

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<p>JODI GILL, as Representative and Next Friend of GLENN OSCAR GILL, a Long Term Care Facility Resident, on his behalf and on behalf of all others Similarly Situated</p> <p>and</p> <p>GREG HUBERT, as Representative and Next Friend of NETHIA KNIGHT, a Long Term Care Facility Resident, on her behalf and on behalf of all others Similarly Situated</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">vs.</p> <p>PENNSYLVANIA DEPARTMENT OF HEALTH Health & Welfare Building 8th Floor West 625 Forster Street Harrisburg PA 17120</p>	<p>Hon. Harvey Bartle</p> <p>Case No. 20-cv-02038</p> <p>COMPLAINT -CLASS ACTION</p>
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FIRST AMENDED COMPLAINT – CLASS ACTION

INTRODUCTORY STATEMENT

1. This case concerns the Pennsylvania Department of Health (PA DOH) policy and practice of denying appropriate safeguards and care to nursing home residents (Long Term Care Facility residents) in the Commonwealth of Pennsylvania, in violation of the Rehabilitation Act, 29 U.S.C. 794, the Americans with Disabilities Act, 42 U.S.C. §§ 12131-12134, 42 U.S.C. §§ 12181, et seq.; the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116; 45 C.F.R. §§ 92.101(a), 92.101(b)(2)(i); and federal and state regulations concerning inspections and investigations of Long Term Care Facilities (LTCFs), including the Social Security Act, 42 U.S.C. 301, et seq., and its implementing regulations, 42 C.F.R. 483.1 et seq.; the Civil Rights Act, 42 U.S.C. § 1983 as it applies to the Federal Nursing Home Reform Amendments (FNRA), 42 U.S.C. § 1396r et seq.; and the Pennsylvania Disease Prevention and Control Law, 35 P.S. 521.1 et seq.
2. This case also concerns biomedical research without authorization or consent. These claims are based on the Nuremburg Code and Declaration of Helsinki. These lay out the minimum conduct required governing biomedical research on human beings.
3. The PA DOH is tasked with ensuring the safety and health of all Pennsylvania citizens including the residents of Long Term Care Facilities (LTCFs) and enforcing proper facility operation and conduct.
4. The PA DOH is required to inspect LTCFs to ensure the safety and health of the residents pursuant to the Code of Federal Regulations under the Social Security Act.
5. Residents of LTCFs are disabled as defined by the Rehabilitation Act.
6. These inspections have come nearly to a halt, thereby putting all LTCF residents at risk of infectious disease transmission. Specifically, these residents are at high risk for contracting SARS-COV-2 (the virus that causes COVID-19) which is pervasive within the community-at-large, and which is easily transmissible from close contact (respiratory droplets) and from surfaces (fomites).

7. The failure of the PA DOH to conduct inspections has also resulted in the apparent biomedical experimentation on residents under the guise of clinical trials. It is unlikely that such egregious conduct could have occurred had inspections not been halted.
8. Residents of LTCFs are the most medically fragile and high-risk members of our society. The decision to stop inspections of LTCFs was made arbitrarily and without consideration for the health, safety, and welfare of the residents.
9. By severely limiting the number of facility inspections the PA DOH has caused a direct, present, and credible threat to the health and wellbeing of the LTCF residents; and has caused death and injury.
10. The current public health emergency¹ presents discrete and specific dangers to high risk groups. The disabled are at high risk individually. Disabled individuals residing in LTCFs are at higher risk because of their disabilities and their close proximity to others.
11. The Pennsylvania Disease Prevention and Control Law gives the PA DOH through the Secretary of Health, and local boards of health, responsibility to safeguard the health and wellbeing of the citizens of the Commonwealth of Pennsylvania and requires the PA DOH to take action to mitigate the spread of disease. When the Secretary fails to act, anyone may move to enforce the law. 35 P.S. 521 et seq.
12. Residents of LTCFs cannot adequately distance themselves from others, thereby placing them at high risk for community infection. Moreover, staff are not properly equipped with Personal Protective Equipment (PPE) sufficient to prevent infection and cross contamination; and testing is not taking place to identify residents and staff who may be ill and able to transmit SARS-COV-2. This is in contrast to the type of infection control and testing available to those who reside outside of LTCFs. The control of infection spread outside LTCFs is also wielded by the PA DOH and all management direction comes from the Pennsylvania Secretary of Health, Dr. Rachel Levine. The application of this authority is disparate and places the LTCF disabled in a higher risk category solely because of their disability.

¹ Governor Wolf issued an Emergency Order effective March 16, 2020 (Ex A) which requires Pennsylvania residents to stay at home unless they are essential workers. A subsequent guidance from the U.S. Health and Human Services Department (Ex B) on March 13, 2020 directed facilities to self-evaluate for infection control purposes. A second guidance issued on March 23, 2020 directed state departments of health to prioritize only certain types of inspections. (Ex C).

13. The Pennsylvania Department of Health has a history of segregating the disabled from the non-disabled when considering who is to be protected and receive appropriate care and treatment during the current public health emergency. PA DOH issued Interim Guidelines on March 22, 2020 which applied as follows:

“When a situation is statewide: These triage guidelines apply to all healthcare professionals , clinics, and facilities in the Commonwealth of Pennsylvania. The guidelines apply to all patients.”²

Only after a complaint was lodged with the Office of Civil Rights of the Department of Health and Human Services, were these guidelines revised. The intent of the Guidelines was to keep the disabled from using resources which could be allocated to the non-disabled, thereby causing them harm. This was a blatant attempt to create policy which stated that the lives of the disabled are not as valuable as the lives of those who are not disabled. This is the essence of discrimination solely on the basis of disability.

14. Moreover, the PA DOH had knowledge that at least one LTCF was experimenting on its residents with unproven, unauthorized medication in an attempt to see if it prevented them from contracting COVID-19. The PA DOH failed to take action.
15. PA DOH had knowledge of poor conditions at many LTCFs and failed to take any substantive action that would have addressed or improved these conditions, including the failure to physically inspect and assist these facilities with infection control, staffing, testing, and modifications to prevent further spread of disease.
16. Moreover, the PA DOH had a plan in mid-March 2020 to protect LTCF patients using quick strike teams of medical professionals who were to have responded to nursing homes as soon as just a few positive cases were confirmed. They were to have shown up within hours of a call for help. But the entire plan and process was shelved without explanation. Now, the PA DOH is apparently only assisting LTCFs “virtually”. See, Exhibit “G”, Pattani, A., Moss R. “Pa had an

² A copy of the Interim Guidelines can be found here:
<https://www.health.pa.gov/topics/Documents/Diseases%20and%20Conditions/COVID-19%20Interim%20Crisis%20Standards%20of%20Care.pdf> (Version 2, accessed 4/27/20);
<https://int.nyt.com/data/documenthelper/6850-pennsylvania-triage-guidelines/02cb4c58460e57ea9f05/optimized/full.pdf> (Version 1, accessed 4/27/20)

early plan to protect nursing home residents from coronavirus, but never fully implemented it.”
Philadelphia Inquirer. May 9, 2020 (accessed 0745 a.m.).

17. LTCFs in Pennsylvania have been asking for help from the PA DOH for several weeks, yet have received very little in response to their pleas. See, collectively, articles attached as Exhibit “H”.
18. Plaintiffs, on behalf of persons with disabilities residing within LTCFs in the Commonwealth of Pennsylvania, seek a preliminary and permanent injunction requiring Defendants to:
 - a. Accommodate all class members by enforcing the infection control and other regulations in each and every LTCF in the Commonwealth, to include testing, monitoring, quarantine, and any other necessary public health benefit available to the rest of the public;
 - b. Prevent class members from being experimented upon without consent;
 - c. Inspect LTCFs to determine whether cases of COVID-19 exist in the facility;
 - d. Take appropriate public health action to segregate individuals who are COVID-19 positive and to mitigate and prevent the transmission of the virus to others;
 - e. Provide residents with appropriate personal protective equipment;
 - f. Provide staff with COVID-19 testing at appropriate intervals to safeguard not only residents, but also staff caring for those residents;
 - g. Report publicly and to residents (and families) of each LTCF, the number of COVID-19 positive residents with a plan for mitigation and options/plans for each resident who is COVID-19 negative to avoid infection;
 - h. Employ sufficient staff to fully undertake its responsibility to these disabled individuals to protect them and safeguard their well-being; and numbers of staff sufficient to maintain records required to be maintained in this (COVID19) type of public health emergency;
 - i. Appoint and direct appropriate and qualified personnel to assist facilities in person with the care of residents, when requested by the facility.

- j. Maintain records subject to inspection by appropriate authorities, including the Court or appointed Master if necessary;
 - k. Consider the needs of persons with disabilities in LTCFs in planning any future public health program, plans or actions involving SARS-COV-2 and COVID-19.
19. Plaintiffs therefore bring this action on behalf of all class members to ensure that they are not subject to ongoing and incipient harm as a result of the failure of the PA DOH to enforce regulations for the health, safety and wellbeing of the class members.

PARTIES

20. Plaintiff is Jodi Gill. She is authorized to take this action on behalf of her father, Glenn Oscar Gill, age 81, who is a resident of Brighton Rehabilitation and Wellness Center in Beaver, Pennsylvania. Mr. Gill suffers from disabilities within the meaning of the Rehabilitation Act, including advanced dementia and cardiovascular disease. Mr. Gill has been a resident at Brighton since September 25, 2019. She is a class representative.
21. In early April, Brighton announced that it would treat all of its residents as presumptively positive. On April 10th, Ms. Gill was called by a nurse at the facility and convinced to sign a “consent” for an experimental drug study she was told was to find out whether the drug combination of hydroxychloroquine and zinc would prevent infection with COVID-19. The full document is attached as Exhibit “D” and is as follows:

CONSENT FOR EXPERIMENTAL POST EXPOSURE PROPHYLAXIS DURING A NATIONAL PANDEMIC

I, _____, understand and agree that:

1. The United States is currently under a pandemic, or widespread infection, of the COVID-19 virus, which is a potentially fatal and easily transmittable virus that primarily effects the ability of a person to breathe and can result in serious injury or death.
2. At the time of this Consent, there is no known medicine that can prevent someone from being infected with COVID-19.
3. Medical research is currently underway to determine if a person taking the drug hydroxychloroquine in conjunction with a zinc tablet can be medically prevented from becoming infected with COVID-19.
4. The use of hydroxychloroquine in conjunction with a zinc tablet is not currently approved by the U.S. Food and Drug Administration (FDA) for preventing a person from being infected with COVID-19. Because this treatment is not FDA-approved, taking hydroxychloroquine in conjunction with a zinc tablet is an "off-label" use, which is to say that the drug manufacturers of hydroxychloroquine, nor the FDA, have said the drug can be, or should be, used to prevent a person from becoming infected with COVID-19.
5. Generally, hydroxychloroquine has few side effects when used for short periods. The most common side effect is upset stomach. However, some serious side effects such as injury to the heart may occur. In addition to these risks, the use of hydroxychloroquine and zinc may harm you in unknown ways, and could cause serious injury, sickness, permanent injuries, and/or death.
6. Understanding the risks associated with the off-label and experimental use of hydroxychloroquine and zinc tablets to prevent becoming infected with COVID-19, I wish to proceed with this treatment as I believe it to be the best course of action in the current National Emergency.

Date: _____ Time: _____

Patient Signature: _____

Witness Signature: _____ Printed name: _____

22. There is no evidence that this “study” was approved by an Institutional Review Board, or that a Data Safety Monitoring Board was engaged, or that any kind of actual informed consent was sought or given. In fact, Ms. Gill was coerced to sign the form because she was told that it would help her father and by not signing it, she would not be helping him. She was told that there were hundreds of people who had to be called about the “study” and that she needed to hurry up and make up her mind. Emails between Ms. Gill and the facility as well as the Director of Skilled Nursing Facilities for the Commonwealth of Pennsylvania are attached hereto as Exhibit “E”.
23. Mr. Gill has been exposed to SARS-COV-2. It is unknown if he is positive at this time. It is unknown if he has suffered physical injury as a result of the unapproved biomedical research study that was conducted on him and hundreds of others in the Brighton facility. It is certain that Mr. Gill is at imminent risk for contracting COVID-19.
24. Mr. Gill and the other residents at Brighton as well as at other LTCFs are at immediate risk of contracting COVID-19 and are clearly at immediate risk of being experimented upon. These individuals represent the most fragile in our society and deserve protection, not exploitation
25. Plaintiff is Greg Hubert. He is authorized to take this action on behalf of his grandmother, Netha Knight, age 96, who is a resident of York Rehabilitation and Nursing Center in Philadelphia, Pennsylvania. Ms. Knight suffers from disabilities within the meaning of the Rehabilitation Act, including dementia, hypertension, diabetes and ambulation difficulties. Ms. Knight has been a resident at York for four years. She is a class representative.
26. York Rehabilitation and Nursing Center has COVID-19 -positive patients. Upon information and belief, Ms. Knight was recently moved from her room on the second floor which she shared with two other residents, to the first floor (to a room also with two other residents) which is known to be the COVID-19 -positive floor. At the time she was moved, her family believed she was COVID-19 -negative. Ms. Knight was apparently tested for COVID-19 but the results have not been provided.
27. These named plaintiffs are only two of the more than 75,000 nursing home residents in Pennsylvania. The situations and conditions of their loved ones are not unique. See, Exhibit “F”, Declaration of George Emerson (complaints to PA DOH concerning conditions and infection at Brighton were met with no response).

28. Defendant is the Pennsylvania Department of Health which is the department responsible for the inspection of LTCFs and enforcement of the infection control and other regulations applicable to them, as well as the enforcement of applicable public health statutes and regulations. PA DOH is responsible for safeguarding the health of the citizens of the Commonwealth, especially during times of public health emergency.

JURISDICTION

29. All previous paragraphs are hereby incorporated by reference as though each were fully set forth herein.

30. This is an action for declaratory and injunctive relief to enforce the Plaintiffs' rights as aforesaid. This Court has subject matter jurisdiction over this action under 28 U.S.C. 1331 and 1343(a)(3) and (4) This action arises under Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, et seq.; the Americans with Disabilities Act, 42 U.S.C. §§ 12131-12134, 42 U.S.C. §§ 12181, et seq.; the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116; 45 C.F.R. §§ 92.101(a), 92.101(b)(2)(i); the Social Security Act, 42 U.S.C. 301, et seq., and its implementing regulations, 42 C.F.R. 483.1 et seq.; the Civil Rights Act, 42 U.S.C. § 1983 as it applies to the Federal Nursing Home Reform Amendments (FNRA), 42 U.S.C. § 1396r et seq.; and the Pennsylvania Disease Prevention and Control Law, 35 P.S. 521.1 et seq.

31. This Court has supplemental jurisdiction under 28 U.S.C. 1367 over Plaintiffs' claims under the Pennsylvania state and local laws and regulations prohibiting disability discrimination; the public health laws and regulations, and the laws and regulations regarding LTCF inspection, safety, and control.

32. Venue properly lies in this district pursuant to 28 U.S.C. 1391(b).

CLASS ACTION ALLEGATIONS

33. All prior paragraphs are hereby incorporation by reference as though each were fully set forth herein.

34. Plaintiffs bring this action pursuant to Rule 23(a) and Rule 23(b)(2) of the Federal Rules of Civil Procedure on their own behalf and on behalf of all others similarly situated.

35. Plaintiffs' class consists of all individuals in Pennsylvania who are residents of Long Term Care Facilities (LTCFs) all of whom are disabled within the meaning of the Rehabilitation Act, for the reasons as aforesaid.
36. The class is so numerous that joinder of all members is impracticable.³
37. Upon information and belief, based on the number of LTCF residents and the number of LTCFs in Pennsylvania, and the highly infectious nature of SARS-COV-2, that every LTCF resident is at incipient risk for infection with SARS-COV-2, and subsequent community transmission to others. These residents are also at immediate risk for exploitation via unauthorized biomedical research.
38. The laws and regulations which address the nature of this action and that form the basis of this complaint are common to all members of the class. The relief sought will apply to all of them.
39. Questions of law common to the members of the class include whether defendants violated the Rehabilitation Act, the Americans with Disabilities Act, the Social Security Act, the Patient Protection and Affordable Care Act, the Pennsylvania statutes and regulations relative to the public health and infection control, and other regulations relative to LTCFs, and common law duties, by failing to conduct activities and inspections as aforesaid, and to ensure that the disabled are afforded the same protections as the rest of the public.
40. The claims of the Plaintiffs are typical of the claims of the entire class. Defendant's violation of the laws as alleged herein has deprived Plaintiffs and members of the class to be deprived of the safety and wellbeing afforded to the rest of the public by the PA DOH. Therefore, all class members will suffer the same or similar injuries for the purposes of the injunctive and declaratory relief sought.
41. The named plaintiffs are capable of fairly and adequately representing the class and protecting interests. Counsel for the Plaintiffs are attorneys with substantial class action litigation experience as well as substantial experience in litigating on behalf of plaintiffs with disabilities. Counsel are aware of no conflicts among members of the proposed plaintiff class.

³ There are nearly 76,000 nursing home residents in Pennsylvania according to the 2018-2019 data from the State which is the most recent census available. (<https://www.health.pa.gov/topics/HealthStatistics/HealthFacilities/NursingHomeReports/Pages/nursing-home-reports.aspx> Accessed 5/3/2020).

42. The prosecution of separate actions by individual members of the class would create a risk of inconsistent and varying adjudications that would establish incompatible standards of conduct for the defendant.
43. The prosecution of separate actions by individual members of the class would also create a risk of adjudications with respect to individual members which would, as a practical matter, substantially impair the ability of other members to protect their interests.
44. Defendants have acted or refused to act on grounds generally applicable to the class, making appropriate injunctive and declaratory relief with respect to the class as a whole.

STATUTORY FRAMEWORK

45. All prior paragraphs are hereby incorporated by reference as though each were fully set forth herein.
46. Section 504 of the Rehabilitation Act, 29 U.S.C. 794 prohibits federally funded programs or activities from excluding, denying benefits to, or discriminating against, an “otherwise qualified individual with a disability in the United States. . . solely by reason of her or his disability.”
47. Title II of the ADA prohibits public entities (such as state and local governments) from excluding people with disabilities from their programs, services, or activities, denying them the benefits of those services, programs, or activities, or otherwise subjecting them to discrimination. 42 U.S.C. §§ 12131-12134.
48. Title III of the ADA imposes almost identical prohibitions on public accommodations, which includes hospitals and other health care providers. 42 U.S.C. §§ 12181(7)(F), 12182. Specifically, Title III bars health care providers from excluding people with disabilities from the full and equal enjoyment of their services and facilities. 42 U.S.C. § 12182(a). Congress construed this non-discrimination mandate broadly to bar, *inter alia*: use of eligibility criteria that screen out or tend to screen out people with disabilities; failure to make reasonable modifications to policies, practices, and procedures necessary to avoid discrimination; and aiding or perpetuating discrimination by others. 42 U.S.C. §§ 12182(b)(1)(D)(ii), 12182(b)(2)(i)-(ii); *accord* 28 C.F.R. §§ 36.204, 36.301, 36.302.
49. The breadth of Section 504’s prohibition on disability discrimination is co-extensive with that of the ADA.

50. Section 1557 of the ACA provides that no health program or activity that receives federal funds may exclude from participation, deny the benefits of their programs, services or activities, or otherwise discriminate against a person protected by Section 504 of the Rehabilitation Act, 42 U.S.C. § 18116; 45 C.F.R. §§ 92.101(a), 92.101(b)(2)(i). This includes an obligation to make reasonable modifications in policies, practices, and procedures necessary to avoid discrimination. 45 C.F.R. § 92.205
51. The Social Security Act, 42 U.S.C. 301 et seq is enforced relative to LTCFs via the Code of Federal Regulations, specifically 42 C.F.R. 483.1 et seq, which govern oversight and requirements for the operation of LTCFs and the enforcement of those operations and the safety, health, and welfare of LTCF residents.
52. The Pennsylvania Department of Health accepts money from the federal department of Health and Human Services. As such, it is obligated to follow and abide by the Rehabilitation Act, the ADA, ACA, Social Security Act, Federal Nursing Home Reform Amendments, Civil Rights Act, and all of their implementing regulations.
53. The Rehabilitation Act's implementing regulations further provide that "[a] [federal funds] recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant. . . unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program." 28 C.F.R. 41.53.
54. An entity's failure to provide a reasonable accommodation to a disabled individual that the individual needs in order to enjoy meaningful access to the entity's benefits and/or services constitutes discrimination under the Rehabilitation Act.
55. A disability includes "a physical or mental impairment that substantially limits one or more major life activities of [an] individual[.]" See 29 U.S.C. 705(20)(B) (citing 42 U.S.C. 12102(1)).
56. A major life activity includes, but is not limited to the ability to ambulate, eat independently, [multiple citations] 29 U.S.C. 705(20)(B) (citing 42 U.S.C. 12102(2)).
57. Included in the Rehabilitation Act's definition of "program or activity" are "all of the operation of . . . an entire corporation. . . or other private organization . . . which is principally engaged in the business of providing. . . health care. . ." 29 U.S.C. 794(b)(3)(A)(ii). Any entity receiving federal financial assistance is subject to the Act. 29 U.S.C. 794(a). All of the operations of the

department, agency...or other instrumentality, any part of which is extended federal financial assistance” is subject to the Act. 29 U.S.C. 794(b)(1)(A) and (B).

58. The Federal Nursing Home Reform Amendments (FNRA), 42 U.S.C. § 1395i-3 et seq., and 1396r et seq. create rights which inure to the individual nursing home resident. The Plaintiff seeks redress of the violations of these rights through 42 U.S.C. 1983. These rights include:

- a. A safe and infection-controlled environment;
- b. Prevention of the development of disease;
- c. The right to have a safe environment free from discrimination;
- d. The right to have all violations of the residents’ rights investigated by the State which is obligated to provide oversight and assurance that the needs and rights of the residents are being met and respected; and to require the conditions are such that the residents’ health and welfare are protected;
- e. The right to have immediate steps taken by the State for deficiencies and risks to the residents’ health and safety.

59. The Pennsylvania Disease Prevention and Control Law gives the PA DOH through the Secretary of Health, and local boards of health, responsibility to safeguard the health and wellbeing of the citizens of the Commonwealth of Pennsylvania and requires the PA DOH to take action to mitigate the spread of disease. When the Secretary fails to act, anyone may move to enforce the law. 35 P.S. 521 et seq. The main purpose of the DPCL is to institute a system of mandatory reporting, examination, diagnosis, and treatment of communicable diseases. A public health system depends on public oversight and accountability.

60. Federal regulations require that a skilled nursing facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infection. 42 C.F.R. 483.80. The regulations also require that the facility’s infection control program must include minimum elements which include a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, and that they must follow national standards. 42 C.F.R. 483.80(a) and (a)(1).

61. A skilled nursing facility is required to operate and provide services in compliance with all applicable federal, state, and local laws and regulations, and within accepted professional standards and principles which apply to professionals providing services in such a facility. 42 U.S.C. 1395i-3, et seq.
62. Moreover, a state must maintain procedures and adequate staff to investigate complaints of violations and to monitor on-site on a regular basis a facility's compliance with the requirements of applicable federal rules and regulations. 42 U.S.C. 1395i-3, et eq.
63. Defendant is principally engaged in the provision and oversight of health care services; policy enactment, enforcement, oversight and coordination.

FRAMEWORK OF THE NUREMBURG CODE & DECLARATION OF HELSINKI

64. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
65. The Nuremberg Code and the Declaration of Helsinki are the minimum international standards of conduct governing biomedical research on human subjects; they are in essence world statutes to which the citizens of all nations are subject.
66. The Nuremberg Code, drafted in response to the horrors of Nazi experimentation on human subjects, set forth basic principles "to satisfy moral ethical and legal concepts."
67. The Nuremberg Code provides in pertinent part:

The voluntary consent of the human subject is absolutely essential. . . . before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

...

The experiment should be designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem understudy that the anticipated results will justify the performance of the experiment.

...

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

...

Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

...

The experiment should be conducted only by scientifically qualified persons.

68. The World Health Organization established the Declaration of Helsinki to further the goals of the Nuremberg Code and to set the minimum acceptable standards in all nations in which human clinical trials are conducted.

These include:

Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

...

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

...

Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person..

...

Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk to the subject.

Concern for the interests of the subject must always prevail over the interest of science and society.

...

The right of the research subject to safeguard his or her integrity must always be respected.

...

Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable.

...

In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.

69. The common law has recognized such standards as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial, and such is a right of all citizens under the Constitution of the United States and of the Commonwealth of Pennsylvania.

70. Defendants' actions, as set forth above, fell below the minimum standards of conduct set forth under the Nuremberg Code and the Declaration of Helsinki and were a breach of the right of plaintiffs and the class to be treated with dignity.

DEFENDANT’S FAILURE TO COMPLY WITH THE ADA, REHABILITATION ACT, SOCIAL SECURITY ACT, ACA FNHRA, the CIVIL RIGHTS ACT (Sec. 1983) and the DISEASE PREVENTION AND CONTROL LAW

71. All prior paragraphs are hereby incorporated by reference as though each were fully set forth herein.
72. The Pennsylvania Department of Health has a history of segregating the disabled from the non-disabled when considering who is to receive appropriate care and treatment during the current public health emergency. PA DOH issued Interim Guidelines on March 22, 2020 which applied as follows:

“When a situation is statewide: These triage guidelines apply to all healthcare professionals , clinics, and facilities in the Commonwealth of Pennsylvania . The guidelines apply to all patients.”⁴

Only after a complaint was lodged with the Office of Civil Rights of the Department of Health and Human Services, were these guidelines revised, yet they still contain language tacitly directing the rationing of care at the expense of the disabled. The intent of the Guidelines was to keep the disabled from using resources which could be allocated to the non-disabled, thereby causing them harm. This is the essence of discrimination solely on the basis of disability.

73. As aforesaid, Defendants have already excluded, denied services to, and discriminated against, the disabled residents of LTCFs in Pennsylvania in violation of the Rehabilitation Act. As a result, these individuals have been injured, died or are in danger of incipient injury and death, as aforesaid.
74. Defendants knew or had reason to know of the disabilities of these individuals at the time the decision was made to fail to take warranted, required and appropriate action that would have safeguarded these individuals.
75. Defendant’s failure to conduct appropriate inspections, oversight and management of its duties with regard to LTCFs threatens Plaintiff’s class members with real, immediate, and substantial

⁴ See, URLs at footote 2.

harm by impeding their ability to access the safeguards of the laws and regulations designed to protect them.

COUNT ONE

Violation of 29 U.S.C. 794 – Rehabilitation Act

76. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
77. As a result of Defendant’s policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF.
78. As a direct and proximate result of the Defendant’s actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT TWO

Violation of the Americans with Disabilities Act

79. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
80. As a result of Defendant’s policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF.
81. As a direct and proximate result of the Defendant’s actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT THREE

Violation of the Affordable Care Act

82. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
83. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF.
84. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT FOUR

Violation of the Social Security Act

85. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
86. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF. Defendants are obligated to conduct appropriate inspections and enforcement under the SSA which responsibility they have abrogated to the detriment of the Plaintiffs and class members.
87. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT FIVE

Violation of the Federal Nursing Home Reform Amendments (1983 Action)

88. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
89. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF. Defendants are obligated to conduct appropriate inspections and enforcement under the SSA which responsibility they have abrogated to the detriment of the Plaintiffs and class members.
90. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT SIX

Violation of the Pennsylvania Disease Prevention and Control Law

91. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
92. As a result of Defendant's policy and practice of segregating Plaintiffs and their class members, and as a result of denying appropriate safeguards to the residents of LTCFs, Defendant has failed to care for its most fragile citizens and discriminated against them because of their disability. Defendant has excluded them from appropriate oversight, protection, care, safety, wellbeing, and all other protections afforded to the public, and those not confined to a LTCF. Defendant is required under the DPCL to take all action required to prevent, identify, examine, diagnose and cause to be treated every potential communicable disease within the Commonwealth.
93. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

COUNT SEVEN

Violations of the Nuremburg Code and Declaration of Helsinki and the Constitution of the United States and Commonwealth of Pennsylvania

94. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
95. The common law has recognized the standards of the Nuremburg Code and the Declaration of Helsinki as a source of the right of every human subject to be treated with dignity in the conduct of a clinical trial. These are constitutional rights of dignity under the federal and state constitutions.
96. The Plaintiff and the class members were not afforded these basic rights and suffered as a result.
97. As a direct and proximate result of the Defendant's actions and inactions, the Plaintiffs and their class members have been harmed or are in danger of incipient harm as aforesaid.

DECLARATORY AND INJUNCTIVE RELIEF

98. All prior paragraphs are hereby incorporated by reference as though each were fully set forth at length herein.
99. Plaintiff respectfully requests that this Court:
 - a. Assert jurisdiction over this matter;
 - b. Issue a declaratory judgment in favor of Plaintiffs declaring that:
 - i. Defendants must provide appropriate oversight and enforcement of the rules and regulation respecting LTCF operation which oversight shall include the following:
 1. Immediate inspection of facilities to determine the adequacy of infection control procedures in light of the current public health emergency;
 2. Immediate action including but not limited to testing (swab and serum antibody) of all residents, and documentation of all cases of COVID-19

in all LTCFs in Pennsylvania in order to protect those currently infected as well as those at imminent risk for infection due to the nature of the disease and its ease of transmission;

3. Record and report all cases of COVID-19 by facility and make this data available to the public on a rolling, as-collected, basis;
 4. Report all positive COVID-19 cases to the resident and family of residents who test positive for the disease;
 5. Immediately take steps to safeguard LTCF residents in accordance with standards of care for highly communicable diseases, including the implementation and enforcement of all public health recommendations with regard to those at highest risk for contracting COVID-19. These steps should include, at a minimum, following the recommendations of a court-approved medical monitoring physician/team who will determine the minimum set of monitoring required.
 6. Immediately take steps to cause all non-IRB approved biomedical research studies to cease and to identify any and all studies that have taken place, their physical locations, and the principal investigators or persons directing said studies.
- c. Issue a permanent injunction that bars Defendant from:
- i. Withholding appropriate testing or other safeguards, including treatment, appropriate monitoring, and personal protective equipment from the disabled residents of LTCFs
 - ii. Excluding, denying services to, or discriminating against disabled residents of LTCFs
 - iii. Failing to protect disabled residents of LTCFs from unethical and unauthorized biomedical research.

- d. Issue a permanent injunction which requires Defendant to follow the guidance of and report to a medical/public health monitor to ensure compliance with standards of care and oversight
- e. Award Plaintiffs the costs of this action including attorneys fees pursuant to statute;
- f. Award such other relief as this Court deems just and appropriate

Respectfully submitted,

/s/ Theresa M. Blanco

Robert L. Sachs, Jr., Esquire
Theresa M. Blanco, Esquire

May 12, 2020