

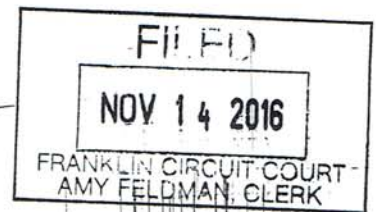
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15-CI-00063

11/02/2016

Amy Feldman, Franklin Circuit Clerk

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
CASE NO. 15-CI-00063



[Filed Electronically]

BRIAN WOODCOCK, RUBEN RIOS
SALINAS, and KEATH BRAMBLETT,
individually and on behalf of all others
similarly situated,

PLAINTIFFS

V.

COMMONWEALTH OF KENTUCKY (for
injunctive relief only),

-and-

RODNEY BALLARD, individually
Serve: Office of the Commissioner
Kentucky Department of Corrections
275 East Main
Frankfort, KY 40601-2321

-and-

LADONNA THOMPSON, individually
Serve: Office of the Commissioner
Kentucky Department of Corrections
275 East Main
Frankfort, KY 40601-2321

-and-

DOUG CRALL, MD, individually
Serve: Kentucky Department of Corrections
275 East Main
Frankfort, KY 40601-2321

-and-

COOKIE CREWS, individually
Serve: Kentucky Department of Corrections
275 East Main

Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)

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Frankfort, KY 40601-2321)

-and-)

FREDERICK KEMEN, MD, individually)

Serve: Kentucky State Reformatory)

3001 West Highway 146)

LaGrange, KY 40032)

-and-)

CORRECT CARE SOLUTIONS, LLC)

Serve: Business Filings Incorporated)

306 West Main St., Suite 512)

Frankfort, KY 40601,)

DEFENDANTS.)

FIRST AMENDED CLASS ACTION COMPLAINT**I. Introduction**

1. The Hepatitis C virus – HCV -- poses an unreasonable and substantial risk of serious present and future medical and physical harm to those who are infected with it, and to the general public when infected inmates are released from prison. *Roe v. Elyea*, 631 F.3d 843 (7th Cir. 2011).

2. Conscious delay, denial, or interference in medical treatment of HCV for non-medical reasons -- standing alone -- states a plausible claim against prison officials for deliberate indifference to the serious medical needs of a prisoner in violation of the Eighth and Fourteenth Amendments to the United States Constitution and 42 U.S.C. §1983. *Erickson v. Pardus*, 551 U.S. 89, 90 (2007).

3. Plaintiffs are all inmates of the Kentucky Department of Corrections ("KDOC") who are infected with the Hepatitis C virus ("HCV"). Defendants have refused Plaintiffs' repeated requests to be treated commensurate with the standard of care, or delayed such

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treatment, for non-medical reasons of administrative convenience or cost, which are not related to the individual medical needs of Plaintiffs.

4. This is a class action that seeks injunctive relief where and as appropriate, and recovery of damages, under 42 U.S.C. §1983 and other applicable state claims, for Defendants' violation of the Eighth Amendment as a result of their deliberate indifference to the serious medical needs of Plaintiffs and all others similarly situated.

5. HCV, if left untreated, may progress toward end-stage liver disease and death. Major advances in treatment have recently been made with the introduction of medication regimens having increasingly higher success rates, fewer side effects, and much shorter treatment durations. The Kentucky Department of Corrections ("KDOC") is currently preparing a new HCV treatment plan ("the New Plan"). However, even if the New Plan meets the prevailing standard of care, future developments in treatment are likely to render it obsolete, and it is anticipated that there will be inconsistencies, inaccuracies and unwarranted deviations in its implementation, particularly given the expense of new treatment regimens. In addition, the New Plan is the first amendment to the KDOC's old HCV treatment plan ("the Old Plan") *since 2007*, and many members of the class may have been harmed by Defendants' failure to regularly and consistently update the plan to mirror the established standard of care. Finally, there may be issues concerning the reliability of the testing to which HCV-infected inmates are subjected, raising questions as to the integrity of and motivations underlying, such testing.

6. It is the purpose of this litigation not only to protect Plaintiffs and the class, but the general public into which Plaintiffs and members of the class will be released.

II. Jurisdiction and Venue

7. Plaintiffs and the class seek injunctive relief where and as appropriate, and damages under the Civil Rights Act of 1871, 42 U.S.C. § 1983, for Defendants' violations of the rights, privileges and immunities guaranteed Plaintiffs and the class by the Eighth Amendment to the U.S. Constitution. Plaintiffs and the class also seek damages for negligence, gross negligence, outrageous conduct, intentional infliction of emotional distress, and violations of applicable Kentucky regulations and KDOC policies. Defendants are all domiciled in Franklin County, Kentucky, and venue is therefore proper in this Court.

III. Parties

8. Plaintiffs are all inmates of the KDOC who are infected with HCV.

9. The Commonwealth of Kentucky, through its agency the KDOC, is the entity charged with the care and custody of Plaintiffs, and is sued for injunctive relief only.

10. Rodney Ballard is presently Commissioner of the KDOC, and has ultimate responsibility for all operations of institutions within the KDOC, the promulgation, implementation and enforcement of all of the KDOC's policies, procedures, protocols, customs and practices, and the employment, training and supervision of employees of the KDOC.

11. LaDonna Thompson was formerly, at times pertinent to this litigation, Commissioner of the KDOC, and she had ultimate responsibility for all operations of institutions within the KDOC, the promulgation, implementation and enforcement of all of the KDOC's policies, procedures, protocols, customs and practices, and the employment, training and supervision of employees of the KDOC.

12. Doug Crall, MD, is, and has been at all times pertinent to this litigation, the Medical Director of the KDOC, and he has responsibility for all operations of institutions within

the KDOC, the promulgation, implementation and enforcement of all of the KDOC's policies, procedures, protocols, customs and practices, and the employment, training and supervision of employees of the KDOC, that concern inmates' medical care.

13. Cookie Crews is, and has been at all times pertinent to this litigation, the Health Services Administrator of the KDOC, and she has responsibility for all operations of institutions within the KDOC, the promulgation, implementation and enforcement of all of the KDOC's policies, procedures, protocols, customs and practices, and the employment, training and supervision of employees of the KDOC, that concern the health services that are available to the KDOC's inmates.

14. Frederick Kemen, MD, is, and has been at all times pertinent to this litigation, the person responsible for managing the KDOC's HCV treatment plan at all institutions within the KDOC, and as such, has responsibility for training on, and supervision and enforcement of both the Old and New Plans, and their satisfaction of the applicable standard of care.

15. Defendant CorrectCare Solutions, Inc., for all periods relevant to this complaint beginning March 1, 2014: is registered with the Kentucky Secretary of State to do business in Kentucky; provided medical services to inmates of the KDOC; employed the medical professionals who dealt directly with Plaintiffs and the class and are therefore vicariously liable for the injuries caused by their wrongful conduct in the course and scope of their employment under the doctrine of *respondeat superior*; were responsible for the health, welfare, and medical needs of Plaintiffs and the class, for complying with their reasonable medical requests, and for seeing that they were treated commensurate with the prevailing standard of care; and were responsible for training and supervising the medical professionals in their employ to insure that they properly attended to the medical needs of Plaintiffs and the class.

16. Plaintiff's assertion of liability against the individual Defendants identified above is based upon their failure to employ qualified individuals for positions of responsibility (or to terminate individuals upon demonstration of their lack of qualifications), their failure to promulgate, implement and enforce policies, procedures, protocols, customs and practices for the care of inmates with HCV in the KDOC's institutions, their failure to properly train and supervise the employees for whom they were responsible, and their personal participation in the failure to properly treat inmates with HCV, and to implement, update and enforce the HCV plan to maintain its compliance with the prevailing standard of care.

IV. Class Action Allegations

17. This is a class action under Rule 23(a) and (b) of the Federal Rules of Civil Procedure.

18. Plaintiffs are representatives of a class composed of all prisoners in the custody of the KDOC who have been diagnosed as having HCV.

19. Because the prevalence of HCV is estimated to be anywhere from 9.6% to 41.1% of the prison population nationally, membership in the class among the KDOC's total inmate population of 21,833 individuals (as of November 6, 2015) is probably between 2,000 and 9,000 individuals, and the class is therefore so numerous that joinder of all members is impracticable.

20. Plaintiffs' claims involve common questions of law and fact that are typical of the claims of the class as a whole. The claims concern Defendants' protocol and practice for treating HCV, which is applicable to all prisoners with HCV. Common questions include (1) whether Defendants have been deliberately indifferent to the serious medical needs of Plaintiffs and the members of the class; (2) whether Defendants have failed and refused to provide the necessary staging of HCV patients in accordance with the prevailing standard of care, including the

pretreatment testing and specialist consults that are needed to determine the severity of the disease and the need for treatment; (3) whether Defendants have failed and refused to provide treatment for Plaintiffs and the members of the class with the newest, most effective medications for HCV in accordance with the prevailing standard of care; and (4) whether Defendants' failure to provide treatment to Plaintiffs and the class in accordance with the prevailing standard of care for treatment of HCV has caused them compensable injury.

21. Each day treatment is postponed, the likelihoods of cirrhosis of the liver, liver cancer, a liver transplant, and death from HCV grow for each member of the Class, as does the likelihood of infection for those with whom they come in contact in KDOC facilities and for members of the general public after they are released.

22. These common questions predominate over any questions affecting only individual class members. Defendants have acted and refused to act on grounds generally applicable to the class so that final declaratory and injunctive relief would be appropriate to the class as a whole.

23. Plaintiffs have a strong personal interest in the outcome of this litigation, and they are represented by competent, class-action experienced counsel who will adequately and fairly protect the interests of the class.

24. A class action is superior to any other available method for a fair and efficient adjudication of this controversy. Separate actions by individual members of the class would create a risk of inconsistent or differing adjudications and delay the ultimate resolution of the issues at stake.

V. Facts

a. HCV Defined

25. Hepatitis C is a blood borne disease caused by the Hepatitis C virus ("HCV"). The virus brings about inflammation that damages liver cells. It is a leading cause of liver disease and liver transplants.

26. There are several different genotypes of HCV, with subtypes. Genotype 1 is the most common type of HCV in the United States.

27. Approximately 80% of people who become infected with the HCV virus will develop chronic HCV.

28. Chronic HCV patients develop fibrosis (liver scarring), which can worsen liver function until the patient develops cirrhosis. Ultimately, patients may end up with end-stage liver disease, cancer, or other serious illnesses. Some patients will need a liver transplant, and others will die.

29. HCV is transmitted by infected blood. Methods of transmission include: (a) physical activity in sports, (b) tattooing, (c) use of a needle not properly cleaned and sterilized, (d) exposure to an infected person's blood in the course of medical care, (e) barber and cosmetology care, (f) sexual activity, (g) sharing of eating utensils and food, (h) sharing razors or other personal grooming supplies, (i) sharing bathrooms or shower facilities, (j) sharing living quarters, or (k) physical violence between inmates or involving staff.

30. It is widely accepted that the number of reported cases of HCV nationwide understates its actual prevalence. In 2000, the United States Surgeon General called HCV a "silent epidemic," and estimated that as much as two percent of the adult U.S. population had HCV.

31. The last decade has seen a spike in reported cases of HCV among young people. This increase in new cases of HCV is largely attributable to the increase in opioid addiction and the resulting use of intravenous drugs.

32. The incidence of HCV is not diminishing, and its effects are worsening. In 2011, the CDC reported that HCV had overtaken HIV as a cause of death.

b. HCV in Prison

33. The prevalence of HCV in prison is higher than in the general population. It is estimated to be anywhere from 9.6% to 41.1% of the prison population nationally.

34. In 1997, according to one study, 29% to 43% of all people infected with HCV in the United States passed through a correctional facility. Combatting HCV demands effective response in the correctional setting, particularly in states with serious intravenous drug problems like Kentucky.

c. History of HCV Treatment

35. Treatment exists for chronic HCV. The available treatments have changed over time.

36. In 1991, a drug called Interferon was approved to be used alone. Seven years later, the FDA approved the use of Ribavirin alongside Interferon, and in 2001, Ribavirin was paired with Pegylated Interferon. This regimen was referred to as combination therapy.

37. The standard of care after 2001 was to treat Genotypes 2 or 3 with combination therapy, and to treat Genotype 1 with combination therapy if the patient had reached a certain stage of liver damage, typically measured by a liver biopsy. If, after treatment, the virus was not suppressed, or if it was suppressed during treatment but later returned, there was no other treatment available for the so-called nonresponder or relapser.

38. 2011 saw the FDA approval of two protease inhibitors that produced better results when either one was taken with combination therapy, especially for Genotype 1 (SVR of 60-80%).

39. In 2013 and 2014, the FDA approved more new antiviral medications. These medications can now be taken as part of an Interferon-free regimen. The change is dramatic; the worst side effects are avoided. The regimen is a much shorter duration – 12 weeks for some, 24 weeks for others. Best of all, the success rate for these regimens is better than combination or triple therapy – well over 90%, including for nonresponders and relapsers.

40. In October 2013, the Food and Drug Administration's (FDA's) announcement of new "breakthrough" direct-acting antiviral (DAA) drugs to cure HCV caused the American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA), the two relevant professional medical associations concerned with the treatment and cure of HCV, to convene the AASLD/IDSA "HCV Guidance Panel." Thirty national experts, including gastroenterologists and hepatologists with experience in treating HCV, comprise the HCV Guidance Panel.

41. The AASLD/IDSA adopted the "breakthrough" drug 12-week daily oral medication protocol with the 95% cure rate, as the HCV medical treatment community medical standard of care in January 2014, consistent with the medical treatment community standard of medical care definition of *U.S. v. Kubrick*, 444 U.S. 111 (1979).

42. By June 2014, the Federal Bureau of Prisons (FBOP), the Center for Disease Control, the United States Public Health Service, the FDA, and the United States Department of Veterans Affairs had all recognized the changed standard of care for HCV patients in their

approval and implementation of one-pill-per-day, 12-week protocols for the treatment of HCV patients.

43. In October 2014, the FDA approved more advanced HCV breakthrough DAA drugs that cure at a 95% rate, and eliminate Interferon injections completely – Harvoni and Viekira-Pak. On June 29, 2015, the AASLD/IDSA updated the HCV standard of care, which now requires that treatment providers eliminate Interferon in any form as a recommended treatment for HCV. Only the October 2014 non-Interferon "breakthrough" DAA drugs, Harvoni and Viekira-Pak, now meet the undisputed community standard of care for all HCV treatment providers.

44. Current AASLD/IDSA standard-of-care also requires that HCV treatment providers treat all HCV-infected patients as soon as possible with the most-recently approved DAA drugs to remove the HCV infection, no matter what the level of infection. Chemical dependency testing and treatment are not relevant, nor is a correction facility's claim of lack of resources to justify treating some more severely symptomatic patients, and not others.

45. As of June 29, 2015, all HCV treatment providers are professionally obligated to prescribe non-Interferon DAA drugs (currently Harvoni or Viekira-Pak) to any HCV patient, with recommended treatment to begin immediately at any level of infection, no matter how recent or low the level of infection. This is the case for all treatment providers irrespective of their employment situation.

46. The standard of care evolved to include so-called triple therapy – one of the two protease inhibitors, taken with Interferon and Ribavirin – for Genotype 1 patients. Triple therapy was effective on nonresponders and relapsers, giving them a new option and potential cure.

47. The duration of treatment with triple therapy remained the same as with

combination therapy, as did the side effects. The expense increased because of the additional medication.

48. There have also been changes in how the disease is monitored. To measure fibrosis, providers now generally forego a liver biopsy in favor of non-invasive tests. Blood tests can offer an accurate assessment of liver fibrosis, and these tests can be coupled with certain types of scanning if desired.

49. These new developments in staging the disease, and treating it, have eliminated the barriers to a cure.

d. History of HCV Treatment in the KDOC

50. The KDOC's Old HCV Plan was developed in 2007 by state officials in response to litigation by prisoners complaining of their HCV treatment. *See Paulley v. Chandler*, No. 3:99-CV-00549, 2000 WL 33975579, at *1 (W.D. Ky. 2000). When a prisoner was diagnosed with HCV, the Old Plan laid out the procedure for treating and controlling the disease.

51. Even though the Old Plan required compliance with the prevailing standard of care, and despite the advances in HCV treatment over the last decade, it has not yet been updated. The Old Plan made no mention of the triple therapy treatment that had been the standard of care since 2011. Without policy and procedure guidance, testing and treatment of HCV by the KDOC has been ad hoc, arbitrary and capricious, and responsive to cost and administrative convenience, not the medical needs of Plaintiffs and the class. Moreover, since around July 2014, other than the most serious cases of HCV in the KDOC's institutions, *no one* with HCV was treated pending developments in HCV treatment options. Defendant Kemen testified in August 2014 that the KDOC was in "the earlier stages of ... revising or maybe replacing the [HCV] algorithm now." But the New Plan is

still in development. Whether the New Plan meets the applicable standard of care is currently the subject of litigation in *Woodcock v. Kentucky Dept. of Corrections, et al.*, Case No. 5:12-cv-135 (W.D.Ky.). Whether the New Plan will be followed and implemented in all deserving cases, together with the damages incurred from the delay in its implementation, is the subject of this case.

e. The Named Plaintiffs

i. Brian Woodcock

52. Mr. Woodcock is an inmate at the Kentucky State Penitentiary ("KSP"). A biopsy of Mr. Woodcock's liver in December 2011 showed that the fibrosis in his liver -- an indication of the severity of his condition -- had progressed from Stage 1 to Stage 2. For that reason, no less an authority than Dr. Steven Shedlofsky, the creator and then-director of the Old Plan, found that Mr. Woodcock qualified for antiviral prescription medication under the provisions of the Old Plan. However, after the KDOC terminated its association with Dr. Shedlofsky, a dispute arose over whether Mr. Woodcock qualified for treatment under the Old Plan and, if so, the appropriate treatment for his condition.

53. It was not until almost four years after filing a *pro se* lawsuit in federal court (*Woodcock v. Kentucky Dept. of Corrections, et al.*, Case No. 5:12-cv-135 (W.D.Ky.)) that Mr. Woodcock began receiving treatment for his condition, but not before his infection had progressed almost to Stage 4 cirrhosis. His request for leave to amend his complaint in that case to assert a claim for actual damages resulting from the delay in his treatment was recently denied.

ii. Ruben Rios Salinas

54. Mr. Salinas is an HCV-infected inmate at the Kentucky State Penitentiary ("KSP").

55. Mr. Salinas has been denied testing and treatment of his chronic HCV infection. On October 26, 2011, Mr. Salinas was told that he would receive the new HCV "triple-therapy" once it became available to the KDOC. When, on February 27, 2015, Mr. Salinas filed a "Petition for Mandamus" that initiated this litigation, in order to obtain testing and treatment for his condition, his petition was met by Defendants not with testing and treatment, but with a motion to dismiss his petition to this Court for relief.

iii. Keath Bramblett

56. Mr. Bramblett is an inmate at KSR, who acquired his HCV as a consequence of one of the infection-control positions he has held during his incarceration. Mr. Bramblett's ALT/AST levels – a measure of the severity of his infection – are high, 295 and 245 respectively. As a consequence, he has been denied participation in any educational or reentry programming involving working with food.

57. Mr. Bramblett has been denied any treatment for his condition. However, when the electric razor he had been prescribed for his own personal use due to his HCV condition ceased working, KSR's administration rejected doctor's orders that he be provided another one, and have required him to use "community" razors that are shared by other inmates.

VI. Causes of Action**Count 1: Violation of Eighth and Fourteenth Amendments to U.S. Constitution**

58. Paragraphs 1-57 above are incorporated herein by reference and made this Paragraph 58.

59. Plaintiffs and the class have HCV, an obviously serious medical need. Instead of receiving effective treatment for their condition, compliant with the standard of care, they have either been denied any treatment, and/or have had their treatment interrupted by its inept implementation, and/or have been required to engage in practices that are entirely inconsistent with treatment and may actually be hastening a spread of the infection. Defendants' conduct that directly or indirectly contributed to a worsening of the condition of Plaintiffs and any member of the class was intentional, reckless, deliberate, wanton and/or malicious, and was indicative of their total, deliberate and reckless disregard of and indifference to the lives and constitutional rights of Plaintiffs and the class.

60. Plaintiffs believe and, after reasonable discovery, will show that their treatment by Defendants was not unusual, but was part of a continuing policy, procedure, protocol, custom and/or practice of Defendants of willfully and deliberately ignoring the medical needs of inmates with HCV, and/or leaving their fates in the hands of correctional and medical employees that were ill-trained and ill-supervised, and that had long demonstrated their lack of qualifications to responsibly discharge their duties. Such conduct is the result of policies, procedures, protocols, customs and/or practices of Defendants, either written or unwritten, which are systematically applied to all persons who are diagnosed with HCV while incarcerated in KDOC institutions. Such practices constitute an arbitrary use of government power, and evince a total, intentional, deliberate and unreasonable disregard for and indifference to the lives and constitutional and common law rights of Plaintiffs and the class, and the wholesale violations of those rights likely to result from the regular and systematic pursuit of such policies, procedures, protocols, customs and/or practices.

61. As a result of the foregoing, Plaintiffs and the class, through Defendants' deliberately indifferent -- if not reckless, intentional and/or malicious -- conduct, were subjected to cruel and unusual punishment in violation of the Eighth and Fourteenth Amendments to the U.S. Constitution and 42 U.S.C. §1983.

**Count 2: Violation of the Rehabilitation Act of 1978, 29 U.S.C. §§791-794a
and the Americans With Disabilities Act, 42 U.S.C. §§12131-32.**

62. Paragraphs 1-61 above are incorporated herein by reference and made this Paragraph 62.

63. Plaintiffs and the class are handicapped individuals with a disability, specifically, their HCV infection, a physical impairment that substantially affects the major life activities of digestive systems, circulatory systems, and life itself.

64. Defendants have failed and refused to reasonably accommodate the handicaps and disabilities of Plaintiffs and the class, so as not to exclude them from participation in, or deny them the benefits of, the federally-funded services, programs, or activities of the KDOC, and by failing to provide treatment compliant with the standard of care.

Count 3: Negligence/Gross Negligence

65. Paragraphs 1-64 above are incorporated herein by reference and made this Paragraph 65.

66. By virtue of the foregoing, all Defendants were negligent and grossly negligent in their treatment of Plaintiffs and the class; in addition, the medical professionals responsible for the care of Plaintiffs and the class failed to meet the standard of care applicable to their professions in their treatment of Plaintiffs and the class.

Count 4: Intentional Infliction of Emotional Distress/Outrage

67. Paragraphs 1-66 above are incorporated herein by reference and made this Paragraph 67.

68. Defendants' intentional treatment of Plaintiffs and the class caused extreme mental and emotional distress that cannot be compensated by any other cause of action in this Complaint, and was so beyond the bounds of human decency that it exemplifies the tort of outrage.

VII. Injunctive Relief

69. Paragraphs 1-68 above are incorporated herein by reference and made this Paragraph 69.

70. Plaintiffs and the class reserve their right to pursue injunctive relief in the event Defendants fail to properly implement the New Plan as to all deserving class members.

VIII. Damages

71. Paragraphs 1-70 above are incorporated herein by reference and made this Paragraph 71.

72. The injuries suffered by Plaintiffs and the class was unnecessary and preventable. Lack of monitoring and treatment of HCV-infected inmates commensurate with the standard of care is inexcusable. A delay in treatment can increase susceptibility to liver cancer, shorten life expectancy, and increase future medical monitoring and treatment costs. As a consequence, Plaintiffs and the class are entitled to recover actual damages to compensate them for (a) any loss of their power to labor and earn money, (b) their past and future mental and physical pain and suffering, and (c) any future medical and medication expenses they must bear as a result of Defendants' misconduct. In addition, Defendants' violations of the constitutional and common

law rights of Plaintiffs and the class were cruel, malicious, and evinced a total and reckless disregard for their lives and rights, warranting an award of punitive damages from Defendants in order to deter such conduct in the future.

WHEREFORE, Plaintiffs and the class request certification of the class defined above, injunctive relief as and where appropriate, and that they be awarded: (a) actual damages for (i) their lost power to labor and earn money, (ii) their past and future mental and physical pain and suffering, and (iii) any future medical and medication expenses they must bear as a result of Defendants' misconduct; (b) punitive damages; (c) costs; (d) attorneys' fees pursuant to 42 U.S.C. §1988; (e) pre- and post-judgment interest on all sums awarded; and (f) all other relief to which they are entitled under law or in equity.

Respectfully submitted,

/s/ Gregory A. Belzley

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing was emailed, this 2nd day of November, 2016, to:

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/s/ Gregory A. Belzley
Gregory A. Belzley

Presiding Judge: HON. PHILLIP J. SHEPHERD (648260)

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