

September 7, 2022

Andy Jassy, President and CEO  
David Zaplosky, Esq., Senior VP and General Counsel  
Amazon.com, Inc.  
2021 7<sup>th</sup> Ave.  
Seattle, WA 98121-2601  
*By email and USPS*

Re: Amazon.com's prohibited distribution of unapproved homeopathic drugs

Dear Messrs. Jassy and Zaplosky:

We write to you on behalf of the Center for Inquiry, Inc. (CFI), a national nonprofit organization dedicated to the promotion of science, reason, freedom of inquiry and humanist values. CFI has long worked to battle the ills of pseudoscience, quackery and all forms of confidence schemes that are intended to defraud the vulnerable, unknowing and ill-informed. Healthcare fraud and the resultant harms wrought by ineffective products sold as alternatives to medicine is of particular concern.

Despite unambiguous legal prohibitions, and in contravention of its own policies, Amazon sells thousands of homeopathic drugs—not one of which has been approved by the FDA in regards to its safety or effectiveness. A significant number of the prohibited products are explicitly intended to be used as treatments for ill and injured babies, infants and children. Amazon has both a legal and moral obligation to immediately cease the trade in these harmful, prohibited items.

### **Background**

The U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) recently issued a Warning Letter to Amazon.com, Inc. (Amazon).<sup>1</sup> The warning details Amazon's distribution of prohibited products in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301, *et seq.*

The products for which Amazon was warned are intended to be used for mole and skin tag removal. Because the items are intended to cure, mitigate, treat or prevent health issues, the products are “drugs” under the FDCA. Therefore, before they were introduced into commerce, the drugs were required to obtain FDA approval. As CDER's Office of Unapproved Drugs and Labeling Compliance made clear to Amazon, the products were not approved. In fact, the agency continued, “[t]here are no over-the-counter (OTC) drugs that can be legally sold for mole or skin tag removal.” Accordingly, Amazon's trade in the unapproved drug products is prohibited by federal law.

---

<sup>1</sup> Warning Letter MARCS-CMS 629452, August 4, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/amazoncom-inc-629452-08042022>.

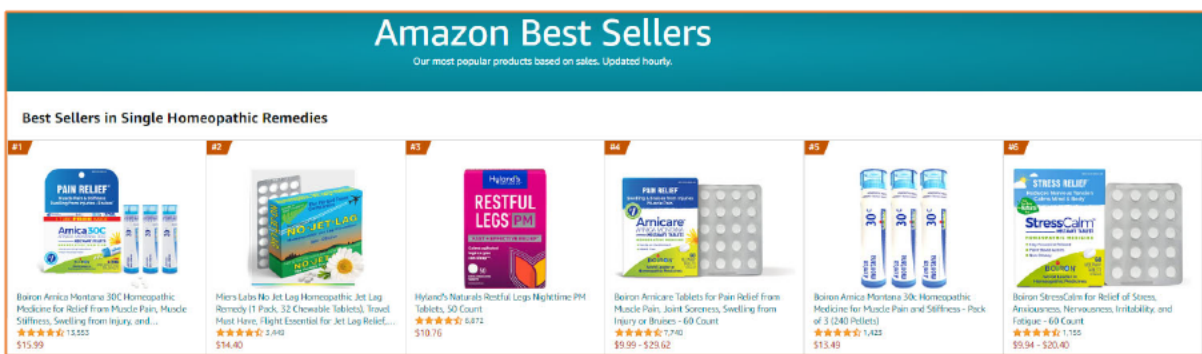
## Amazon Regularly Trades in Prohibited Products

Consumers place great trust in Amazon when they search for medicine to treat illness and injury; they must not be readily exposed to the harms of unsafe and unproven products. While CFI welcomes the action taken by CDER, and we anticipate Amazon will quickly remove all similar unapproved mole and skin tag products,<sup>2</sup> these items are a tiny portion of the multitude of unapproved drugs currently offered, sold and shipped by Amazon.

These violations, and Amazon's regular trade in unapproved drugs, typify our concerns about the company's continuous and demonstrable failure to protect its customers from the harms of pseudoscientific snake oil products. Amazon regularly disregards federal and state laws,<sup>3</sup> as well as its own policies, all while putting at risk the health, safety and welfare of the most vulnerable: babies, infants and children.

### No homeopathic drugs sold by Amazon are approved as safe or effective.

Amazon's trade in "homeopathic medicine," as evidenced by thousands upon thousands of different homeopathic products offered for sale, is substantial. In just one section of Amazon's Health Care Products Department, "Single Homeopathic Remedies," there are more than 4,000 product results.<sup>4</sup> There, Amazon gathers, ranks and advertises to consumers the section's best sellers:



**Amazon Best Sellers**  
Our most popular products based on sales. Updated hourly.

**Best Sellers in Single Homeopathic Remedies**

Rank	Product Name	Price
#1	Baion Amica Montana 30C Homeopathic Medicine for Relief from Muscle Pain, Muscle Stiffness, Swelling from Injury, and...	\$15.99
#2	Miers Lulu No Jet Lay Homeopathic Jet Lay Remedy (1 Pack, 32 Chewable Tablets), Travel Must Have, Flight Essential for Jet Lag Relief...	\$14.40
#3	Hyland's Natural Restful Legs Nighttime PM Tablets, 50 Count	\$10.76
#4	Baion Amica Montana 30C Homeopathic Medicine for Muscle Pain, Joint Stiffness, Swelling from Injury or Bruises - 60 Count	\$9.99 - \$29.62
#5	Baion Amica Montana 30C Homeopathic Medicine for Muscle Pain and Stiffness - Pack of 3 (240 Pellets)	\$13.49
#6	Baion StressCalm for Relief of Stress, Anxiousness, Nervousness, Irritability, and Fatigue - 60 Count	\$15.94 - \$20.40

<sup>2</sup> A search for "skin tag remover" returned multiple results for items still available on Amazon's website. See, e.g., Skin Tag Remover, Effective and Suitable for Face and Body, <https://www.amazon.com/Skin-Remover-Effective-Suitable-Face/dp/B0B3DQCTLY> (last visited Aug. 26, 2022).

<sup>3</sup> In addition to the FDCA, the marketing of homeopathic products described below contravenes the Federal Trade Commission Act, 15 U.S.C. §§ 41, *et seq.* Each offending product contains claims it is able to prevent, treat, or cure human disease. The truthfulness of these claims, at the time they are made, must be substantiated as true through the use of competent and reliable scientific evidence—including, when appropriate, well-controlled human clinical studies. No such evidence exists nor can it.

<sup>4</sup> 1-24 of over 4,000 results for "Single Homeopathic Remedies," [https://www.amazon.com/b?node=3767781&ref=sr\\_nr\\_n\\_10](https://www.amazon.com/b?node=3767781&ref=sr_nr_n_10) (last visited Aug. 26, 2022).

<sup>5</sup> Best Sellers in Single Homeopathic Remedies, [https://www.amazon.com/gp/bestsellers/hpc/3767781/ref=zg\\_b\\_bs\\_3767781\\_1](https://www.amazon.com/gp/bestsellers/hpc/3767781/ref=zg_b_bs_3767781_1) (showing #1 to #6 of top 100) (last visited Aug. 26, 2022).



Collectively, these products claim to effectively treat, cure, mitigate or prevent myriad conditions, including:

- Nerve Pain
- Bone Trauma
- Polyps, Tubercles and Warts
- Surgical Wounds
- Fibroids and Ovarian Cysts
- Muscle Pain and Swelling
- Fever
- Cradle Cap
- Hemorrhoids
- Skin Eruptions
- Diarrhea with Vomiting and Weakness
- Sore Throat
- Skin Rash
- Nervousness, Sleeplessness in Children
- Motion Sickness
- Runny Nose, Congestion, Sinus Pressure, Headache
- Canker Sores
- Bloating and Lower Back Pain during Menstruation
- Hay Fever
- Hives
- Fatigue
- Restless Legs, Leg Cramps, and Shooting Pain

No matter the varying “active ingredients” or wide array of claims, each and every homeopathic product listed on Amazon.com shares at least two characteristics—each product lacks any competent scientific evidence to support its claims; each product is an unapproved drug, not officially determined to be either safe or effective.

To be certain, FDA unambiguously states that,

“[t]here are **no FDA-approved products labeled as homeopathic**; this means that any product labeled as homeopathic is being **marketed in the U.S. without FDA evaluation for safety or effectiveness**. . . [H]omeopathic drug products have not been approved by FDA for any use, [and] they may **not meet modern standards for safety, effectiveness, and quality**.”<sup>6</sup>

Therefore, just as with the unapproved mole and skin tag removal products, Amazon’s marketing, sale and fulfillment of orders of unapproved homeopathic drugs violates the FDCA; it must cease.

In addition to running afoul of clear legal prohibitions, offering unapproved homeopathic drugs for sale violates Amazon policies. Amazon requires that “[p]roducts offered for sale on Amazon must comply with all laws and regulations and with Amazon’s policies.”<sup>7</sup> That the FDCA prohibits sale of the products is sufficient to violate this policy. In addition, however, the company’s “restricted products policy” explicitly states that, “[d]rug products must be approved by the FDA for over-the-counter (OTC) sale.”<sup>8</sup> As no homeopathic drug is approved by FDA, each item offered is a restricted product and should not be permitted to be listed on Amazon.com.

<sup>6</sup> U.S. Food & Drug Administration, Homeopathic Products, <https://www.fda.gov/drugs/information-drug-class/homeopathic-products> (emphasis added) (last visited Aug. 26, 2022).

<sup>7</sup> Amazon Seller Central, Restricted products, <https://sellercentral.amazon.com/help/hub/reference/external/G200164330?locale=en-US> (last visited Aug. 26, 2022).

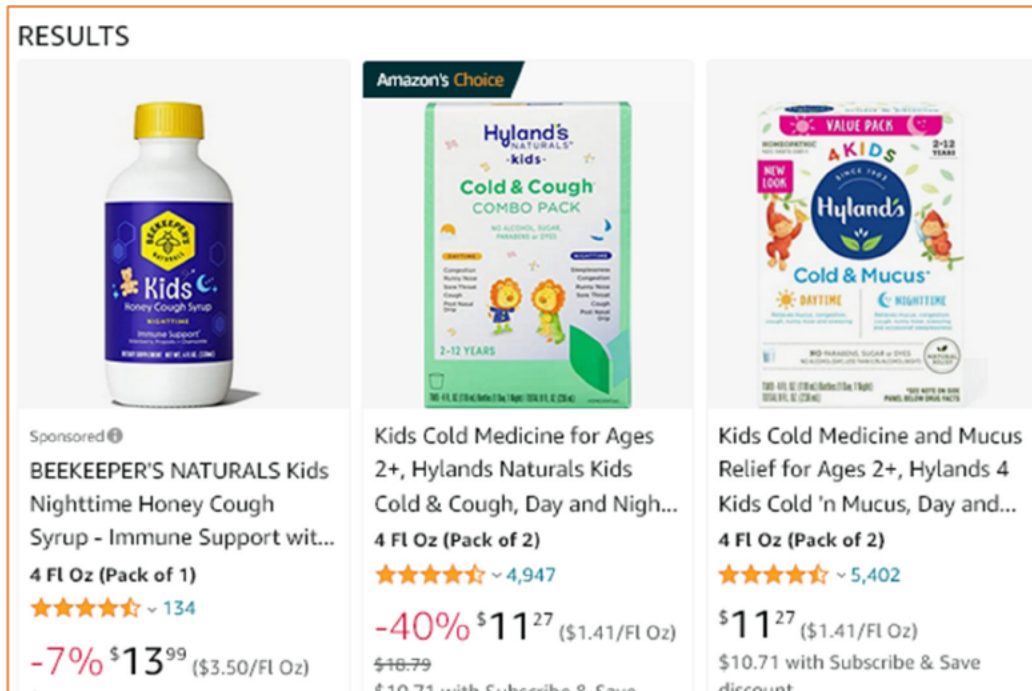
<sup>8</sup> Amazon Seller Central, Drugs & drug paraphernalia, <https://sellercentral.amazon.com/help/hub/reference/external/G200164490?locale=en-US> (last visited Aug. 26, 2022).

Amazon recommends unapproved homeopathic drugs for babies, infants and children.

While Amazon works to address the overall problem of prohibited sales, we call the company's attention to a category of drugs that requires immediate attention and decisive action:

Homeopathic products marketed as Baby, Infant and Children's Medicine

When a parent or guardian, worried and caring for a sick child, searches for "cold and cough medicine for kids," Amazon shows:



**RESULTS**

**Sponsored**

**BEEKEEPER'S NATURALS Kids Nighttime Honey Cough Syrup - Immune Support wit...**  
 4 Fl Oz (Pack of 1)  
 ★★★★★ ~ 134  
 -7% \$13<sup>99</sup> (\$3.50/Fl Oz)

**Amazon's Choice**

**Kids Cold Medicine for Ages 2+, Hylands Naturals Kids Cold & Cough, Day and Nigh...**  
 4 Fl Oz (Pack of 2)  
 ★★★★★ ~ 4,947  
 -40% \$11<sup>27</sup> (\$1.41/Fl Oz)  
 \$10.71 with Subscribe & Save

**Kids Cold Medicine and Mucus Relief for Ages 2+, Hylands 4 Kids Cold 'n Mucus, Day and...**  
 4 Fl Oz (Pack of 2)  
 ★★★★★ ~ 5,402  
 \$11<sup>27</sup> (\$1.41/Fl Oz)  
 \$10.71 with Subscribe & Save discount

The first (non-sponsored) result, "Kids Cold Medicine for Ages 2+, Hyland's Naturals Kids Cold & Cough," is sold and shipped by Amazon. The product is intended to treat, cure and mitigate a child's "cough, runny nose, sneezing, nasal and chest congestion and sore throat with accompanying sleeplessness."<sup>10</sup> Consumers are assured that the product is:

**Amazon's Choice** for "cold and cough medicine for kids"

11

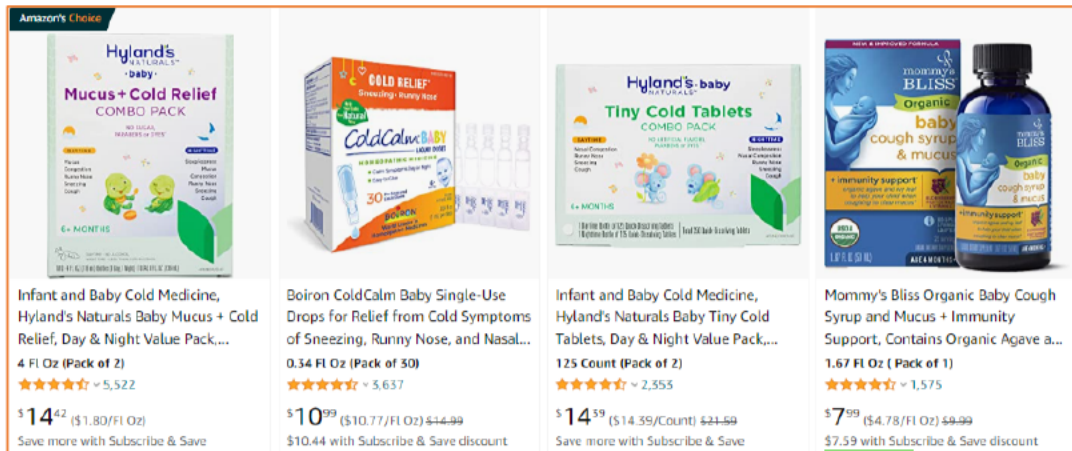
<sup>9</sup> 1-48 of 392 results for "cold and cough medicine for kids", [https://www.amazon.com/s?k=cold+and+cough+medicine+for+kids&prefix=cold+and+cou%2Caps%2C84&ref=nb\\_sb\\_ss\\_ts-doa-p\\_3\\_12](https://www.amazon.com/s?k=cold+and+cough+medicine+for+kids&prefix=cold+and+cou%2Caps%2C84&ref=nb_sb_ss_ts-doa-p_3_12) (last visited Aug. 26, 2022).

<sup>10</sup> *Id.*

<sup>11</sup> Kids Cold Medicine for Ages 2+, Hylands Naturals Kids Cold & Cough, Day and Night Combo Pack, Syrup Cough Medicine for Kids, Nasal Decongestant, Allergy Relief, 4 Fl Oz Each, <https://www.amazon.com/Hylands-Natural-Common-Symptom-Relief/dp/B00L3LAK7S/ref=>



When searching for “baby cold medicine,” the parent or guardian is shown:



The screenshot shows four Amazon product listings for baby cold medicine. Each listing includes the product name, a brief description, the number of items in the pack, the price, and the number of reviews. The products are: Hyland's Baby Mucus + Cold Relief (4 Fl Oz, \$14.42), Boiron ColdCalm Baby (0.34 Fl Oz, \$10.99), Hyland's Baby Tiny Cold Tablets (125 Count, \$14.59), and Mommy's Bliss Organic Baby Cough Syrup (1.67 Fl Oz, \$7.99).

12

The first product, “Hyland's Naturals Baby Mucus + Cold Relief,” is intended to treat “colds, including accumulation of mucus in chest, throat and nose; cough with expectoration of thick, discolored mucus; runny nose, sneezing and nasal congestion, irritability, fussiness and occasional sleeplessness for babies 6 months and up.”<sup>13</sup> Consumers are assured that the product is:

**Amazon's Choice** for “baby cold medicine”

14

As with all homeopathic products sold by Amazon, these products are unapproved drugs that have not been officially recognized as safe or effective by the FDA:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
4 Kids Cold and Cough Daytime and Nighttime	54973-3378-1		KIT			Hyland's	54973-3378	orion, calcium sulfate, sodium chloride, anemone pulsatilla, arabica coffee bean, matricaria chamomilla, sulfur, phosphorus and goldenseal		HUMAN OTC DRUG	06/08/2018	N/A	UNAPPROVED HOMEOPATHIC	1 KIT in 1 CARTON (54973-3378-1) * 118 mL in 1 BOTTLE, PLASTIC (54973-3075-1) * 1 BOTTLE, PLASTIC in 1 CARTON (54973-3375-1) * 118 mL in 1 BOTTLE, PLASTIC	N/A	N/A

sr\_1\_2?keywords=cold+and+cough+medicine+for+kids&qid=1661274378&srefix=cold+and+cou%2Caps%2C84&sr=8-2 (last visited Aug. 26, 2022).

<sup>12</sup> 1-48 of 549 results for “baby cold medicine”, [https://www.amazon.com/s?k=baby+cold+medicine&crd=13LDM4WUGHY6F&srefix=baby+cold+medicine%2Caps%2C215&ref=nb\\_sb\\_noss\\_1](https://www.amazon.com/s?k=baby+cold+medicine&crd=13LDM4WUGHY6F&srefix=baby+cold+medicine%2Caps%2C215&ref=nb_sb_noss_1) (last visited Aug. 26, 2022).

<sup>13</sup> Infant and Baby Cold Medicine, Hyland's Naturals Baby Mucus + Cold Relief, Day & Night Value Pack, Decongestant and Cough Relief, 8 Fl Oz, [https://www.amazon.com/Hylands-Mucus-Relief-Night-Packaging/dp/B01NB0P702/ref=sr\\_1\\_5?keywords=baby+mucus+medicine&qid=1661531130&srefix=baby+mucus%2Caps%2C93&sr=8-5](https://www.amazon.com/Hylands-Mucus-Relief-Night-Packaging/dp/B01NB0P702/ref=sr_1_5?keywords=baby+mucus+medicine&qid=1661531130&srefix=baby+mucus%2Caps%2C93&sr=8-5) (last visited Aug. 26, 2022).

<sup>14</sup> *Id.*

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
BABY MUCUS PLUS COLD RELIEF DAYTIME AND NIGHTTIME	54973-3374-1		KIT			Hyland's	54973-3374	calcium sulfide, phosphorus, sulfur, rumex crispus root, sodium chloride, arabica coffee bean, anemone pulsatilla, silicon dioxide, goldenseal, onion, bryonia alba root, euphrasia stricta and matricaria chamomilla		HUMAN OTC DRUG	11/01/2018	N/A	UNAPPROVED HOMEOPATHIC	1 KIT in 1 CARTON (54973-3374-1) * 118 mL in 1 BOTTLE (54973-3373-2) * 118 mL in 1 BOTTLE PLASTIC (54973-3284-1)	N/A

15

And, while the sale of these items alone is prohibited, they are also deceptively marketed to consumers. Indeed, according to a survey sponsored by a homeopathic product industry trade group, of those who purchased a brand of homeopathic products, **85 percent did not know** it was homeopathic.<sup>16</sup> The parents who see advertisements and rely upon a recommendation to purchase the drugs are likely unaware they are homeopathic (let alone a prohibited drug.)

Indeed, Hyland's packaging could serve as an exemplar of deceptive "small print:"



These particular products, and the troubling manner in which they are sold, is not unique. Rather, throughout Amazon's website, all manner of homeopathic drugs and pseudoscientific healthcare products are deceptively offered and unlawfully sold. Their promises of illness treatment, disease prevention and restored health are as fanciful as they are impossible to achieve. These items, like homeopathy in general, are ineffective for the purposes they are sold; like all homeopathic products, they are harmful.

<sup>15</sup> U.S. Food & Drug Administration, National Drug Code Directory, <https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm> (from results of "Labeler" search for "Hyland's") (last visited Aug. 26, 2022).

<sup>16</sup> The State of Homeopathy, The Emerson Group and American Association of Homeopathic Pharmacists (2020).



The harm caused by homeopathy is not limited to wasted money.

Spurred on by the growing desire of consumers for quick health fixes, unscrupulous companies increasingly take advantage of the sick and injured for quick profits. Because of its high costs to consumers and low costs to manufacturers—ordinary sugar being the predominant pill ingredient—commercial homeopathy has grown into one of the more pervasive forms of pseudoscientific alternatives to medicine. Concocted by a confirmed conman, professional translator and destitute failed doctor, homeopathy has never, does not and simply cannot work.

That’s why countless governmental authorities, trusted professionals and reliable scientific studies conclude:

“There are **no health conditions** for which there is reliable evidence that homeopathy is effective.”<sup>17</sup>

“There is **little evidence** to support homeopathy as an effective treatment for any specific condition.”<sup>18</sup>

“The scientific claims made for homeopathy are **implausible** and inconsistent with established concepts from chemistry and physics. ... The promotion and use of homeopathic products **risks significant harms**.”<sup>19</sup>

The harms caused by the sale, purchase and use of homeopathy are varied and significant. Perhaps most obvious, consumers and patients suffer financial injury when induced to purchase these sham products—often at exorbitant prices. For instance, Oscillococcinum, an “Amazon’s Choice” product, is a homeopathic drug intended to treat flu.<sup>20</sup> Despite the fact it should not be sold pursuant to Amazon’s “Prohibited product claims” policy,<sup>21</sup> the product carries a list price of \$18.78 for six doses. At this cost, a consumer would pay more than \$3.00 for each one gram “dose.” Yet, each

---

<sup>17</sup> National Health and Medical Research Council, NHMRC Statement: Statement on Homeopathy, March 11, 2015, <https://www.nhmrc.gov.au/media/releases/2015/nhmrc-releases-statement-and-advicehomeopathy>.

<sup>18</sup> National Center for Complementary and Integrative Health, Homeopathy: What You Need To Know, April 2015, <https://nccih.nih.gov/health/homeopathy#hed8>.

<sup>19</sup> European Academies’ Science Advisory Council, Homeopathic products and practices: assessing the evidence and ensuring consistency in regulating medical claims in the EU, Sept. 2017, [https://easac.eu/fileadmin/PDF\\_s/reports\\_statements/EASAC\\_Homeopathy\\_statement\\_web\\_final.pdf](https://easac.eu/fileadmin/PDF_s/reports_statements/EASAC_Homeopathy_statement_web_final.pdf).

<sup>20</sup> Boiron Oscillococcinum for Relief from Flu-Like Symptoms of Body Aches, Headache, Fever, Chills, and Fatigue - 6 Count, <https://www.amazon.com/gp/product/B006H9THXY> (last visited Aug. 26, 2022).

<sup>21</sup> Amazon Seller Central, Prohibited product claims, <https://sellercentral.amazon.com/help/hub/reference/external/202024200> (“Amazon prohibits the sale of products that claim to cure, mitigate, treat, or prevent diseases in humans or animals without FDA approval. The following are some example of diseases that products cannot claim to cure, mitigate, treat, or prevent: ...Flu [and] Influenza.”) (last visited Aug. 26, 2022).



*one gram dose* is said to contain *one gram of sugar*. In the end, the consumer simply ends up with an extremely expensive sugar pill.

Homeopathic products also encourage patients to rely on ineffective treatments to the exclusion of proven scientific remedies, often with dire consequences. The website “what’s the harm?” details many such cases, including that of Isabella Denley.<sup>22</sup> A toddler from Melbourne, Australia, Isabella was an epileptic whose neurologist prescribed her anticonvulsant medication; her parents, instead, chose to treat her exclusively with homeopathy. She died aged thirteen months.<sup>23</sup> Lucille Craven, diagnosed in with a small, pea-sized carcinomatous breast tumor, is another sad example. Her doctor recommended mastectomy and lumpectomy. Instead, Lucille sought homeopathic and other alternative medical treatments; she died within thirty-six months.<sup>24</sup>

Further, absent oversight of the rigorous FDA drug approval process, the homeopathic product itself may be harmful. One of many incidents involved homeopathic teething tablets marketed by Hyland’s, Inc.:

FDA analysis found the levels of atropine and scopolamine in some of...  
Hyland’s tablets far exceeded the amount stated on the products’ labels.<sup>25</sup>

Hundreds of adverse effects were reported.<sup>26</sup> After concluding that the products “contain[ed] inconsistent amounts of belladonna alkaloids that may differ from the calculated amount on the products’ labels,” the FDA requested Hyland’s Baby Teething Tablets be recalled.<sup>27</sup>

### **Conclusion**

Amazon owes a duty to its customers and shareholders to comply with all applicable laws and adhere to the standards of ethical business practices. Inherent in this duty is the obligation to protect against prohibited, harmful and otherwise worthless products deceptively sold as alternatives to science-based medicine. The trust placed in Amazon to recommend safe and effective products, especially for the care of the most vulnerable, compels the company to refrain from furthering the healthcare fraud that is homeopathy. To that end, CFI is glad to offer Amazon assistance as the

---

<sup>22</sup> what’s the harm?, <http://whatstheharm.net/homeopathy.html> (last visited Aug. 26, 2022).

<sup>23</sup> Lucy Atkins, *When there’s no real alternative*, The Guardian, Dec. 16, 2003 (<https://www.theguardian.com/society/2003/dec/16/health.medicineandhealth>).

<sup>24</sup> Richard Craven, *My Wife’s Death from Cancer*, QuackWatch, Feb. 27, 2002 (<https://www.quackwatch.org/01QuackeryRelatedTopics/Victims/craven.html>).

<sup>25</sup> FDA News Release, *FDA confirms elevated levels of belladonna in certain homeopathic teething products*, Jan. 27, 2017 (<https://www.fda.gov/news-events/press-announcements/fda-confirms-elevated-levels-belladonna-certain-homeopathic-teething-products>).

<sup>26</sup> Sheila Kaplan, *Hundreds of Babies Harmed by Homeopathic Remedies, Families Say*, Scientific American, Feb. 21, 2017 (<https://www.scientificamerican.com/article/hundreds-of-babies-harmed-by-homeopathic-remedies-families-say>).

<sup>27</sup> U.S. Food and Drug Administration, *Standard Homeopathic Company Issues Nationwide Recall of Hyland’s Baby Teething Tablets and Hyland’s Baby Nighttime Teething Tablets Due to Mislabeling*, April 13, 2017 (<https://www.fda.gov/safety/recalls/ucm552934.htm>).





company implements the changes necessary to curb ongoing wrongdoing and prevent reoccurrence.

Through its longstanding advocacy for science and the protection of consumers, CFI developed unparalleled expertise in holding producers and distributors of homeopathic products accountable for the harms they cause.<sup>28</sup> As we await Amazon's quick and meaningful action, CFI remains obligated to pursue all available avenues for the protection of consumers. We look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read 'N. J. Little', written in a cursive style.

Nicholas J. Little  
*Vice President and General Counsel*  
nlittle@centerforinquiry.org

A handwritten signature in black ink, appearing to read 'A. D. Green', written in a cursive style.

Aaron D. Green  
*Staff Counsel*  
agreen@centerforinquiry.org

---

<sup>28</sup> CFI is presently engaged in litigation brought against CVS, Walmart and Boiron for unfair and deceptive trade practices employed in the advertising and sale of homeopathic products. Ctr. for Inquiry, Inc. v. Walmart, Inc.; Ctr. for Inquiry, Inc. v. CVS, Inc., Case no. 20-CV-0392, *argued* Jan. 13, 2022 (D.C. Ct. App.); Ctr. for Inquiry, Inc. v. Boiron, Inc., Case no. 2022-CA-1610, *Complaint* filed Apr. 18, 2022 (D.C. Sup. Ct.).