



*The*  
**Legal Atmosphere**  
*for*  
**Aerospace Medicine Professionals**  
*in Commercial Human Spaceflight*

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# Celestial Bodies of Law

## **\* \*\*** State Law Predominates

- \* Despite the traditionally federal character of spaceflight activity, liability for human spaceflight accidents will be determined by a given state's *tort law*.
- \* *i.e.* basic state-based law of:
  - \* *Negligence* (including medical malpractice)
  - \* *Product liability*

## **\* \*\*** Federal Law?

## **\* \*\*** International Space Treaties?

# Anatomy of a Negligence Lawsuit

**\*\*DUTY:** The relationship between defendant and plaintiff must be such that the defendant had a “*duty of care*” to plaintiff;

**\*\*BREACH:** Defendant must have breached the duty by falling below the *standard of reasonable care* under the circumstances; and

**\*\*CAUSATION:** The defendant’s breach must have *caused* the claimed injury.

**ONCE THESE ELEMENTS ARE MET, THE AMOUNT OF JUDGMENT IS BOUND ONLY BY THE *AMOUNT OF PROVABLE DAMAGE***

# Anatomy of a Negligence Lawsuit (cont.): The *Breach* Element

**BREACH = *Failure to Observe Applicable Standard of Care.***

**\*\*“Standard of Care” depends on the *activity*--**

- ✱ Direct dealings with crew and spaceflight participants (“SFPs”)—medical examinations, consultations, designing training regimens
- ✱ Industry support—
  - ✦ for *launch operators*—e.g. developing SFP & crew screening protocols, training programs etc.
  - ✦ For *spacecraft and subsystem manufacturers*—e.g. design of environmental control systems, crashworthiness features etc.

# Direct Dealings with Crew & SFPs

The Million \$ Question: *What Will Be The “Standard of Care”?*

## Uncharted Territory. . .

- \*\*** Unlike NASA human spaceflight program, SFPs will often be soft, untrained, unaware of limitations, aeromedically naive, lacking a comprehensive medical record, non-captive, elderly and disabled.
- \*\*** Unlike traditional medical examinations given to passengers to assess suitability for flight, consultations with SFPs will require an understanding not only of the SFP’s condition, but also of the launch architecture of the particular spacecraft, environmental and survivability systems, altitudes, inflight g-forces and landing impact forces, and radiation exposures.
- \*\*** Examiners will likely be conduct exams according to not only their own standards, but also the launch provider’s. (*Aeromedical professionals will be an extremely important part of a launch provider’s risk management program!*)

# Direct Dealings with Crew & SFPs

## One Solution: *Industry Guidelines*. . .

- \***\*** What physical condition makes the cut for a given launch & recovery mode, and flight duration?
- \***\*** What will be the methodology for ascertaining that condition?
- \***\*** Will launch providers impose their own, more stringent criteria, and if so how shall the examiner's assessment be interpreted against that criteria?
- \***\*** Will "standard of care" dictate a training regimen in all cases, and if so, consisting of what, and how will progress be measured?
- \***\*** Will post-mission follow-up and monitoring be accepted practice?
- \***\*** Will launch providers make accessible to aeromedical professionals all medically relevant information on launch architectures, equipment and operations?
- \***\*** What health risk disclosures should be the standard?

Standard of Care--

# Special Considerations as to Crewmember Screening

*(Its Not Your Grandfather's 2<sup>nd</sup> Class Medical Exam!)*

Whereas in the aviation context, pilots are evaluated in strict accordance with FAA requirements and published guidelines, medical examiners of astronaut crewmembers *blaze their own trail.*

- \***\*** Traditional purpose of crewmember medical examination has been to avoid death, incapacitation or impairment due to *natural causes* while flying the aircraft → cursory exam sufficient. In commercial human spaceflight, must also prevent those occurrences as a result of *the spaceflight activity and environment* → much more is required.
- \***\*** Human Spaceflight FARs' requirement for a 2nd Class Medical Certificate = irrelevant as practical matter?

# Standard of Care-- Industry Support

for  *Launch Providers. . .*  
 *Manufacturers*



- ✦ SFP & crew screening protocols
- ✦ training programs
- ✦ inflight monitoring
- ✦ incident management/abort criteria
- ✦ health risk disclosure protocols (i.e. radiation)



- ✦ environmental control systems
- ✦ spacecraft-SFP interface
- ✦ survivability systems and suits
- ✦ crashworthiness
- ✦ crewmember human factors



# The *Human Spaceflight Regulations*

“Human Space Flight Requirements for Crew and Space Flight Participants”

14 CFR parts 401 *et seq.*

## 14 CFR part 460.5: *Crew qualifications and training*

- \* **subd. (b):** Each member of a flight crew must demonstrate an ability to withstand the stresses of space flight, which may include high acceleration or deceleration, microgravity, and vibration, in sufficient conditions to safely carry out his or her duties.
- \* **subd. (c):** A pilot and a remote operator must—(1) Possess and carry an FAA pilot certificate with an instrument rating.
- \* **subd. (e):** Each crew member with a safety-critical role must possess and carry an FAA second-class airman medical certificate issued in accordance with 14 CFR part 67, no more than 12 months prior to the month of launch and reentry.

# Human Spaceflight Regulations (cont.)

## Part 460.11: Environmental Control & Life Support Systems

- \* (a) An operator must provide atmospheric conditions adequate to sustain life and consciousness for all inhabited areas within a vehicle. The operator or flight crew must monitor and control the following atmospheric conditions in the inhabited areas or demonstrate through the license or permit process that alternate means provides an equivalent level of safety—
  - (1) Composition of the atmosphere, which includes oxygen and carbon dioxide, and any revitalization;
  - (2) Pressure, temperature and humidity;
  - (3) Contaminants that include particulates and any harmful or hazardous concentrations of gases, or vapors; and
  - (4) Ventilation and circulation.
- \* (b) An operator must provide an adequate redundant or secondary oxygen supply for the flight crew.
- \* (c) An operator must--
  - (1) Provide a redundant means of preventing cabin depressurization; or
  - (2) Prevent incapacitation of any of the flight crew in the event of loss of cabin pressure.

# Human Spaceflight Regulations (cont.)

## Part 460.15: Human Factors

An operator must take the precautions necessary to account for human factors that can affect a crew's ability to perform safety-critical roles, including in the following safety-critical areas—

- \* (a) Design and layout of displays and controls;
- \* (b) Mission planning, which includes analyzing tasks and allocating functions between humans and equipment;
- \* (c) Restraint or stowage of all individuals and objects in a vehicle; and
- \* (d) Vehicle operation, so that the vehicle will be operated in a manner that flight crew can withstand any physical stress factors, such as acceleration, vibration and noise.

# Liability Insurance

## State of the Market

**\*\* Current Picture for Industry as a Whole:** Market is shaping up for spaceflight companies to obtain the insurance required by the human spaceflight FARs, but not much more.

**\*\* Forecast for *Medical Malpractice Coverage*:** Like most segments of insurance underwriting, will be challenging to obtain until there is a *track record*.

- \* Will adverse medical and physiological episodes prove to be a common occurrence in commercial human spaceflight?
- \* If so, will involved physicians tend to be targets in litigation?
- \* What will be typical ranges of monetary recovery?



**WHAT COULD BE BETTER ...**



**...than lawyers in space?**