

References and Glossary

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ABBREVIATIONS

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|--------------|---|
| ADR | alternative dispute resolution |
| AIDS | acquired immunodeficiency syndrome |
| ALI | American Law Institute |
| ARAC | AIDS Research Advisory Committee (NIAID) |
| AVCTN | AIDS Vaccine Clinical Trials Network |
| AVEU | AIDS Vaccine Evaluation Unit (NIH) |
| AVEG | AIDS Vaccine Evaluation Group (NIH) |
| AZT | Zidovudine |
| CDC | Centers for Disease Control and Prevention, (PHS) |
| CIOMS | Council for International Organizations of Medical Sciences |
| CTL | cytotoxic T lymphocytes |
| DAIDS | Division of AIDS (NIAID) |
| DES | diethylstilbestrol |
| DHHS | U.S. Department of Health and Human Services |
| DNA | deoxyribonucleic acid |
| DOD | U.S. Department of Defense |
| DTP | diphtheria, tetanus, and pertussis |
| ELISA | enzyme-linked immunosorbent assay |
| EIA | enzyme immunoassay |
| FDA | Food and Drug Administration, U.S. (PHS) |
| GPA | Global Programme on AIDS (WHO) |

| | |
|----------------|---|
| HAV | hepatitis A virus |
| HBV | hepatitis B virus |
| Hib | <i>Haemophilus influenzae</i> type B |
| HIV | human immunodeficiency virus |
| HIV-1 | human immunodeficiency virus, type 1 |
| HIV-2 | human immunodeficiency virus, type 2 |
| HIVIG | human immunodeficiency virus immune globulin |
| HIVNET | HIV Trial Network (NIH) |
| IND | investigational new drug |
| IOM | Institute of Medicine |
| IPV | injected polio vaccine |
| NCI | National Cancer Institute (NIH) |
| NIAID | National Institute of Allergy and Infectious Diseases (NIH) |
| NIH | National Institutes of Health, (PHS) |
| OIG | Office of the Inspector General (DHHS) |
| OPV | oral polio vaccine |
| PAHO | Pan American Health Organization |
| PCR | polymerase chain reaction |
| PHS | Public Health Service (DHHS) |
| R&D | research and development |
| RNA | ribonucleic acid |
| SIV | simian immunodeficiency virus |
| UNICEF | United Nations Children's Emergency Fund |
| WHO | World Health Organization |

GLOSSARY

Acquired immunodeficiency syndrome

see *AIDS*.

Adenovirus

Any of a group of DNA-containing viruses originally identified in human adenoid tissue, causing respiratory diseases, and including some capable of inducing malignant tumors in experimental animals. See also *virus*; compare *reovirus* and *retrovirus*.

Adjuvant

A substance or treatment given in conjunction with another treatment. In immunology, a substance, such as alum, added to a vaccine which non-specifically enhances its antigenicity.

ADR

See *alternative dispute resolution*.

AIDS (acquired immunodeficiency syndrome)

A disease caused by infection with HIV (human immunodeficiency virus) and characterized by impaired immune function. The primary defect in AIDS is an acquired, persistent, quantitative functional depression within the T4 subset of lymphocytes. This depression often leads to infections caused by microorganisms that usually do not produce infections in individuals with normal immunity. HIV infection can be transmitted from one infected individual to another by means that include the sharing of contaminated, intravenous needles and engaging in unprotected sexual intercourse (i.e., intercourse without condoms), as well as transmission from infected mother to newborn (vertical transmission).

Alternative dispute resolution (ADR)

A process outside the judicial system for resolving legal claims. Decisions are made by dispute resolution professionals. ADR can be binding or nonbinding. See *arbitration*.

Amino acid

Any of a group of 20 molecules that join together in various combinations to form proteins. A protein's shape, properties, and biological functions are determined in part by the specific sequence of its constituent amino acids.

Anaphylaxis

An uncommon potentially life-threatening allergic reaction that occurs immediately (within minutes) following exposure to a previously encountered antigen,

such as from an insect bite or vaccine injection. It can be manifested as either a localized response (an allergic attack) or as an extreme and generalized reaction (anaphylactic shock) in which difficult breathing, pallor, hypotension, loss of consciousness, and possibly heart failure may result if untreated. Anaphylaxis is has not been observed with HIV vaccine candidates studied.

Annuity

A set sum is paid at maturity.

Antibiotic

A chemical substance that is administered to inhibit the growth of bacterial and fungal infections in humans or animals. Examples are penicillin, tetracycline, erythromycin, and cephalosporins.

Antibody

A blood protein (immunoglobulin) produced by B lymphocytes, a type of white blood cell, in response to the introduction of a specific antigen (e.g., vaccine antigen, invading bacteria, incompatible red blood cells, inhaled pollen grains, or foreign tissue grafts). Once produced, the antibody has the ability to combine, a process called neutralization with the specific antigen that stimulated antibody production, and thereby render the antigen harmless. This reaction to foreign substances is part of the immune response. The production of neutralizing antibody is one important biological measure of vaccine protection.

Appeasement

Assuaging the victim's desire for vengeance through compensation.

Antigen

A substance that elicits an immune response. Vaccine antigen is protein, derived from a microbe, which can induce a protective immune response when administered to a recipient.

Arbitration

A form of alternative dispute resolution in which the parties agree to have one or more trained arbitrators hear the evidence of the case and make a determination on liability or damages. The rules of evidence and other procedural matters may often be specified by the parties. There are two types of arbitration: binding and nonbinding. In binding arbitration the arbitration decision is subject to every limited judicial review. If arbitration is nonbinding, the parties may proceed to trial if they are not satisfied with the outcome of the

arbitration. Some states require parties to submit a claim to nonbinding arbitration before trial.

Assumption of risk

A person is aware of risks of harm inherent in a decision, and accepts responsibility for the consequences of the decision.

Attenuated vaccine

A vaccine derived from pathogenic organisms that has been altered or weakened so that it is incapable of producing disease, but still capable of causing an inapparent infection and inducing immunity.

Attorney fee limits

Legislation that either limits a plaintiff's attorney fees to a set percentage of the award or allows for court review of the proposed fee and approval of what it considers to be a "reasonable fee."

Autoantibody

An antibody that is formed by an individual against the individual's own tissues. See *antibody*.

Autoimmune

Referring to an aberrant response of the immune system directed against an individual's own tissues, an abnormal reaction (the immune system is designed to respond to foreign tissue) believed to contribute to a number of chronic diseases (e.g., rheumatoid arthritis, diabetes mellitus type I). Some traditional vaccines may cause disease by this mechanism

Autonomous choice

Refers to an individual's ability to independently make choices in his or her own interests.

Avirulent

Lacking virulence (the ability to produce a significant infection or disease); used to refer to mutant strains of ordinarily pathogenic organisms.

Awarding costs, expenses, and fees

Statutes that provide that the losing party in a frivolous suit may be required to pay the other party's reasonable attorney and expert witness fees and court costs. These provisions are designed to deter the pursuit of frivolous medical injury claims.

AZT

See *Zidovudine*.

B lymphocytes (or B cells)

An immune lymphocyte that can produce antibody in response to an antigen. B indicates its bone marrow origin. See *lymphocyte*.

Beneficence

Mercy, kindness, or charity. In ethics, it is the principle that one has a duty to confer benefits or to help others to further their legitimate interests.

Beyond a reasonable doubt

A standard of evidence typically used in criminal cases, that means fully satisfied, entirely convinced, satisfied to a moral certainty; and phrase is the equivalent of the words clear, precise, and indubitable.

Biologics

Drug products made from living organisms and their products, including viruses, serums, vaccines, antigens, antitoxins, allergenic, or analogous products.

Biotechnology

Commercial techniques that use living organisms or substances from those organisms to make or modify a product for use in medicine and industry. Biotechnology includes the use of novel biological techniques such as recombinant DNA and cell fusion.

Blinded trial

Clinical trial in which the investigator and/or the subjects are not made aware of whether the subject has been assigned to the treatment group or a comparison group. In a single-blind trial, only the investigator knows to which group the subject has been assigned. In a double-blind trial, both the investigator and the subject are not aware of which group the subject has been assigned. The investigator and/or the subject is kept unaware of which group the subject has been assigned in order to minimize bias.

Blood cells

Cells found in whole blood, including red blood cells (erythrocytes) and various types of white blood cells (such as granulocytes, monocytes, and lymphocytes).

Blood plasma

See *plasma*.

Blood serum

The clear liquid that separates from blood after the red blood cells, fibrin, and clotting factors are removed by centrifugation or vigorous stirring.

Blood

A liquid (plasma) containing red blood cells (erythrocytes), white blood cells (leukocytes), and platelets (thrombocytes) that circulates through the heart, arteries, veins, and capillaries, carrying oxygen and nutrients to body tissues, removing carbon dioxide and other wastes, transferring hormonal messages between organs, carrying substances that prevent excessive bleeding and protect injury sites with clots, and transporting antibodies and infection-fighting cells to sites of infection.

Caps on damages

Legislative limits on the amount of money that can be awarded to the plaintiff for economic or noneconomic damages in a personal injury claim, such as medical malpractice or product liability. The limit is imposed regardless of the actual amount of economic and noneconomic damages.

Cause-based compensation

A system of compensation where one's entitlement to compensation for injury depends on its cause.

CDH-receptor

The target receptor for HIV infection.

CD4⁺ binding site

Domain on the HIV-1 envelope protein that attaches to the CD4⁺ cell receptor. See *CD4⁺ cell*.

CD4⁺ cell

A type of helper T lymphocyte that bears CD4 receptors on its surface. The CD4⁺ cell is a target for HIV infection. The virus binds to the CD4 receptor in the process of cell entry.

CD8⁺ cell

A type of cytotoxic T lymphocyte that bears CD8 receptors on its surface; CD8⁺ lymphocytes are able to lyse infected cells that are otherwise hidden from antibody. See *cytotoxic T lymphocytes*.

Cell-mediated immunity

Immune protection provided by a network of white blood cells in the blood and tissues; immune protection provided directly by the direct action of immune cells, without the intermediation of antibodies.

Cell-mediated immunity

Immunity resulting from an increase of activity by living cells in the blood and other tissues (e.g., T lympho-

cytes, cytotoxic T lymphocytes) that directly and non-specifically destroys infected cells and other foreign material. Compare *humoral immunity*.

Challenge

In immunology, administration of an antigen to assess the state of immunity. In vaccine testing, a vaccinated animal or person is challenged with an infectious agent or antigen to determine whether the vaccine has increased the animal or person's ability to fight infection.

Children's Vaccine Initiative

See *National Vaccine Injury Compensation Program*.

Clade

A major subgroup of viral strains; for HIV, at least five clades have been identified. Clade B is predominant in the Americas and Western Europe.

Claimant

Person who is requesting compensation for injury.

Classic prophylactic vaccination

Vaccination of uninfected individuals to prevent infection or disease. Compare *second order prophylactic vaccination*.

Clear and convincing proof

Proof beyond a reasonable (i.e., well founded) doubt.

Clinical trial

Experimental research in which preventive, diagnostic, or therapeutic agents, devices, regimes, and procedures are given to human subjects under controlled conditions in order to define their safety and effectiveness. In a randomized clinical trial, subjects are assigned at random to one or more treatment groups or to a control group that is given a placebo or a comparison treatment. See *phase I, II, III, and IV studies*.

Collateral source offsets

Reduce the amount of awards to the plaintiffs by prohibiting plaintiffs from collecting payment for insured losses, such as medical expenses.

Compensation

In personal injury, refers to replacing a victim's losses.

Compensatory damages

In personal injury, refers to money awarded to the plaintiff to compensate the plaintiff for losses incurred as a result of an injury.

Compensatory justice

Principle of fairness in compensation for harms.

Confidentiality (of the physician/patient relationship)

The state or quality of being confidential, that is intended to be held in confidence or kept secret. Courts and legislatures have established a physician-patient privilege to protect the confidentiality of communications between physicians and their patients and have established similar privileges to ensure the confidentiality of communications between other types of health care providers and their patients or clients.

Contingency fee

Legal fees that are dependent on the plaintiff's recovery.

Contract

A legally binding agreement between two or more parties.

Contractors

A person entering a contract, often seen as a businessperson striking a bargain. As long as the bargaining process is fair, contractors may be entitled to no more than what they bargained for, and may be seen as seeking an unfair advantage if they later demand more.

Control group

In a randomized clinical trial, the group receiving no treatment or some treatment with which the group receiving experimental treatment is compared. The control treatment is generally a standard treatment, a placebo, or no treatment. Compare *experimental group*.

Core antigens

Proteins that make up the internal structure or core of a virus. The core proteins of HIV are the products of the genes *gag* and *pol*. Compare *envelope antigens*.

Cross-protection

The ability of immunization for one strain of virus to provide protection against infection against another strain of virus.

Cross-reactivity

The property of an organism to be able to provoke an immunological reaction against a different organism. The tuberculosis vaccine BCG, for example, is an attenuated strain of *Mycobacterium bovis* (a bovine tuberculosis) that provokes the immune reaction against *M. tuberculosis*, the cause of human tuberculosis.

CTL

See *cytotoxic T lymphocytes*.

Cyclophilins

Proteins that function in immune modulation; acted on by Cyclosporin A, a potent immunosuppressant drug.

Cytokines

Molecules secreted from cells that affect growth or other activity in closely proximate cells. Cytokines are often thought of as short-range hormone, accomplishing cell to cell communications.

Cytotoxic T lymphocytes (CTL)

T lymphocyte characterized by its ability to recognize and destroy cells producing HIV-1; see *CD8⁺ lymphocytes*.

ddC (zalcitabine)

An inhibitor of HIV replication by interfering with viral DNA synthesis, indicated in combination with Zidovudine, is used in patients with advanced HIV infection and immunosuppression.

ddl (didanosine)

An inhibitor of the replication of HIV, used in HIV infected patients who are intolerant or nonresponsive to Zidovudine. Also known by its brand name Videx (Bristol-Myers).

Damages

In personal injury litigation, refers to money that is awarded by the court to the plaintiff for injuries for which the defendant is legally responsible.

Defendant

In personal injury litigation, refers to the party that is alleged to be responsible for the injury.

Denaturation

The separation of double-stranded DNA into its single strands or of protein into its constituent peptides through treatment with chemicals, heat, or extremes of pH. Denaturation also results in loss or reduction of the biological properties of the substance.

Deoxyribonucleic acid

See *DNA*.

Design defect

When an object is lacking in some particular that is essential to its completeness, rendering it not fit for the purpose for which it was sold and used. A design is defective if the product could have been developed so as

to reduce its inherent danger to the user without significantly decreasing its effectiveness.

Deterrence

The creation of disincentives for socially undesirable activities.

Developmental risk

The danger or hazard of incurring financial losses through litigious action resultant from research, development, and trials of a vaccine.

Diagnostic test

A medical test administered to those asymptomatic but high-risk individuals identified by a screening test, or a test used to identify the cause of abnormal physical signs or symptoms. Compare *predictive test* and *screening test*.

Diethylstilbestrol (DES)

A white, crystalline, synthetic non-steroidal estrogen having estrogenic activity similar to but greater than that of estrone. Diethylstilbestrol is one of several drugs that have been withdrawn from the market in the United States because of adverse reactions.

Diphtheria

An acute infectious disease affecting primarily the membranes of the nose, throat, or larynx, characterized by the formation of a gray white pseudomembrane; attended by fever and pain of varying degree and aphonia and respiratory obstruction in the laryngeal form; caused by the toxigenic gram-positive bacillus *Corynebacterium diphtheriae*.

Diphtheria, tetanus, pertussis (DTP) vaccine

A combination vaccine composed of two toxoids (diphtheria and tetanus) and one inactivated whole-cell bacterial vaccine (pertussis). Included among vaccines recommended in childhood.

Disability insurance

Insurance that provides payments to insured people should they be unable to work due to physical or mental incapacitation.

Disease

Any deviation from or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of symptoms and signs whose etiology, pathology, and prognosis may be known or unknown.

Distributive justice

Fairness in the distribution of benefits and burdens among members of society.

DNA

(deoxyribonucleic acid) The genetic material of most living things (exceptions include some RNA viruses, such as HIV) that determines the hereditary characteristics by directing protein synthesis in the cells. DNA is composed of two strands of nucleotide bases that are linked and wound around each other to form a spiral-shaped molecule. Compare *RNA*.

Double-jeopardized CD4⁺ T cells

Vaccine-activated CD4⁺ T cells with specificity for HIV. One theoretical risk is that vaccination may facilitate HIV infection by “activating” CD4⁺ T cells. Active CD4⁺ T cells are better hosts for HIV entry, integration, and replication. In addition, CD4⁺ T cells activated by HIV vaccine will search for HIV-infected cells to bind to, increasing the rate of dissemination of HIV infection among CD4⁺ T cells.

DT vaccine

Combined vaccine against diphtheria and tetanus.

DTP vaccine

See *diphtheria, tetanus, pertussis vaccine*.

Economic damages

Monetary damages that compensate the plaintiff for his or her actual economic losses—i.e., past and future medical expenses, lost wages, rehabilitation expenses, and other tangible losses.

Economic efficiency

The state in which the greatest direct and indirect gains (benefits) are derived from the resources expended (costs) to achieve a stated objective.

Effectiveness

Same as efficacy (see below) except that it refers to “...average or actual conditions of use.” Compare *efficacy*.

Efficacy

The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. Efficacy is generally evaluated in controlled trials of an experimental therapy and a control condition. Compare to *effectiveness*.

Efficiency

See *economic efficiency*.

Encephalitis

Inflammation of the brain.

Encephalopathy

Any degenerative disease of the brain.

Endogenous retroviruses

Genes present in the host genome that code for retroviruses. One theoretical risk is that HIV vaccines could activate latent disease-causing retroviruses present in the host genome.

***env* gene**

Gene coding for HIV *env* envelope protein.

Envelope (*env*) antigens

Proteins that constitute the envelope or surface of a virus. For HIV, these include the gp 160, gp 120, and gp 41 proteins. Compare *core antigens*.

Enzyme immunoassay (EIA)

An assay based on antigen-antibody interactions, which uses enzymes to measure the reaction.

Enzyme-linked immunosorbent assay (ELISA)

A type of enzyme immunoassay for determining the amount of protein or other antigen in a given sample by means of an enzyme-catalyzed color change. ELISA is used as a screening test to detect the presence of antibodies to HIV in human sera. ELISA tests that are positive for HIV are confirmed by the Western blot test. See *enzyme immunoassay*.

Enzymes

Proteins that are produced by living cells and that mediate and promote the chemical processes of life without themselves being altered or destroyed.

Episome

The genome of a virus that remains free in the nucleus of the host cell. Compare *provirus*.

Epitope

A structural part of an antigen that is responsible for an antibody response against that antigen. Also known as an “antigenic determinant.”

Equity

The concept of fairness or justice.

Erythrocytes

Red blood cells. These cells contain hemoglobin and are adapted for the transport of oxygen in the blood.

Excise tax

A tax imposed on the performance of an act, the engaging in an occupation, or the enjoyment of a privilege.

Experimental group

In a randomized clinical trial, the group receiving the treatment being evaluated for safety and efficacy.

Federal Tort Claims Act (FTCA)

Enacted in 1946 (28 U.S.C.A. sec. 1346(b)(Supp. 1988)), the FTCA allows an injured party to sue the U.S. government.

forum non conveniens

Motion to dismiss a case brought by foreign plaintiffs in U.S. courts on the basis that a more suitable alternative forum exists (usually the home country of the victim, or the place where the injury occurred).

Fraud

An intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right.

Free virus

Virus that resides outside of cells.

***gag* gene**

A gene that codes for HIV structural core (internal) proteins p18, p24, and p15. See *core antigens*.

Gene

The basic unit of genetic information. Each gene codes for a specific antigen.

Genome

The total genetic information or collection of genes in an organism, composed of RNA or DNA subunits.

gp 120

An HIV surface glycoprotein that bears the principle sites for induction of neutralizing antibody and binding to the host CD4 receptor. These are sites where vaccine-induced antibody can block viral replication.

gp 160

A membrane-bound surface glycoprotein that projects through the virus envelope surface. Also termed “envelope” or *env* protein, the gp160 protein is comprised of an external portion (gp120) protein, and a transmembrane region (gp 41 protein).

Gross negligence

The intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another.

***Haemophilus influenzae* type b (Hib)**

A parasitic bacterium that occurs in an encapsulated form. In children and debilitated older adults, infection may result in destructive inflammation of the larynx, trachea, and bronchi, and may also cause subacute bacterial endocarditis and purulent meningitis. Immunization against Hib is available through inoculation with anti-*Haemophilus influenzae* serum.

***Haemophilus influenzae* type B (Hib) vaccine**

Vaccine included among those recommended in childhood. See *Haemophilus influenzae* type b.

Hepatitis A

Viral hepatitis, type A. An acute inflammation of the liver caused by infection with hepatitis A virus, which is transmitted by fecal contamination of food or water (e.g., through infected people handling food), or through parenteral infection (by contaminated needles or administration of blood products). Formerly known as “infectious hepatitis.”

Hepatitis B

Viral hepatitis, type B. An acute inflammation of the liver caused by infection with hepatitis B virus, which is transmitted mainly by sexual contact, parenteral exposure (contaminated needles or administration of blood products), and from carrier mother to baby. In some cases, infection may be severe and result in prolonged illness, destruction of liver cells, cirrhosis, and death. Formerly known as “serum hepatitis.”

Herd immunity

Resistance of a population to spread of infection. Vaccines can induce herd immunity by decreasing the transmission of infection among members of the population. The immunity to infection of some members of the population may reduce the likelihood of spread of infection to other members of the population, including spread to members who are not immune. Models for herd immunity include the worldwide smallpox

vaccination program and the U.S. childhood vaccination program. Compare *individual immunity*.

Heroes

Willing volunteers who assume risks in order to accomplish a goal, ordinarily for someone else’s sake.

HIV-1

Human immunodeficiency virus, type 1; a virus found in most of the world that causes the immune deficiency leading to AIDS; a member of the retrovirus subfamily that includes HIV-2 and SIV.

HIV-2

Human immunodeficiency virus, type 2; a retrovirus that is found in West Africa; in the same virus subfamily as HIV-1 and SIV.

HIV

See *human immunodeficiency virus*.

HIV-related diseases

Diseases that occur more frequently in persons who are infected with the human immunodeficiency virus (HIV).

Horizontal justice

The concept that similarly situated individuals should be treated in a like manner.

Host

In virology, the organism used for growth and reproduction of viruses.

Human immunodeficiency virus (HIV)

A retrovirus that is the etiologic agent of AIDS and whose infection has been associated with depression of the immune system and various opportunistic diseases. HIV infects and disables the CD4+ subset of T lymphocytes, which are key elements of the immune system. See *AIDS*.

Humoral immunity

Immunity associated with antibodies that circulate in the blood.

Hypersensitivity

In immunology, a state of heightened reactivity to a previously encountered antigen; may cause mild allergy or severe anaphylactic shock.

Idiotypic (or idiotope)

An antigenic determinant specific for an individual immunoglobulin molecule; idiotypes are regions near the antigen binding site of an antibody that act as anti-

gens themselves by stimulating the production of antibodies.

Immediate post-exposure vaccination

Vaccination of individuals immediately after infection to prevent the infection from becoming permanently established. An example is rabies vaccine, which is administered immediately after being bitten by a rabies-infected animal.

Immune deficiencies

Any number of disorders, including AIDS, resulting from a failure or malfunction of the bodily defense mechanisms, or immune system.

Immune enhancement

The facilitation of infection and disease progression by the immune system. One theoretical risk of an HIV vaccine is that vaccination may induce the production of antibodies that may facilitate entry of HIV into phagocytic cells (cells such as macrophages that ingest microorganisms or other substances), and thereby increase dissemination of HIV infection in those cells.

Immune response

A defensive reaction of the body in response to exposure to certain substances not recognized as normal body components (pathogenic microorganisms, transplanted tissue, etc.). Immune responses may involve the production of antibodies that react with antigens on the surface of the foreign substances to render them harmless, as well as a variety of physical and chemical responses from other cells of the immune system.

Immune system

The group of organs, specialized cells, and cell products that protect the body from harmful microorganisms, contribute to allergy and hypersensitivity reactions, are involved in the rejection of transplanted tissue and organs, and may play a role in the development of cancer.

Immune

Protected against disease by innate or acquired resistance to specific foreign or pathogenic substances or organisms. See *immunity*.

Immunity

The condition of being immune, or being protected against disease by the action of the immune system. Immunity may be either innate or acquired; innate immunity is present from birth having been passed to

the baby from the mother during pregnancy; acquired immunity may be active (resulting from either previous exposure to the disease-causing agent or vaccination) or passive (resulting from the injection of preformed antibodies derived from an individual already immune to a particular antigen).

Immunization

The deliberate introduction of an antigenic substance (vaccination, or active immunization) or antibodies (passive immunization) into an individual, with the aim of inducing immunity or resistance to disease. Compare *vaccination*.

Immunocompetence

The capacity to respond immunologically to an antigen.

Immunodeficient

A defect in the host's ability to mount an effective immune response.

Immunogenic

Able to cause an immune response.

Immunogenicity

The ability to generate an immune response in the host.

Immunoglobulin

Any of a group of specific proteins (produced by white blood cells) that react to the presence of a foreign antigen, react more quickly to a previously encountered antigen than to a new one, and under normal circumstances, do not respond to components of its own body. They are found in the blood plasma and lymph and in other body tissues and fluids. There are five basic classes of immunoglobulins—IgA, IgD, IgE, IgG, and IgM. See *antibody*.

Immunology

The scientific study of the ability of organisms to identify and attack foreign substances, to distinguish self from nonself, to form antibodies and antigen-reactive lymphocytes, and to become hypersensitive to common allergens.

Immunopathogenesis

A process in which the course of a disease is altered or affected by an immune response (either the cellular (T-cell) or humoral (B-cell) response) or by products of an immune reaction, such as the antigen-antibody-complement complexes deposited in renal glomeruli.

Immunosuppression

Inhibition or suppression of the immunologic response (e.g., by infection, as in AIDS, or by the administration of drugs to prevent rejection of tissue grafts or transplanted organs, or by irradiation or biochemical agents).

Immunosuppressive

Pertaining to or inducing the artificial prevention or diminution of the immune response. See *immunosuppression*.

Implied warranty of merchantability

An implied contract between seller and purchaser of consumer goods that the goods meet each of the following: 1) pass without objection in the trade under the contract description; 2) are fit for the ordinary purposes for which such goods are used; 3) are adequately contained, packaged, and labeled; 4) conform to the promises or affirmations of fact made on the container or label.

Influenza

A viral disease that is characterized by prominent systemic symptoms, such as weakness, fever, and malaise; usually occurs in epidemics.

In vitro test

Experimentation using cells, tissues, or explants grown in a nutritive medium rather than using living animals or human subjects.

In vivo

Literally, “in the living,” pertaining to a biological process or reaction taking place in a living organism. In biomedical research, used to describe the experiments or processes in whole animals (e.g., mice, rats, humans), as opposed to those in a test tube or other experimental system.

Individual immunity

A person’s ability to resist infection and disease. Compare *herd immunity*.

Infectivity

The ability or propensity to transmit infection.

Informed consent

As applied to human research, the agreement of a person (or his/her legally authorized representative) to serve as a research subject, in full knowledge of all anticipated risks and benefits of the experiment. Informed consent requires that the researcher impart to the prospective subject any information that might in-

fluence the subject’s decision to participate or not participate in the research, including an explanation of the methodology to be used, the availability of alternative therapies, and the prospective subject’s freedom to withdraw from the experiment at any time, without prejudice.

Informed consent

As applied to clinical care, a patient’s agreement to allow a medical procedure based on full disclosure of the material facts needed to make an informed decision. The required elements of disclosure differ from state to state, but generally include the duty of health care providers to inform patients of the risks and benefits of medical tests or treatments, and to the patient’s right to refuse medical care.

Institutional Review Board (IRB)

A group established by an institution conducting medical research to assess the legal, ethical, and scientific aspects of that research on human subjects. IRB approval is required by the Department of Health and Human Services before proposals can receive federal funding. IRBs must review research protocols on a regular basis, but not less than once a year.

Internal protein

Protein found inside the cell.

Investigational New Drug (IND) application

An application submitted by a sponsor to the Food and Drug Administration (FDA) before beginning human testing on an unapproved drug or on an approved drug for an unapproved use.

Joint and several liability

A rule under which each of the defendants in a tort suit can be held liable for the total amount of damages, regardless of his or her individual responsibility. In other words, even if a defendant was only 20 percent responsible, he or she could be held liable for 100 percent damages if other defendants are unable to pay. Several states have eliminated joint and several liability so that defendants are liable only in proportion to their responsibility.

Jurisdiction

In law, refers to the authority of a court to decide the case that is before it.

Justice

In liability for personal injury, refers to imposing the costs of injury on the one who causes it.

Learned intermediary Rule

A manufacturer of prescription drugs or vaccines need only provide product warnings to the prescribing physician, not the patient receiving the product.

Leukocyte

White blood cells (WBCs), including lymphocytes, monocytes, neutrophils, basophils, and eosinophils. WBCs are formed in lymph nodes and bone marrow and are present in the blood and lymphatic circulation. Their main function is to protect the body against infection and to fight infection when it occurs.

Liability

Legal responsibility.

Litigation

A lawsuit. Legal action, including all proceedings therein.

Lump sum payment

In tort, refers to an award, the entirety of which is to be made in a single payment.

Lymphocytes

Specialized white blood cells involved in one type of immune response that does not depend directly on antibody attack (cell-mediated immunity). Lymphocytes originate from fetal stem cells and develop in the bone marrow. They normally comprise about 25 percent of the total white blood cell count and increase in number in response to infection. They occur in two forms: B cells and T cells. B cells, which circulate in an immature form and secrete antibodies that are carried on their surface membranes, search out, identify, and bind with specific antigens. T cells mature in the thymus gland and differentiate into thymocytes when exposed to an antigen; they divide rapidly and produce large numbers of new T cells sensitized to that antigen.

Lymphoma

A neoplastic disorder of the lymphoid tissue. Malignant lymphomas are classified based on their predominant cell type. B cell lymphomas have predominantly B-lymphocyte-type cells.

Lyse

To damage or rupture a cell membrane, allowing the release of cell contents into the extracellular medium.

Macrophage

A large, specialized immune cell in the circulation or tissues that is an important intermediary in many stages of the immune response, including engulfing

bacteria and other foreign particles; the macrophage is one target of HIV infection.

Manufacturing defects

Something other than the product intended by the manufacturer is produced; the manufacturing process fails to conform to the manufacturer's own specifications; generally limited to particular units or batches of the product.

Maternal-fetal HIV transmission

Transmission of the human immunodeficiency virus across the placenta from the mother to the fetus.

Measles, mumps, rubella (MMR) vaccine

A combination vaccine composed of the three live, attenuated virus vaccines providing long-term immunity against measles, mumps, and rubella; given by injection in a two-dose schedule, usually at 15 months of age and again at school entry.

Measles

A highly contagious viral disease involving primarily a hacking cough with steadily mounting fever followed by the eruption of red papules on the skin. It is spread by respiratory contact, primarily airborne droplets of nasal secretions containing the virus.

Microbe

A minute living organism; the term especially applies to those minute forms of life that are capable of causing disease in animals and man, including bacteria, protozoa, viruses, and fungi.

Model

A disease in animals used to study an analogous disease in man. SIV infection of chimpanzees and Asian monkeys has been used as a model for HIV infection and disease progression in man.

Molecular biology

The study of biology at the level of individual molecules, such as proteins and DNA.

Mucosa

The thin membrane lining various tubular structures of the body, including the colon, small and large intestine, mouth, nasal cavity, pharynx, and esophagus. The mucosal surfaces of the vagina, anus, and rectum are common sites of sexual transmission of HIV.

Mucosal immunity

Immune protection provided by antibody and immune cells located in the surface of mucous membranes.

Mumps

An acute, viral infection that produces painful inflammation and swelling of the salivary glands in the face and neck; occurs most commonly in school-aged children.

Mutation

A change in the structure or amount of genetic material (DNA, or in RNA viruses, RNA), either by changes in the base sequence of DNA or RNA, by changes affecting larger portions of a chromosome, or by the loss or addition of an entire chromosome. Mutations can be induced (e.g., caused by exposure of genetic material to a physical or chemical agent), spontaneous (occurring in the absence of any known causative agent), or heritable (changes in genetic material passed from parent to offspring). The human immunodeficiency virus (HIV) is characterized by frequent spontaneous mutations. This, in combination with selection, allows HIV to evade immune control.

National Childhood Vaccine Injury Act

Enacted by Congress in 1986 (42 U.S.C. SCCS. 3000aa *et seq.*), this Act sets up a program of administrative hearings to review claims for adverse reactions resulting in injury or death from taking a childhood vaccine. The amount of compensation for adverse reactions to these vaccines is determined by reference to a vaccine injury table. Currently, MMR, DPT and polio vaccines are covered under the Program.

National Vaccine Development and Compensation Act of 1992

Introduced by Congressman Fournety (Pete) Stark, This Act (H.R. 5893) sought to provide the framework, based on the 1986 National Childhood Vaccine Injury Act, for dealing with AIDS vaccine liability concerns both during the period of research and development phase, as well as in the marketing phase.

National Vaccine Injury Compensation Program

This program sets up administrative hearings to review claims that injuries or deaths resulted from adverse reactions to approved childhood vaccines.

Natural killer cell

A type of lymphocyte that attacks cancerous or virus-infected cells without previous exposure to the antigen.

Natural selection

The process by which simpler ancestral species of animals and plants evolve into new species, based on

variations among traits in populations and differential reproductive success that selects for certain of those traits; described by Charles Darwin in 1858 in *On the Origin of Species*.

Negligence

The doing of some act that a person of ordinary prudence would not have done under similar circumstances or failure to do what a person of ordinary prudence would have done under similar circumstances. In product liability law, negligence is conduct by the product maker that deviates from standards of acceptable conduct adhered to by the ordinary manufacturer of similar products and that results in harm to the product user.

Neutralizing antibody

Antibody with capacity to inactivate virus directly. The capacity of antibody to neutralize virus is tested in vitro by mixing the antibody and virus, and then assaying residual viable virus in sensitive cells. It is a biologically significant measure of protection, i.e., when compared to antibody that can physically bind viral antigen but cannot neutralize.

New Drug Application

An application to the FDA for approval to market a new chemical (non-biological) drug for human use in U.S. interstate commerce.

NK cell

See natural killer cell.

No-fault compensation

A system of compensation where one's entitlement to compensation is not contingent upon establishing who is at fault for an injury; claimants must merely establish that they were injured and that the injury arose from a specified cause.

Non-economic damages

In personal injury litigation, refers to claims for harms from the injury that cannot be expressed in sums certain of money, such as pain and suffering.

Nucleic acid

Macromolecules composed of sequences of nucleotides that carry genetic information. Two kinds of nucleic acids exist, occurring as double- or single-stranded molecules *DNA*, which contains the coded instructions for an organism's development in the chromosomes and is transferred to daughter cells; and *RNA*, which helps transport, translate, and implement

the DNA instructions, particularly the biosynthesis of proteins.

Nucleotide

A subunit of DNA or RNA, consisting of a nitrogenous base (adenine, guanine, thymine, cytosine, or uracil), a phosphate molecule, and a sugar molecule (deoxyribose in DNA or ribose in RNA). The linkage of thousands of these subunits forms the DNA or RNA molecule.

Nucleus

The membrane-enclosed structure in eukaryotic cells that contains the genetic material (DNA).

Oncogenes

Genes present in the host genome that, if activated, have the potential to cause cancer. One theoretical risk is that HIV vaccines could, upon integration into the host genome, activate latent oncogenes.

Oncogenic

Cancer inducing.

Original antigenic sin

Fixing of an immune response in a non-adaptive pattern. One theory is that HIV vaccination may induce a non-adaptive immune response that, in response to infection with a closely related strain of HIV, produces antibodies that are directed to the vaccine strain of HIV, but that weakly bind to the infecting strain of HIV.

Peptide

A compound consisting of two or more amino acids linked together by chemical bonds. Peptides are the building blocks of proteins.

Per capita

According to the number of individuals; in the law of descent and distribution, that method of dividing an intestate estate by which an equal share is given to each of a number of persons, all of whom stand in equal degree to the decedent, without reference to their stocks or the right of representation.

Periodic payment

In tort, refers to an award of damages that are to be paid in portions over a specified time interval; contrast *lump sum payment*.

Personal injury action

A suit brought in court based on a hurt or damage done to a man or woman's person, such as a cut or bruise, a

broken limb or the like, as distinguished from an injury to property or reputation. In statutes the term "personal injury" is also used in a much wider sense, including any injury that is an invasion of personal rights, and in this signification it may include such injuries to the person as libel or slander, criminal conversation, malicious prosecution, false imprisonment, and mental suffering.

Pertussis

An acute, infectious inflammatory respiratory disease of children caused by the bacterium *Bordetella pertussis*. The disease is characterized by explosive attacks of coughing ending in an inspiratory whoop or choking on mucus and occurs in infants and children who have not been immunized against the disease. Also known as "whooping cough."

Petition

A written request to a court officer, legislature, or other body for the exercise of its authority in the redress of some wrong, or the grant of some favor, privilege, or license.

Petitioner

One who presents a petition to a court, officer, or legislative body.

Phase I, II, III, IV studies

Specific phases of the clinical (human) testing of new drug or vaccine products. Phase I studies of vaccines are small trials usually involving only healthy uninfected volunteers to document the safety and immune response it produces. Phase II studies further test the vaccine's safety and immunogenicity and note any adverse reactions in vaccinated individuals. Phase III studies assess the vaccines effectiveness and risks among a large number of volunteers under conditions of ordinary use. These trials are randomized, placebo-controlled, and double-blind in design. Phase IV studies refer to surveillance conducted after a vaccine is already approved for marketing, to further determine its safety and efficacy.

Placebo

A drug or procedure with no intrinsic therapeutic value. In a randomized clinical trial, a placebo is given to patients in control groups as a means to blind investigators and patients as to whether the patient is receiving the experimental or control treatment.

Plaintiff

In personal injury litigation, refers to the injured party.

Plasma

The liquid portion of blood, excluding blood cells but including a large number of dissolved substances (e.g., salts, hormones, glucose, amino acids, fats, vitamins, and waste products). Compare *blood serum*.

***pol* gene**

In HIV, a gene coding for three enzymes, including polymerase reverse transcriptase. See *core antigens*, *reverse transcriptase*.

Poliomyelitis

An acute, infectious, viral disease, occurring sporadically and in epidemics. The disease is caused by three strains of poliovirus, which attack the central nervous system, leading to the selective destruction of motor neurons of the spinal cord and brain stem, followed by extensive paralysis. The disease is preventable through use of the oral polio vaccine.

Polymerase chain reaction (PCR)

A very sensitive laboratory test to detect the presence of HIV RNA or DNA in the circulating blood.

Postmarketing surveillance

Surveillance for adverse reactions occurring after the drug or biologic has been approved by the FDA and placed on the market.

Preclinical research

Laboratory and animal research conducted prior to the clinical testing of a new chemical entity. Preclinical research may include basic research and applied non-clinical research.

Predictive test

A medical test generally applied to asymptomatic individuals to provide information regarding the future occurrence of disease. Compare *diagnostic test* and *screening test*.

Preemption

Doctrine adopted by U.S. Supreme Court holding that certain matters are of such a national, as opposed to local, character that federal laws preempt or take precedence over state laws. As such, a state may not pass a law inconsistent with federal law.

Premarket testing

Testing of pharmaceuticals and medical devices that occurs before a product can be introduced into the

market. The FDA requires clinical evidence of safety and efficacy before a drug or medical device can be sold in the United States.

Premium

A reward for an act done.

Preponderance of the evidence

Standard of evidence, typically used in civil litigation, that means more likely than not, or a majority of the evidence.

Presumption

A rule of law, statutory or judicial, by which finding of a basic fact gives rise to existence of presumed fact, until presumption is rebutted.

Product liability

Refers to the legal liability of manufacturers and sellers to compensate buyers, users, and even bystanders, for damages or injuries suffered because of defects in goods purchased.

Prophylactic vaccine

Vaccine to prevent infection or disease in uninfected individuals (classic prophylaxis), or to reduce their infectivity should they subsequently become infected (second order prophylaxis).

Prophylaxis

The prevention of disease and preservation of health.

Protein

A molecule composed of many linked amino acids in a specific sequence, which is, in turn, determined by the sequence of nucleotides in DNA in the gene coding for the particular protein. Proteins are required for the structure, function, and regulation of the various cells, tissues, and organs in the body.

Provirus

The genome of a virus integrated into the chromosome of the host cell, and thereby replicated in all of the host's daughter cells. Compare *episome*.

Punitive damages

Money that is awarded to the plaintiff to punish the defendant for wrongful (usually intentional) activity.

Quasispecies

New viral mutants that have evolved from initial infecting strains of virus.

Randomized clinical trial (RCT)

An experiment designed to test the safety and efficacy of a medical technology in which people are randomly allocated to experimental or control groups, and outcomes are compared.

Rebuttable presumption

A legal presumption that can be rebutted upon presentation of sufficient evidence. See *presumption*.

Recklessness

The state of mind accompanying an act, which either pays no regard to its probably or possibly injurious consequences, or which, though foreseeing such consequences, persists in spite of such knowledge.

Recombinant DNA (rDNA) technology

Techniques involving the incorporation of DNA fragments, generated with the use of restriction enzymes, into a suitable host organism's DNA (a vector). The host is then grown in culture to produce clones with multiple copies of the incorporated DNA fragment. The clones containing this particular DNA fragment can then be selected and harvested. Also called genetic engineering.

Recombinant DNA

Genetic material that contains DNA from different sources that have been combined by genetic engineering methods. Rearrangement of the genes is artificially induced using enzymes to break DNA into fragments, allowing recombination in different sequences.

Recombinant technology

Scientific knowledge of the process of forming new combinations of genes as a result of crossing over between homologous chromosomes.

Recombination

In genetics, the formation of new combinations of genes as a result of crossing over between homologous chromosomes. One theoretical risk is that genetic material from a live vector or naked DNA HIV vaccine could recombine in the vaccinated host with preexisting or newly acquired HIV or other viruses.

Red blood cells

see *erythrocytes*.

Reovirus

Any group of relatively large, widely distributed, and possibly tumor-causing viruses with double-stranded RNA. Unlike retroviruses, which also contain RNA, reoviruses replicate in the cytoplasm of the cells they

invade and do not produce DNA analogs to their RNA for incorporation into the host cell's genome. The genus name "reovirus" is derived from the term *respiratory enteric orphan virus*, to denote both respiratory and enteric tropism and isolation of the virus in the absence of known disease. See also *virus*; and compare *adenovirus* and *retrovirus*.

Replication

In genetics, the synthesis of new DNA from existing DNA.

Respondent

In equity practice, the party who makes an answer to a bill or other proceeding in equity. In appellate practice, the party who contends against an appeal (i.e., the appellee). In the civil law, one who answers or is security for another.

Restatement of Torts

American Law Institute's treaties that summarize several fields of law. Widely considered to be the most authoritative statement of tort law in the country. Most states have adopted its provisions, albeit not uniformly, and some states have interpreted its technical requirements somewhat differently.

Retributive justice

Assuaging the victim's and society's desire for vengeance or retribution through punishment.

Retrovirus

A family of viruses with an RNA genome and an intermediary DNA stage, which is persistently integrated into the genome of the host cell chromosome. A retrovirus contains two identical single strands of RNA, not DNA, and that reproduces by making a double-stranded DNA transcription of itself in a process catalyzed by a virally encoded enzyme known as a "reverse transcriptase." The resulting DNA product may integrate into the cell genome (as a provirus) or may remain free in the nucleus (as an episome). Either way, it remains as a latent infection to be activated later (by a variety of factors) to a virus-producing form. Retroviruses are found widely in nature and are associated with a variety of diseases, including cancer, neurologic disorders, and immune deficiency syndromes, notably AIDS. Four well-characterized retroviruses are HIV-1 and HIV-2 (major causative agents of AIDS), and HTLV-I and HTLV-II (associated with T-cell leukemia and lymphoma). See also *provirus* and *virus*; and compare *adenovirus* and *retrovirus*.

Reverse transcriptase

Also called RNA-dependent DNA polymerase. Enzyme present in HIV and other retroviruses that allows the virus to turn RNA genetic information into DNA genetic information. See *retrovirus* and *reverse transcription*.

Reverse transcription

The creation of DNA genetic information using RNA genetic information as a template. HIV and other retroviruses are unique in their RNA genetic information into DNA, which is subsequently integrated into the DNA genome of the host. This process is accomplished by the enzyme “reverse transcriptase.”

RGB

Purified recombinant glycoprotein expressed in a host cell.

Ribonucleic acid

See *RNA*.

Right of subrogation

A provision typically found in health and disability insurance contracts that requires a plaintiff to reimburse the insurance company for any payments received from the tort system that were for services reimbursed by the insurer.

Risk-benefit analysis

A determination of whether the risks to health and the environment of using a chemical, drug, or vaccine exceed the economic benefits that accrue from its use. In the case of drugs and vaccines, benefits are measured in terms of therapeutic efficacy.

Risk deterrence

The prevention or deterrence of avoidable risk.

RNA

Ribonucleic acid. A type of nucleic acid that carries genetic instructions and assists in the assembly of proteins. RNA is a single-stranded chain of repeating units of adenine, cytosine, guanine, and uracil. Specialized types of RNA include: messenger RNA (mRNA), which carries a transcript of a DNA sequence to be used as a template for protein synthesis; transfer RNA (tRNA), which attaches the correct amino acid to the protein chain being synthesized at a ribosome; and ribosomal RNA (rRNA), a structural constituent of ribosomes. In some viruses, RNA contains the instructions for viral replication. The HIV-1 genome is composed of RNA. However, HIV-1 assumes a

DNA form when persistently integrated into host cell (e.g. CD4+ lymphocytes) genetic material as part of its replication cycle.

Rubella (German measles)

An acute viral illness that causes a diffuse reddish rash and swollen lymph glands. Infection during pregnancy, especially in early stages, can cause miscarriage or congenital rubella syndrome, a potentially fatal disorder involving deafness, cataracts, mental retardation, and/or heart lesions (depending on when infection occurred in gestation). The disease is preventable through vaccination.

Schedule of damages

A set of guidelines for juries to use in deciding appropriate awards for noneconomic damages in malpractice cases.

Screening test

Generally, a test used to sort out apparently well persons who probably have disease from those who probably do not. A screening test is not intended to be diagnostic. Compare *diagnostic test* and *predictive test*.

Second order prophylactic vaccination

Vaccination of uninfected individuals to reduce their ability to transmit subsequently acquired infections. Compare *classic prophylactic vaccination*.

Section 402A liability

Section 402A of the Restatement of Torts (2nd) makes manufacturers of drugs and vaccines strictly liable for adverse reactions in the absence of warnings.

Selection

In combination with mutation, a source of rapid genetic change of HIV. See *Natural selection*.

Selective advantage

In biology, an organism’s increased probability of reproduction and producing offspring, conferred by its genetic characteristics.

Selective pressure

In biology, the influence of factors extrinsic to an organism (i.e., environmental factors) on its ability to compete with other organisms for reproductive success.

Sequelae

Aftereffects or secondary consequences of a disease, disorder, or injury.

Seroconversion

The initial development of antibodies specific to a particular agent.

Seropositive

In the context of HIV, the condition in which antibodies to the virus are found in the blood.

Serum

See *blood serum*.

Settlement

In the context of a civil suit, refers to a private agreement of a plaintiff not to further pursue a court judgment in return for compensation from the defendant.

Simian immune deficiency virus (SIV)

A retrovirus from the same virus subfamily as HIV-1 and HIV-2 that infects chimpanzees and Asian monkeys; SIV infection of chimpanzees and Asian monkeys has been used as a model for HIV infection in man.

SIV

See *Simian immunodeficiency virus*.

Spontaneous mutation

In the absence of any known causative agent, a change in the structure DNA or in the number of chromosomes. Also called a “background” mutation. HIV is characterized by frequent spontaneous mutations. See *mutation*.

Statute of limitations

A statute prescribing limitations to the right of action on certain described causes of action or criminal prosecutions; that is, declaring that no suit shall be maintained on such causes of action, nor any criminal charge be made, unless brought within a specified period of time after the right accrued.

Strain

A group of organisms of the same species having a distinctive quality or characteristic (biochemical, pathogenic, or other) that can be differentiated, but is not different enough to constitute a separate species.

Strict liability

A legal concept that states liability lies with the party best able to prevent injury or absorb its costs even if that party was not responsible for causing the specific injury in question through negligence or intent. See *malpractice*.

Subrogation

See *right of subrogation*.

Subunit vaccine

A vaccine that contains only portions of an antigenic molecule from a pathogen. Subunit vaccines can be prepared by using recombinant DNA technology to produce all or part of the antigenic molecule or by artificial (chemical) synthesis of short peptides.

Sunset clause

Clause that provides for the automatic expiration of legislation.

Swine Flu Act

Enacted in 1976, the Act held harmless manufacturers of the swine flu vaccine from claims of individuals injured by the vaccine. The Act also permitted claimants to file suit against the U.S. government under the Federal Tort Claims Act for compensation for injuries from the swine flu vaccine.

Swine flu vaccine

Vaccine against the swine flu, an especially virulent strain of influenza that spread throughout the United States during the fall and winter of 1976.

Systemic

Pertaining to or affecting the body as a whole.

T4 cell

See *CD4⁺ cell*.

T8 cell

See *cytotoxic T lymphocyte*.

T helper cell

See *CD4⁺ cell*.

T lymphocyte (T cell)

A lymphocyte produced in the bone marrow that matures in the thymus and is integral to cell-mediated immunity. T cells regulate the growth and differentiation of other lymphocytes and are involved in antibody production. See *lymphocytes*.

Teratogen

Physical or chemical agents, (e.g. thalidomide, radiation, alcohol, and certain viruses) that act on the fetus in utero to cause congenital malformations.

Teratogenic

Capable of inducing the formation of developmental abnormalities in a fetus.

Tetanus

An acute, potentially fatal disease of the central nervous system caused by infection of a wound with spores of the bacterium *Clostridium tetani*; these spores release a poisonous neurotoxin (tetanus toxoid) that causes trismus ("lockjaw"), generalized muscle spasm, arching of the back, glottal spasm, seizures, respiratory spasms, and paralysis. Short-term immunity can be derived through vaccination. Tetanus vaccine is among vaccines recommended for children. See *DTP vaccine*.

Therapeutic vaccine

Vaccine to prevent or reduce disease progression in infected individuals, or to reduce disease transmission to persons who come in contact with infected individuals.

Tort law

A body of law that provides citizens a private, judicially enforced, remedy for injuries caused by another person. Legal actions based in tort have three elements: existence of a legal duty from defendant to plaintiff, breach of that duty, and injury to the plaintiff as a result of that breach.

Tort liability

Liability imposed by a court for breach of a duty implied by law, contrasted with contractual liability, which is breach of duty arising from an agreement. A legal basis for compensation when property has been damaged or a person has been injured. The tort liability system determines fault and awards compensation for civil wrongs, including medical malpractice and product liability.

Tort reform

A legal reform that changes the way tort claims are handled in the legal system or removes claims from the civil judicial system.

Transaction costs

In personal injury, refers to the administrative costs associated with transferring compensation to the injured.

Transcription

In genetics, the process by which RNA is formed from a DNA template during protein synthesis. Compare *translation*, *reverse transcription*.

Translation

The process in which the genetic code contained in the nucleotide base sequence of messenger RNA directs the synthesis of a specific order of amino acids to produce a protein. Compare *transcription*.

Transmission

In infectious disease, the passage of a pathogen from one host to another host or from vector to host.

Vaccination

The deliberate introduction of an antigenic substance (vaccine) into an individual, with the aim of producing active immunity to a disease. Compare *immunization*.

Vaccine

A preparation of living, attenuated, or killed bacteria or viruses, fractions thereof, or synthesized antigens identical or similar to those found in the disease-causing organisms that is administered to produce or increase immunity to a particular disease.

Vaccinia virus

The organism that causes cowpox; its injection into humans results in immunity to the related smallpox virus.

Varicella

Virus that causes chickenpox.

Vector

In HIV vaccines, refers to a live attenuated virus or bacterium carrying selected HIV genes, which produces desired antigenic proteins when administered to a recipient. Proteins produced in a living microorganism are generally capable of inducing cytotoxic T lymphocyte responses in addition to antibody.

Victims

Persons misused or injured without their consent.

Virology

The study of viruses and the diseases they cause; also, the isolation and identification of viruses associated with specific infection.

Virus

Any of a large group of submicroscopic agents infecting plants, animals, and bacteria and characterized by a total dependence on living cells for reproduction and by a lack of independent metabolism. A fully formed

virus consists of nucleic acid (DNA or RNA) surrounded by a protein or protein and lipid coat. See also *adenovirus*, *provirus*, *reovirus*, and *retrovirus*.

Warning defects

There are two types of warning defects: 1) a failure to provide warnings of risks inherent in the use of the product (failure to warn); and 2) providing directions and warnings that fail to adequately describe product risks (inadequate warning).

Western Blot

A laboratory technique used to detect the presence of antibodies to specific antigens, including those specific for HIV infection. The method is often used to check the validity of a positive ELISA screening test for HIV. It is also used to clinical trials to detect vaccine induced antibody. Electrophoresis is used to separate proteins by their molecular weights, and each protein is identified through combining with its respective antibody or antigen. For example, in Western Blot testing for HIV antibodies, the protein components of HIV are first separated electrophoretically, transferred to

blots, then mixed with sera suspected of containing HIV antibodies. The presence of antibodies to specific proteins of HIV is revealed by the combination of antibodies with their specific protein components of HIV.

White blood cells

Cells in the blood stream and tissues, including lymphocytes, macrophages, and neutrophils, that provide immune protection. See *leukocyte*.

Whole, killed-virus vaccine

Vaccine formed from virulent virus that has been altered so that the virus is no longer able to replicate.

Workers compensation

System that provides compensation for work-related injuries, regardless of the fault of the employer.

Zidovudine (AZT)

An inhibitor of the replication of some retroviruses including HIV, used in the treatment of persons with HIV infection who have evidence of impaired immunity. Also known by its brand name, Retrovir (Burroughs Wellcome).