muscle spasms or tremors.

I respect the right everyone has to make their own informed medical decisions and take no issue with *fully informed and consenting* adult patients who are provided with data from the drug's clinical trials choosing to receive these injections.

Medicine (and much of life) is a series of risk/benefit analyses, and thankfully, we all have the right to make our own medical decisions. I always tell my swallowing patients that I am not the "diet police," and that my role (like other medical professionals) is to educate and inform, not dictate and decide.

I just don't want to see any of you in the botulism support groups one day, okay?

CONCLUSION.

My mother is and always has been the most beautiful woman I've ever met.

Despite going through an awful 80s hair phase and rocking a Willy Wonka bob (Johnny Depp, not Gene Wilder) throughout my childhood, she was my beauty muse, and there was no one I held in higher regard than her.

When I was growing up, her bathroom makeup drawer consisted of exactly two shades of Mary Kay lipstick (hot pink and candy apple red - duh, it was the 80s!), a cream blush palette, and a dried out 10-year-old tube of mascara that was reserved for special occasions.

I don't remember her ever getting a massage or facial (she claims she's had two), let alone any cosmetic injections. She was never "religious" about wearing sunscreen (she didn't own any, **gasp**) or completing a 5-step nightly

skincare routine. She was no diva, but to me, she was a goddess.

She was confident in her own skin, and while she always looked put together and attractive, she was never overly concerned with her physical appearance. Her version of beauty, including an indifferent approach to makeup and total acceptance of her wrinkly, aging face the way the good Lord made it, is a far cry from the artificially smoothed-out, grossly unrealistic images of women that are glorified today.

The desire to look younger and more attractive is nothing new, of course, and I'm not here to argue that it's shameful or for simpletons, either. It's in our DNA, and we're all just hairless apes running around with our giant egos in tow.

My mom in 2009, rocking the banged bob, patiently waiting out the 40 years it would take to cycle back into style.

I'm not above these desires and I won't pretend to be; I, too, like to look good for my hairless ape mate (and trust me, I looked a helluva lot better before I lost half of my hair to botulism).

I just think that as women we were doing a perfectly fine job of looking good and aging

with grace without risking our health until cosmetic injections came onto the beauty scene.

From day one, the makers of these products have proven themselves to be all-too-eager to capitalize on our deep-rooted primal insecurities.

Want youthful, wrinkle-free skin like those airbrushed celebrities you see on TV? Whatever you do, don't *think about the impossible beauty standards we created that led you to obsess over your face in the first place… just pay us inordinate amounts of money to "prevent" and "fix" your imperfections with our products!*

Their nauseatingly pervasive magazine advertisements and social media sponcon leave many women feeling like the grass must be greener on the other side of a syringe.

Botox and its wannabes promise a seductive, previously unimaginable result of nearly-wrinkle-free skin for life if you just start

early enough (in your 20's, of course!), and are able to afford the small, humble price tag of a few hundred dollars every three months 'til you're six feet under.

Look, even though I could, I'm not going to do my whole spiel about how women are beautiful just the way they are, or how what really matters is what's on the inside, and blah blah blah. I would just be telling you things you already know. You *know* deep down that nobody who truly cares about you has ever been interested in the quantity or depth of your wrinkles.

Cosmetic procedures like Botox are something we do for *ourselves*, or for the eyes of other women, and again, I'm not trying to persuade you to completely stop caring about the way you look.

What I do hope I've encouraged you to do is reconsider exactly which risks you're willing to

take to achieve your personal ideal of attractiveness.

If you're like me, and you have children to care for, a job to keep, or a life to live beyond your couch, then BoNT's risk profile, with its potentially life-altering, long-lasting adverse effects, is simply never worth the short-lived benefits.

Since 1990, the FDA has received over 14,600 serious (life-threatening) adverse events and 2,000 death reports following BoNT injections. Multiple these figures by 50 and you probably have the real numbers (730,000 serious AEs and 100,000 deaths).

However small the risk, do you really want to be the person who is hospitalized or *dies* after their cosmetic injections?!

Not me.

May we all take a page from my mom's beauty playbook and give a few less shits about

our wrinkles (or, at least find ways to minimize them that don't involve the risk of *botulism*).

Smooth foreheads do not make people more content or confident, intelligent or interesting, loving or loveable. No one will remember if yours had 3, 5, 7, or (creepily) 0 creases when you were excited to see them.

Plus, as any one of us IB survivors will tell you, wrinkles feel *much* better than botulism.

POST-SCRIPT FOR THOSE NOT YET CONVINCED TO GIVE UP THEIR TOX

For those of you who still believe you'll make it out of your 4-times-a-year tox injections for the next two decades healthy as an ox, may I humbly remind you of the following:

For at least 20 years, the makers of BoNT injections have been receiving reports about their products *injuring and killing children with disabilities* via the torturous and terrifying symptoms of botulism. Since business has continued as usual, I'm not convinced they care.

I don't know about you, but I refuse to give a single cent to companies that may believe the short-lived benefits of their drug outweigh the risk of further disabling some of the most vulnerable people on Earth.

If you agree, then come and join me in the #notox movement.

Bring your friends and your Frownies.

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