1	Thomas E. Drendel, Esq.							
2	Nevada State Bar No. 0655 BRADLEY, DRENDEL & JEANNEY, LTD. P.O. Box 1987							
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4	Facsimile No. (775) 335-9999							
5	Attorneys for Plaintiff							
6	UNITED STATES DISTRICT COURT							
7	DISTRICT OF NEVADA							
8	HOWARD MCMASTER, Case No.							
9	Plaintiff,							
10	v.							
11	FRANCK'S LAB, INC., doing business as FRANCK'S COMPOUNDING LAB; PAUL							
12	W. FRANCK; ANTHONY JAMES CAMPBELL; and DOES 1 through 10,							
13	inclusive,							
14	Defendant.							
15	COMPLAINT AND JURY DEMAND							
16	COMES NOW, Plaintiff HOWARD MCMASTER, by and through his counsel of record							
17	Thomas E. Drendel, Esq., of the law offices of Bradley, Drendel & Jeanney, Ltd., and for causes							
18	of action against the Defendants, and each of them, alleges:							
19	JURISDICTION & PARTIES							
20 21	1. This is an action for personal injuries arising from a defective product. This Cour							
$\begin{bmatrix} 21 \\ 22 \end{bmatrix}$	has diversity jurisdiction as this is a controversy between parties of diverse citizenship and an							
23	amount in controversy that exceeds \$75,000 pursuant to the provisions of 42 U.S.C. §1332.							
24	2. Plaintiff, HOWARD MCMASTER, is a citizen of Reno, Nevada.							
25	3. Defendant, FRANCK'S LAB, INC., dba FRANCK'S COMPOUNDING LAB is							
26	a corporation incorporated under the laws of Florida with its principal place of business in the							
20 27	State of Florida and selling compounded or formulated products for utilization in the medical							
$\begin{bmatrix} 27 \\ 28 \end{bmatrix}$	field, including Brilliant Blue-G ("BBG") dye; Triamcinolone ("TMC") and Avastin.							
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	4.	Defendant, PAUL W. FRANCK is a citizen of the State of Florida, is
a princ	cipal and	d shareholder of defendant FRANCK'S LAB INC. and was involved in the
manag	gement a	and operations of FRANCK'S LAB, INC., and direction the manner in which BBG,
TMC a	and Ava	stin were compounded in the laboratory.

- 5. Defendant, ANTHONY JAMES CAMPBELL, is a citizen of the State of Florida, was a lead chemist with FRANCK'S LAB, INC. and had responsibility for overseeing the laboratory operations and assuring compliance with the rules, laws and regulations concerning compounding pharmacies, including the federal rules and regulations concerning the manufacture, sale and distribution of drugs, including BBC, TMC and Avastin.
- 6. The true names and capacities of DOES 1 through 10 are unknown to Plaintiff at this time. Plaintiff is informed and believes and thereon alleges that these DOE defendants are in someway liable for the events referred to in this Complaint and caused damage to Plaintiff. Plaintiff will amend this Complaint when their identities and relationship to his injuries are discovered. Does 1 through 10 and not citizens of the State of Nevada or corporations with their principal place of business in the State of Nevada.
- 7. Plaintiff is informed and believes that at all time herein mentioned, the defendants, and each of them, were the agents, servants, employees, joint venturers, and partners of each other and at all times were acting within the course and scope of said relationships.
- 8. Venue is proper in this district and in this, the unofficial northern division thereof, because Plaintiff is a citizen in this district, the tort occurred in this district and the Defendants were doing business in this district at the time of the injury.

FIRST CAUSE OF ACTION (FOR PRODUCT LIABILITY - NEGLIGENCE)

- 9. Plaintiff incorporates herein by reference paragraphs 1-8 as though fully set forth herein.
- 10. On November 15, 2011, Plaintiff underwent a vitrectomy procedure on his left eye performed by Dr. Steven Friedlander at the Northern Nevada Medical Center located at 2375 E. Prater Way in Sparks, Nevada. During the procedure, Dr. Friedlander injected Plaintiff's eye

with BBG, the product the defendants formulated, manufactured, compounded, marketed and sold as an appropriate product to be utilized in such procedure. The Defendants represented that BBG was pure, sterile, and fit for the represented purpose of assisting in procedures like vitrectomies and the product could be injected into an eyeball in order to assist the doctor in achieving the desired result.

- 11. Plaintiff's condition worsened after the November 15, 2011, procedure, and he lost his vision and use of his left eye.
- 12. Plaintiff was advised that numerous other patients who were injected with BBG had suffered similar complications. Plaintiff was further advised that the sudden, unexpected and unusual number of patients who developed the same or similar complications led to an investigation by the doctor, the Federal Drug Enforcement Agency (FDA) and others which concluded that all of the patients who suffered these complications due to BBG which was negligently manufactured.
- 13. The investigation by numerous state, county and federal health agencies concluded that the Defendants' BBG product was negligently manufactured and that the Defendants had violated numerous federal rules and regulations. On July 9, 2012, the United States Food and Drug Administration ("FDA") issued a Warning Letter FLA-12-38, which advised PAUL W. FRANCK and FRANCK'S LAB, INC., that:
- a. The subject BBG was adulterated within the meaning of Section 501(a)(1) of the Act [21 U.S.C.§ 351 (a)(1)] and that it was contaminated with filthy, putrid or decomposed substances;
- b. The BBG was adulterated within the meaning of Section 501(c) of the Act [21 U.S.C.§ 351 (c)] in that its strength different from, or its purity or quality fell below, that which is purported to possess;
- c. The BBG and all sterile drugs compounded by the defendants were adulterated under Section 501(a)(2)(A) of the Act [21 U.S.C.§ 351 (a)(2)(A)] in that they were prepared, packed and stored under unsanitary conditions whereby they may have been contaminated by filth;

- d. The BBG was misbranded within the meaning of Section 502(a) of the Act [21 U.S.C.§ 352 (a)] because their labeling was false and misleading;
- e. The FDA investigators observed numerous instances of unsanitary and inappropriate practices by compounding technicians who left and re-entered clean rooms without changing lab coats, who were touching non-sterile items while wearing their sterile gloves and then returned to compounding activities, etc.; and
- f. The BBG drug products were misbranded insofar as they were labeled as being sterile, and they contained filthy, putrid, or decomposed substances.
- 14. The Defendants knew that failing to follow safe and appropriate compounding practices could result in complications, including fatal ones. In 2009, the Defendants compounded cocktails that were given to prized polo horses from the Venezuelan-owned Lechuza Caracas team in preparation for championship matches near West Palm Beach, Florida. Twenty-one of these prized polo horses died from errors committed by the Defendants in compounding these cocktails.
- 15. The FDA investigation following the incident with the polo horses led the agency to conclude that the defendants were mixing brews outside of federal guidelines and were utilizing drugs that had not been approved for use in the United States.
- 16. Tragic complications of the patients who ended up receiving injections of the contaminated BBG are just one example of the problems in the largely unregulated area of compounding pharmacies. Recently, hundreds of patients who underwent steroid injections were stricken with meningitis due to the contamination of the steroid fluid.
- 17. The Defendants owed a duty of reasonable care to Plaintiff to design, compound, manufacture, market, sell and distribute the BBG in a condition that was safe for its intended purpose and consistent with the representations that it was a sterile product. The Defendants' duty included a duty to insure that the product did not cause patients who were injected with BBG in their eye to suffer from unreasonable risks of injury from the product, especially in light of the fact that it is known that infections in the eye are extremely difficult to treat.

- 18. Defendants breached their duty to Plaintiff in the testing, design, compounding, manufacturing, packaging, storing, warnings, marketing, advertising, promotion and distribution of BBG and otherwise failed to exercise ordinary care to avoid the risk of infection and harm.
- 19. The Defendants knew prior to the date of Plaintiff's surgery of November 15, 2011, that their dye was contaminated, non-sterile and unfit to be used in eye surgery procedures; posed an unreasonably dangerous risk of infection and they failed to do anything to recall the product from the market or warn the medical community and the public of the substantial risk of serious complications.
- 20. The Defendants recklessly and wantonly conducted their laboratory compounding practices in clear violation of applicable federal law and allowed such filthy and inappropriate conditions to exist to the point that it was all but certain that the drugs they were compounding were going to be contaminated.
- 21. The Defendants knew that the patients who were going to be injected with their BBG were at risk for developing serious injuries and complications but they nevertheless continued with their practices in conscious disregard of the health and safety of the ultimate consumes of BBG.
- 22. As a direct, proximate and legal result of the negligence, carelessness, recklessness and other wrongdoing actions of the Defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER sustained general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.
- 23. The Defendant's conduct was so reckless, malicious, oppressive, fraudulent and despicable and carried on with a willful and conscious disregard for the safety of the patients who were likely to be injected with BBG. Therefore, punitive damages should be imposed upon the defendants, and each of them, by way of an example and to punish such conduct in an amount to be determined by the trier of fact.

LAW OFFICE OF BRADLEY, DRENDEL & JEANNEY P.O. BOX 1987

SECOND CAUSE OF ACTION (FOR STRICT LIABILITY)

- 24. Plaintiff incorporates herein by reference paragraphs 1-23 as though fully set forth herein.
- 25. The subject BBG was defective in its compounding and manufacture since it was different from the manufacturer's intended result as set forth on the packaging and related material that accompanied the product, specifically that the product was sterile and free of any contamination. Plaintiff is informed and believes that the batch of the product that included the BBG that was injected into his eye was defective in compounding and manufacture in that it differed from other batches of BBG from these defendants.
- 26. The defect in the compounding and manufacture of the product, specifically the contamination and non-sterile nature of the product, existed in the product when it left the possession of the defendants.
- 27. The defect in the compounding and manufacture of the BBG resulted in complications to the Plaintiff's procedure and blindness in his left eye.
- 28. The use of this contaminated BBG, by the Plaintiff or by his physician during his procedure, was completely foreseeable by the Defendants and each of them since the Plaintiff's doctor was utilizing the product as intended by the Defendants and the medical community.
- 29. The BBG injected into the Plaintiff's eye failed to perform as safely and reasonably as a consumer would expect when used as intended.
- 30. As a direct, proximate and legal result of the strict liability and other wrongdoing actions of the Defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER suffered general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.

31. The Defendant's conduct was so reckless, malicious, oppressive, fraudulent and despicable and carried on with a willful and conscious disregard for the safety of the patients who were likely to be injected with BBG. Therefore, punitive damages should be imposed upon the defendants, and each of them, by way of an example and to punish such conduct in an amount to be determined by the trier of fact.

THIRD CAUSE OF ACTION (FOR STRICT LIABILITY - FAILURE TO WARN)

- 32. Plaintiff incorporates herein by reference paragraphs 1-31 as though fully set forth herein.
- 33. The BBG which was injected into Plaintiff's eye on November 15, 2011, was defective in that there was no warning on the product that it was, or could be, contaminated with filth or foreign matter.
- 34. The Defendants, and each of them, knew that doctors would utilize their BBG relying on the representations of the Defendants that the product was sterile and that they would have no reason to believe that the product was not sterile and, in fact the Defendants knew, or reasonably should have known based upon their background and experience, that a contaminated dye to be injected into the eye could cause serious and debilitating injuries, including blindness of the injected eye.
- 35. As a direct, proximate and legal result of the failure to warn and other wrongdoing actions of the defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER suffered general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.
- 36. Plaintiff understands that the defendants were aware of the problems with their BBG prior to November 15, 2011, yet failed to recall the product, issue warnings to the medical community or otherwise do anything to avert this contaminated product being injected into the eye of patients like the Plaintiff.

37. The conduct of the Defendants, and each of them, was reckless, malicious, fraudulent and depressive and so despicable and contemptible that punitive damages should be awarded by the trier of fact.

FOURTH CAUSE OF ACTION (FOR BREACH OF WARRANTY)

- 38. Plaintiff incorporates herein by reference paragraphs 1-37 as though fully set forth herein.
- 39. The Defendants represented and warranted to Plaintiff through the medical community that their BBG dye was safe and effective to be utilized in conjunction with eye surgery.
- 40. The subject BBG dye product that was utilized in the Plaintiff's eye procedure was, in fact, not inconsistent with the warranties and representations of the defendants but, instead, was non-sterile and contaminated that caused plaintiff serious and permanent injuries as further set further herein.
- 41. As a direct, proximate and legal result of the breach of warranty and other wrongdoing actions of the defendants, and each of them as described herein, Plaintiff HOWARD MCMASTER suffered general damages from debilitating and painful injuries including blindness of his left eye and was required to undergo additional invasive surgeries and procedures, all to no avail, causing him additional pain, suffering, anxiety, worry and depression. Plaintiff has also incurred and is likely to incur in the future, special damages for medical, hospital and related services in an amount to be established at the time of trial.

WHEREFORE, Plaintiff prays for judgment as follows:

- 1. For general damages in a sum to be determined at the time of trial;
- 2. For special damages for past and future medical expenses according to proof;
- 3. For other damages incurred as a result of the conduct of the defendants, according to proof;
- 4. For punitive damages in an amount sufficient to deter this kind of conduct which is becoming more common in the field of compounding pharmacies;
- 5. For pre-judgment interest;

6. For cost of suit incurred herein; and

7. For any such other relief as the Court may deem appropriate.

DATED this _____ day of March 2013.

BRADLEY, DRENDEL & JEANNEY

Thomas Drendel, Esq. Attorneys for Plaintiff

LAW OFFICE OF BRADLEY, DRENDEL & JEANNEY P.O. BOX 1987 RENO, NV 89505 (775) 335-9999

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SJS 44 (Rev. 12/07) Case 3:13-cv-00100-LR**CIWICCOXETRESHIEZET**Filed 03/04/13 Page 1 of 1

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS HOWARD MCMASTER			DEFENDANTS FRANCK'S LAB, INC., doing business as FRANCK'S COMPOUNDING LAB, PAUL W. FRANCK, ANTHONY						
(b) County of Residence	of First Listed Plaintiff Washoe		County of Residence of First Listed Defendant						
(E	XCEPT IN U.S. PLAINTIFF CASES)			(IN U.S. PLAINTIFF CASES O	•				
			NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.						
(c) Attorney's (Firm Name	e, Address, and Telephone Number)		Attorneys (If Known)						
	q., Bradley, Drendel & Jeanney, Ltd., F	P.O.							
Box 1987, Reno, Nevac									
II. BASIS OF JURISI	DICTION (Place an "X" in One Box Only)		[TIZENSHIP OF P] (For Diversity Cases Only)	RINCIPAL PARTIES	Place an "X" in One Box for Plaintiff and One Box for Defendant)				
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government Not a Party)		en of This State		PTF DEF incipal Place				
☐ 2 U.S. Government Defendant	■ 4 Diversity	Citize	en of Another State	2 Z Incorporated and P of Business In A					
	(Indicate Citizenship of Parties in Item III)	Citize	en or Subject of a	3	□ 6 □ 6				
IV NATURE OF SHI	T m (SVIII o D o l)	Fo	reign Country						
CONTRACT	T (Place an "X" in One Box Only) TORTS	F(ORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES				
☐ 110 Insurance	PERSONAL INJURY PERSONAL INJURY		0 Agriculture	1 422 Appeal 28 USC 158	☐ 400 State Reapportionment☐ 410 Antitrust				
☐ 120 Marine ☐ 130 Miller Act	□ 310 Airplane □ 362 Personal Injury - □ 315 Airplane Product Med. Malpractice		20 Other Food & Drug 25 Drug Related Seizure	423 Withdrawal 28 USC 157	☐ 410 Antitrust ☐ 430 Banks and Banking				
☐ 140 Negotiable Instrument	Liability 🕱 365 Personal Injury -		of Property 21 USC 881	PROPERTY RIGHTS	☐ 450 Commerce ☐ 460 Deportation				
☐ 150 Recovery of Overpayment & Enforcement of Judgment			80 Liquor Laws 80 R.R. & Truck	■ 820 Copyrights	☐ 470 Racketeer Influenced and				
☐ 151 Medicare Act	☐ 330 Federal Employers' Injury Product		50 Airline Regs. 50 Occupational	☐ 830 Patent ☐ 840 Trademark	Corrupt Organizations 480 Consumer Credit				
152 Recovery of Defaulted Student Loans	☐ 340 Marine PERSONAL PROPER	TY	Safety/Health	5 640 Hademark	☐ 490 Cable/Sat TV				
(Excl. Veterans) ☐ 153 Recovery of Overpayment	☐ 345 Marine Product ☐ 370 Other Fraud Liability ☐ 371 Truth in Lending		00 Other	SOCIAL SECURITY	☐ 810 Selective Service ☐ 850 Securities/Commodities/				
of Veteran's Benefits	☐ 350 Motor Vehicle ☐ 380 Other Personal	- 71	0 Fair Labor Standards	□ 861 HIA (1395ff)	Exchange				
☐ 160 Stockholders' Suits ☐ 190 Other Contract	☐ 355 Motor Vehicle Property Damage Product Liability ☐ 385 Property Damage		Act 20 Labor/Mgmt. Relations	☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g))	875 Customer Challenge 12 USC 3410				
☐ 195 Contract Product Liability	☐ 360 Other Personal Product Liability		30 Labor/Mgmt.Reporting	☐ 864 SSID Title XVI ☐ 865 RSI (405(g))	890 Other Statutory Actions 891 Agricultural Acts				
☐ 196 Franchise REAL PROPERTY	Injury CIVIL RIGHTS PRISONER PETITION	NS 13 74	& Disclosure Act 10 Railway Labor Act	FEDERAL TAX SUITS	☐ 892 Economic Stabilization Act				
☐ 210 Land Condemnation	☐ 441 Voting ☐ 510 Motions to Vacate		00 Other Labor Litigation 01 Empl. Ret. Inc.	☐ 870 Taxes (U.S. Plaintiff or Defendant)	893 Environmental Matters 894 Energy Allocation Act				
☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment	☐ 442 Employment Sentence ☐ 443 Housing/ Habeas Corpus:		Security Act	☐ 871 IRS—Third Party	☐ 895 Freedom of Information				
 240 Torts to Land 245 Tort Product Liability 	Accommodations	75. N	IMMIGRATION	26 USC 7609	Act ☐ 900Appeal of Fee Determination				
☐ 290 All Other Real Property	☐ 445 Amer. w/Disabilities - ☐ 540 Mandamus & Oth		2 Naturalization Application		Under Equal Access				
	Employment	46	63 Habeas Corpus - Alien Detainee		to Justice 950 Constitutionality of				
	Other	□ 46	55 Other Immigration Actions		State Statutes				
	☐ 440 Other Civil Rights		Actions						
V. ORIGIN (Place an "X" in One Box Only) (Place an "X" in On									
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):									
VI. CAUSE OF ACTION Brief description of cause:									
VII. REQUESTED IN CHECK IF THIS IS A CLASS ACTION DEMAND \$ COMPLAINT: CHECK IF THIS IS A CLASS ACTION DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No									
VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER									
DATE SIGNATURE OF ATTORNEY OF RECORD									
FOR OFFICE USE ONLY									
	MOUNT APPLYING IFP		JUDGE	MAG. JUI	OGE				
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