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REPRODUCTIVE AND DEVELOPMENTAL HAZARDS: A GUIDE FOR OCCUPATIONAL HEALTH PROFESSIONALS

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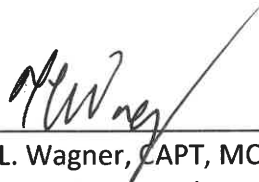
620 John Paul Jones Circle, Suite 1100
Portsmouth, VA 23708-2103

REPRODUCTIVE AND DEVELOPMENTAL HAZARDS: A GUIDE FOR OCCUPATIONAL HEALTH PROFESSIONALS

ACKNOWLEDGEMENTS

The 2019 edition of the manual is an update of the 2010 edition, with additions to the main text and to the chemical, pharmacological, and biological hazards sections. Major contributors to this update include Roger Scott Akins, CAPT, MC, Douglas Talk, LCDR, MC, Robert Walton, LCDR, MC, James Smith, Jr., PhD, Amy Delong, PhD, and John Muller, MD, MPH (primary editor). Special thanks are given to CAPT Todd Wagner, MC, USN, for his leadership as Commander of Navy and Marine Corps Public Health Center (NMCPHC).

Reviewed and Approved



T. L. Wagner, CAPT, MC, USN
Commander

PURPOSE

This manual provides guidance to Navy occupational health (OH) professionals in the evaluation and management of reproductive and developmental (ReproDev) hazards in the workplace.

DISCLAIMER

This manual does not establish policy. It is to be used to assist in decision-making and execution of an overall program to control hazards in the workplace. Where a conflict in this manual exists between a regulatory or statutory reference or a requirement, the default is to the basic reference or requirement. Assistance in interpretation or clarification of statements or concepts contained in this manual can be obtained from the Occupational and Environmental Medicine (OEM) Department, NMCPHC. The authors do not take any responsibility for any references or links, or for the maintenance of Web sites and Web documents other than those under the auspices of the NMCPHC. Updating hyperlinks is an ongoing process. While effort has been made to verify that links are working at the time this document was published, it is readily acknowledged that hyperlinks may be outdated. If a hyperlink in this document is found to be functioning incorrectly, the reader is encouraged to search the Internet for the referenced document, as it may be available from a different Internet address.

USING THE MANUAL

This manual provides general guidance in the recognition, assessment, and control of reproductive and developmental (ReproDev) hazards to both male and female uniformed and civil service personnel. It primarily focuses on ReproDev hazards associated with the occupational exposures of workers. Strategies for managing individuals potentially exposed to ReproDev hazards in the workplace are presented. This manual promotes a consistent, scientific and evidence-based approach to the assessment and disposition of workplace ReproDev issues throughout the Navy.

The manual utilizes the policy and guidance from many regulatory and non-regulatory agencies, including OSHA, EPA, the Food and Drug Administration (FDA), the National Toxicology Program (NTP), and the Centers for Disease Control (CDC). Information from other sources regarding potential reproductive and developmental hazards may be incorporated into the manual, if considered appropriate and scientifically rigorous. This document is not intended as a guide to investigation of outbreaks or “clusters” of adverse effects. Providers and others dealing with environmental investigations are directed to the [NMCPHC web site](#) for additional resources.

Numerous references and hyperlinks to sources other than those maintained by the Navy are included in the manual. Hyperlinks are marked by colored text, and PubMed numbers are hyperlinked to abstracts (in the format [PMID 000000](#)). Internet hyperlinks are supplied to expand the utility and versatility of this document. References (many of which are hyperlinked to PubMed abstracts) are supplied to enable health professionals in the field to access more

detailed information, or to document the basis for statements that may not be commonly known or that represent recent scientific knowledge. Other recognized sources providing ReproDev guidance not cited in this manual should be considered using professional judgment.

COMMENTS

Comments, including notification of broken links, are always appreciated and will assist in continual improvement of this manual. They may be sent to the OEM Department, Navy and Marine Corps Public Health Center, 620 John Paul Jones Circle Suite 1100, Portsmouth, VA 23708, or e-mail usn.hampton-roads.navmcpubhlthcenpors.list.nmcphc-repro@mail.mil.

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(I) ABBREVIATIONS AND ACRONYMS USED IN THIS MANUAL

ACGIH	American Conference of Governmental Industrial Hygienists (ACGIH®)
BUMED	Bureau of Medicine and Surgery
Cd	Cadmium
CFR	Code of Federal Regulations
DBCP	1,2-dibromo-3-chloropropane
DES	Diethylstilbestrol
DON	Department of the Navy
EPA	Environmental Protection Agency
ETO	Ethylene Oxide
FSH	Follicle-Stimulating Hormone
FDA	Food and Drug Administration
HCP	Health Care Practitioner
HCW	Health Care Worker
Hg	Mercury
HIV	Human Immunodeficiency Virus
IH	Industrial Hygiene
IUGR	Intrauterine Growth Retardation
LH	Luteinizing Hormone
L/min	Liters per Minute
LMP	Last Menstrual Period
MTF	Medical Treatment Facility
NMCPHC	Navy and Marine Corps Public Health Center
NEPMU	Navy Environmental and Preventive Medicine Unit
NH	Naval Hospital
NHC	Naval Health Clinic
NIOSH	National Institute for Occupational Safety and Health
NAVMEDCEN	Naval Medical Center
NTP	National Toxicology Program
OEM	Occupational and Environmental Medicine
OH	Occupational Health
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
Pb	Lead
PCBs	Polychlorinated Biphenyls
PEL(s)	Permissible Exposure Limit(s)
PHEL	Physiological Heat Exposure Limits
ppm	Parts of a substance per million parts
ppb	Parts of a substance per billion parts
PPE	Personal Protective Equipment

ReproDev	Reproductive and Developmental
RDA	Recommended Dietary Allowance
REL	Recommended Exposure Limits
SDS	Safety Data Sheet
TCDD	2,3,7,8-tetrachlorodibenzo-para-dioxin
TLV	Threshold Limit Value (TLV®)
TV	Tidal Volume
TWA	Time-Weighted Average
WBGT	Wet-Bulb Globe Temperature

(II) INTRODUCTION

This manual provides general guidance to Navy medical department personnel in the recognition, assessment, and control of workplace reproductive and developmental (ReproDev) hazards to both male and female uniformed and civil service personnel (hereafter collectively referred as “workers”). Strategies for managing potentially-exposed workers are presented, and potential command concerns about ReproDev issues are addressed. This manual promotes a consistent, scientific and evidence-based approach to the assessment and disposition of workplace ReproDev issues throughout the Navy.

Increasingly, Navy medical providers have had to respond to concerns related to contaminants in drinking water, groundwater, surface water, ambient air, soil, and sediment, and to vapor intrusion. In addition, the number of emerging contaminants (those without current standards) are growing. Occupational and environmental exposures to ReproDev hazards may be very different with regard to the exposure media (e.g., soil, water, ambient air), routes of exposure (e.g., inhalation, ingestion, direct contact), the populations exposed (civilian workers, military service members, civilian beneficiaries), the exposure scenarios (e.g., industrial, residential, recreational), and the acceptable exposure levels. Because environmental exposure levels of concern (EPA Screening Levels) tend to be much lower than occupational ones (OSHA Permissible Exposure Limits, PELs), different management strategies may be required. Investigating disease clusters (the manifestation or recognition of an adverse health effect) may include considering both occupational and environmental exposures. Site-specific strategies are necessary for the scientific investigation (to exercise due diligence) and to address stakeholder’s health risk concerns. Outbreak investigations are beyond the scope of this document. Providers and others dealing with environmental investigations are directed to the [NMCPHC web site](#) for additional resources.

A hazard is a source of danger that has the ability to cause injury or harm. Hazards may be chemical, physical, biological, psychological, and ergonomic agents and conditions. The hazard associated with a toxic substance is a function of its toxicity and the potential for exposure to the substance. Toxicity refers to effects caused by chemicals (in any form—solid, liquid, gas, dust, vapor, fume, etc.). The probability of exposure to the substance resulting in an untoward effect is described as the risk. A reproductive hazard is a hazard that alters male or female fecundity or that affects couple-specific factors (factors related to the ability of two specific individuals to produce offspring), and results in an alteration in fertility at a dose below that which causes harm to the individual. A developmental hazard is a hazard that alters the structure or function of a developing embryo or fetus, apparent either before or after birth. Reproductive hazards are of concern when exposed workers have the potential to initiate conception. Developmental hazards are of significance to workers actively trying to conceive, pregnant workers, breastfeeding workers, and workers who have young children at home. A birth defect or congenital malformation is a structural, functional, or biochemical abnormality that is either genetically determined or induced during gestation, and is not produced by birth trauma. Very early in pregnancy (up to week 3), developmental hazards generally either have no effect or cause fetal demise (miscarriage or “spontaneous abortion”). During the embryonic period (weeks 3-10), developmental hazards can disrupt organ systems and cause structural

birth defects. After the embryonic period, developmental hazards can affect the growth and development of the fetus, but do not typically cause structural defects.¹ [Table 1](#) contains more definitions related to reproduction and development.

Although the occupational environment for a given worker may not be of scientific or medical significance in terms of ReproDev risks, people may consider the workplace the single greatest threat to their ability to parent normal offspring. Workers' concerns must be promptly recognized and adequately addressed, regardless of the level of actual ReproDev risk. An effective ReproDev hazard control program must include worker participation, management support, and scientific and medical knowledge. Emphasis should be placed on worker/supervisor education and compliance, including appropriate work practices and healthy lifestyles. Thorough, cooperative workplace evaluations for ReproDev hazards by safety, industrial hygiene (IH), toxicologists and other occupational health (OH) professionals are necessary to appropriately identify ReproDev hazards so that they can be controlled to the greatest degree possible. Elimination is preferred when practical; however, steps to minimize exposure may also be effective. Appropriate medical surveillance and counseling regarding risks to health, including ReproDev health, must be provided for workers potentially exposed to existing hazards.

Table 1 – Definitions

Chromosome	A thread-like structure in the nucleus of a cell that is made up of coiled double-stranded DNA and histone proteins.
Deformity, birth	Malformation, present at birth, of the body or a body part.
Developmental toxicity	The potential to cause harmful effects on the developing child, whether before or after birth, up to adulthood. The manifestation of the effect may happen at any time during the person’s life span.
DNA	Deoxyribonucleic acid. A carrier of genetic information for all organisms except the RNA viruses. [†] Deoxyribonucleic acid is a coiled, self replicating, double stranded molecule present in nearly all living organisms. It confers heritable genetic information from one generation to the next.
Embryo	The developing human from pregnancy weeks 3 to 10 based on the menstrual cycle.
Embryotoxicity	Potential to cause adverse effects on the embryo, generally attributed to a substance that enters the mother and crosses the placental barrier or to an environmental or physical agent.
Fecundability	The probability of becoming pregnant in a single menstrual cycle.
Fecundity	The capability of a person or couple to produce offspring. When referring to populations, fecundity may be the reproductive rate of a population or the probability of achieving a live birth in a single menstrual cycle.
Fertility	The production of offspring or the ability to produce offspring.
Fetotoxicity	Adverse health effect on the fetus. Generally, this is applied to agents in the maternal circulation that cross the placenta and cause fetal demise, growth restriction, or other adverse health effect.
Fetus	The unborn baby in the post-embryonic period (week 10 of pregnancy).
Gene	A portion of chromosomal DNA consisting of a series of nucleotides that codes for a specific trait and serves as the basic unit of heredity.
Histones	A group of simple proteins found in chromatin that confer structure to DNA in chromosomal regions.
Infertility	The failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse. ²
Mutagen	Anything (generally a chemical or a physical agent) that causes or leads to genetic change.

Mutation	A change in the structure of a gene by alteration of single nucleotide bases within DNA, or the deletion, insertion, or rearrangement of DNA fragments, that may result in the transmission of a heritable changes in DNA sequence to subsequent generations.
Ovulation	The discharge (release) of the ova, or ovules, from the ovary.
Ovum	An egg (ova) or mature female reproductive cell that, once fertilized by a male cell, can divide to give rise to an embryo.
Reproductive toxicity	The potential to cause adverse effects on fertility and to cause developmental toxicity.
RNA	Ribonucleic acid, a single-stranded nucleic acid that principally functions as a messenger required in protein synthesis. Lesser RNA molecules may be important in the regulation of protein translation and transcription.
Spermatogenesis	The production or development of mature spermatozoa.
Spermatozoa	Mature motile male sex cell, typically having a head and one or more flagella for movement, which fertilizes the ovum.
Subfertility	A reduction in the expected birth rate due to factors other than choice. This includes a delay in time to conception.
Teratogen	Anything that causes physical defects in the developing embryo.

(III) EVALUATION AND MANAGEMENT OF WORKPLACE REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

A) INTRODUCTION

Questions and inquiries concerning possible ReproDev hazards in the workplace may arise in a variety of settings. Healthcare providers should strive to provide thorough, timely responses in a sensitive manner to address workers' concerns.

The identification and evaluation of potential ReproDev hazards is an ongoing process. Workers with concerns about potential ReproDev hazards from specific stressors may request evaluation from their local medical treatment facility (MTF), Occupational and Safety Health (OSH) office, or IH office. This request should include information such as the occupational situation in which the material/stressor is encountered, a current Safety Data Sheet (SDS) for each substance of concern, and, if applicable, the scientific or medical information upon which the concern is based.

When assessing the possible physiologic effects of potential ReproDev hazards, OH professionals should consider the nature of the hazard (chemical, biological, physical, or ergonomic), the dose (concentration/level and duration), the potential route of exposure, the frequency and duration of the exposure, and the timing of exposure within the reproductive or developmental process. To assist in this assessment, Chapter [\(VI\) The Biology of Reproductive and Developmental Hazards](#) contains a brief review of reproductive biology and the critical periods of embryonic development.

Qualified OH personnel, such as nurses and physicians, should utilize exposure assessment information from the current IH survey of a worksite or task when evaluating health risk to a worker, or group of workers, from potential ReproDev hazards. Further collaboration with the industrial hygienist may be necessary to fully understand the nature and intensity of worker exposure to ReproDev hazards. In addition, supervisory and OSH personnel may be contacted regarding specific workplace conditions or requirements that may pose special safety risks to the worker (particularly the pregnant worker), such as climbing ladders, working at heights, heat stress conditions, lifting, pushing, pulling, or respirator use. The healthcare provider or professional should first consult local medical resources (Obstetrician/Gynecologist or Occupational and Environmental Medicine (OEM) physician). If these medical specialists are not available locally, the OEM Department at the Navy and Marine Corps Public Health Center (NMCPHC) can provide a response that addresses the OEM considerations.

Chapters [\(VII\) Occupational Chemical Reproductive and Developmental Hazards](#), [\(VIII\) Drug Reproductive and Developmental Hazards](#), and [\(IX\) Occupational Biological Reproductive and Developmental Hazards](#) contain lists of recognized chemical, biological, physical, and ergonomic ReproDev hazards. The lists are limited to **known** ReproDev hazards. Objective criteria are used for adding or removing agents from the lists. The criteria used to identify a hazard as a "known hazard" are the Occupational Safety and Health Administration (OSHA) criteria for reproductive toxicants category 1 ([OSHA](#)).³ The chemicals and medications lists in Chapters [\(VII\)](#)

and [\(VIII\)](#) were adopted from other similar lists, such as the [State of California's Reproductive and Developmental Toxicity List](#).⁴ Although the potential for significant exposure to workers by some of the agents is considered remote, all known current chemical and pharmacological agents with ReproDev toxicity are included. The lists will assist in preventing procurement of these materials into the Navy supply system and to identify those already in the system for their control or elimination.

B) INDUSTRIAL HYGIENE

Based on all available information and using Chapters [\(VII\) Occupational Chemical Reproductive and Developmental Hazards](#), [\(VIII\) Drug Reproductive and Developmental Hazards](#), and [\(IX\) Occupational Biological Reproductive and Developmental Hazards](#), the industrial hygienist, in consultation with the OEM staff, determines the existence of known ReproDev hazards in the workplace and identifies the tasks that require further evaluation. If the OEM department does not have the services of an industrial hygienist, IH support may be requested from the cognizant Naval Medical Center (NAVMEDCEN)/Naval Hospital (NH)/Naval Health Clinic (NHC), Navy Environmental and Preventive Medicine Unit (NEPMU), or NMCPHC.

The identification and evaluation of potential reproductive and developmental hazards is an ongoing process. The current IH survey of the worksite, the hazardous materials inventory, and the authorized use list are used to develop a list of ReproDev hazards at a supported command. If a comprehensive IH survey has not been performed, or if the previous survey needs to be updated, additional measurements and evaluation will be required to update the worksite evaluation to specifically address ReproDev hazards. The workplace exposures identified must be discussed with workers and documented in their medical records. Where stressor specific standards either do not exist, or were developed without consideration of reproductive health risk, local review in consultation with the OEM staff may be necessary.

Routine industrial hygiene assessments of workplaces should be focused to the toxic effects of the stressors present as based on some trigger of exposure. A ReproDev hazard “action level” (one half of the Occupational Exposure Limit), except for the physical stressors) can be used as a trigger for implementing “non-negative” assessment actions that would require hazard abatement with control recommendations and inclusion of specific training due to unknown risks, see Chapter [\(IV\) Reproductive and Developmental Hazards in Occupational Safety and Health Administration Standards](#). If skin is a significant route of entry, dermal uptake should be included as part of the worksite assessment for all stressors.

In instances where the duration of use is too short to adequately characterize the potential exposure, professional judgment must be applied to estimate the hazard. In these instances, the industrial hygienist performing this critical function must be qualified and competent by virtue of specialized training, education, and experience (see the [Navy Industrial Hygiene Field Operations Manual](#)).⁵ Consideration should be given to the frequency of the potential exposure as well as to a “worst case” exposure scenario.

C) OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

The OEM Department plays a coordinating role in the evaluation and management of ReproDev hazards and the medical management of exposed workers.

In this role, the OEM Department:

1. Reviews the list of safety and health hazards in the worksites of the supported command (maintained by command's OSH office and compiled by the IH departments).
2. When necessary, requests additional IH evaluations (exposure measurement and characterization), and actual worksite visits to directly evaluate ReproDev stressors and work practices and control ReproDev hazards.
3. Compiles or reviews data on occupational illnesses and injuries at the worksite to identify conditions and outcomes that may have potential adverse effects on reproduction or development. If applicable, review and analyze pregnancy outcomes, looking for trends potentially related to the work environment.
4. Assists in the assessment of the hazards in the workplace. Using the ReproDev hazards lists—Chapter [\(VII\) Occupational Chemical Reproductive and Developmental Hazards](#) to Chapter [\(X\) Occupational Physical Reproductive and Developmental Hazards](#)—determine the level of ReproDev risk for a given task or workplace. If sufficient OEM support is not available locally, consultation may be obtained from the OEM department (located at many larger NHCs and most NHs) or NMCPHC.

D) WORKER INQUIRIES

Workers, individually or through a collective group such as a union or rate/specialty association, may raise questions about the ReproDev risk of an agent or condition. Frequently, review of the agent or condition in light of the available literature or information, and discussion with the inquiring party (or parties) by an OH professional, is sufficient to satisfactorily answer these questions. Occasionally, a worker with concerns about issues of reproduction or development may request job modification or even removal from exposure to a specific hazard. These instances require a review of the worker's actual exposure—to determine if there is a potential ReproDev hazard and, if there is, to what extent that exposure occurs (amount, concentration level, frequency, and duration). If additional information is necessary, a worksite visit may be required. Chapter [\(X\) Occupational Physical Reproductive and Developmental Hazards](#) is a summary of physical agents and conditions (hazards) that should be considered when reviewing potential ReproDev hazards in the workplace. Chapter [\(XII\) Occupational Exposures of Reproductive and Developmental Concern - Supervisor's and Worker's Statements](#) discusses questionnaires (forms) that may be used for any worker with ReproDev concerns, including the worker's self-assessment of his/her occupational/non-occupational exposures to physical, chemical, biological, and environmental agents. These questionnaires and the pertinent SDSs should be reviewed by the OEM physician and/or the worker's personal physician. If needed, the OEM physician may call upon IH to assist in quantifying workplace exposures. Once the OEM practitioner makes a medical management decision, it must be discussed with the worker and his or her personal physician. [Figure 1](#) and

[Figure 2](#) are flow charts that can be used by the OH staff in managing a worker's request for job modification or reassignment. See Chapter [\(V\) Evaluating and Managing the Pregnant Employee](#) for further guidance about pregnant active duty members or civil service employees.

Figure 1 – Evaluation of a Reproductive and Developmental Hazard

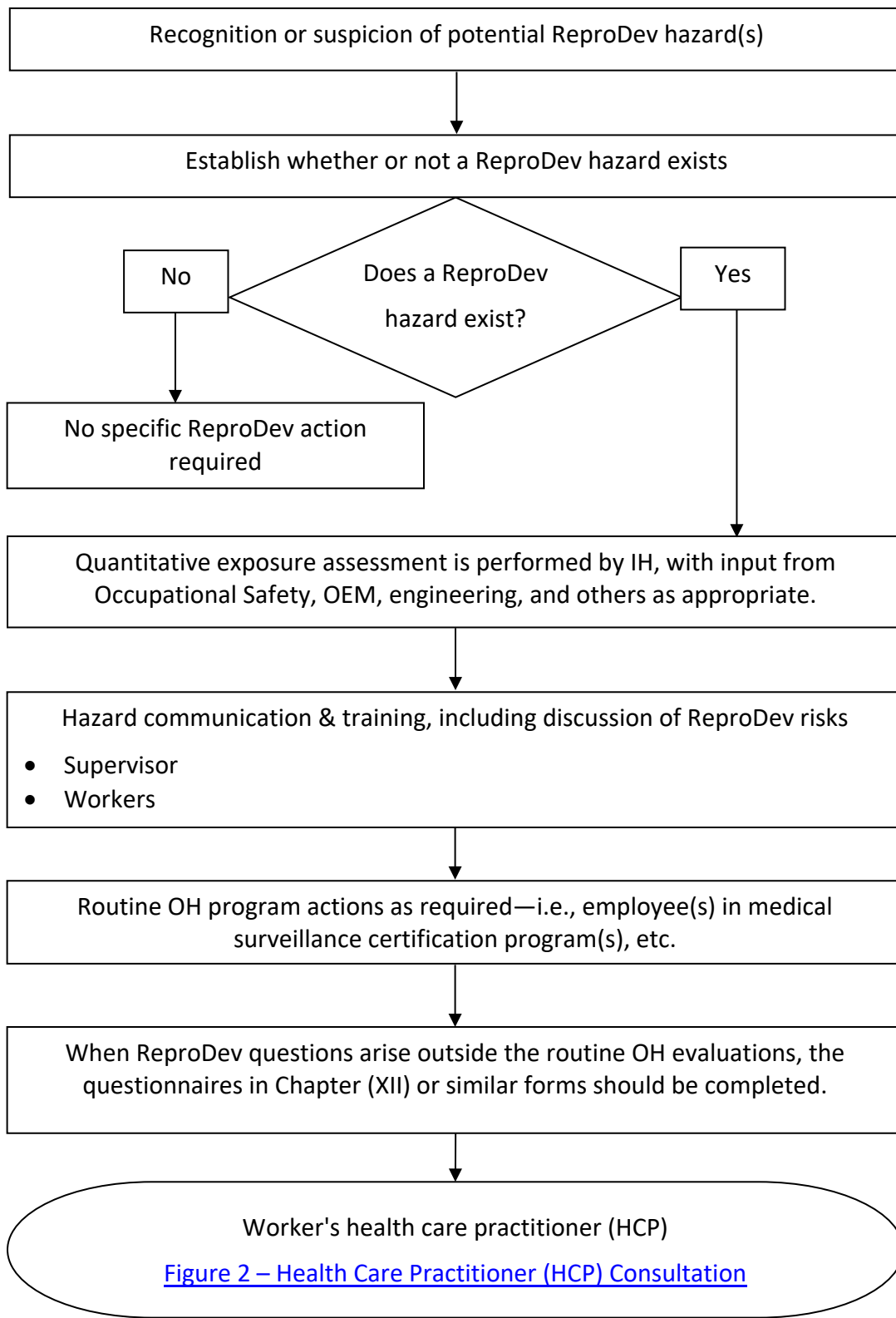
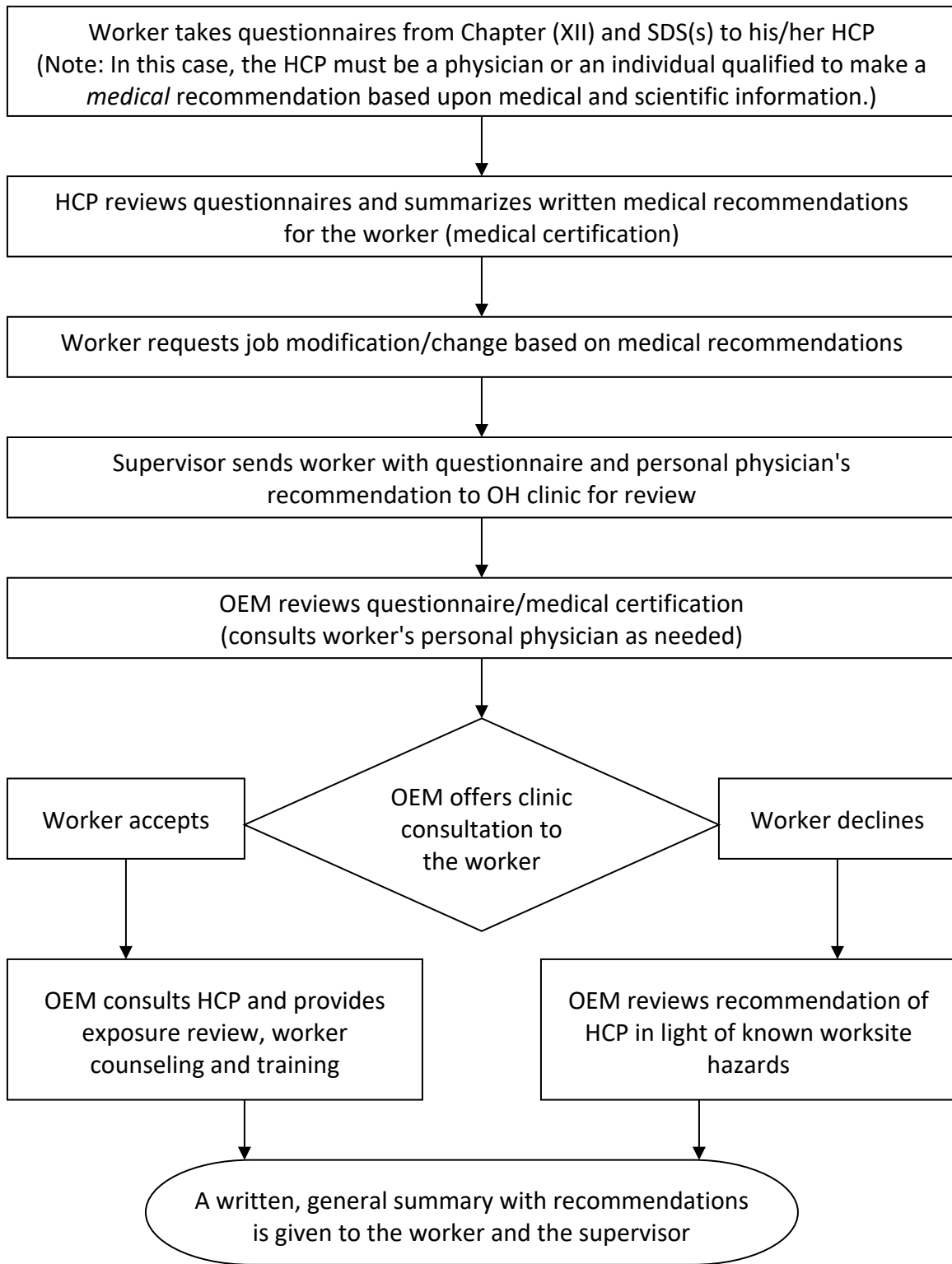


Figure 2 – Health Care Practitioner (HCP) Consultation



E) COMMAND ISSUES

Requests for information concerning ReproDev hazards associated with specific exposures or jobs may be directed to the local OEM Department. The command's IH survey may have already addressed the ReproDev issues associated with the process where the material is used. The supporting OSH office may also be contacted for assistance as necessary.

F) INVESTIGATION OF UNDESIRABLE OUTCOMES

The occurrence of an undesirable event (such as spontaneous abortion or birth defect), or cluster of undesirable events, may lead to the request for an evaluation of the workplace to investigate a possible connection with workplace exposure. The association of an untoward outcome and occupational exposure does not prove that the exposure and the outcome are causally related. Establishing causality requires further scientific investigation. "Clustering" of events in time and place may occur in natural or disease conditions and may be due to chance alone [[PMID 1820268](#)].⁶ The OEM Department has the expertise to determine whether or not the event or cluster may have occurred by chance or from exposure to ReproDev hazards in the workplace. The physician or other OEM practitioner should work closely with the industrial hygienist, OSH manager, and other command personnel as appropriate from the very beginning of an investigation.

The collection of complete information at the outset of an investigation is critical. The information may reveal that individual events are dissimilar and not related—or are not attributable to workplace exposures. The type of birth defect (congenital malformation) may not be uniform, spontaneous abortions may have been caused by individual medical conditions, or the job requirements and exposures of the employees concerned may not be the same. Satisfactory (complete) investigations of such clusters may require evaluation of reproductive or developmental outcomes observed at other commands. Documenting and evaluating all undesired ReproDev outcomes of workers are good practices and enable epidemiological evaluation and identifying trends. Combining individual outcomes (collective data) allows identification of a rare event.

The extent of the evaluation by the staff of each MTF will depend on the situation and resources locally available. A complete investigation may require assistance obtained in accordance with local procedures, which may be from the OEM Department at the supporting MTF. These activities can arrange supplemental assistance from NMCPHC if needed.

The investigation process includes the following steps:

1. Schedule an individual appointment with the OEM physician for each involved worker. In some cases, it is prudent to include the worker's spouse in such discussions, with the consent of the worker. Adequate time must be allowed for the worker to fully explain his/her concerns or complaints. After a thorough and complete history is obtained, a medical examination may be indicated. Consultation with another specialist, including but not limited to medical genetics, may be required. There must be documentation in the

medical record, and the worker must be assured that the medical information will remain confidential.

2. If indicated and necessary to such investigations, medical records pertinent to the investigation should be obtained through standard request procedures, with signed consent from the worker for release of specific information.
3. Review the diagnosis and the medical records of the cases in question. Determine if the worker (or workers) has/have a past history of a similar event. Consider factors that may affect the event in question, such as illness, drug use (prescribed, over-the-counter, or illicit), and activities outside of the work environment. Coordination with the worker's HCP may facilitate identification of cases due to causes other than occupational exposure. The worker's privacy must be protected at all times during the conduct of the investigation.
4. Review the list of ReproDev hazards in that task/worksites. Consult IH for past and present records of sampling. Additional sampling may be needed to complete a satisfactory evaluation. Visit the worksite to identify stressors and work practices or conditions that may be associated with an adverse effect on reproduction or development.
5. Determine the timing and duration of exposure, and ascertain if the onset of exposure is consistent with the occurrence of the event. This is discussed in detail in Chapter [\(VI\) The Biology of Reproductive and Developmental Hazards](#).
6. If more than one worker is involved, determine if the affected workers have a common exposure and if a particular task, shift, or location is over-represented.
7. Review this manual and other medical literature to determine if the stressors to which the worker(s) is/are exposed have been found to produce adverse reproductive or developmental effects—and under what specific conditions.
8. When the OEM Department cannot confidently rule out a cluster, it may request assistance from the cognizant epidemiology, risk assessment, or toxicology support (if any), or supplemental assistance from NMCPHC.
9. Complaints of infertility should be recorded (and handled as confidential) to alert both the OEM and the OSH Departments. When evaluated collectively, such complaints may reveal an increased incidence of infertility in the worksite over the expected rate for the general population. If a medical cause cannot be identified after taking a complete personal, occupational, and environmental history, then a workplace assessment for possible stressors should be considered. Individual worker infertility issues will require a consultation with a specialist in toxicology, reproductive endocrinology, or other appropriate field.

(IV) REPRODUCTIVE AND DEVELOPMENTAL HAZARDS IN OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION STANDARDS

A) INTRODUCTION

The potential for hazardous substance exposure to cause adverse reproductive or developmental effects is becoming an increasingly important issue, particularly in the American workforce. In the past, ReproDev effects have not been a significant toxicity of concern in setting standards for a substance. However, several comprehensive OSHA standards have been written with greater consideration of the potential effects of hazardous substance exposure on the reproductive health of exposed individuals. OSHA standards that include consideration of ReproDev effects of chemicals are ethylene oxide (ETO) ([29 CFR 1915.1047](#)),⁷ lead (Pb) ([29 CFR 1910.1025](#)⁸ and [29 CFR 1926.62](#)⁹), and 1,2-dibromo-3-chloropropane (DBCP)([29 CFR 1910.1044](#)¹⁰ and [29 CFR 1926.1144](#)),¹¹ and cadmium (Cd) ([29 CFR 1910.1027](#)).¹² Reproductive toxicity of glycol ethers is currently being considered as another such standard with this emphasis and a discussion of this class of compounds is included here. Moreover, reproductive health outcomes are now routinely given greater consideration in writing new standards. OSHA standards now require a reproductive history in medical surveillance programs for substances known to cause reproductive toxicity.

The comprehensive health standards mentioned above specifically discuss ReproDev health effects requiring medical intervention. Medical intervention is triggered by an “action level” for ETO and Pb. An action level is the exposure concentration at which an employer must begin compliance activities specified in the OSHA standard. The action level is defined normally as an exposure of one-half of the Permissible Exposure Limit (PEL) of a particular chemical. For DBCP, there is no defined action level. The medical interventions ordinarily required for substances causing potential ReproDev health harm include targeted ReproDev history-taking, worker education, and specialty medical referral for infertility evaluations in some circumstances. These standards are discussed below.

B) ETHYLENE OXIDE

ETO is a highly reactive epoxide that has a variety of uses and consequently is a major industrial chemical produced in the United States. ETO is primarily found in chemical factories, where it is produced and used in the manufacture of ethylene glycol for automotive antifreeze, polyester fibers and films, and detergents. ETO is also used for gas sterilization of equipment and supplies in hospitals and health care facilities, and as a fumigant in the manufacture of food and medical products and in libraries and museums. The major use of ETO in the Navy and Marine Corps is gas sterilization of medical devices, equipment, and supplies. ETO is also used for sterilization of non-medical items within Naval activities. Exposure to ETO has been linked to an increased risk of cancer and to ReproDev effects, including decreased male fertility, fetotoxicity, and spontaneous abortions.

C) LEAD

Since the 19th Century, it has been well known that exposure to Pb can have serious effects on reproductive function in both males and females, and on development. Workers with the greatest exposure include smelters, metal workers (including welders), painters, typesetters, glass artists, firing range personnel, and those involved in the manufacture of batteries, paint, ink, ceramics, pottery, ammunition, textiles, and leaded gasoline. Additionally, workers in the construction sector involved in demolition, bridge painting and repair, and other such tasks are also at risk. The concentration of Pb has been greatly lowered in many types of commercial and residential paints; however, industrial paints used to protect bridges and other structures, as well as marine applications, still contain significant concentrations. With respect to Naval forces, Pb exposure may occur from paint removal operations (use of deck-crawlers, needle guns, grinders, sanders), “hot operations” (welding or cutting of metal products that have been painted with Pb-containing paints), and indoor weapons firing and range operations.

In males, the reproductive effects of Pb exposure include decreased libido (sex drive), impotence (inability to have or maintain an erection), malformed sperm, decreased number of healthy sperm, decreased total sperm count, decreased sperm motility, and sterility. Of note, decreased sperm count [[PMID 3579367](#)],¹³ sperm motility [[PMID 9987558](#)],¹⁴ and production of malformed sperm [[PMID 1442789](#)]¹⁵ have been found at elevated blood Pb levels: 40 micrograms per deciliter ($\mu\text{g}/\text{dl}$)ⁱ has been noted in a review article [[PMID 9764095](#)].¹⁶

Higher incidence of infertility, premature births, spontaneous abortions, pre-eclampsia, hypertension in pregnancy, and premature rupture of membranes have been reported in women exposed to high Pb levels [[PMID 8247405](#)].¹⁷ Pb is known to cross the placental barrier, with resulting levels in the umbilical cord blood at birth comparable to concentrations in the mother's blood [[PMID 10025415](#)].¹⁸ Fetal blood Pb levels have been noted to increase with maternal occupational exposure [[PMID 7448135](#)].¹⁹

Fetal and infant/child neurological damage may occur at blood Pb levels above 5 $\mu\text{g}/\text{dl}$ [[CDC](#)],²⁰ and may be manifested by childhood learning difficulties [[PMID 7679348](#)].²¹ Infants of mothers with Pb poisoning have been found to have low birth weight, slow growth, increased risk of death during the first year, and nervous system disorders.

Considering the demonstrable ReproDev risks associated with untoward exposure to Pb, including the risk of genetic damage in both the ovum and sperm, the Pb standard promulgated in 1978 established a 30 $\mu\text{g}/100\text{g}$ maximum permissible blood level in both males and females who wish to bear children.²² However, given scientific advances on the ReproDev effects of Pb, clinicians may reasonably counsel patients to achieve even lower blood levels prior to conceiving. Good work practices and current IH control technologies, including the availability of effective respiratory protection, makes achievement of lower blood Pb levels (< 20 $\mu\text{g}/\text{dl}$ in older workers with previous Pb exposures or <10 $\mu\text{g}/\text{dl}$ in younger workers) easily attainable.

ⁱ Laboratory values of measurements in blood are usually reported in units per deciliter. However, some references and OSHA standards are given in units per 100 grams of blood.

Elevated blood Pb levels during pregnancy have been attributed to mobilized skeletal Pb stores [[PMID 9242366](#)].²³ It has been recommended that a woman with a blood Pb above 20 µg/dl and desiring to become pregnant be advised to avoid uncontrolled Pb exposure for 1 to 2 years before attempting pregnancy.²⁴

Although no threshold has been found to trigger the adverse health effects of lead, in nonpregnant adults blood lead levels less than 5 µg/dl are considered normal, blood lead levels between 5 µg/dl and 10 µg/dl require follow-up, and blood lead levels greater than 10 µg/dl are managed with environmental assessment and abatement of exposures. Chelation therapy is considered at blood lead levels greater than 40 µg/dl for symptomatic individuals, and levels greater than 70 µg/dl are considered a medical emergency. In children, treatment with chelation is recommended at blood lead levels of 45 µg/dl (a level considered a critical health concern) or greater.^{25,26,27} The CDC recommends that pregnant women with blood lead concentrations of 10 µg/dl or higher be removed from occupational lead exposure [[CDC](#)].²⁸

Clinicians treating or counseling male and female workers with significant exposure to Pb should take a careful and complete ReproDev history including history of infertility, impotence, loss of libido, abnormal menstruation, miscarriages, stillbirths, or children with birth defects. A ReproDev history should also be considered in formulating work plans, including establishing alternative duty assignment, when a woman is trying to conceive or is pregnant. Comprehensive guidance for the administrative and healthcare management of pregnant servicewomen is provided elsewhere.²⁹

Lead appears in human breast milk (see [Breastfeeding](#), page 25) [[PMID 9755144](#)],³⁰ and may be passed on to the child during breast feeding.

D) 1,2-DIBROMO-3-CHLOROPROPANE

DBCP is a nematocide (pesticide used to control worms) that was widely used in agriculture in the U.S. and abroad from the mid-1950s until 1977. The discovery of adverse reproductive effects in humans led to the United States imposing a partial ban in 1977 and a total ban in 1987.

DBCP has been shown unequivocally to produce testicular toxicity and sterility in exposed male workers in a dose-response relationship [[PMID 556420](#)].³¹

OSHA requires that employers ensure that no employee is exposed to an airborne concentration of DBCP in excess of 1 part per billion (ppb) of air as an 8 hour time-weighted average (TWA). Also, as DBCP has been shown to cause reproductive dysfunction, OSHA requires that physical examination be part of a DBCP medical surveillance program. Testicle size, semen analysis, and serum determination of levels of reproductive hormones including follicle-stimulating hormone (FSH), luteinizing hormone (LH), and (in females only) estrogen, are to be included.

E) CADMIUM

Cd is a metal with toxic qualities that is encountered in industry, especially in metalworking (including welding), as well as elsewhere (such as in cigarettes). Among other adverse health effects, Cd is associated with decreased birth weight (with inhalation exposure, ATSDR),³² placental toxicity (Miller),³³ preterm delivery ([PMID 8094678](#)),³⁴ and possibly with prostate cancer ([29 CFR 1910.1027 App D](#)).³⁵ OSHA requires that employers provide pre-placement and periodic detailed medical and work history, to include a reproductive history with an emphasis on reproductive dysfunction ([29 CFR 1910.1027](#)).³⁶

F) GLYCOL ETHERS (ETHOXYETHANOL OR "CELLOSOLVE", METHOXYETHANOL OR "METHYLCELLOSOLVE")

Two members of the large family of "glycol ethers," ethylene glycol monomethyl ether and ethylene glycol monoethyl ether and their acetates, have been associated with male reproductive effects. The glycol ethers (including the ones specifically addressed above) are widely used as solvents in the manufacture of lacquers, varnishes, resins, printing inks, textile dyes, and as an anti-icing additive in jet fuel. They are also used in consumer products such as latex paints and cleaners. Naval exposures may result from the use of these substances. It is important to recognize that the other chemical members of the glycol ether family have not been demonstrated to cause reproductive or developmental effects. ReproDev effects are the primary health concerns associated with exposure to glycol ethers because of exhibited abnormalities in the blood and male reproductive system of exposed workers. The major reproductive effect observed among exposed male workers is a reduced sperm count. The current PELs for different glycol ethers vary widely depending on the specific chemical.

(V)EVALUATING AND MANAGING THE PREGNANT EMPLOYEE

A) INTRODUCTION

Exposure to ReproDev hazards can affect workers, or their children, in a variety of ways. Important concerns are the potential for mutagenesis, abnormal development of the fetus, and interference with the physiology of pregnancy leading to spontaneous abortion, premature delivery, or fetal injury. Unfortunately, the guidance for occupational exposures provided by consensus standards, such as Threshold Limit Values (TLVs), rarely provide adequate guidance when dealing with the pregnant worker. The same limitation is found with the statutory PELs, as these standards are based upon exposure to the average non-pregnant worker. (In other words, just because TLVs or PELs say nothing about ReproDev hazards, it does not imply there is no hazard or that any substance with a given TLV or PEL is “OK” in regards to ReproDev issues.) Therefore, evaluating and caring for the pregnant worker often requires an individualized approach.³⁷ Industrial hygienists, OEM physicians, and obstetrical practitioners need to be involved in a combined effort.

B) OCCUPATIONAL HISTORY

The first step in evaluating the pregnant worker is to take a detailed personal, social, occupational, and environmental history. The occupational history should consider past and current jobs, including job title and a description of actual tasks performed, duration of employment, and occupational exposures (chemical, physical, biological, radiological, and psychological stressors). A spousal history, if available, should be taken as well, preferably directly from the spouse. This may be important, as workers may unknowingly take home toxicants from the workplace (in the form of dust, dirt, or stains on their skin, clothes, shoes, etc.), or may work with toxicants in the home (in the so-called “cottage industry”). Such exposure mechanisms have been known to affect other family members, including children [[PMID 8352287](#)].³⁸ A National Institute for Occupational Safety and Health (NIOSH) study of contamination of workers' homes with hazardous chemicals and substances (including infectious agents) transported from the workplace noted that the problem is worldwide and has “resulted in a wide range of health effects and death among workers' families exposed to toxic substances and infectious agents” (NIOSH).³⁹ Contaminants of ReproDev concern identified in the study include the following (NIOSH).⁴⁰

Table 2 – Contaminants That Have Caused Health Effects Among Workers' Families

Lead	Pesticides
Mercury	Chlorinated hydrocarbons
Arsenic	Estrogenic substances
Cadmium	Infectious agents

Taken from: NIOSH. Protect your family--reduce contamination at home a summary of a study conducted by the National Institute for Occupational Safety and Health. U.S. Department of Health And Human Services Public Health Service Centers For Disease Control And Prevention, National Institute for Occupational Safety and Health. Cincinnati, Ohio. DHHS (NIOSH) Publication No. 97-125.

Chapter [\(XII\) Occupational Exposures of Reproductive and Developmental Concern - Supervisor's and Worker's Statements](#) discusses forms that may be used as part of this evaluation. IH data must be incorporated into the evaluation. Existing exposure data relative to ReproDev concerns should be used when available. In the absence of data, IH needs to be involved in assessing the workspaces and processes, and in characterizing exposures.

As part of the OH history, the worker may be asked if she, or any co-worker(s), has had signs or symptoms that may raise the index of suspicion for occupational illness, such as chronic cough or skin irritation. It is important to ascertain the temporal relationship of these signs and symptoms to work exposures. Prior work experience, especially if the worker is relatively new to the job, should be addressed. Special attention needs to be paid to agents which accumulate in the body and have prolonged half-lives, such as Pb and polychlorinated biphenyls (PCBs).

Community and home exposures can be significant, and should be part of the evaluation, including:

- Personal habits, such as diet and the use of tobacco, alcohol, and nutritional supplements
- Proximity to a toxic waste site or incinerator
- Pesticide application (indoor and outdoor)
- Air pollution (particulate matter, as measured by PM₁₀ have been associated with adverse pregnancy outcomes [[PMID 18231086](#)])⁴¹
- Prolonged intense sound exposure
- Known water contamination
- Use of household products (cleaning solvents, paints)
- Hobbies and crafts (such as ceramics, photography, stained glass, or furniture refinishing) and home renovations
- Exposure to hazardous substances from household members (environmental tobacco smoke, or Pb or other toxic dust brought home on work clothes)

If a pregnant active duty member or civil service employee asks for a change of duties or assignment, she should provide the OEM physician a medical certification from her personal physician, stating that work limitations are necessary. This document must state specifically what duties she can perform, and under what conditions these duties can be performed. This written certification is in turn reviewed by the OEM physician. It is recommended that both physicians discuss the individual's specific requirements. The employing activity should make every reasonable effort to accommodate these requests.

Prior to making a "work prescription" it is necessary to know something about the workplace environment and worker attitudes (e.g., interpersonal relationships), job flexibility, the possibility of temporary assignment, the worker's preference, and the availability of amenities (toilets and rest facilities, and, after childbirth, breastfeeding/pumping areas).

C) PHYSIOLOGIC AND ANATOMIC CHANGES OF PREGNANCY

There are many normal maternal changes that occur during the course of a pregnancy. Occupational and environmental exposure during pregnancy may cause effects to either the mother or the developing child. The attending HCP must differentiate normally occurring events from those caused by an occupational or environmental exposure. The exposure must be of sufficient dose (concentration and duration), and occur at the hazard-specific critical time period during pregnancy, to cause an adverse developmental effect.

PLACENTA: The “fetal-placental unit” is unique to pregnancy. This functional unit provides a partial barrier to some chemicals and limits their transfer from the maternal blood to the fetal blood. Chemicals with a small molecular size (molecular weight <500 Daltons) cross the placenta rapidly by simple or facilitated transport. Small, uncharged, unbound, lipid soluble molecules will cross the placenta most readily [[PMID 7758253](#)].⁴² Most drugs with molecular weight < 500 Daltons cross the placenta, and most drugs with molecular weight > 1000 Daltons do not cross the placenta (e.g., heparin, protamine, insulin). For example, neither succinylcholine (low molecular weight but highly ionized) or non-depolarizing neuromuscular blocking drugs (high molecular weights) cross the placenta.

CARDIOVASCULAR SYSTEM: The maternal cardiovascular system undergoes significant changes during pregnancy. Blood volume increases 30-40% beginning in the first trimester and peaks at 32 weeks (well into the third trimester). Cardiac output parallels volume change, increasing 1-1.5 liters/minute (L/min), greatly influenced by body position. Cardiac volume increases about 10%. The resting heart rate increases 10-15 beats per minute. The change in cardiac output is greater with twins or other multi-fetal gestations than with the usual single pregnancy. With multiple gestations, there is also an increased force of cardiac contraction (positive inotropic effect) that possibly indicates a decreased cardiovascular reserve.⁴³ The enlarging uterus presses on the inferior vena cava causing venous pressure to rise in the lower extremities, contributing to the development of hemorrhoids and varicose veins.

PULMONARY SYSTEM: The pulmonary system similarly undergoes marked changes during pregnancy. Diaphragmatic excursion is increased during pregnancy, and tidal volume (TV) increases almost 40%. The diaphragm is elevated about 4 cm, which is not offset by the 6 cm increase in thoracic circumference. Residual volume falls 20%, with a net minute ventilation increase from 7 to 10 L/min.⁴⁴ Due to this increased ventilatory volume, the pregnant worker breathes in more air and is exposed to a larger dose of airborne contaminants than are either non-pregnant females or males of comparable size. Although pregnancy increases the oxygen demand, it is less than the increased TV and increased hemoglobin in the circulation provide. Thus, the arterio-venous oxygen difference is decreased in pregnancy. Since respiratory rate does not change significantly, there is a “relative hyperventilation,” with the decreased arterial pCO₂ (32 mm Hg) and respiratory alkalosis partially compensated for by a decrease in plasma bicarbonate.⁴⁵ These changes make the pregnant female (and fetus) more sensitive to the toxic effects of carbon monoxide. Capillary dilation occurs throughout the respiratory tract, leading to increased sensitivity to dusts and airborne irritants. The anatomic and physiologic changes

of pregnancy (especially later in pregnancy) may make it increasingly difficult to use some types of respirators.

EYE: Changes in the eye noted during pregnancy include decreased intra-ocular pressure, decreased corneal sensitivity (later in pregnancy), slightly increased corneal thickness, and transient loss of accommodation (also noted during lactation). Brown-red opacities on the posterior surface of the cornea (“Krukenberg spindles”) may be increased. Visual fields are probably not affected by the increased pituitary size associated with pregnancy.⁴⁶

SKIN: The skin of pregnant females may undergo changes including hirsutism, hyperpigmentation (of nipples, areola, nevi, linea alba, and freckles, and the “mask of pregnancy,” called melasma or chloasma—irregular brown facial pigment changes), striae gravidarum, palmar erythema, arterial spiders, and increased sweating. Increased pigmentation may alter the response of the skin to sun exposure. To avoid increased (and usually uneven) tanning, avoidance of unnecessary sun exposure or the use of pregnancy-safe sun block preparations may be advised. Several skin conditions (dermatoses) are unique (or nearly unique) to pregnancy. Pruritic urticarial papules and plaques of pregnancy (“PUPP”) is a common cause of itching during pregnancy.⁴⁷ The lesions begin on the abdomen and move to the extremities and usually spare the face. Resolution of pruritus is complete and spontaneous following delivery. Papular dermatitis and prurigo gestationis are pruritic conditions generally appearing late in the second or during the third trimester of pregnancy. Herpes gestationis (pemphigoid gestationis) is a serious, rare (1 in 50,000 pregnancies) blistering, pruritic condition usually seen in late pregnancy (but may be seen from early pregnancy to one week postpartum). It is not herpes virus-induced (despite the name), and recurs in subsequent pregnancies. Impetigo herpetiformis is a rare condition of late pregnancy, and may persist for months after delivery. Erythematous patches surrounded by sterile pustules are seen, usually in conjunction with systemic symptoms and mild pruritus. In order to appropriately treat and avoid exposure to the causal agent(s), the etiology of dermatologic conditions must be evaluated. Dermatology should be consulted if needed to evaluate skin conditions or complaints in pregnant workers in order to ensure proper treatment and disposition.

MUSCULOSKELETAL SYSTEM: Pregnancy places marked stress on the musculoskeletal system. There are significant weight changes and the center of gravity changes almost daily as the uterus rises and the breasts become heavier. With accentuated curvature of the spine (lordosis of the lumbar spine and kyphosis of the upper back), low backache is a common problem. The redistribution of weight and the center of gravity increases the risk of falls, and may necessitate removal of pregnant women from jobs where balance is crucial. Pregnant workers should wear low-heeled shoes with non-slip soles. The ability to lift objects can be significantly compromised since the horizontal distance of a load from the axial skeleton becomes progressively greater. Of particular operational concern is the potential difficulty that pregnant women may experience in emergency or escape situations.

Ergonomic factors require special attention. As pregnancy progresses, modification of the intensity, frequency, or pattern of physical tasks often is necessary. Work that requires long

periods of standingⁱⁱ during the third trimester contributes to decreased utero-placental blood flow and preterm births and reduced birth weight [[PMID 8899916](#)][[PMID 2306429](#)][[PMID 2293743](#)].^{48,49,50} Excessive sitting (including during prolonged trips) or standing (promoting venous stasis, thought related to the increased incidence of deep vein thrombosis in pregnancy) may cause blood clots in legs and exacerbate hemorrhoids, as well as back and leg pain. Pregnant women are at increased risk for carpal tunnel syndrome, therefore attention should be directed toward prevention. Active prevention and protection efforts to reduce the chances of physical trauma should be made. With increased body size and weight, and a changing center of gravity, the pregnant worker may be slow to react to quickly changing or dangerous situations. Even minor blows to the abdomen can cause placental abruption with potential fetal and maternal death. The protuberant maternal abdomen may also be a hazard in certain situations where inadvertently bumping equipment or personnel may be dangerous.

D) MODIFICATION OF THE WORK ENVIRONMENT

Specific guidelines for management of pregnant servicewomen are described in [OPNAVINST 6000.1D](#).⁵¹ The basic principles involved in providing a workplace free from ReproDev hazards are the same as those used in the practice of OH in general.

- Product substitution (replace a hazardous condition or substance with a less hazardous one). Unfortunately, this cannot always be done soon enough to assist with an individual pregnancy as the pregnancy is often not identified sufficiently early. A program to utilize less hazardous products and correct hazardous conditions can help the command move toward a more healthful workplace.
- Engineering controls (improving exhaust, enclosing processes, powered lift assistance),
- Administrative controls (rotation or reassignment) and, as a last choice,
- Personal protective equipment (PPE), such as aprons, gloves, or respirators.

The industrial hygienist can be very helpful in recommending measures that can most effectively minimize exposures.

E) WOMEN ABOARD SUBMARINES

Historically, women have been excluded from permanent assignment aboard submarines. OPNAVINST 6420.1 excluded pregnant females from traveling aboard submarines.⁵² The Navy Submarine Research Laboratory addressed the medical implications of stationing women as crew members aboard submarines, noting “Risks to the developing fetus are at present unknown. Categorical reassurance cannot be given that the submarine environment is safe for a developing fetus. Extensive animal research is needed.”⁵³ It convened an Expert Panel to review Submarine Atmosphere Control Limits (SACLs) to protect mixed gender submarine crews. A submarine is a unique enclosed work environment that cannot easily be modified. Submariners are exposed to airborne contaminants 24 hours a day, 7 days a week, for up to 90

ⁱⁱ One duration used in the literature is 3 or more hours per day (Ha E, Cho SI, Park H, Chen D, Chen C, Wang L, Xu X, Christiani DC. Does standing at work during pregnancy result in reduced infant birth weight? J Occup Environ Med. 2002 Sep;44(9):815-21).

days, in contrast to workers that have a respite from exposure after an 8 hour shift and a 5 day work week. Information applicable to other worksites also applies to submarines. Female officers began serving aboard submarines in 2011 and female enlisted began serving aboard submarines in 2016. This led to the rescinding of the 1994 Direct Combat Exclusion Act (restricting women from serving onboard submarines) and the Chairman of the Joint Chiefs of Staff directing Armed Forces to integrate women into occupational fields. As of 2017, a total of 18 crews and 11 boats have been integrated. More than 100 female officers have joined the submarine force and more than 40 have successfully completed submarine warfare qualifications.

1) Oxygen

The partial pressure of oxygen in the air aboard a submerged submarine is likely to be lower than that of ambient air at sea level, and the resulting blood oxygenation (PaO_2) may approximate that of living at higher altitudes, sometimes of 8000 feet or more above sea level (see [Altitude](#), section [\(X\)A](#), page 121). Such altitudes have known ReproDev effects, but the ReproDev effects of low oxygen at pressure (i.e., at 1 atmosphere barometric pressure), if any, have not been determined.

2) Evacuation

While women are not to be assigned shipboard after 20 weeks gestation, complications of early pregnancy (such as tubal or ruptured ectopic pregnancy) are medical emergencies requiring care not available aboard submarines. Emergency medical evacuation from submarines is hazardous and risks discovery of the submarine's location.

3) Chemical Hazards

The principles of determining the presence of chemicals and characterizing exposure are no different aboard submarines than aboard other ships, although methods may require modification. The atmosphere aboard submarines has been carefully studied in the past, and chemical stressors have been identified.⁵⁴ Of the chemicals identified, 26 compounds have been more extensively addressed.⁵⁵ As with other occupational exposures, current IH sampling data is necessary. While submarines have powerful atmosphere "scrubber" systems, the scrubber system must not be relied on to eliminate all chemical exposures. PPE may be required in the immediate vicinity of certain chemicals. However, chemical use (e.g., applying a solvent or machine oil) in one part of the submarine does not indicate the entire crew must use PPE.

4) Ionizing Radiation

While PELs of chemical occupational hazards apply to pregnant and non-pregnant personnel, ionizing radiation exposure limits for pregnant workers are more strictly defined (see [Ionizing Radiation](#), [below](#)). Under most conditions, these would only need consideration aboard certain areas of nuclear submarines.

F) RECOVERY FROM DELIVERY

After delivery, a variety of important physiological, psychological, and physical adaptations of the postpartum period take place. Recovery from blood loss and resumption of non-pregnant physiology, as well as wound healing, is accomplished. Mothers who do not breastfeed will experience several weeks of breast tenderness. Breastfeeding mothers will experience several weeks of nipple soreness and cracking. For the most part, however, these conditions should be well under control when the worker returns to the job.

G) BREASTFEEDING

1) Overview

Depending on personal desires, breastfeeding may go on for one year or more. Breastfeeding provides significant benefits to both mother and infant. Babies who are fed breast milk have fewer illnesses and there may be a better “bond” established between the mother and baby. Breastfeeding is certainly more cost effective than formula feeding and can be a major benefit in helping the mother lose weight gained during pregnancy. Breastfeeding cessation is a risk factor for increased anxiety and depression [[PMID 22621668](#)].⁵⁶

The rate of breastfeeding in the United States is sub-optimal, and work conditions are generally not supportive of breastfeeding. A recent review found a strong and consistent association of breastfeeding with maternal age and level of education, and a consistent negative association between maternal smoking habits and breastfeeding duration. Also found was evidence to suggest that fathers play an important role in the breastfeeding decision and that intended duration is a strong predictor of actual duration [[PMID 10197366](#)].⁵⁷ The likelihood of returning to work for breastfeeding mothers is approximately half that of non-breastfeeding mothers one to three months after delivery, and one-third that of non-breastfeeding mothers nine to 12 months after delivery [[PMID 8829985](#)].⁵⁸

A 1997 [American Academy of Pediatrics policy statement](#) noted many advantages of breastfeeding, including “reduced employee absenteeism for care attributable to child illness.” The same statement called for “employers to provide appropriate facilities and adequate time in the workplace for breast-pumping.”⁵⁹ This is relatively simple to do. To allow successful breastfeeding, an employer must provide flexible time (a “nursing break”) for feeding or pumping, a clean room with running water, and a refrigerator for pumped milk. This minimal level of support will often make the difference between whether or not a mother continues breastfeeding. Breastfeeding should be encouraged under most circumstances despite the presence of trace amounts of environmental toxins [[PMID 7702761](#)].⁶⁰

2) Occupational Exposures and Breastfeeding

There are some occupational medicine concerns related to working mothers who breastfeed. A variety of chemicals, both toxic and non-toxic, can be excreted in breast milk. Most substances in the maternal circulation cross into breast milk to a certain extent. Human milk is high in fat and therefore fat-soluble substances can exist in higher concentrations in milk than in plasma. Examples of toxic substances that can be found in breast milk include Pb, mercury (Hg), pesticides, radioisotopes, and PCBs. Workplace exposures must be evaluated

with respect to potential and actual conditions and levels of exposure. While the usual methods and guidelines for minimizing worker exposure apply (administrative and engineering controls and use of PPE such as respirators), in certain situations specific controls may be helpful in minimizing both exposures and concerns (e.g., issuing non-lead bullets to breastfeeding personnel who carry weapons and temporarily lifting requirements to attend indoor shooting ranges).

A specific area requiring attention is exposure to surgical (medical, dental, or veterinary) anesthesia. When anesthetic gases (e.g., nitrous oxide, halothane, etc.) are used, both fetal and breast-fed infant exposures to substances with potential ReproDev toxicity are possible. Halothane is fat soluble (as are other anesthetic gases), and it has been found in breast milk at a concentration of 2 parts per million (ppm) [[PMID 986147](#)].⁶¹ Hospital operating rooms usually use a “scavenging” system to remove anesthetic gases. However, post-anesthesia care units (recovery rooms) often have no scavenging system, and post-operative surgical patients may give off anesthetic gases. Health care workers (HCWs) in such situations should not breast feed unless there are adequate, functioning scavenging systems in place (McDiarmid).⁶² NIOSH has published recommendations on controlling exposures to nitrous oxide during anesthetic administration [[NIOSH](#)].⁶³

Breastfeeding women should not handle antineoplastics or work in areas where they are handled (McDiarmid).⁶⁴ These agents may contaminate surfaces in pharmacy drug preparation areas and drug administration areas [[PMID 10428450](#)]⁶⁵ and even occasionally penetrate gloves [[PMID 10595805](#)].⁶⁶ The assessment of any of these types of exposures should be performed by a qualified IH in consult with appropriate medical staff (OEM, OB/GYN, Pharm D).

H) AVIATION

According to the Aeromedical Reference and Waiver Guide published by the Naval Aerospace Medical Institute, pregnancy is considered disqualifying for all aviation duties except for Air Traffic Controllers [[NAMI](#)].⁶⁷ Waivers in certain circumstances may be obtained (OPNAVINST 3710.7 and OPNAVINST 6000.1 series are referenced).

(VI) THE BIOLOGY OF REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

A) INTRODUCTION

Reproduction requires the proper and timely functioning of multiple body systems, both prior to and throughout the reproductive process.

B) NORMAL REPRODUCTIVE AND DEVELOPMENTAL BIOLOGY

1) Hormonal Control

The hypothalamus, located at the base of the brain, initiates many of the processes leading to sexual development and reproductive capacity. Gonadotropin releasing hormone is secreted by the hypothalamus and triggers the pituitary to secrete LH and FSH. The function of the testes and ovaries are directly dependent on the action of LH and FSH.

2) Male

Under the influence of LH and FSH, testes produce sperm (also called spermatozoa) and synthesize testosterone. Testosterone and related compounds are responsible for the growth and development of sexual organs and secondary sexual characteristics (deep voice, male body hair distribution, and male muscle development).

In adult males, sperm are continuously produced from cells known as spermatogonia. The process, called spermatogenesis, takes an average of 74 days. If the spermatogonia are damaged, the ensuing decrease in sperm production may prevent reproduction. Depending on the injury, damage to spermatogonia may be reversible or irreversible. Sperm are released from the body in seminal fluid by ejaculation, which is under sympathetic control involving the first and second lumbar spinal cord nerve fibers.

3) Female

In the female, LH and FSH regulate the development and release of oocytes (eggs) from the ovaries. The number of oocytes is established in early childhood and declines in adulthood.⁶⁸ By puberty, approximately 400,000 oocytes exist, whereas after age 36 there are less than one-tenth that number.⁶⁹ There is no mechanism for the replacement of damaged oocytes. In the adult female, the cyclical release of LH and FSH establishes the menstrual cycle. The LH and FSH promote the development of estrogen-producing ovarian follicles (the group of cells surrounding an oocyte).

Estrogens are instrumental in the preparation of the uterus for the implantation of the fertilized ovum. Estrogens are also responsible for the development and maintenance of secondary sex characteristics (breast development, body fat pattern) and the changes in cervical mucus associated with the menstrual cycle.

During each menstrual cycle, usually one ovarian follicle matures and releases an ovum. This process is termed ovulation. Union of the ovum and sperm usually occurs in the fallopian tube, and the fertilized ovum migrates to the uterus and implants in the uterine wall. After

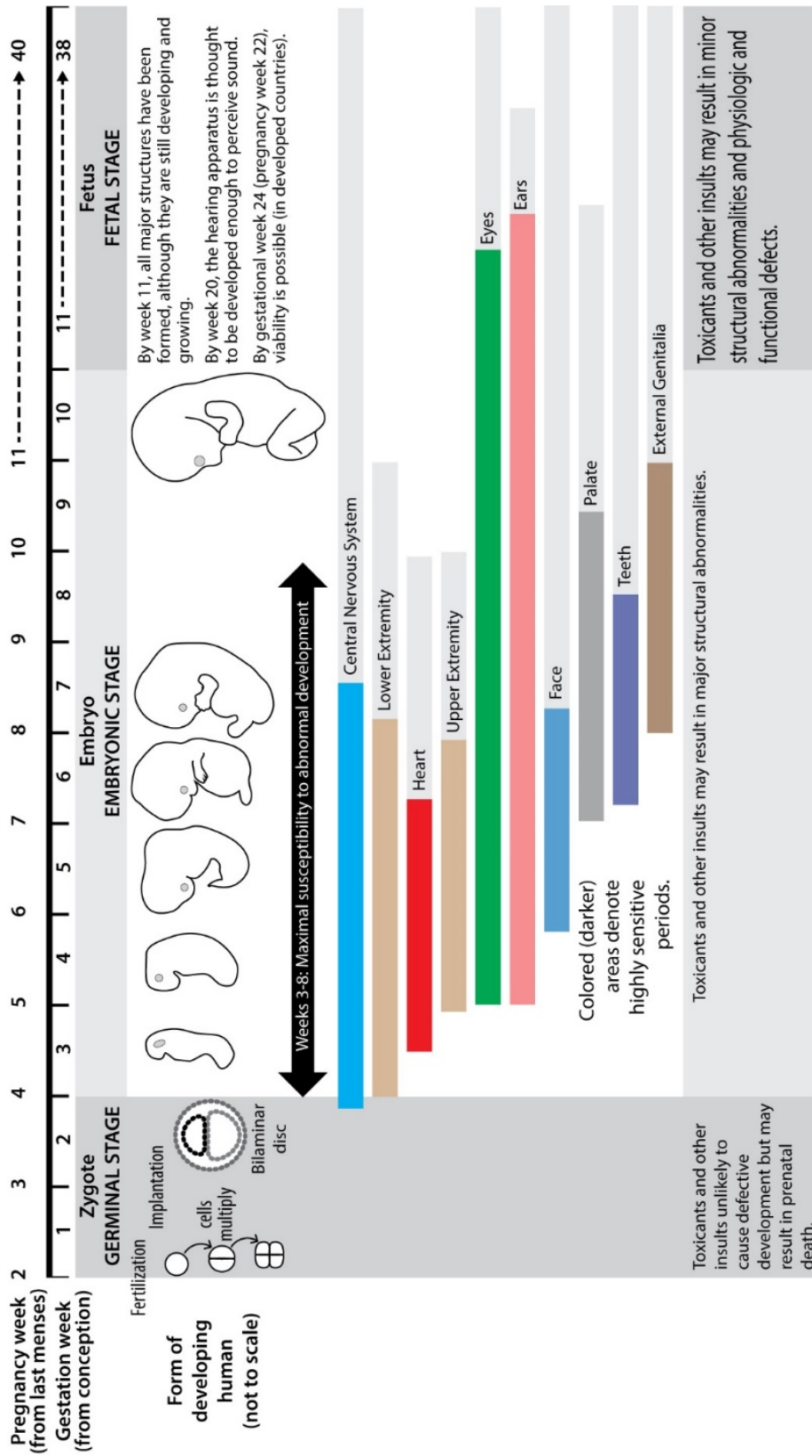
ovulation, the cells of the ovarian follicle produce progesterone and estrogen to prepare the uterus to receive the fertilized ovum. If the fertilized ovum is not implanted in the uterus, the ovarian secretion of hormones is decreased, the lining of the uterus is discharged, and menstruation occurs.

4) Embryogenesis and Fetal Development

Fertilization (the successful union of sperm and ovum) generally occurs two minutes to several hours after ovulation.⁷⁰ The fertilized ovum begins cell division and is known as a blastocyst. After three to four days, the blastocyst reaches the uterus and is implanted. During the following two weeks, the extra-embryonic membranes (which become the amniotic sac and placenta) differentiate, and the three main cell lines of the embryo develop (endoderm, mesoderm, and ectoderm).

The embryonic period or phase begins the third week after conception and ends with completion of major organogenesis (end of week eight). This is a critical period of development for each organ. Consequently, it is the period in which there is the greatest sensitivity to teratogens—but many women are unaware of their pregnancy during the majority of this period! The fetal period starts at eight weeks (day 56) and continues to delivery. Exposures during this period may result in growth retardation or functional defects. During this period, the developing fetus may have increased sensitivity to carcinogens. During periods of rapid growth or differentiation, organs are more susceptible to damage by infections, toxicants, trauma, or compromise in blood flow. There are critical periods of development for specific organs or body systems.

Figure 3 - Critical Periods of Development



C) REPRODUCTIVE DYSFUNCTION

During the normal reproductive process, there are many opportunities for the process to fail and not result in a normal pregnancy. In young, fertile women, fertilization after exposure to spermatozoa occurs only about 88 percent of the time.⁷¹

Up to 50 percent of embryos fail to survive the first 2 weeks following fertilization. By the time a pregnancy is recognizable, for each occasion the sperm reaches the ovum, the “normal” estimated probability of a resulting live birth is about 30 percent (see [Table 3](#)).

Table 3 –Rates of Reproductive Success

Reproductive or developmental event	Outcome
Couples attempting pregnancy	100
Positive serum hCG	90*
Unrecognized pregnancy loss	22*
Recognized pregnancy loss	9*
Stillbirth (after 16 weeks pregnancy)	1 [†]
Premature, postmature, growth retardation	10 [‡]
Term births	58**
Developmental abnormality	3 [§]

* Wilcox AJ, Weinberg CR, O'Connor JF, Baird DD, Schlatterer JP, Canfield RE, Armstrong EG, Nisula BC. Incidence of early loss of pregnancy. N Engl J Med. 1988 Jul 28;319(4):189-94.
[†] Rasmussen S, Irgens LM, Skjaerven R, Melve KK. Prior adverse pregnancy outcome and the risk of stillbirth. Obstet Gynecol. 2009 Dec;114(6):1259-70. doi: 10.1097/AOG.0b013e3181c22422.
[‡] Vayssière C, Sentilhes L, Ego A, et al. Fetal growth restriction and intra-uterine growth restriction: guidelines for clinical practice from the French College of Gynaecologists and Obstetricians. Eur J Obstet Gynecol Reprod Biol. 2015 Oct;193:10-8.
[§] CDC. Update on Overall Prevalence of Major Birth Defects --- Atlanta, Georgia, 1978—2005. MMWR. January 11, 2008 / 57(01);1-5.
** Calculated from above.

D) REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

1) Reproductive Hazards

i) Stressors

If a discussion of hazards was limited only to the untoward or harmful effects of chemicals (toxicity), the phrase "developmental and reproductive toxicology" or "DART" would be used to describe that specific category of hazard. However, the term "hazard" includes other exposure conditions that do not occur from chemicals. Exposures can occur to other categories of agents that are commonly referred to in OH jargon as "stressors". In addition to chemical agents, stressors include physical, biological, psychological, and ergonomic factors. Physical agents include ionizing radiation, heat, intense sound, and vibration. Viruses, bacteria, and fungi are examples of biological agents. Psychological factors give rise to the mental and emotional effects of working and living in general—“stress”. For example, women who have a spouse deployed during pregnancy are at increased risk for preterm birth and postpartum depression

[\[PMID: 26244533\]](#).⁷² Ergonomic factors and physical activity are stressors that affect the musculoskeletal and nervous systems as a consequence of human interaction with mechanical systems.

ii) Timing

As with all health hazards, determinants of ReproDev risks include factors such as route of exposure and dose (including the total amount, concentration, and duration of exposure, and whether exposures are single, multiple, extremely high, etc.). In addition, timing of exposure—exactly when in the ReproDev process the exposure occurs—can be critical for the development of adverse effects. For example, in humans, thalidomide caused ear abnormalities and duplication of thumbs when administered 34 to 38 days after the last menstrual period (LMP), but leg phocomelia (short, missing, or otherwise abnormal limbs) 42 to 47 days after the LMP.⁷³ Pb exposure causes decreased fecundity before pregnancy,⁷⁴ but developmental delays during later pregnancy and in early childhood.

If a person is exposed to a ReproDev hazard, there may or may not be a risk to that person's child or children. Specifically, inclusion in one or more of the lists in this manual does not mean exposures to that factor pose a ReproDev risk. For example, exposure to sound is unavoidable, and generally is not a threat to pregnancy. However, some exposures to sound during pregnancy may pose a risk, not a certainty, of impaired hearing in the child—but only exposure to high sound levels, and only after ear development has begun.

In addition to directly decreasing libido and fecundity, reproductive effects can occur at many points in reproduction:

- death of stem cells,
- gametogenesis—arrested development, aberrant development, reduced number,
- decreased semen production,
- interference with fertilization—oocyte penetration, flagella movement,
- interference with ovum transit through the oviduct,
- interference with implantation—shedding of the zona pellucida,
- interference with cleavage and development of the ovum, or
- embryogenesis.

Agents that affect development can impact fetal growth, birth, and/or lactation. Developmental effects occur after the establishment of the embryo and continue through the remainder of pregnancy and through childhood.

2) Genetic Toxicology

A reproductive or developmental agent may cause damage through action at a specific site on a chromosome or it may affect the entire chromosome. For example, anticancer drugs have been associated with an excess of abnormalities of chromosome 5 [\[PMID: 20881619\]](#).⁷⁵ Gene mutations and chromosomal aberrations in a somatic (general body) cell can affect that

particular cell and the future daughter cells (cells produced as a result of cell division). This may result in a change in function or structure of that cell line (for example, resulting in carcinogenesis). Alterations in the DNA of germ cells (spermatozoa or oocytes) become incorporated into the genetic makeup of every cell in the new organism and are passed on to offspring. These changes can result in damage or death. From the biological point of view, it should be noted that many, but not all, mutations are harmful or deleterious to a cell, tissue, organ, or organism.

Table 4 – Genetic Hazards

benzene chemotherapy agents (for example, adriamycin, cyclophosphamide, cisplatin) coal tars (polycyclic aromatic hydrocarbon compounds) cyclophosphamide ethylene oxide ionizing radiation nickel compounds styrene vinyl chloride

3) Developmental Hazards

In the context of biological reproduction, embryonic and fetal (prenatal) development refers to the period commencing with fertilization and ending at term delivery (40 weeks). Developmental hazards cause deleterious effects during one or more critical time periods of prenatal development, but as discussed above, developmental hazards may affect the child after birth.

Deficiency of an essential factor may also adversely affect development. Folic acid is a vitamin found to be critical in early pregnancy. Deficiency of folic acid around the time of conception has been associated with neural tube defects (spina bifida, anencephaly, and encephalocele). Thus, folic acid supplementation has been recommended for all women with child-bearing potential. In addition to gestational diabetes, hypertension, operative delivery, macrosomia, and birth trauma, a meta-analysis identified obesity (body mass index >30) as a risk factor for spina bifida, neural-tube defects, hydrocephaly, anorectal atresia, limb reduction anomalies, cardiovascular anomalies, cleft lip, and cleft lip and palate, and overweight (body mass index 25-30) as a risk factor for neural-tube defects and cardiovascular anomalies [[PMID 19211471](#)].⁷⁶

Developmental hazards that have been identified include chemical, biological, and physical agents, as well as psychological conditions as listed below.

Table 5 – Selected Developmental Toxicants and Their Period of Toxic Activity

Fertilization	Pre-implantation		Development
	Body and/or brain weight deficit, or embryo lethality	Exposure leading to fetal malformations	
Ethylene oxide (e.g., HCWs using gas sterilization) Ethylnitrosourea (e.g., researchers working with this laboratory reagent) Triethylene melamine (trisaziridinyltriazine)	DDT (e.g., personnel exposed outside of continental US, such as in malaria control) Nicotine Methyl mercury (contaminated seafood from Minimata Bay, Japan)	Methylnitrosourea (neural tubular defects, cleft palate) Cyproterone acetate	Metals Cadmium (e.g., welders, painters) Arsenic (e.g., pesticide and wood preservative applicators, metal workers) Hg (operators of instruments containing Hg; chemical, dental, and nursing technicians) Pb (metal workers, painters and paint removers, battery workers) Recreational drugs (including cigarette smoke) Drugs of abuse (ethanol, cocaine)

4) Drugs in Pregnancy and Lactation

The use of prescription and non-prescription drugs during pregnancy and lactation presents a challenge to health care professionals. While the physician and pharmacist are the parties primarily responsible for prescribing and dispensing medications, personnel may be occupationally exposed in the manufacturing, distributing, or dispensing of pharmaceuticals, “recreationally” exposed through smoking, alcohol use, and use of illicit drugs, and “environmentally exposed” through the use of “over-the-counter” (non-prescription) medications and dietary supplements (including vitamins and natural products). Exposure to these agents must also be considered in the overall assessment and evaluation of potential ReproDev hazards.

E) EFFECT OF WORKPLACE EXPOSURES ON REPRODUCTIVE AND DEVELOPMENTAL DYSFUNCTION

1) Libido and Potency

Agents that alter hormone secretion or that affect the central or peripheral nervous system may affect libido and/or potency. This may or may not be largely dependent on the effect on the hypothalamus, which is the main central nervous system influence on the pituitary gland. In the male, Pb and Hg have been implicated as affecting libido and potency.

2) Pituitary

Agents that mimic, antagonize, or bind estrogen or testosterone may interfere with LH and FSH secretion by the pituitary. Direct damage to the pituitary (such as by radiation, tumor, infarct, or trauma, whether occupational or non-occupational) may also affect hormone secretion.

3) Ovary

Interference in release of LH or FSH by the pituitary, as well as factors that impede the ovary from recognizing the pituitary hormones, may prevent ovulation. Ovarian dysfunction may also result in defective ova being released or in an unsuitable secretion of estrogen and progesterone.

4) Sperm

Decreased motility, decreased number, or altered morphology of sperm may prevent fertilization. The following have been noted:⁷⁷

Table 6 – Effects of Selected Occupational Exposures on Sperm Parameters

Lowered number of sperm	Altered sperm transfer	Abnormal sperm shape
Bromine vapor	Bromine vapor	Bromine vapor
DBCP	2,4-Dichlorophenoxy acetic acid (2,4-D)	Carbaryl (Sevin™)
Dinitrotoluene	Ethylene dibromide	2,4-Dichlorophenoxy acetic acid (2,4-D)
Ethylene dibromide	Heat	Ethylene dibromide
Ethylene glycol monoethyl ether	Kepone	Pb
Heat	Pb	Perchloroethylene
Military radar	Perchloroethylene	Plastic production (styrene and acetone)
Pb	Radiation	Radiation
Radiation	Welding	Welding
Toluenediamine		

Adapted from [NIOSH](#). The Effects of Workplace Hazards on Male Reproductive Health. 549-180/40015, Publ. No. 96-132. Washington, DC: U.S. Government Printing Office: 1996.

Direct measurement of a substance in semen or sperm, rather than its measurement in blood, may be of theoretical—but currently not practical—value in evaluating reproductive

toxicity. Elevated levels of aluminum in spermatozoa of industrial employees were associated with decreased sperm motility [[PMID 9512240](#)].⁷⁸ Semen Pb was not found to be a valuable adjunct to blood Pb monitoring [[PMID 9787850](#)].⁷⁹ An animal (rabbit) study found no consistent significant decrease in fertilization by sperm exposed to cadmium (Cd^{2+}) or lead (Pb^{2+}) at levels much higher than semen concentrations reported in exposed workers [[PMID 10613392](#)].⁸⁰ Measurement of the concentration of zinc and copper in seminal plasma was felt to have “little value in the routine investigation of infertility” [[PMID 6628713](#)].⁸¹

5) Mutations

A mutation is a change in a gene due to chromosomal (DNA) damage. Chromosomal damage may occur in the ova or sperm prior to or during fertilization. If a mutation only occurs in the ova or sperm, the mutation may not be evident in either of the parents but result in a birth defect in the offspring. Spermatozoa are constantly produced, so if the agent producing chromosomal damage in sperm is removed, production of normal sperm may resume. Chromosomal damage to ova is permanent and can affect the survival of the embryo. Although attributing birth defects to parental exposures months or years before conception may be theoretically plausible, whether the literature actually supports such a hypothesis is questionable.⁸²

6) Pregnancy

Fetal exposures to hazardous agents may cause spontaneous abortion, fetal death, growth retardation, malformation, organ malfunction, preterm delivery, low birth weight, developmental delay or disability, or cancer. Agents that interfere with embryonic or fetal development are known as teratogens. Functional and biochemical effects can occur that are not grossly apparent but result in a significant negative impact on the embryo or fetus. Structural teratogens cause visible, physical defects of the embryo and fetus.

7) Breast Milk

Breastfeeding is widely regarded as the preferred method of infant feeding. Inert material, such as silicone, or environmental toxicants, such as organophosphate pesticides, chlorinated hydrocarbons, solvents, and heavy metals, have been identified in human milk [[PMID 7702761](#)].⁸³ Breast milk concentrations of various substances may be at levels 1/100 to 100 times maternal plasma levels. Some substances (especially those that are fat-soluble) are concentrated in breast milk. Breast milk concentration of a chemical increases with fat solubility, low molecular weight, high pH (basic rather than acidic molecules), and low polarity (neutral molecules).⁸⁴ The nursing infant can receive a significantly greater dose (mg/kg body weight) of a fat-soluble substance than the working mother originally received.

Table 7 – Types of Reproductive and Developmental Risk Factors

General health	Social history	Medical history
Age (before age 17 or after 35)	Substance abuse	Ethnicity (“race”)
Nutrition	Tobacco use	Medication
Body weight (obesity or underweight)	Economic status (income, wealth, poverty)	Polycystic ovary syndrome
Exercise	Health insurance	Endometriosis
	Occupation (stress, exertion, shift duration and rotation)	Pelvic inflammatory disease
	Occupational exposures	Chronic illness (hypertension, diabetes, HIV, renal, autoimmune, thyroid disease, cancer, epilepsy, etc.)
	Social network and support (family, friends)	HIV
	Education	
	Paternal age, health, fertility, exposures	
	Hobbies	
Pregnancy-specific		
Parity (nulliparity, grand multiparity)	History of pre-term birth	
Multiple gestation	Rh injection	
History of three or more miscarriages	Threatened abortion	
History of late abortion	Infection (pelvic or systemic)	
History of stillbirth	Placental abnormalities	
Child with genetic problem	Gestational diabetes	
History of post-partum depression	Weight gain during pregnancy	
Time since last pregnancy	Fetal size (intrauterine growth retardation)	
Toxemia (pre-eclampsia/eclampsia)		
Societal		
Life expectancy		
Food (availability and quality)		
Availability of outpatient care (prenatal and follow-up of mother and baby)		
Access (transportation, cost) to medical care		
Availability of advanced medical care (maternal and neonatal)		
Cultural norms (value of women, allowing women to receive medical care, allowing women to be examined by males, acceptance of women working outside the home, etc.)		
Ethnicity (member of marginalized group)		
Government policy (e.g., approved drugs)		
Environment (e.g., nutrition during the winter)		

(VII) OCCUPATIONAL CHEMICAL REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

A) INTRODUCTION

This list contains chemical substances **known** to cause ReproDev toxicity in humans, or **known** to cause ReproDev toxicity in animals by mechanisms of action directly applicable to humans. It generally does not include agents considered “possible” hazards. Sources used to compile this list include those published by state and federal agencies and the recognized scientific literature. The list contains chemical ReproDev hazards to which Navy personnel may be exposed.

Statutory or recommended occupational exposure levels are not included in this list. Current exposure standards are generally based on human health effects other than those related to the reproductive system. Workers are usually exposed to many hazardous substances and conditions. Repetitive, low-level exposures to a combination of ReproDev hazards may have a greater effect on an individual than a single, high-level exposure to a single hazard. Additionally, the timing of the exposure before, during, or after pregnancy can have a dramatic effect on the outcome (see previous sections).

When using this list, **it is recommended that each worker be evaluated on a case-by-case basis**. Chemicals generally administered to people (i.e., pharmaceuticals, drugs of abuse, etc.) are listed separately in Chapter [\(VIII\) Drug Reproductive and Developmental Hazards](#). While exposure to most of these chemical hazards may be assumed to occur at worksites, it should be noted that potential for exposure of Navy personnel to pharmaceuticals may occur when pharmaceuticals are handled (in manufacture, distribution, dispensing, or inadvertent or intentional non-prescribed ingestion).

Frequent reference is made to JL Schardein's “Chemically induced birth defects,” currently in its third edition, to which the reader is directed for further information.

The list is meant to be inclusive, but cannot be exhaustive, as information on the ReproDev toxicity of many chemicals is unknown at this point. For some listed substances, while the toxicity to humans is unknown, the mechanism of toxicity to animal species, or the consistency of toxicity among several animal species, is such that human toxicity must be suspected. Without human data, controversy will always exist as to the degree of certainty with which one may hold that a particular substance is hazardous to humans. The position of this manual is one of hesitancy to include a suspected substance without substantial supporting data. Thus, some substances included in other listings (for example, California Proposition 65) are not included here. Not including a substance on this list does not represent an endorsement of the safety of the substance nor does it represent a criticism of any other list. This list represents the drugs and chemicals that may be harmful to the developing fetus. This list is based on a literature review done in August 2017. As the data for drugs and chemicals is constantly updated, the reader is encouraged to review the current data for updates.

(For a description of the “categories” listed for some of the chemicals, please see Section [\(VIII\)D](#) on Page 60.)

Table 8 – Chemical Reproductive and Developmental Hazards List

Agent	CAS Number	Date Added	Notes
α -Naphthyl-N-methylcarbamate	63-25-2		(See Carbaryl)
Acetaldehyde	75-07-0		Primary metabolite of ethanol [PMID 9105505] ⁸⁵ [PMID 1789375] ⁸⁶
Acetylaminofluorene	53-96-3	11-1-2017	No human data, but skeletal defects and cleft lip in mice, and DNA adducts in vitro [PubChem] ⁸⁷
Alcohol			(See Ethanol)
Anesthetic gases			(See Drug Reproductive and Developmental Hazards List)
Antimony	7440-36-0	12/06/2017	Female: menstrual cycle disturbances, increased spontaneous abortion Developmental: decreases in infant body weight gain [ATSDR] ⁸⁸

Agent	CAS Number	Date Added	Notes
Arsenic	7440-38-2		<p>Pregnancy: Occupational exposure to inhaled inorganic arsenic associated with increased incidence of congenital malformations and decreased birth weight [ATSDR];⁸⁹ Ingested inorganic arsenic has been reported in association with premature delivery and subsequent neonatal death [ATSDR].⁹⁰ Occupational exposure to high levels of inorganic arsenic (>50 ppb) in air and drinking water is associated with increased risk of spontaneous abortion, stillbirth and low birth weight. Further research is needed on the impact of low-moderate arsenic concentration exposures on pregnancy outcomes.⁹¹</p> <p>Placental toxicity Appears in cord blood in almost same levels as maternal blood [PMID 9742656]⁹²</p> <p>Breastfeeding: Low concentrations in breast milk [PMID 9742656]⁹³</p>
Atrazine	1912-24-9	12/06/2017	Increased risk of pre-term delivery [ATSDR] ⁹⁴
Benzene	71-43-2	03/10/00	Pregnancy: Spontaneous abortion, premature births, neonatal complications [Schardein] ⁹⁵
Benzimidazoles	---		(See Carbendazim)
Bischloroethyl nitrosourea	154-93-8	09/30/94	Category D [USPDI] ^{96,97} Breastfeeding: Contraindicated [Briggs 1997] ⁹⁸
2-Bromopropane	75-26-3	12/06/2017	Male: decreased sperm count and sperm motility Female: failure to menstruate [NTP] ⁹⁹

Agent	CAS Number	Date Added	Notes
1,3-Butadiene	106-99-0	07/25/00	<p>No human data. Animal data (inhalation exposure)[ATSDR]:¹⁰⁰</p> <p>Male: Increased incidence of sperm-head abnormalities and testicular atrophy (mice)</p> <p>Female: Increased incidence of ovarian atrophy (mice)</p>
Butiphos	---	06/27/00	<p>Pregnancy: Malformations, stillbirths, and difficult deliveries from occupational contact (one report) [Schardein]¹⁰¹</p>
Cadmium	7440-43-9	2-11-00	<p>Males (inhalation exposure): No consistent effect [ATSDR],¹⁰² OSHA notes an increased risk of prostate cancer (29 CFR 1910.1027 App D).¹⁰³ Disruption of the blood-testis barrier and oxidative stress have been noted, with onset of widespread necrosis at higher dosage exposures.¹⁰⁴</p> <p>Pregnancy: Decreased birth weight (with inhalation exposure) [ATSDR],¹⁰⁵ placental toxicity [Miller],¹⁰⁶ associated with preterm [PMID 8094678]¹⁰⁷</p> <p>Abnormalities in the embryo, depending on the stage of exposure and dose given: craniofacial, neurological, cardiovascular, gastrointestinal, genitourinary, and limb anomalies.¹⁰⁸</p> <p>Breastfeeding: No reported effect [AAP]¹⁰⁹</p>
Carbarsone	121-59-5	03/06/00	<p>Category D (contains 29% Arsenic) [Briggs 4th]¹¹⁰</p>

Agent	CAS Number	Date Added	Notes
Carbaryl	63-25-2	06/07/00	Males: Abnormal sperm shape [PMID 6791917] ¹¹¹ [NIOSH] ¹¹² Development: No human developmental data, teratogenic in several animal species [EPA] ¹¹³
Carbendazim	37953-07-4	06/07/00	Human data lacking, but reproductive/ developmental effects are noted in several animal species. May influence the hypothalamus–pituitary–gonad axis [PMID 24863245]. ¹¹⁴ Male (rat): Testicular [PMID 9719423] ¹¹⁵ /sperm toxicity [PMID 2227156] ¹¹⁶ [PMID 9070363] ¹¹⁷ Embryotoxic [PMID 1601229] ¹¹⁸ [PMID 1609414] ¹¹⁹ Teratogenic [Cummings/USEPA] ¹²⁰
Carbon dioxide	124-38-9	11/01/2017	Fetal resorption at 3% [NAMRU]. ¹²¹
Carbon disulfide	75-15-0	09/30/94	Male: Spermatotoxic [Paul] ¹²² [PMID 5079601], ¹²³ decreased libido, impotence [Schardein] ¹²⁴ Female: Menstrual irregularities, decreased fertility, increased spontaneous abortion [Schardein] ¹²⁵ Pregnancy: 4 ppm (10 mg/m ³) recommended as occupational exposure limit during pregnancy [OSHA], ¹²⁶ birth defects reported [Bao], ¹²⁷ children's intelligence hindered significantly when one or both of their parents were exposed to carbon disulfide at levels greater than 10 mg/m ³ (3 to 4 ppm), in addition to birth defects [Li] ¹²⁸ Breastfeeding: Can cross the placental barrier and be secreted into mothers' milk [PMID 7216838] ¹²⁹

Agent	CAS Number	Date Added	Notes
Carbon monoxide	630-08-0	09/30/94	Pregnancy (fetal hemoglobin binds O ₂ more avidly than adult hemoglobin): Low birth weight [PMID 9872713], ¹³⁰ CNS abnormalities reported [PMID 2125322], ¹³¹ hyperbaric O ₂ not contraindicated in pregnancy [PMID 7772366] ¹³² Animal studies have shown immunological [PMID 8115310] ¹³³ and neurobehavioral [PMID 7786165] ¹³⁴ [PMID 8711066] ¹³⁵ effects
Chlordecone	143-50-0	09/30/94	Male: Oligospermia, decreased sperm motility, but no loss of fertility [ATSDR] ¹³⁶
Cigarette smoke	---		(See Tobacco smoke - environmental)
Ciguatoxin	---		Category X [Briggs 4th] ¹³⁷ (a case report of fetal agitation with neonatal facial palsy and meconium aspiration after preterm maternal ciguatoxin poisoning noted [PMID 7070322]) ¹³⁸ Breastfeeding: Excreted in breast milk [Briggs 4th], ¹³⁹ [Bagnis], ¹⁴⁰ although not consistently reported [PMID 19325530] ¹⁴¹
Cycloheximide	66-81-9	09/30/94	Human studies lacking, but cycloheximide is a known protein synthesis (meiosis) inhibitor [PMID 9592729], ¹⁴² developmental defects in rats and mice, but not in rabbits [Schardein] ¹⁴³
2,4-D	94-75-7		(See 2,4-Dichlorophenoxy acetic acid)
DBCP (1,2-dibromo-3-chloropropane)	96-12-8		Male: Toxicity [EPA] ¹⁴⁴ (lowered number of sperm [NIOSH]) ¹⁴⁵

Agent	CAS Number	Date Added	Notes
DDT (p,p'-Dichlorodiphenyl-trichloroethane)	50-29-3		<p>Pregnancy: Possible association with spontaneous abortion, toxemia, and low birth weight [Schardein].¹⁴⁶</p> <p>Developmental: Little teratogenic potential [Schardein].¹⁴⁷ However, there is concern about cumulative (over several generations) reproductive toxicity, due to bio-accumulation and widespread environmental exposure [EPA].¹⁴⁸</p> <p>Breastfeeding: Excreted in human milk [PMID 2551196],¹⁴⁹ no reported effects [AAP].¹⁵⁰</p>
DEHP			(See di(2-ethylhexyl) Phthalate)
1,2-Dibromo-3-chloropropane	96-12-8		(See DBCP)
1,2-Dibromoethane	106-93-4	12/06/2017	Male: changes in sperm velocity and count, decreased sperm concentration and semen volume [ATSDR]. ¹⁵¹
2,4-Dichlorophenoxy acetic acid	94-75-7	06/27/00	<p>Male: Abnormal sperm shape, altered sperm transport [NIOSH].¹⁵²</p> <p>Pregnancy: Associated with spontaneous abortion and premature birth [Schardein].¹⁵³</p> <p>Developmental: One report of multiple congenital anomalies [Schardein],¹⁵⁴ teratogenic in several animal species [Schardein].¹⁵⁵</p>

Agent	CAS Number	Date Added	Notes
di(2-ethylhexyl) Phthalate (DEHP)	117-81-7	07/26/00	Developmental: "Concern" about developing male reproductive tract ¹⁵⁶ Mice exposure to DEHP at doses relevant to human exposure during sex determination significantly affected ovarian function in female adult offspring and carried through subsequent generations. ¹⁵⁷ Pregnancy: Associated with pre-term birth [PMID24247736] ¹⁵⁸
Dimethylaminopropionitrile (DMAPN)	1738-25-6	02/12/2007	Male: Impotence, decreased libido [PMID 6243374 , ¹⁵⁹ PMID 7330630] ¹⁶⁰
Dinocap (fungicide)	39300-45-3	09/30/94	Animal data: Developmental toxicity: Increased post-implantation mortality, reduced newborn viability, abnormalities of the musculoskeletal and hepatobiliary systems, craniofacial abnormalities, behavioral abnormalities, and delayed growth in mice [EPA]
Dinoseb (herbicide)	88-85-7	09/30/94	Male: Reduced fertility index in rats, decreased seminal vesicle weight, decreased sperm count and increased incidence of abnormal sperm [EPA] Developmental: Decreased pup weights, developmental malformations and/or anomalies, an increased incidence of an absence of ossification for a number of skeletal sites and supernumerary ribs neural tube defects [EPA]
2,4-Dinitrotoluene	121-14-2	03/10/00	Male: Lowered number of sperm [NIOSH] ¹⁶¹
2,6-Dinitrotoluene	606-20-2		(See 2,4-Dinitrotoluene)

Agent	CAS Number	Date Added	Notes
Dioxin	1746-01-6		(A group of dibeno-p-dioxins containing from 1 to 8 chlorine atoms of which the 2,3,7,8-isomer is the most toxic. See TCDD or specific compound)
Disodium cyanodithio- midocarbonate (DCDIC)	138-93-2	03/10/00	Developmental: Both maternal and fetal effects in rabbits and rats [EPA] ¹⁶²
Epichlorohydrin	106-89-8	03/10/00	Male: Impaired fertility, however human data do not confirm animal data [PMID 2010350] ¹⁶³ demonstrating impaired male fertility [EPA] ¹⁶⁴
Ethanol	64-17-5		(See Ethanol under Drug Hazards)
2-Ethoxyethanol	110-80-5		(See Ethylene glycol monoethyl ether)
Ethyl alcohol	64-17-5		(See Ethanol under Drug Hazards)
Ethyl carbamate	51-79-6		(See Urethane)
Ethylene dibromide	106-93-4	03/10/00	Male: Reproductive toxicity [PMID 2980345] ¹⁶⁵ [PMID 3297130] ¹⁶⁶ (lowered number of sperm, abnormal sperm shape, altered sperm transport [NIOSH]) ¹⁶⁷
Ethylene glycol monoethyl ether	110-80-5	09/30/94	Male: Lowered number of sperm [NIOSH] ¹⁶⁸ Male and female reproductive effects in multiple animal species [NIOSH] ¹⁶⁹
Ethylene glycol monomethyl ether	109-86-4	09/30/94	Male and female reproductive effects in multiple animal species [NIOSH] ¹⁷⁰
Ethylene glycol monomethyl ether acetate	110-49-6	09/30/94	Developmental: Hypospadias and other male genital abnormalities [PMID 2357456] ¹⁷¹ [Johanson] ¹⁷² (See Ethylene glycol monomethyl ether –toxicological profile is almost identical [PMID 2357456]) ¹⁷³

Agent	CAS Number	Date Added	Notes
Ethylene oxide	75-21-8	03/10/00	<p>Male: Appears in testes in higher concentrations than in blood, has been associated with sister chromatid exchanges in humans occupationally exposed, but effects on sperm were inconclusive [NIOSH]¹⁷⁴</p> <p>Female: spontaneous abortion rates in ethylene oxide sterilizer personnel in hospitals in Finland were found to be significantly higher than those of non-exposed workers.¹⁷⁵</p> <p>Developmental: Malformations in animals (mice) [Kimmel]¹⁷⁶</p>
Ethylene thiourea (Ethylenethiourea)	96-45-7	06/30/95	Developmental: Teratogen [NIOSH] ¹⁷⁷
EthylNitrosourea	759-73-9		<p>Developmental: CNS tumors in rats born to rats exposed in the latter part of gestation [PMID 4321468]¹⁷⁸ [EPA]^{179,180,181}</p> <p>Induces congenital anomalies in fetuses and affects placenta when administered to pregnant animals.¹⁸²</p>
Gasoline	8006-61-9 ? or is it: 86290-81-5	07/10/00	<p>Pregnancy: Fetal gasoline syndrome (narrow forehead, upslanting palpebral fissures, full cheeks, spastic positioning) with high levels of inhalation exposure ("sniffing") [Schardein]¹⁸³</p>
Hexachlorocyclohexane (Lindane®)	58-89-9	12/6/17	Increase in serum luteinizing hormone levels in men [ATSDR] ¹⁸⁴

Agent	CAS Number	Date Added	Notes
Hexachlorobenzene	118-74-1	06/30/95	Fetal death due to pembe yara ⁱⁱⁱ [PMID 7138315] ¹⁸⁵ Breastfeeding: Possible association with porphyria cutanea tarda symptoms, reduced growth, and arthritic changes in the appendages [EPA] ¹⁸⁶ (excreted in human milk)[PMID 2590490], ¹⁸⁷ skin rash, diarrhea, vomiting, dark urine, neurotoxicity, death [AAP] ¹⁸⁸
Hexamethylphosphoramide	680-31-9	06/30/95	Testicular atrophy and aspermia (rats), testicular development inhibition (cockerels) [NIOSH] ¹⁸⁹
Hexamethylphosphoric triamide	680-31-9		(See Hexamethylphosphoramide)
HMPA	680-31-9		(See Hexamethylphosphoramide)
Iodides	---		(See Iodine)
Iodine	7553-56-2		Iodine excess and iodine deficiency during pregnancy can have adverse effects on the fetal thyroid and possibly on brain development and hearing. Category D [Briggs 4th] ¹⁹⁰ Breastfeeding: Not compatible (concentrated in breast milk, and long term use may adversely affect the nursing infant's thyroid activity) [Briggs 1997] ¹⁹¹
Kepone®			(See Chlordecone)

ⁱⁱⁱ "Pink sore", a low grade cellulitis that quickly deteriorates into a limb- or life-threatening soft tissue infection.

Agent	CAS Number	Date Added	Notes
Lead (Pb)	7439-92-1	09/30/94	<p>Male: [PMID 6441528]¹⁹² Lowered number of sperm, abnormal sperm shape, altered sperm transport [NIOSH]¹⁹³</p> <p>Female: Premature membrane rupture and preterm births [PMID 1257615]¹⁹⁴</p> <p>Developmental [PMID 6716624]¹⁹⁵. Prenatal lead exposure impairs children's neurodevelopment, placing them at increased risk for developmental delay, reduced IQ, and behavioral problems.¹⁹⁶</p> <p>Breastfeeding: Possible neurotoxicity [AAP]¹⁹⁷ Not recommended if lead level is above 40 µg/dL.¹⁹⁸</p>
Lindane (see Hexachlorocyclohexane)			
Mercury and mercury compounds (see specific compound)	Various	09/30/94	<p>Exposure varies with the form of the mercury. Elemental mercury poses little oral exposure route risk (GI absorption is <0.01%), its vapors are highly toxic. In contrast, mercury salts (like that found naturally in soils) and organic mercury (like that in fish tissues) do not tend to be volatile. Each of these has its own relative bioavailability through the oral route. Their toxicity is largely a result of their oral availability. Historically, methyl mercury is associated with oral consumption of mercury in foods (fish and whale meat).</p> <p>Breastfeeding: May affect neurodevelopment [AAP]¹⁹⁹</p> <p>Present in breast milk [PMID 9098513]²⁰⁰</p>

Agent	CAS Number	Date Added	Notes
Mercury, elemental	7439-97-6	05/31/00	<p>Male: Maternal spontaneous abortions [ATSDR]²⁰¹</p> <p>Female: Reproductive failure [ATSDR]²⁰² adverse neurological outcomes in children. Mercury found in dental amalgams has not been shown to be associated with adverse outcomes.</p> <p>Developmental: Decreased birth weight [ATSDR]²⁰³</p> <p>Breastfeeding: May affect neurodevelopment [AAP]²⁰⁴</p> <p>Mercury is transferred to the milk from dental amalgams, but the amount that is transferred is small. Infants who are exclusively breastfed by women with mercury amalgam have been found to have low weight gain but did not have adverse neurological outcomes. The advantages of breast-feeding likely outweigh any potential risks in terms of dental amalgam mercury.</p>
Mercury, inorganic	---	03/10/00	<p>Spontaneous abortion [ATSDR]²⁰⁵</p> <p>May lead to an increased risk of stillbirth and fetal growth restriction, but there does not appear to be an increased risk of poor neurological outcomes</p>
Mercury, organic	---	03/10/00	<p>Developmental (CNS neurological impairment [ATSDR])²⁰⁶ microcephaly, cerebral palsy, seizures</p> <p>Breastfeeding: May affect neurodevelopment [AAP]²⁰⁷</p>
2-Methoxyethanol			(See Ethylene glycol monomethyl ether)
Methyl benzimidazole-carbamate	10605-21-7		(See Carbendazim)

Agent	CAS Number	Date Added	Notes
Methyl Cellosolve acetate			(See Ethylene glycol monomethyl ether acetate)
Methylene blue	61-73-4		Category C [Briggs 4th] ²⁰⁸ Category D if injected intra-amniotically [Briggs 4th] ²⁰⁹ (hemolytic anemia, jaundice, intestinal atresia with intra-amniotic injection [PMID 9434858]) ²¹⁰
Methyl isocyanate	624-83-9	07/10/00	Pregnancy: Associated with spontaneous abortion and neonatal deaths [Schardein] ²¹¹
Methyl mercury	22967-92-6	09/30/94	(See also Mercury, organic , and Mercury and mercury compounds) Pregnancy: Microcephaly, cerebral palsy, abnormal reflexes [PMID 9434858], ²¹² abnormal dentition, neurological deficits [Schardein] ²¹³ Breastfeeding: May affect neurodevelopment [AAP] ²¹⁴
Methylmethane sulfonate	66-27-3		Pregnancy: Embryo lethality and malformations in rats [Nagao] ²¹⁵ [PMID 2595598], ²¹⁶ embryotoxicity in mice [PMID 4349609] ²¹⁷
Methylnitrosourea	684-93-5		Animal data: Male: Malformed ribs in offspring of exposed males [PMID 3821763] ²¹⁸ Developmental: Teratogenic in rats (microcephaly [PMID 8016749]) ²¹⁹ and mice (in mice it was teratogenic and embryo-lethal one-half day before implantation [PMID 2520503]) ²²⁰
MIC			(See Methyl isocyanate)

Agent	CAS Number	Date Added	Notes
Mirex	2385-85-5		Animal studies only [ATSDR] ²²¹ Male: Decreased sperm counts and fertility ²²² Female: Decreased litter size and number of offspring ²²³ Developmental: Increased resorptions and stillbirths, arrhythmias, and other anomalies ²²⁴ Edema and cardiac toxicity in the offspring of rats exposed during pregnancy Breastfeeding: Appears in human milk [ATSDR] ²²⁵
α-Naphthyl-N-methylcarbamate	63-25-2		(See Carbaryl)
Nickel	7440-02-0	07/07/00	Pregnancy: Increased structural malformations and spontaneous abortions in occupationally exposed women who also lifted heavy weights and may have experienced heat stress [ATSDR] ²²⁶
o,p'-DDT	789-02-6		(See DDT)
Oryzalin	19044-88-3	06/27/00	Male: One report of spontaneous abortion and heart defects born to spouses of occupationally exposed males [Schardein] ²²⁷ Based on experimental animal studies, oryzalin is not expected to increase the risk of congenital anomalies under typical exposure conditions.

Agent	CAS Number	Date Added	Notes
Oxydemeton methyl	301-12-2	03/10/00	<p>Developmental: Human case report (multiple cardiac defects, bilateral optic nerve colobomas, left eye microphthalmia, cerebral and cerebellar atrophy, and facial anomalies [PMID 2583071])²²⁸ Based on experimental animal studies, oxydemeton is not associated with an increased the risk of congenital anomalies with normal use. The case report of a fetus with multiple anomalies but also exposure to other agents. Animals: Chick embryos [PMID 8248858],²²⁹ rats [WHO]²³⁰</p>
p,p'-DDT	50-29-3		(See DDT)
p,p'-Dichlorodiphenyltrichloroethane	50-29-3		(See DDT)
PCBs	1336-36-3		(See Polychlorinated biphenyls)
Perchloroethylene (PCE)	127-18-4	06/27/00	<p>Male: Altered sperm transport [NIOSH]²³¹ Based on human and animal studies, there is no increased risk for birth defects. There may be an increased risk of miscarriage, but only for highly-exposed workers in the dry-cleaning business. Breastfeeding: Obstructive jaundice, dark urine [AAP]²³²</p>
Phthalates			<p>Several associated with pre-term labor. (See di(2-ethylhexyl) Phthalate)</p>

Agent	CAS Number	Date Added	Notes
Polychlorinated biphenyls (PCBs)	1336-36-3	09/30/94	<p>Yusho Disease/Yu-Cheng Disease (hyperpigmentation [PMID 3921364],²³³ low birth weight, nail and conjunctival abnormalities, neurobehavioral deficits, developmental delays [PMID 3133768]²³⁴)[EPA]²³⁵</p> <p>Breastfeeding: Discontinue (appears in human milk; exposures are higher in nursing infants than in utero [PMID 2104928],²³⁶ may cause lack of endurance, hypotonia, sullen expressionless facies [AAP]²³⁷</p> <p>Polychlorinated biphenyls are a large group of 209 unique biphenyl compounds containing 1 to 10 chlorine atoms. Environmental fate of these compounds is dictated by their chlorine content. While the more chlorinated compounds tend to be more toxic, perhaps as a result of their greater persistence in the body, the toxicity of individual compounds can vary greatly and include both dioxin-like toxicity as well as non-dioxin toxicity. Some of the more toxic PCB compounds with regard to reproductive effects have non-dioxin-like characteristics.</p>
Sevin®			(See Carbaryl)
TCE			(See Trichloroethylene)

Agent	CAS Number	Date Added	Notes
TCDD	1746-01-6		<p>Male: No known effects [EPA],²³⁸ limited/ suggestive evidence of an association with spina bifida in offspring born to males exposed to Agent Orange, which also contained other substances [IOM]²³⁹ [IOM 1998]</p> <p>Female: Inconclusive [EPA],²⁴⁰ current study results of exposures in Seveso, Italy pending [PMID 10739069]²⁴¹</p> <p>There are no human data that suggest risk of birth defects. There are limited data suggesting an increased risk of sex selection (females over males in Seveso Italy exposed individuals) and spina bifida in offspring of Vietnam veterans, but this is not consistent. Animal studies showed an increased risk of multiple birth defects, some of which (cleft palate in mice) may have little relevance in humans.</p> <p>Breastfeeding: Present in human milk [PMID 9831540]²⁴²</p>
Tetrachloroethylene	127-18-4		(See Perchloroethylene)
2,3,7,8-Tetrachlorodibenzo-p-dioxin	1746-01-6	09/30/94	(See TCDD)

Agent	CAS Number	Date Added	Notes
Tobacco smoke - environmental (secondary/passive)	---	06/08/00	<p>Males: Decreased fertility (fecundability) [PMID 9829871]²⁴³</p> <p>Pregnancy/developmental: LBW at term, small-for-gestational-age [PMID 9987784]²⁴⁴ [PMID 9772856],²⁴⁵ adverse effects on IQ in females [Seidman],²⁴⁶ decreased fertility (fecundability) in adult females [PMID 2705427],²⁴⁷ specifically including those who were exposed to tobacco smoke <i>in utero</i> and who currently smoke (as adults)[PMID 9829871]²⁴⁸</p> <p>Discontinuing smoking by 15 weeks gestation reduces risk [PMID 19325177]²⁴⁹</p>
Toluene	108-88-3	09/30/94	<p>Significant delays in fetal growth following chronic and excessive industrial accidents or intentional abuse [PMID 9143096]²⁵⁰</p> <p>Toluene embryopathy has been reported (motor and intellectual effects) [PMID 9294310]²⁵¹ (developmental delay, CNS dysfunction, hydronephrosis, ventricular septal defects, craniofacial and limb anomalies including microcephaly [PMID 9434858])²⁵²</p> <p>Breastfeeding: Toluene is found in milk but no adverse neurobehavioral outcomes have been found in animal data.</p> <p>Animal studies also suggest developmental toxicity with respiratory exposure [ATSDR]²⁵³</p>
Toluenediamine	95-80-7	06/27/00	Male: Lowered number of sperm [NIOSH] ²⁵⁴
Toluene-2,4-diamine	95-80-7		(See Toluenediamine)

Agent	CAS Number	Date Added	Notes
Trichlorfon	52-68-6	06/26/00	<p>Male: One report of diminished seminal fluid volume, sperm count, motility, and viability, and increased number of abnormally-shaped sperm [PMID 5932734]²⁵⁵</p> <p>Pregnancy: One report possibly associating consumption of contaminated fish with congenital abnormalities [PMID 8094783],²⁵⁶ skeletal abnormalities in several animal species [Schardein]²⁵⁷</p>
Trichloroethylene (TCE)	79-01-6	11/30/00	<p>Male: impotence (occupational exposure)²⁵⁸</p> <p>Female: amenorrhea, irregular menses (after accidental exposure to high levels)²⁵⁹</p> <p>TCE exposure in rats is associated with cardiac defects, which US EPA suggests occurs during gestational exposure. Similar cardiac effects are observed for TCE metabolites dichloroacetic acid (DCA) and trichloroacetic acid (TCA).</p>
Urethane (ethyl carbamate - NOT "polyurethane")	51-79-6	06/30/95	<p>Animal data: Oncogenic in several mammalian species; crosses the placenta [PMID 3050270],²⁶⁰ genotoxic in mice [Platzek],²⁶¹ preconception exposure of male and female mice produced neoplasms in offspring [PMID 10406931]²⁶²</p>
VCM	75-01-4		(See Vinyl chloride)

Agent	CAS Number	Date Added	Notes
Vinyl chloride (monomer—not polyvinyl chloride or PVC)	75-01-4	03/10/00	This has not been shown to consistently be associated with adverse reproductive outcomes. Fetal loss in wives of exposed males [PMID 56545] ²⁶³ CNS defects in communities of polyvinyl chloride polymerization plants [PMID 1069539] ²⁶⁴ Increased incidence of birth defects (not limited to a single organ system, association lacking substantiation) [PMID 6879459] ²⁶⁵
Xylenes	1330-20-7	03/10/00	Female: Menstrual disorders Pregnancy: Possible association with spontaneous abortion [ATSDR], ²⁶⁶ "adverse effects" with high levels of maternal exposure [ATSDR], ²⁶⁷ xylene has known neurological effects, but insufficient human data to confirm neurological effects from in utero exposure [ATSDR] ²⁶⁸

(VIII) DRUG REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

A) INTRODUCTION

Several drugs (folate antagonists and alkylating agents) are known to induce spontaneous abortions as well as congenital malformations. However, compilations of drugs that cause ReproDev adverse effects are usually based upon drugs known to cause teratogenicity. Therapeutic agents known to have teratogenic effects in humans are thalidomide, androgenic hormones, folate antagonists, anti-thyroid drugs, and diethylstilbestrol.

Estrogens, in high pharmacologic doses, are used as post-coital contraceptives and cause early pregnancy loss. Diethylstilbestrol (DES), a non-steroidal estrogen, causes adenocarcinoma of the vagina (but not other cancers, to date [[PMID 9718055](#)])²⁶⁹ in female offspring of treated mothers and disorders of reproductive function in male and female offspring of treated mothers. Male disorders associated with DES include epididymal cysts, microphallus, cryptorchidism, testicular hypoplasia, diminished semen analyses, and decreased sperm penetration assays; however, impairment of fertility has not been demonstrated. Female abnormalities associated with DES include structural defects of the cervix, vagina, uterus, and fallopian tubes, and adverse pregnancy outcomes contributed to by increased rates of spontaneous abortion, ectopic pregnancy, premature delivery, and perinatal deaths [[PMID 6121486](#)].²⁷⁰ Studies involving the self-reporting of immune system effects associated with the use of DES have been contradictory [[PMID 8606329](#), [PMID 9578280](#)].^{271,272}

B) HEALTH CARE WORKERS AND HAZARDOUS OCCUPATIONAL EXPOSURES

There are several potential ReproDev hazards to which HCWs are uniquely exposed. Although HCWs are often not thought of as working in typical “industrial” or manufacturing settings, HCWs routinely have close contact with hazards that directly impact human health. Females (for example, nurse-anesthetists) occupationally exposed to anesthetic gases were shown to have increased spontaneous abortions ([PMID 5114397](#),²⁷³ [PMID 4414878](#)),²⁷⁴ decreased fecundity ([PMID 4113412](#)),²⁷⁵ fetal growth retardation ([PMID 63667](#)),²⁷⁶ and congenital malformations ([PMID 4412215](#)).²⁷⁷ Even spouses of males occupationally exposed to anesthetic gases have had increased rates of malformations ([PMID 620176](#)).²⁷⁸ Dispensing pharmaceuticals (for example, those with ReproDev activity, such as antineoplastics) may result in exposure via inhalation of vaporized medications ([PMID 10986478](#)),²⁷⁹ percutaneous absorption, and hand-to-mouth ingestion of dust (shown to contaminate surfaces of both pharmacy drug preparation and drug administration areas, [PMID 10428450](#)).²⁸⁰ HCWs using, removing (including housekeeping), or cleaning sharps (needles, scalpels, etc.) may be exposed to punctures and lacerations. Additionally, medical instruments may act as transport mechanisms for blood-borne or other body fluids-borne pathogens, such as hepatitis B or human immunodeficiency virus (HIV). Air and droplet spread of communicable disease may be a ReproDev hazard to which HCWs are occupationally exposed. Sterilization of medical supplies, whether by chemicals (for example, gas sterilization with ethylene oxide) or by heat, may expose HCWs to significant ReproDev hazards. Finally, while not unique to HCWs, rotating shifts are often associated with medical work. (Also see the section on [Shift Work and Extended Hours of Duty](#).)

C) ANTINEOPLASTIC AGENTS

The hazards of occupational exposure to antineoplastic agents were addressed by the National Study Commission on Cytotoxic Exposure. The following are excerpts from the Commission's statement on the handling of cytotoxic agents by women who are attempting to conceive, are pregnant, or are breastfeeding:

There are substantial data regarding the mutagenic, teratogenic and abortifacient properties of certain cytotoxic agents both in animals and humans who have received therapeutic doses of these agents. Additionally, the scientific literature suggests a possible association of occupational exposure to certain cytotoxic agents during the first trimester of pregnancy with fetal loss or malformation. These data suggest the need for caution when women who are pregnant or attempting to conceive, handle cytotoxic agents. . . . it is prudent that women who are breast feeding should exercise caution in handling cytotoxic agents. . . . Personnel should be provided with information to make an individual decision. This information should be provided in written form and it is advisable that a statement of understanding be signed. . . . It is essential to refer to individual state right-to-know laws to ensure compliance.²⁸¹

The 2016 OSHA Technical Manual, [Controlling Occupational Exposure to Hazardous Drugs](#), gives more detailed and current information dealing with occupational hazards of administering pharmaceuticals in general and addresses antineoplastics in particular.²⁸² These recommendations provide the best guidance available at this time.

D) DRUG PREGNANCY RISK CATEGORIES

The US Food and Drug Administration began using pregnancy risk categories in 1979 for pharmaceuticals as set forth in the [Table 9](#).²⁸³ In 2015, the FDA replaced the A, B, C, D and X risk categories with text summarizing risk and discussing use related to pregnancy and lactation. While that is generally more useful than simply a category designation, information on specific drugs often continues to refer to category, and narrative text would be unwieldy in this document. Therefore, in many cases the use of those categories is continued here. For further information, the information supplied in the new format by the drug manufacturer should be consulted first.²⁸⁴

Table 9 – ReproDev Pregnancy Risk Category Key²⁸⁵

Category	Description	Interpretation
A	Controlled human studies show no risk.	Adequate, well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester of pregnancy.
B	No evidence of risk in humans.	Adequate, well-controlled studies in pregnant women have not shown increased risk of fetal abnormalities despite adverse findings in animals, or, in the absence of adequate human studies, animal studies show no fetal risk. The chance of fetal harm is remote, but remains a possibility.
C	Risk cannot be ruled out.	Adequate, well-controlled human studies are lacking, and animal studies have shown a risk to the fetus or are lacking. There is a chance of fetal harm if the drug is administered during pregnancy; but the potential benefits may outweigh the potential risk.
D	Positive evidence of risk.	Studies in humans, or investigational or post-marketing data, have demonstrated fetal risk. Nevertheless, potential benefits from the use of the drug may outweigh the potential risk. For example, the drug may be acceptable if needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective.
X	Contraindicated in pregnancy.	Studies in animals or humans, or investigational or post-marketing reports, have demonstrated positive evidence of fetal abnormalities or risk which clearly outweighs any possible benefit to the patient.

E) DRUG REPRODUCTIVE AND DEVELOPMENTAL HAZARDS LIST

The following table is a list that may be used as a guideline by health care professionals when dealing with pharmaceuticals or drugs of abuse.

Table 10 – Drug and Pharmaceutical Reproductive and Developmental Toxicants List

Drug/Substance	CAS Number	Date Added	Comments/Notes
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea	13010-47-4	06/30/95	(See Lomustine)
1,25-Dihydrocholecalciferol		10/17/00	(See Calcitriol)
1,4-Butanediol dimethylsulfonate	55-98-1	06/30/95	(See Busulfan)
2-Chloro-2'-deoxyadenosine	4291-63-8		(See Cladribine)

Drug/Substance	CAS Number	Date Added	Comments/Notes
2-Chloroadenosine		10/17/00	(See Cladribine)
4-Aminopteroylglutamic acid	54-62-6		(See Aminopterin)
5-Fluorouracil	51-21-8		(See Fluorouracil)
5-FU	51-21-8		(See Fluorouracil)
6-Mercaptopurine	50-44-2		(See Mercaptopurine)
8-Methoxypsoralen		10/20/00	(See Methoxsalen)
8-MOP		10/20/00	(See Methoxsalen)
Accupril®			(Quinapril, see ACE Inhibitors)
Accutane®			(See Isotretinoin)
ACE Inhibitors	Captopril 62571-86-2 Enalapril 75847-73-3 Lisinopril 76547-98-3 Benazepril 86541-75-5 Fosinopril 98048-97-6 Quinapril 85441-61-8 Ramipril 87333-19-5		<p>Pregnancy: Not recommended during pregnancy. Use in any trimester associated with oligohydramnios resulting fetal lung hypoplasia and skeletal malformations. Use in pregnancy is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate [PMID: 24150027].²⁸⁶</p> <p>Renin Angiotensin System Blockade Fetopathy (also called ACE inhibitor fetopathy), renal, pulmonary, cardiac, skeletal, and central nervous system abnormalities, characterized by fetal hypotension, anuria-oligohydramnios, growth restriction, pulmonary hypoplasia, renal tubular dysplasia, and hypocalvaria [PMID 26130112]²⁸⁷ [PMID 8507813]²⁸⁸ [PMID 22753220])²⁸⁹</p> <p>Breastfeeding: Excretion into milk negligible, but authors differ as to advisability [PMID 9673832]²⁹⁰ [PMID 9520613]²⁹¹ Acceptable for use in breastfeeding women. Monitoring of the nursing child's weight for the first 4 weeks is recommended [PMID: 24150027].²⁹²</p>
Acetohydroxamic acid	546-88-3	06/30/95	Category X (may cause fetal harm) ²⁹³ Breastfeeding: Discontinue ²⁹⁴

Drug/Substance	CAS Number	Date Added	Comments/Notes
Acetyladriamycin	---		(See Daunorubicin citrate)
Achromycin®			(See Tetracycline hydrochloride)
Acitretin	55079-83-9	11/20/00	(See Isotretinoin and Etretinate [TERIS]) ²⁹⁵ (Converted to Etretinate in the body [TERIS]) ²⁹⁶
Actinomycin D	50-76-0	06/30/95	(See Dactinomycin)
Adderall®			(See Amphetamines)
Adriamycin®			(See Doxorubicin hydrochloride)
Adrucil®			(See Fluorouracil)
Alfenta®		10/16/00	(See Alfentanil)
Alfentanil	71195-58-9		Pregnancy: Adverse events have been observed in some animal reproduction studies. Use during labor and immediately prior to labor is not recommended by the manufacturer [PMID: 12100826] . ²⁹⁷ Category C ²⁹⁸ (D if used for prolonged periods or in high doses at term [Briggs 4th]) ²⁹⁹ Breastfeeding: Express and discard breast milk once before resuming nursing after use ³⁰⁰ Decision to continue or discontinue breast-feeding during therapy should weigh infant risk/benefit. Breast-feeding infants should be monitored for apnea and sedation [PMID: 12100826] . ³⁰¹
Alkeran®		10/20/00	(See Melphalan)
All-transretinoic acid		10/20/00	(See Tretinoin)
Alprazolam	28981-97-7	06/30/95	Category D (may cause fetal harm and postnatal withdrawal) ³⁰² Breastfeeding: See Benzodiazepines
Altace®			(Ramipril) (See ACE Inhibitors)
Altretamine	645-05-6	08/20/99	Category D ³⁰³ Breastfeeding: Discontinue [Facts and Comparisons] ^{304,305}
Amethopterin®		10/20/00	(See Methotrexate)
Amikacin	39831-55-5		(See Aminoglycosides)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Amikin®			(Amikacin) (See Aminoglycosides)
4-Aminopteroylglutamic acid	54-62-6		(See Aminopterin)
Aminoglutethimide	125-84-8	06/30/95	Category D [USPDI] ³⁰⁶ [Schardein] ³⁰⁷ (can cause fetal harm [Facts and Comparisons]) ³⁰⁸ Breastfeeding: Discontinue [Facts and Comparisons] ³⁰⁹
Aminoglycosides	Amikacin 39831-55-5 Gentamicin 1403-66-3 Kanamycin 8063-07-8 Streptomycin 57-92-1 Tobramycin 32986-56-4	06/30/95	Category D (can cause fetal harm) ³¹⁰ All cross placenta. <i>In utero</i> aminoglycoside ototoxicity has been reported to date with tobramycin and streptomycin, but not with amikacin, gentamicin, or kanamycin [USPDI]. ³¹¹ However, kanamycin causes deafness in fetal sheep [PMID 12297800]. ³¹² Breastfeeding: Compatible [Briggs 1997] ³¹³ (excreted in milk but are poorly absorbed and problems in nursing infants have not been documented [USPDI]) ³¹⁴
Aminopterin	54-62-6	09/30/94	Category X [Schardein] ³¹⁵ (abortifacient [PMID 507011], ³¹⁶ aminopterin embryopathy [PMID 10413333] ³¹⁷ /syndrome [PMID 675555] ³¹⁸) <i>Note: Currently used as a rodenticide.</i>
Amiodarone	1951-25-3	06/23/00	(See Amiodarone hydrochloride)
Amiodarone hydrochloride	19774-82-4	03/06/00	Pregnancy: May cause fetal harm when administered to a pregnant woman. Oral or IV amiodarone should be used in pregnant women only to treat arrhythmias refractory to other treatments or when other treatments are contraindicated [PMID: 21873418]. ³¹⁹ Breastfeeding: Discontinue ³²⁰

Drug/Substance	CAS Number	Date Added	Comments/Notes
Amitriptyline	549-18-8		Category D [Briggs 4th] ³²¹ Category C ³²² Breastfeeding: Discontinue (excreted in milk) ³²³
Amobarbital		10/17/00	(See Barbiturates)
Amphetamines (amphetamine, dextroamphetamine, methamphetamine)	---		Category C [Briggs 4th] ³²⁴ (illicit use is associated with IUGR, preterm labor [PMID 2240103], ³²⁵ and fetal cerebrovascular accidents, withdrawal in infants born to amphetamine addicted mothers [Briggs 6 th]) ³²⁶ Breastfeeding: Contraindicated [Briggs 1997] ³²⁷ (irritability, poor sleeping pattern [AAP]), ³²⁸ discontinue (excreted in breast milk) [Facts and Comparisons] ³²⁹ (concentrated in breast milk) [Briggs 6 th] ³³⁰
Amytal®		10/17/00	(See Barbiturates) (Amobarbital)
Anabolic steroids (nandrolone, oxandrolone, oxymetholone, stanozolol)	---	03/10/00	Category X [Facts and Comparisons] ³³¹ Breastfeeding: Discontinue [Facts and Comparisons] ³³²
Anacufen®		10/20/00	(See Methandriol)
Anadrol®-50			(See Oxymetholone)
Andro LA 200®		10/17/00	(See Testosterone enanthate)
Androderm®			(See Testosterone)
Androgens (testosterone, methyltestosterone, fluoxymesterone)	---		Pregnancy: Contraindicated [Schardein], ³³³ masculinization (pseudohermaphroditism [Schardein], ³³⁴ virilization of female fetuses [Schardein]) ³³⁵
Android®-10 & 25		10/17/00	(See Methyltestosterone)
Android-F®			(See Fluoxymesterone)
Andropository-200®		10/17/00	(See Testosterone enanthate)
Anesthetic gases	---	03/10/00	Female: Reduced fertility ³³⁶ Pregnancy: Spontaneous abortion, IUGR ³³⁷

Drug/Substance	CAS Number	Date Added	Comments/Notes
Angiotensin converting enzyme inhibitors	---	06/30/95	(See ACE Inhibitors)
Anisindione	117-37-3	06/30/95	Category D [Briggs 4th] ³³⁸ (congenital malformations have been reported) [USPDI] ³³⁹ Breastfeeding: Monitor nursing infant for evidence of hypoprothrombinemia [USPDI] ³⁴⁰
Antabuse®		10/20/00	(See Disulfiram)
Antihistamines (brompheniramine, diphenhydramine)	---		Breastfeeding: Contraindicated ^{341,342} (first generation antihistamines may inhibit lactation through anticholinergic actions; use not recommended as small amounts are distributed into breast milk with risk to infant of unusual excitement or irritability [USPDI]) ³⁴³
Antineoplastics (cancer chemotherapeutic drugs in general)		07/27/00	Male: Infertility [DLI] ³⁴⁴ Female: Infertility [DLI] ³⁴⁵ Pregnancy: Spontaneous abortion, birth defects, growth retardation [DLI] ³⁴⁶
ARA-C		10/17/00	(See Cytarabine)
Aspirin	50-78-2	06/30/95	Category C dose ≤ 150 mg/day [Briggs 4 th , ³⁴⁷ PMID: 27640943] ³⁴⁸ Category D if full-dose aspirin used in 3 rd trimester [Briggs 4th] ³⁴⁹ (avoid in the last trimester, especially 1 week prior to and during delivery) ³⁵⁰ Breastfeeding: Avoid (excreted in breast milk), ³⁵¹ compatible but use with caution (one reported case of metabolic acidosis [AAP] ³⁵² [Briggs 1997] ³⁵³
Atenolol	29122-68-7	03/10/00	Category D (can cause fetal harm) ³⁵⁴ Breastfeeding: Cyanosis, bradycardia [AAP] ³⁵⁵ with caution (excreted in human milk, may cause bradycardia in nursing infants) ³⁵⁶
Ativan®		10/17/00	(See Lorazepam)
Atromid-S®		10/17/00	(See Clofibrate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Azathioprine	446-86-6		Category D [Briggs 4th] ³⁵⁷ Breastfeeding: Discontinue (drug and its metabolites transmitted in breast milk at low level [Facts and Comparisons]) ³⁵⁸
Bactrim®			(See Sulfonamides)
Barbiturates (amobarbital, butalbital, mephobarbital, metharbital, pentobarbital, phenobarbital, secobarbital)	---	06/30/95	Category D (can cause fetal damage [Briggs 4th]) ³⁵⁹ Breastfeeding: With caution (sedation, infantile spasms after weaning from milk containing phenobarbital, methemoglobinemia [AAP] ³⁶⁰ small amounts excreted in breast milk [Briggs 4th]) ³⁶¹
BCNU	154-93-8		(See Carmustine)
Benadryl®		10/17/00	(See Diphenhydramine)
Benazepril	86541-75-5	4/25/00	Pregnancy: Adverse fetal events well documented with exposure in pregnancy. ACE inhibitor use in pregnant women is not recommended [PMID: 24150027]. ³⁶² Category C in 1 st trimester, Category D in 2 nd and 3 rd trimesters [Briggs 6 th] ³⁶³ Breastfeeding: See ACE Inhibitors (distributed into breast milk [USPDI]) ³⁶⁴
Bentyl®		10/17/00	(See Dicyclomine)
Benzodiazepines (alprazolam, chlorazepate, chlordiazepoxide, diazepam, estazolam, flunitrazepam, flurazepam, halazepam, lorazepam, midazolam, oxazepam, quazepam, temazepam, triazolam)	---	06/30/95	Category X (as a class [Schardein]), ³⁶⁵ or see specific agents. If used lorazepam preferred. Breastfeeding: Not recommended. Occasional use compatible, use with caution [Briggs 1997], ³⁶⁶ excreted in breast milk [Facts and Comparisons]; ³⁶⁷ since neonates metabolize benzodiazepines more slowly than adults, accumulation of the drug and its metabolites may occur [USPDI] ³⁶⁸

Drug/Substance	CAS Number	Date Added	Comments/Notes
Benzphetamine hydrochloride	5411-22-3	06/30/95	(See Amphetamines)
Betadine®			(See Povidone-iodine)
BiCNU®	154-93-8		(See Carmustine)
Blenoxane®		10/17/00	(See Bleomycin)
Bleomycin	11056-06-7		Category D [Briggs 4th] ³⁶⁹ Breastfeeding: Contraindicated [Briggs 1997] ³⁷⁰
Bromides (anticonvulsant/sedative)	---		Category D [Briggs 4th] ³⁷¹ Breastfeeding: Potential absorption and bromide transfer into milk [AAP] ³⁷² not recommended [Briggs 4th] ³⁷³
Bromocriptine	25614-03-3		Category C [Briggs 4th] ³⁷⁴ Breastfeeding: With caution (suppresses lactation; may be hazardous to the mother [AAP] ³⁷⁵ suppresses lactation [Briggs 1997] ³⁷⁶
Brompheniramine	86-22-6		Category C [Briggs 4th] ³⁷⁷ Breastfeeding: Contraindicated ³⁷⁸
Bumetanide	---		Category D [Briggs 5th] ³⁷⁹ Breastfeeding: Contraindicated [Briggs 5th] ³⁸⁰
Bumex®		10/17/00	(See Bumetanide)
Busulfan	55-98-1	06/30/95	Category D (may cause fetal harm) ³⁸¹ Breastfeeding: Discontinue ³⁸²
Butalbital		10/17/00	(See Barbiturates)
1,4-Butanediol dimethylsulfonate	55-98-1	06/30/95	(See Busulfan)
Butazone®	50-33-9	07/10/00	(See Phenylbutazone)
Calcijex®		10/17/00	(See Calcitriol)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Calcitriol	32222-06-3	07/10/00	<p>CAT C Adverse effects observed in some animal reproduction studies. Mild hypercalcemia has been reported in a newborns following maternal use of calcitriol during pregnancy [PMID: 20926527].³⁸³</p> <p>Category A [Briggs 4th]³⁸⁴</p> <p>Category D if recommended dietary allowance (RDA) exceeded [Briggs 4th]³⁸⁵ [Schardein]³⁸⁶</p> <p>Breastfeeding: CAT B [PMID: 20926527].³⁸⁷</p>
Capoten®		10/17/00	(See Captopril)
Captopril	62571-86-2	03/06/00	<p>Pregnancy: Not recommended during pregnancy. Use in any trimester associated with oligohydramnios resulting fetal lung hypoplasia and skeletal malformations. Use in pregnancy is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate [PMID: 24150027].³⁸⁸</p> <p>Category C (first trimester)³⁸⁹</p> <p>Category D (second trimester) (may cause fetal harm or death)³⁹⁰</p> <p>Breastfeeding: Acceptable for use in breastfeeding women. Monitoring of the nursing child's weight for the first 4 weeks is recommended [PMID: 24150027]³⁹¹ (excreted in human milk and may cause adverse reactions in nursing infants)³⁹²</p>
Carbamazepine	298-46-4	03/10/00	<p>Category D (can cause fetal harm)³⁹³</p> <p>Breastfeeding: Discontinue,³⁹⁴ compatible [AAP]³⁹⁵</p>
Carbatrol®			(See Carbamazepine)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Carbimazole	22232-54-8		Category D [Briggs 6 th] ³⁹⁶ (associated with scalp abnormalities [PMID 1885895]) ³⁹⁷ Breastfeeding: Compatible, but has been associated with goiter [AAP] ³⁹⁸ Possible choanal atresia, tracheoesophageal fistula and clinodactyly [PMID 21807695] ³⁹⁹
Carboplatin	41575-94-4	09/30/94	Category D (may cause fetal harm) ⁴⁰⁰ Breastfeeding: Discontinue ⁴⁰¹
Carmustine	154-93-8	06/28/00	Category D ⁴⁰² Breastfeeding: Discontinue ⁴⁰³
CCNU	13010-47-4		(See Lomustine)
Cd A		10/17/00	(See Cladribine)
CDDP®		10/17/00	(See Cisplatin)
CeeNu®		10/17/00	(See Lomustine)
Cerubidine®			(See Daunorubicin hydrochloride)
Celexa®	59729-33-8	09/28/20 09	Septal heart defects [PMID 19776103] ⁴⁰⁴
Chenix®		10/17/00	(See Chenodiol)
Chenodeoxycholic acid	474-25-9		(See Chenodiol)
Chenodiol	474-25-9	06/30/95	Category X [USPDI] ⁴⁰⁵
Chlorambucil	305-03-3	09/30/94	Males: Reversible sterility, permanent sterility, azoospermia ⁴⁰⁶ Females: Reversible sterility, permanent sterility, amenorrhea ⁴⁰⁷ Category D (can cause fetal harm) ⁴⁰⁸ Breastfeeding: Discontinue ⁴⁰⁹
Chloramphenicol	56-75-7		Category C [Briggs 4th] ⁴¹⁰ Not recommended in pregnancy at term (neonatal "gray baby" disease or "gray syndrome," bone marrow suppression) [USPDI] ⁴¹¹ Breastfeeding: Use with caution [Briggs 1997] ⁴¹² (excreted in breast milk [USPDI]), ⁴¹³ especially with preterm and young infants (<1 month) [PMID: 3292101] ⁴¹⁴
Chlorazepate		10/17/00	(See Benzodiazepines)
Chlordiazepoxide	58-25-3	06/30/95	Category D [Briggs 4th] ⁴¹⁵ Breastfeeding: See Benzodiazepines

Drug/Substance	CAS Number	Date Added	Comments/Notes
Chlordiazepoxide hydrochloride	438-41-5	06/30/95	(See Chlordiazepoxide)
2-Chloroadeoxyadenosine		10/17/00	(See Cladribine)
2-Chloro-2'-deoxyadenosine	4291-63-8		(See Cladribine)
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea	13010-47-4	06/30/95	(See Lomustine)
Chloromycetin®			(See Chloramphenicol)
Chlorothiazide	58-94-6	04/25/00	<p>Pregnancy: Use may cause may cause fetal or neonatal jaundice, thrombocytopenia, or other adverse events observed in adults. Women who required thiazide diuretics for the treatment of hypertension prior to pregnancy may continue their use [PMID: 24150027].⁴¹⁶</p> <p>Category D [Briggs 4th]⁴¹⁷</p> <p>Breastfeeding: Discontinue⁴¹⁸ (excreted in breast milk in low concentrations [Briggs 4th]),⁴¹⁹ has potential to decrease milk volume and suppress lactation[PMID: 24150027]⁴²⁰</p>
Chlorotrianisene	569-57-3		<p>Category X [USPDI]⁴²¹</p> <p>Breastfeeding: Not recommended (distributed into breast milk) [USPDI]⁴²²</p>
Chlorpropamide	94-20-2		<p>Pregnancy: Category C: If chlorpropamide is used during pregnancy, it should be discontinued at least 1 month before the expected delivery date [PubMed 15738045,⁴²³ PubMed 23969827]⁴²⁴</p> <p>Breastfeeding: Not recommended (excreted in human milk)⁴²⁵</p> <p>Discontinue [PubMed 15738045,⁴²⁶ PubMed 23969827].⁴²⁷</p>

Drug/Substance	CAS Number	Date Added	Comments/Notes
Chlortetracycline	57-62-5		Pregnancy: Available only for ophthalmic use, in which problems in humans have not been documented [USPDI] ⁴²⁸ Breastfeeding: Available only for ophthalmic use, in which problems in humans have not been documented [USPDI] ⁴²⁹ (See Tetracycline hydrochloride for consideration of other exposures)
Cholecalciferol	67-97-0	07/10/00	Category A [Briggs 4th] ⁴³⁰ Category D if RDA exceeded [Briggs 4th] ⁴³¹ [Schardein] ⁴³²
Cidofovir	149394-66-1	03/10/00	Males: Inhibition of spermatogenesis in rats and monkeys ⁴³³ Category C ⁴³⁴ Possibly carcinogenic and teratogenic based on animal data. May cause hypospermia. Women of childbearing potential should use effective contraception during therapy and for 1 month following treatment. Males should use a barrier contraceptive during therapy and for 3 months following treatment. ⁴³⁵ Breastfeeding: Should not be administered to nursing mothers ⁴³⁶
Cinobac®		10/17/00	(See Cinoxacin)
Cinoxacin	28657-80-9		Category C (crosses the placenta) [USPDI] ⁴³⁷ Breastfeeding: Not recommended (unknown if excreted in milk, but has caused arthropathy in immature animals) [USPDI] ⁴³⁸
Cipro®			(See Ciprofloxacin)
Ciprofloxacin	85721-33-1		Pregnancy: Category C ⁴³⁹ Breastfeeding: Discontinue (excreted in human milk) ⁴⁴⁰ (do not resume breastfeeding before 48 hours after last dose [Briggs 4th]) ⁴⁴¹ (See also Fluoroquinolones)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Cisplatin	15663-27-1		Category D (can cause fetal harm) ⁴⁴² May cause fetal ototoxicity [PMID 25004323] ⁴⁴³ Breastfeeding: Controversy exists— Do not breastfeed (found in human milk), ⁴⁴⁴ Compatible (not found in milk) [AAP] ⁴⁴⁵
Citalopram	59729-33-8	09/28/2009	Category C: Risk of cardiovascular defects, Serotonin syndrome and Persistent pulmonary hypertension of the newborn (PPHN) reported with SSRI exposure [PMID: 18378767] ⁴⁴⁶ Septal heart defects [PMID 19776103] ⁴⁴⁷ Breastfeeding: Exercise Caution, can cause sedation [PMID: 18378767] ⁴⁴⁸
Cladribine	4291-63-8	03/10/00	Category D ⁴⁴⁹ Breastfeeding: Discontinue ⁴⁵⁰
Clinoril®			(See Sulindac)
Clofibrate	---	06/28/00	Category C [Briggs 4th] ⁴⁵¹ Breastfeeding: Contraindicated [Briggs 1997] ⁴⁵²
Clomid®			(See Clomiphene)
Clomiphene	911-45-5		Category X ⁴⁵³ Breastfeeding: Exercise caution ⁴⁵⁴
Clomocycline	1181-54-0		Category D [Briggs 4th] ⁴⁵⁵ (case report of multiple fetal abnormalities and neonatal death exists [PMID 143981]) ⁴⁵⁶ Breastfeeding: See Tetracycline hydrochloride
Clorazepate dipotassium	57109-90-7	06/30/95	Pregnancy: Use during pregnancy should almost always be avoided ⁴⁵⁷ Breastfeeding: See Benzodiazepines

Drug/Substance	CAS Number	Date Added	Comments/Notes
Cocaine	50-36-2	06/30/95	Category C [Briggs 4th] ⁴⁵⁸ Category X if nonmedicinal use [Briggs 4th] ⁴⁵⁹ (associated with fetal malformations, placental toxicity [PMID 9434858]) ⁴⁶⁰ Breastfeeding: Contraindicated (may cause cocaine intoxication: irritability, vomiting, diarrhea, tremulousness, seizures) [AAP] ⁴⁶¹
Colchicine	64-86-8	06/30/95	Category D [Briggs 4th] ⁴⁶² Breastfeeding: Compatible [AAP] ⁴⁶³
Conjugated estrogens	12126-59-9		Category X [Facts and Comparisons] ⁴⁶⁴ Breastfeeding: Administer only when clearly needed (may be excreted in breast milk; decrease the quantity and quality of breast milk [Facts and Comparisons]) ⁴⁶⁵
Copper ⁶⁴ (64Cu)	13981-25-4		Breastfeeding: Discontinue temporarily (radioactivity in milk present at 50 hours) [AAP] ⁴⁶⁶
Cordarone [®]			(See Amiodarone hydrochloride)
Cortisone	53-06-5	07/10/00	Category C: Should be avoided in pregnancy, especially in first trimester or in high doses [PMID: 20977425] ⁴⁶⁷ Breastfeeding: Appears in breast milk [Facts and Comparisons] ⁴⁶⁸ [PMID: 20977425] ⁴⁶⁹
Cosmegen [®]			(See Dactinomycin)
Coumadin [®]			(See Warfarin)
Cuprimine [®]			(See Penicillamine)
Cyclophosphamide	50-18-0		Category D [Briggs 6 th] ⁴⁷⁰ [USPDI] ⁴⁷¹ Breastfeeding: Contraindicated [Briggs 1997], ⁴⁷² (possible immune suppression, association with carcinogenesis, neutropenia [AAP] ⁴⁷³ not recommended (distributed into breast milk) [USPDI] ⁴⁷⁴

Drug/Substance	CAS Number	Date Added	Comments/Notes
Cyclosporin	79217-60-0		Category C (crosses the placenta, associated with preterm births and low birth weight) [USPDI] ⁴⁷⁵ Breastfeeding: Contraindicated [Briggs 1997] ⁴⁷⁶ (possible immune suppression [AAP] ⁴⁷⁷ compatibility with breastfeeding not established [PMID 7847911], ⁴⁷⁸ not recommended (distributed into breast milk) [USPDI] ⁴⁷⁹
Cyclosporine	79217-60-0		(See Cyclosporin)
Cyproterone acetate	427-51-0		Contraindicated ⁴⁸⁰ [Jahn] ⁴⁸¹ Breastfeeding: Contraindicated (transferred into breast milk) ⁴⁸²
Cytadren®			(See Aminoglutethimide)
Cytarabine	147-94-4	09/30/94	Category D (can cause fetal harm) ⁴⁸³ Breastfeeding: Discontinue ⁴⁸⁴
Cytosar-U®			(See Cytarabine)
Cytosine arabinosine		10/17/00	(See Cytarabine)
Cytotec®			(See Misoprostol)
Cytovene®			(See Ganciclovir)
Cytoxan®			(See Cyclophosphamide)
D.H.E.®		10/20/00	(See Dihydroergotamine mesylate)
Dacarbazine	4342-03-4	06/28/00	Category C [Briggs 4th] ⁴⁸⁵ Breastfeeding: Contraindicated [Briggs 1997] ⁴⁸⁶
Dactinomycin	50-76-0	06/30/95	Category C (can cause malformations and embryotoxicity in animals) ⁴⁸⁷ Breastfeeding: Discontinue ⁴⁸⁸
Dalmane®		10/17/00	(See Flurazepam)
Danacrine®			(See Danazol)
Danazol	1723-88-5	06/30/95	Category X (contraindicated, may result in androgenic effects on the female fetus) ⁴⁸⁹ Breastfeeding: Contraindicated ⁴⁹⁰
Daraprim®			(See Pyrimethamine)
Daunorubicin	20830-81-3		(See Daunorubicin citrate)
Daunorubicin citrate	20830-81-3	05/04/00	Category D (can cause fetal harm) ⁴⁹¹
Daunorubicin hydrochloride	23541-50-6	09/30/94	Category D (may cause fetal harm) ⁴⁹² Breastfeeding: Discontinue ⁴⁹³
DaunoXome®	20830-81-3		(See Daunorubicin citrate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Declomycin®			(See Demeclocycline hydrochloride)
Delatestryl®			(See Testosterone enanthate)
Delta-D®		10/17/00	(See Cholecalciferol)
Demeclocycline hydrochloride (internal use)	64-73-3	06/30/95	Category D [Briggs 4th] ⁴⁹⁴ Breastfeeding: See Tetracycline hydrochloride
Depacon®			(See Valproate sodium)
Depakene®			(See Valproic acid)
Depakote®		10/20/00	(See Valproate sodium)
Depandro®		10/17/00	(See Testosterone cypionate)
Depen®			(See Penicillamine)
Depotest®		10/17/00	(See Testosterone cypionate)
Depo-testosterone®		10/17/00	(See Testosterone cypionate)
DES	56-53-1		(See Diethylstilbestrol)
Desoxyn®			(Methamphetamine) (See Amphetamines)
Diabinese®			(See Chlorpropamide)
Diacetylmorphine	561-27-3		(See Heroin)
Diazepam	439-14-5	06/30/95	Category D [Briggs 4th] ⁴⁹⁵ If Benzodiazepines used lorazepam preferred [PMID: 11773648] ⁴⁹⁶ Breastfeeding: May be of concern [AAP] ⁴⁹⁷ not recommended [PMID: 11773648] ⁴⁹⁸ (excreted in breast milk and may accumulate in breast-fed infants) [Briggs 4th] ⁴⁹⁹
Diazoxide	364-98-7	February 27, 2001	Category C pulmonary hypertension [FDA] ⁵⁰⁰ Breastfeeding: Contraindicated [Briggs 1997] ⁵⁰¹ Neonatal hyperglycemia [Briggs 1997] ⁵⁰²
Dicumarol	66-76-2	06/30/95	Category D [Briggs 6th] ⁵⁰³ Breastfeeding: Compatible [AAP] ⁵⁰⁴
Dicyclomine	67-92-5		Category B ⁵⁰⁵ Breastfeeding: Contraindicated (excreted in human milk) ⁵⁰⁶
Dicycloverine hydrochloride	67-92-5		(See Dicyclomine)
Didrex®		10/17/00	(See Amphetamines) (Benzphetamine hydrochloride)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Dienestrol	84-17-3		Category X ⁵⁰⁷ Breastfeeding: With caution ⁵⁰⁸
Diethyldithiocarbamate	148-18-5	07/26/00	No data, but is metabolized to disulfiram (See Disulfiram)
Diethylstilbestrol (DES)	56-53-1	06/30/95	Category X [USPDI] ⁵⁰⁹ (see Introduction to this section, above) Breastfeeding: Compatible [Briggs 1997] ⁵¹⁰
Diflucan®		09/27/00	(See Fluconazole)
Diflunisal	22494-42-4	07/05/00	Category C [Briggs 4th] ⁵¹¹ Should be avoided in pregnancy, especially during 1st and 3rd trimester [PMID: 24663106] ⁵¹² Category D if used in the 3 rd trimester [Briggs 4th] ⁵¹³ Breastfeeding: Discontinue (excreted in breast milk in concentrations 2%-7% of those in plasma) ⁵¹⁴ Not recommended [PMID: 24663106] ⁵¹⁵
1,25-Dihydrocholecalciferol		10/17/00	(See Calcitriol)
Dihydroergotamine mesylate	6190-39-2	03/10/00	Category X ⁵¹⁶ Breastfeeding: Contraindicated ⁵¹⁷
Dilantin®			(See Diphenylhydantoin)
Diltiazem hydrochloride (CARDIZEM®)	33286-22-5	10/28/03	Category C (excreted in breast milk in concentrations approximating maternal serum levels) ⁵¹⁸ Should be avoided in pregnancy. Women with heart disease who are controlled with diltiazem prior to pregnancy may continue therapy [PMID: 22068434]. ⁵¹⁹ Breastfeeding: Not recommended [PMID: 22068434]. ⁵²⁰
Dimetane®			(See Brompheniramine)
Dimetapp®		10/17/00	(See Brompheniramine)
Dindevan®		10/20/00	(See Phenindione)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Diphenhydramine	58-73-1		Pregnancy: Category B - May be used for the treatment of allergic conditions in pregnant women when a first generation antihistamine is indicated [PMID: 23914886] ⁵²¹ Breastfeeding: Avoid. Second generation antihistamines preferred [PMID: 23914886] ⁵²² (See also Antihistamines)
Diphenylhydantoin	57-41-0	06/30/95	(See Phenytoin)
Disulfiram	97-77-8	07/10/00	Controversy exists as to category— Category X [Schardein] ⁵²³ Category C (noted reports of malformations but unknown relationship to disulfiram; noted embryotoxicity) [Briggs 4th] ⁵²⁴
Diuril®		10/17/00	(See Chlorothiazide)
dl-Penicillamine	52-66-4		(See Penicillamine)
Dolobid®		10/20/00	(See Diflunisal)
Doral®		10/20/00	(See Quazepam)
Doxorubicin	23214-92-8		(See Doxorubicin hydrochloride)
Doxorubicin hydrochloride	25316-40-9		Category D ⁵²⁵ [Briggs 4th] ⁵²⁶ Breastfeeding: Contraindicated (concentrated in human milk, possible immune suppression [AAP] ⁵²⁷ avoid ⁵²⁸)
Doxycycline	564-25-0	06/30/95	Category D Should be avoided during pregnancy [PMID: 20814687] ⁵²⁹ Breastfeeding: Excreted in human milk. Not recommended, ⁵³⁰ [PMID: 20814687]. ⁵³¹
Drisdol®			(See Ergocalciferol)
Durabolin®		10/17/00	(See Anabolic steroids) (Nandrolone)
Duratest®		10/17/00	(See Testosterone cypionate)
Durathate-200®		10/17/00	(See Testosterone enanthate)
Ecstasy			(See MDMA)
Elavil®		10/17/00	(See Amitriptyline)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Enalapril	75847-73-3		<p>Pregnancy: Not recommended during pregnancy. Use in any trimester associated with oligohydramnios resulting fetal lung hypoplasia and skeletal malformations. Use in pregnancy is also associated with anuria, hypotension, renal failure, skull hypoplasia, and death in the fetus/neonate [PMID: 24150027].⁵³²</p> <p>Breastfeeding: Acceptable for use in breastfeeding women. Monitoring of the nursing child's weight for the first 4 weeks is recommended. [PMID: 24150027].⁵³³</p> <p>Excreted in human milk.⁵³⁴</p>
Endoxan®			(See Cyclophosphamide)
Enovid®		10/20/00	(See Norethynodrel)
Enoxacin		10/20/00	(See Fluoroquinolones)
Equanil®		10/20/00	(See Meprobamate)
Ergocalciferol	50-14-6	07/10/00	<p>Pregnancy: Category C - current guidelines recommend a total of 1000 to 2000 units/day until more safety data is available. In women not at risk for deficiency, doses larger than the RDA should be avoided during pregnancy [PMID: 21691184].⁵³⁵</p> <p>Category D in doses above the RDA [Briggs 4th]⁵³⁶</p> <p>Breastfeeding: Can be detected in breast milk. Recommend caution be used if administered to nursing women. Hypercalcemia has been noted in a breast-feeding infant following maternal use of large amounts of vitamin D; calcium serum concentrations should be monitored in nursing infants exposed to large doses [PMID: 21691184].⁵³⁷</p>
Ergostat®		10/20/00	(See Ergotamine tartrate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Ergotamine	113-15-5	06/30/95	Category X ⁵³⁸ [Briggs 6 th] ⁵³⁹ Breastfeeding: Contraindicated [Briggs 1997], ⁵⁴⁰ should not be given (vomiting, diarrhea, convulsions at doses used in migraine medications [AAP] ⁵⁴¹)
Ergotamine tartrate	379-79-3		(See Ergotamine)
Erismodegib			(See Sonidegib)
Esidrix [®]		10/20/00	(See Hydrochlorothiazide)
Eskalith [®]			(See Lithium carbonate)
Estazolam	29975-16-4		Pregnancy: Category D. If Benzodiazepines used lorazepam preferred [PMID: 11773648]. ⁵⁴² Breastfeeding: Not recommended [PMID: 11773648]. ⁵⁴³ See Benzodiazepines (human studies lacking, but appears in animal breast milk [USPDI]) ⁵⁴⁴
Estinyl [®]		10/20/00	(See Ethinyl estradiol)
Estrace [®]		10/20/00	(See Estradiol)
Estradiol	50-28-2		Category X ⁵⁴⁵ Breastfeeding: Decreased quantity and quality of milk, ⁵⁴⁶ but compatible [Briggs 1997] ⁵⁴⁷
Estrogens	---		Category X [Briggs 4 th] ⁵⁴⁸ Breastfeeding: Compatible [Briggs 1997] ⁵⁴⁹
Estropipate	7280-37-7	03/10/00	Category X ⁵⁵⁰ Breastfeeding: Decreased quantity and quality of milk ⁵⁵¹

Drug/Substance	CAS Number	Date Added	Comments/Notes
Ethanol	64-17-5		<p>Category D [Briggs 6th]⁵⁵² Category X (when used in large amounts or for prolonged periods [Briggs 4th])⁵⁵³ (developmental defects, which may include the fetal alcohol syndrome [PMID 9434858],⁵⁵⁴ low birth weight, spontaneous abortion, growth retardation, congenital anomalies [Schardein],⁵⁵⁵ placental toxicity [PMID 1621875])⁵⁵⁶ Alcohol is a teratogen with the potential to cause deleterious effects at all stages of gestation and at any level of consumption. The most severe consequences of prenatal alcohol exposure are stillbirth and fetal alcohol spectrum disorder (FASD), which encompasses the physical, mental, behavioral, and cognitive effects associated with in utero alcohol exposure [PMID: 28586842].⁵⁵⁷ Breastfeeding: Not Recommended [PMID: 28586842].⁵⁵⁸</p>
Ethinyl estradiol	57-63-6		<p>Category X⁵⁵⁹ Breastfeeding: Excreted in milk; decreased quantity and quality of milk,⁵⁶⁰ but compatible [Briggs 1997]⁵⁶¹</p>
Ethisterone	434-03-7	07/10/00	<p>Category D [Briggs 4th]⁵⁶² (case reports of female masculinization [Schardein])⁵⁶³ Breastfeeding: See Oral contraceptives</p>
Ethyl biscoumacetate	548-00-5	06/29/00	<p>Category D [Briggs 4th]⁵⁶⁴ Breastfeeding: Avoid (possible adverse effects on nursing infants [Briggs 4th])⁵⁶⁵</p>
Ethinodiol diacetate	297-76-7	07/10/00	<p>Category D [Briggs 4th]⁵⁶⁶ Breastfeeding: See Oral contraceptives</p>

Drug/Substance	CAS Number	Date Added	Comments/Notes
Etodolac	41340-25-4	03/10/00	Category C ⁵⁶⁷ Possible closure of ductus arteriosus—avoid during late pregnancy ⁵⁶⁸
Etoposide	33419-42-0	09/30/94	Category D ⁵⁶⁹ Breastfeeding: Avoid, ⁵⁷⁰ contraindicated [Briggs 1997] ⁵⁷¹
Etretinate	54350-48-0	06/30/95	Category X [Briggs 4th] ⁵⁷² (small amounts detected more than 2 years after treatment concluded [Facts and Comparisons]) ⁵⁷³ Breastfeeding: Not recommended [USPDI] ⁵⁷⁴
Eulexin®		10/20/00	(See Flutamide)
Everone 200®		10/17/00	(See Testosterone enanthate)
Famciclovir	104227-87-4	06/28/00	Category B [Facts and Comparisons] ⁵⁷⁵ Breastfeeding: Not recommended [Briggs 1997] ⁵⁷⁶
Famvir®		10/20/00	(See Famciclovir)
Fertinex®			(See Urofollitropin)
Finasteride	98319-26-7	06/02/00	Category X [Facts and Comparisons] ⁵⁷⁷ (risk to male fetus); ⁵⁷⁸ women should not handle crushed or broken tablets when pregnant or may potentially be pregnant ⁵⁷⁹ Breastfeeding: Not indicated for use in women ⁵⁸⁰ (not known if excreted in breast milk [Facts and Comparisons]) ⁵⁸¹
Flagyl®			(See Metronidazole)
Floxin®			(See Ofloxacin)
Fluconazole	86386-73-4	09/27/2011	Category D when used in high doses (category C for single 150 mg dose). Brachycephaly, abnormal facies, abnormal calvarial development, cleft palate, femoral bowing, thin ribs and long bones, arthrogyriposis, and congenital heart disease [FDA]. ⁵⁸²
Fludara®		10/20/00	(See Fludarabine)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Fludarabine	21679-14-1	06/28/00	Category D [Facts and Comparisons] ⁵⁸³ Breastfeeding: Contraindicated [Briggs 1997] ⁵⁸⁴
Flunitrazepam		10/17/00	(See Benzodiazepines)
5-Fluorouracil	51-21-8		(See Fluorouracil)
Fluoroquinolones (ciprofloxacin, levofloxacin, norfloxacin, enoxacin, ofloxacin, gatifloxacin, lomefloxacin)	---		Category C Fluoroquinolones should be used during pregnancy only if a safer alternative is not available [PMID: 19181435]. ⁵⁸⁵ Breastfeeding: Avoid [PMID: 19181435]. ⁵⁸⁶
Fluorouracil	51-21-8	09/30/94	Category X ⁵⁸⁷ Breastfeeding: Contraindicated ⁵⁸⁸
Fluoxetine	56296-78-7	11/01/20 17	Ventricular septal defects, right ventricular outflow tract obstruction cardiac defects, and craniosynostosis [BMJ]. ⁵⁸⁹
Fluoxymesterone	76-43-7	06/30/95	Pregnancy: Category X - Use is contraindicated in women who are or may become pregnant. May cause androgenic effects to the female fetus; clitoral hypertrophy, labial fusion, urogenital sinus defect, vaginal atresia, and ambiguous genitalia have been reported [NIOSH]. ⁵⁹⁰ Male: Fertility effects [PMID 137913] ⁵⁹¹ (may be dose dependent [PMID 3435196]) ⁵⁹² Genotoxic effects [PMID 7715612] ⁵⁹³ Category X [Facts and Comparisons] ⁵⁹⁴ Breastfeeding: Avoid [NIOSH]. ⁵⁹⁵

Drug/Substance	CAS Number	Date Added	Comments/Notes
Flurazepam hydrochloride	1172-18-5	06/30/95	<p>Contraindicated in pregnancy⁵⁹⁶ (crosses the placenta, benzodiazepines may cause fetal damage when administered during pregnancy [Facts and Comparisons])⁵⁹⁷ If Benzodiazepines used lorazepam preferred[PMID: 11773648].⁵⁹⁸</p> <p>Breastfeeding: Safety not established [Facts and Comparisons]⁵⁹⁹ Not recommended [PMID: 11773648].⁶⁰⁰</p>
Flutamide	13311-84-7	06/30/95	<p>Male: Reduced sperm counts and spermatogenesis⁶⁰¹</p> <p>Category D⁶⁰²</p> <p>Breastfeeding: Product only indicated for use in males</p>
Fluvastatin	93957-54-1	06/28/00	<p>Category X [Facts and Comparisons]⁶⁰³</p> <p>Breastfeeding: Contraindicated [Briggs 1997]⁶⁰⁴</p>
Folex®		10/20/00	(See Methotrexate)
5-FU	51-21-8		(See Fluorouracil)
Furadantin®			(See Nitrofurantoin)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Gallium ⁶⁷ (67Ga) Gallium ⁶⁸ (68Ga)	7440-55-3		<p>Pregnancy: Category C. No data. Recommend treat 68Ga as 67Ga [Netspot, ⁶⁰⁵ USPDI]. ⁶⁰⁶ Category D: Use may suppress fertility in females, inhibit spermatogenesis in males, and cause birth defects if used in pregnant women. Female patients should undergo pregnancy testing prior to initiation and use effective contraception during and for at least 30 days after therapy. Male patients should use a barrier contraceptive during and for at least 90 days after therapy [NIOSH]. ⁶⁰⁷</p> <p>Breastfeeding: Recommend breastfeeding be interrupted and breast milk discarded for 12 hours after administration [Netspot]. ⁶⁰⁸ Discontinue temporarily (radioactivity in milk present for 2 weeks) [AAP]. ⁶⁰⁹ Not Recommended [NIOSH]. ⁶¹⁰</p>
Ganciclovir	82410-32-0	03/10/00	<p>Category C (may be teratogenic or embryotoxic) ⁶¹¹ Breastfeeding: Discontinue use ⁶¹²</p>
Garamycin®			(Gentamicin) (See Aminoglycosides)
Gatifloxacin		10/20/00	(See Fluoroquinolones)
Gemfibrozil	25812-30-0	03/10/00	<p>Category C ⁶¹³ Breastfeeding: Discontinue [Facts and Comparisons] ⁶¹⁴</p>
Gentamicin	1403-66-3		(See Aminoglycosides)
Goserelin acetate	65807-02-5	03/10/00	<p>Category X (avoid pregnancy for 12 weeks after discontinuing use) ⁶¹⁵ Breastfeeding: Contraindicated ⁶¹⁶</p>
Halazepam	23092-17-3	06/30/95	<p>Category D Category D. If Benzodiazepines used lorazepam preferred [PMID: 11773648]. ⁶¹⁷ Breastfeeding: Not recommended [PMID: 11773648]. ⁶¹⁸</p>
Halcion®			(See Triazolam)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Halotestin®		10/17/00	(See Fluoxymesterone)
HCTZ		10/20/00	(See Hydrochlorothiazide)
Heroin	561-27-3		Pregnancy: Preterm birth [PMID 2304039], ⁶¹⁹ neonatal withdrawal [Williams] ⁶²⁰ Breastfeeding: Contraindicated (tremors, restlessness, vomiting, poor feeding [AAP] ⁶²¹ (excreted in milk [PMID 9363416]) ⁶²²
Hexalen®			(See Altretamine)
Histerone 100®		10/17/00	(See Testosterone)
Histrelin	76712-82-8		(See Histrelin acetate)
Histrelin acetate	---	03/10/00	Category X [Facts and Comparisons] ⁶²³ Breastfeeding: Do not use [Facts and Comparisons] ⁶²⁴
HN ₂		10/20/00	(See Mechlorethamine)
Hormone pregnancy test tablets			Category X [Briggs 4th] ⁶²⁵ Breastfeeding: See Oral contraceptives
Hydrea®		10/20/00	(See Hydroxyurea)
Hydriodic acid	10034-85-2		(See Potassium iodide) (Iodide is the active ingredient) [Briggs 4th] ⁶²⁶
Hydrochlorothiazide	58-93-5	07/10/00	(See Chlorothiazide)
HydroDiuril®		10/20/00	(See Hydrochlorothiazide)
Hydrogen iodide		10/20/00	(See Hydriodic acid)
Hydroxyprogesterone	68-96-2	07/10/00	Category Category C – Indicated for use in the prevention of preterm birth. Avoid in first trimester [PMID: 26921136]. ⁶²⁷ Breastfeeding: Not recommended [PMID: 26921136] ⁶²⁸ (distributed into breast milk) [USPDI] ⁶²⁹
Hydroxyurea	127-07-1		Male: Testicular atrophy, impaired spermatogenesis ⁶³⁰ Category D (embryotoxic, fetal malformations) ⁶³¹ Breastfeeding: Incompatible (excreted in human milk), ⁶³² contraindicated [Briggs 1997] ⁶³³
Hylutin®		10/20/00	(See Hydroxyprogesterone)
Hyprogest 250®		10/20/00	(See Hydroxyprogesterone)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Ibuprofen	15687-27-1	05/30/00	Category B ⁶³⁴ Category D at end of pregnancy (may cause premature closure of ductus arteriosus and delay parturition) [Briggs 4th] ⁶³⁵ Breastfeeding: Compatible [AAP] ⁶³⁶
Idamycin®		10/20/00	(See Idarubicin hydrochloride)
Idarubicin hydrochloride	57852-57-0	03/10/00	Category D (embryotoxic and teratogenic in rats) ⁶³⁷ Breastfeeding: Discontinue prior to taking drug, ⁶³⁸ contraindicated [Briggs 1997] ⁶³⁹
Ifex®		10/20/00	(See Ifosfamide)
Ifosfamide	3778-73-2	09/30/94	Category D ⁶⁴⁰ Breastfeeding: Incompatible, ⁶⁴¹ contraindicated [Briggs 1997] ⁶⁴²
Imuran®		10/17/00	(See Azathioprine)
Imuthiol®		10/20/00	(See Diethyldithiocarbamate)
Indium ¹¹¹ (111In)	7440-74-6		Category C [USPDI] ⁶⁴³ Breastfeeding: Discontinue temporarily (very small amount present at 20 hours) [AAP] ⁶⁴⁴
Indocin®		10/17/00	(See Indomethacin)
Indomethacin	53-86-1		Category B [Briggs 4th] ⁶⁴⁵ Category Category C – indicated for preterm labor. Category D if used for longer than 48 hours or after 30 weeks gestation or close to delivery (may cause premature closure of ductus arteriosus, is associated with fetal anuria, oligohydramnios, persistent pulmonary hypertension [PMID: 27661654]. ⁶⁴⁶ associated with fetal anuria, oligohydramnios, persistent pulmonary hypertension [PMID 9434858] ⁶⁴⁷ Breastfeeding: Not recommended [PMID: 27661654], ⁶⁴⁸ (excreted in milk) ⁶⁴⁹
Iodides	---		(See Iodine)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Iodinated glycerol (anti-tussive/expectorant)	5634-39-9		Category X [Briggs 6 th] ⁶⁵⁰ Breastfeeding: Concentrated in breast milk [Briggs 4th], ⁶⁵¹ but compatible [AAP] ⁶⁵²
Iodine	7553-56-2		Category D [Briggs 4th] ⁶⁵³ Breastfeeding: Not compatible (concentrated in breast milk, and long term use may adversely affect the nursing infant's thyroid activity) [Briggs 1997] ⁶⁵⁴
Iodine ¹²³ (I ¹²³)	15715-08-9		Breastfeeding: Discontinue temporarily (radioactivity in milk present up to 36 hours) [AAP] ⁶⁵⁵
Iodine ¹²⁵ (I ¹²⁵)	14158-31-7		Contraindicated [Merck] ⁶⁵⁶ Breastfeeding: Contraindicated (radioactivity in milk for 12 days) [AAP] ⁶⁵⁷
Iodine ¹³¹ (I ¹³¹)	100043-66-0	03/10/00	Contraindicated [Merck] ⁶⁵⁸ Breastfeeding: Contraindicated (radioactivity in milk for 2 to 14 days) [AAP] ⁶⁵⁹
Isoretinoin	4759-48-2		(See Isotretinoin)
Isotretinoin	4759-48-2	06/30/95	Category X (spontaneous abortions and fetal malformations) [Briggs 4th] ^{660,661} Breastfeeding: Do not give [Facts and Comparisons] ⁶⁶²
Kanamycin sulfate	8063-07-8		Category D [Briggs 4 th]. ⁶⁶³ May cause fetal ototoxicity (based on a case report of high dose kanamycin in pregnancy) [PMID: 4702131]. ⁶⁶⁴ As with any aminoglycoside, can also cause kidney damage. Breastfeeding: Compatible [AAP] ⁶⁶⁵ (excreted in breast milk) [Briggs 4th] ⁶⁶⁶ (See also Aminoglycosides)
Kannasyn®			(See Kanamycin)
Kantrex®		10/17/00	(See Kanamycin)
LDE225			(See Sonidegib)
Lescol®		10/20/00	(See Fluvastatin)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Leukeran®			(See Chlorambucil)
Leuprolide acetate (GnRH analogue)	74381-53-6	03/06/00	Category X ⁶⁶⁷ (but not expected to cause birth defects) Breastfeeding: Do not use ⁶⁶⁸ although no reports of toxicity. Also, GnRH is normally excreted in the milk of humans.
Leustatin®			(See Cladribine)
Levofloxacin		10/20/00	(See Fluoroquinolones)
Levonorgestrel implants (also known as Jadelle and is not available in the US)	797-63-7	03/10/00	Category X ⁶⁶⁹ Breastfeeding: Excreted in breast milk ⁶⁷⁰
Levaquin®			(See Levofloxacin)
Librium®			(See Chlordiazepoxide)
Lithium	7439-93-2		(See Lithium carbonate)
Lithium carbonate	554-13-2	06/30/95	Category D [Briggs 4th] ⁶⁷¹ (cardiac anomalies) ⁶⁷² Breastfeeding: Contraindicated [Briggs 1997]; ⁶⁷³ with caution (one-third to one-half therapeutic blood levels in infants [AAP] ⁶⁷⁴ (excreted in human milk) ⁶⁷⁵
Lithium citrate	919-16-4	06/30/95	(See Lithium carbonate)
Lithostat®		10/16/00	(See Acetohydroxamic acid)
Lodine®		10/20/00	(See Etodolac)
Lomustine	13010-47-4		Category D (embryotoxic and teratogenic in rats) ⁶⁷⁶ Breastfeeding: Not recommended (unknown if excreted in human milk) ⁶⁷⁷
Lopid®		10/20/00	(See Gemfibrozil)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Lorazepam	846-49-1	06/30/95	Category D [Briggs 4th]. Does not appear to be associated with any risk of birth defects. If administered near delivery, may lead to sedation, decreased tone, and respiratory depression in the infant. Breastfeeding: Excreted in breast milk in low concentrations [Briggs 4th], ⁶⁷⁸ effect may be of concern [AAP] ⁶⁷⁹ Probably safe. This is secreted in the milk but at lower doses than through the placenta. May lead to poor feeding or drowsiness.
Lomefloxacin		10/20/00	(See Fluoroquinolones)
Lotensin®			(Benazepril) (See ACE Inhibitors)
Lovastatin	75330-75-5	06/30/95	Category X ⁶⁸⁰ (Based on human data, there is no increased risk of birth defects. However, due to a theoretical concern for the effects of preventing cholesterol formation (as the fetus is completely dependent on maternal cholesterol) as well as lack of benefit for treating maternal hyperlipidemia while pregnant, this drug is generally not given in pregnancy. Note: There are research protocols ongoing now looking at statin use for prevention of preeclampsia in pregnancy, so this class of medicine may be more widely used in the future.) Breastfeeding: Contraindicated ⁶⁸¹
L-PAM		10/20/00	(See Melphalan)
L-Phenylalanine Mustard		10/20/00	(See Melphalan)
L-Sarcosylsin		10/20/00	(See Melphalan)
Macrodantin	67-20-9		(See Nitrofurantoin)
Marcoumar®		10/20/00	(See Phenprocoumon)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Marijuana	---	06/28/00	Pregnancy: "Because of concerns regarding impaired neurodevelopment, as well as maternal and fetal exposure to the adverse effects of smoking, women who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use" [PMID: 28937574]. ⁶⁸² Breastfeeding: "There are insufficient data to evaluate the effects of marijuana use on infants during lactation and breastfeeding, and in the absence of such data, marijuana use is discouraged" [PMID: 28937574]. ⁶⁸³
Matulane®		10/20/00	(See Procarbazine hydrochloride)
Maxaquin®			(See Lomefloxacin)
MDMA			(See N-Methyl-3,4-methylenedioxy-amphetamine)
Measles vaccine, live	---		Category C, but contraindicated in pregnancy, and pregnancy should be avoided for 3 months after vaccination (natural measles is associated with spontaneous abortion, stillbirth, congenital defects, premature delivery) ⁶⁸⁴ Breastfeeding: With caution ⁶⁸⁵
Mebaral®		10/17/00	(See Barbiturates) (Mephobarbital)
Mechlorethamine	51-75-2		Category D (can cause fetal harm) ⁶⁸⁶ Breastfeeding: Incompatible ⁶⁸⁷
Medroxyprogesterone acetate	71-58-9	06/30/95	Category D [Briggs 4th] ⁶⁸⁸ (may cause hypospadias) ⁶⁸⁹ Breastfeeding: Compatible [AAP] ⁶⁹⁰
Megace®		10/20/00	(See Megestrol acetate)
Megestrol acetate	595-33-5	06/30/95	Category X (genital abnormalities) ⁶⁹¹ Breastfeeding: Discontinue ⁶⁹²
Melphalan	148-82-3	06/30/95	Category D ⁶⁹³ Breastfeeding: Discontinue ⁶⁹⁴
Menadiol	---		(See Menadione)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Menadiol sodium diphosphate	---		(See Menadione)
Menadione	58-27-5		Category C [Briggs 4th] ⁶⁹⁵ Category X (in third trimester or close to delivery) [Briggs 5th] ⁶⁹⁶ Breastfeeding: Vitamin K ₁ preferred (may produce newborn toxicity) [Briggs 5th] ⁶⁹⁷ [Drug Information Handbook] ⁶⁹⁸
Menotropins	9002-68-0	06/30/95	Category X ⁶⁹⁹ Breastfeeding: With caution ⁷⁰⁰
Mephobarbital		10/17/00	(See Barbiturates)
Meprobamate	57-53-4	06/30/95	Category D [Briggs 4th] ⁷⁰¹ Breastfeeding: Concentrated in milk [Briggs 4th], ⁷⁰² may cause sedation in the nursing infant [USPDI] ⁷⁰³
6-Mercaptopurine	50-44-2		(See Mercaptopurine)
Mercaptopurine	6112-76-1	06/30/95	Category D (can cause fetal harm, including spontaneous abortion and possibly death in utero) ⁷⁰⁴ Breastfeeding: Discontinue ⁷⁰⁵
Meruvax® II			(See Rubella vaccine, live)
Mestranol	72-33-3		Category X ⁷⁰⁶ Breastfeeding: Discouraged (excreted in milk, may cause jaundice and breast enlargement in nursing children) ⁷⁰⁷
Methacycline hydrochloride	3963-95-9	06/30/95	Category D [Briggs 5th] ⁷⁰⁸ [Briggs 4th] ⁷⁰⁹ Breastfeeding: See Tetracycline hydrochloride (excreted in milk in low concentration; theoretical dental staining and inhibition of bone growth)
Methandriol	521-10-8	07/10/00	(See Androgens)
Metharbital		10/17/00	(See Barbiturates)
Methimazole	60-56-0	06/30/95	Category D [Briggs 4th] ⁷¹⁰ (may cause fetal harm and congenital defects) ⁷¹¹ Breastfeeding: Contraindicated (appears in human milk) ⁷¹²

Drug/Substance	CAS Number	Date Added	Comments/Notes
Methotrexate	59-05-2	09/30/94	Category D [Briggs 4th] ⁷¹³ Breastfeeding: Contraindicated [Briggs 1997] ⁷¹⁴ (possible immune suppression [AAP] ⁷¹⁵)
Methotrexate sodium	15475-56-6	06/30/95	(See Methotrexate)
Methoxsalen	298-81-7	06/28/00	Category C [Facts and Comparisons] ⁷¹⁶ [Briggs 5th] ⁷¹⁷ Breastfeeding: Contraindicated [Briggs 1997] ⁷¹⁸
8-Methoxypsoralen		10/20/00	(See Methoxsalen)
Methylene blue	61-73-4		Category C Category D if injected intra-amniotically [Briggs 4th] ⁷¹⁹ (hemolytic anemia, jaundice, intestinal atresia with intra-amniotic injection [PMID 9434858]) ⁷²⁰
N-Methyl-3,4-methylene-dioxyamphetamine		07/27/00	(See Amphetamines)
Methyltestosterone	58-18-4	06/30/95	Category X ⁷²¹ Breastfeeding: Contraindicated ⁷²²
Methylthiouracil	56-04-2	07/10/00	Pregnancy: Malformations, including one report of retarded ossification [Schardein] ⁷²³
Metrodin®			(See Urofollitropin)
Metronidazole	443-48-1	06/09/00	Category B ⁷²⁴ per manufacturer: Contraindicated in first trimester ⁷²⁵ . However, an investigation found “no association between metronidazole treatment during the first or later trimesters of pregnancy and preterm birth, low birth weight, or congenital anomalies” [PMID: 22751543]. ⁷²⁶ Breastfeeding: Discontinue ⁷²⁷ (excreted in breast milk [Briggs 4th]) ⁷²⁸ Some investigators believe it may be safely used in lactation [PMID: 10845129]. ⁷²⁹
Mevacor®		10/20/00	(See Lovastatin)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Midazolam hydrochloride	59467-96-8	06/30/95	Category D ⁷³⁰ Breastfeeding: With caution (excreted in human milk) ⁷³¹
Mifepristone	84371-65-3		Category X [Briggs 5th] ⁷³² (abortifacient) [PMID 6744860] ⁷³³ Fetal malformations [PMID: 27865944]. ⁷³⁴ Breastfeeding: Minimally excreted in primate milk [PMID 8314974] ⁷³⁵ Probably can be used during lactation [PMID: 20367522]. ⁷³⁶
MIH		10/20/00	(See Procarbazine hydrochloride)
Miltown®		10/20/00	(See Meprobamate)
Minocin®			(See Minocycline hydrochloride)
Minocycline	10118-90-8		(See Minocycline hydrochloride)
Minocycline hydrochloride (internal use)	13614-98-7	06/30/95	Category D ⁷³⁷ Breastfeeding: Discontinue (excreted in human milk) ⁷³⁸
Miradon®		10/17/00	(See Anisindione)
Misoprostol	59122-46-2	06/30/95	Category X [Briggs 6th] ⁷³⁹ (abortifacient, may cause congenital anomalies) ⁷⁴⁰ Breastfeeding: Contraindicated [Briggs 1997] ^{741,742}
Mithracin®			(See Plicamycin)
Mitomycin	50-07-7	06/28/00	Pregnancy: Safety not established (teratological changes in animals) [Facts and Comparisons] ⁷⁴³ Breastfeeding: Contraindicated [Briggs 1997] ⁷⁴⁴
Mitomycin-C		10/20/00	(See Mitomycin)
Mitoxantrone hydrochloride	70476-82-3	09/30/94	Category D (may cause fetal harm) ⁷⁴⁵ Breastfeeding: Discontinue ⁷⁴⁶ Contraindicated [PMID: 22926165]. ⁷⁴⁷
Modrastane®			(See Trilostane)
Monopril®			(Fosinopril) (See ACE Inhibitors)
8-MOP		10/20/00	(See Methoxsalen)
Motrin®		10/20/00	(See Ibuprofen)
MTC		10/20/00	(See Mitomycin)
MTX®		10/20/00	(See Methotrexate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Mumps vaccine, live	---		Category C, but contraindicated in pregnancy, and pregnancy should be avoided for 3 months after vaccination ⁷⁴⁸ Breastfeeding: With caution ⁷⁴⁹
Mustargen®			(See Mechlorethamine)
Mutamycin®		10/20/00	(See Mitomycin)
Mycifradin®		10/20/00	(See Neomycin sulfate)
Myleran®			(See Busulfan)
Mysoline®		10/20/00	(See Primidone)
Nadrobolic®		10/17/00	(See Anabolic steroids) (Nandrolone)
Nafarelin acetate	86220-42-0	06/30/95	Category X (may cause fetal harm) ⁷⁵⁰ Breastfeeding: Contraindicated ⁷⁵¹
Nandrolone		10/17/00	(See Anabolic steroids)
Narcotic analgesics	---		Pregnancy: Associated with neonatal withdrawal syndrome. Breastfeeding: Discouraged (morphine is excreted in milk) ⁷⁵² may cause sedation. (Also see Heroin , Alfentanil)
Nebcin®			(See Tobramycin sulfate)
Nembutal®			(See Pentobarbital sodium)
Neo-mens®			(See Ethinisterone)
Neomycin sulfate (oral)	1405-10-3	06/30/95	Category D [Facts and Comparisons] ⁷⁵³ Breastfeeding: Discontinue [Facts and Comparisons], ⁷⁵⁴ compatible [Briggs 1997] ⁷⁵⁵ See also Kanamycin .
Neoral®		10/17/00	(See Cyclosporin)
Neotigason®		11/20/2000	(See Acitretin)
Netilmicin sulfate	56391-57-2	06/30/95	Category D (can cause fetal harm) ⁷⁵⁶ Breastfeeding: Discontinue ⁷⁵⁷
Netromycin®			(See Netilmicin sulfate)
Neutrexin®			(See Trimetrexate glucuronate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Nicotine	54-11-5	06/30/95	<p>Inconsistent ratings. "If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking." (Glaxo).⁷⁵⁸</p> <p>Category X (nicotine polacrilex [Facts and Comparisons])⁷⁵⁹</p> <p>Category D (nasal spray; can cause fetal harm,⁷⁶⁰ transdermal nicotine [Facts and Comparisons])⁷⁶¹</p> <p>Breastfeeding: Use with caution (excreted in milk)⁷⁶² [Briggs 1997],⁷⁶³ (decrease in milk production and weight gain in the infant [AAP],⁷⁶⁴ discontinue [Facts and Comparisons])⁷⁶⁵</p>
Nicotrol®			(See Nicotine)
Nipent®			(See Pentostatin)
Nitrofurantoin	67-20-9	06/30/95	<p>Category B⁷⁶⁶</p> <p>Contraindicated at term (38-42 weeks gestation), during labor and delivery, or when the onset of labor is imminent⁷⁶⁷</p> <p>Breastfeeding: Discontinue in infants under one month of age (excreted in trace amounts in human milk)⁷⁶⁸</p>
Nitrogen mustard	51-75-2	09/30/94	(See Mechlorethamine)
Nitrogen mustard hydrochloride	55-86-7	06/30/95	(See Mechlorethamine)
N-Methyl-3,4-methylenedioxymphetamine			(See listing alphabetically under "Methyl" as N-Methyl-3,4-methylenedioxymphetamine)
N-Methylhydrazine		10/20/00	(See Procarbazine hydrochloride)
Nolvadex®			(See Tamoxifen citrate)
Non-steroidal anti-inflammatory indene derivatives			(See NSAIDs)

Drug/Substance	CAS Number	Date Added	Comments/Notes
norethindrone/ethinyl estradiol	68-22-4/ 57-63-6	06/30/95	Category X ⁷⁶⁹ Breastfeeding: Discouraged (appears in human milk and may cause adverse effects in the child) ⁷⁷⁰ (See also Mestranol)
norethindrone/mestranol	68-22-4/ 72-33-3	06/30/95	Category X ⁷⁷¹ Breastfeeding: Discouraged (appears in human milk and may cause adverse effects in the child) ⁷⁷² (See also Mestranol)
Norethynodrel	68-23-5		Category X [Briggs 4th] ⁷⁷³ Breastfeeding: See Oral contraceptives (See also Mestranol)
Norfloxacin		10/20/00	(See Fluoroquinolones)
Norgestimate/ethinyl estradiol	35189-28- 7/ 57-63-6	06/01/00	Category X ⁷⁷⁴ Breastfeeding: Discouraged (appears in human milk and may cause adverse effects in the child) ⁷⁷⁵ (See also Mestranol)
Norgestrel/ethinyl estradiol	797-63-7/ 57-63-6	06/30/95	Category X ⁷⁷⁶ Breastfeeding: Discouraged (appears in human milk and may cause adverse effects in the child) ⁷⁷⁷ (See also Mestranol)
Norinyl 1+35 [®]		10/20/00	(See NORETHINDRONE/ETHINYL estradiol)
Norinyl 1+50 [®]		10/20/00	(See NORETHINDRONE/MESTRANOL)
Normethandrone		07/10/00	(See Androgens)
Noroxin [®]			(See Ofloxacin)
Norplant [®] System		10/20/00	(See Levonorgestrel implants)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Nortriptyline hydrochloride	894-71-3		<p>Pregnancy: Can probably be used [PMID: 22283766],⁷⁷⁸ although previously designated as Category D [Briggs 4th]⁷⁷⁹ (safe use not established, transferred through human placenta, case reports of fetal harm—decreased muscle tone, decreased sensitivity to painful stimuli, abnormal EKG in an infant born to a mother who had taken 1.5 to 1.75 grams [PMID 5017806],⁷⁸⁰ urinary retention [PMID 5049831],⁷⁸¹ lower limb deformity with therapeutic doses [PMID 4129246]⁷⁸²)⁷⁸³</p> <p>Breastfeeding: Can probably be used [PMID: 22283766],⁷⁸⁴ although excreted into breast milk [Briggs 4th]⁷⁸⁵</p>
Novantrone®			(See Mitoxantrone hydrochloride)
NSAIDs (ibuprofen, indomethacin, sulindac)	---		<p>Category B (ketoprofen, naproxen, flurbiprofen, diclofenac) [Facts and Comparisons]⁷⁸⁶</p> <p>Category C (etodolac, ketorolac, mefenamic acid, nabumetone, oxaprozin, tolmetin) [Facts and Comparisons]⁷⁸⁷</p> <p>Use during the third trimester of pregnancy may cause fetal harm (including constriction of the ductus arteriosus prenatally, tricuspid incompetence, pulmonary hypertension, platelet dysfunction, intracranial bleeding, renal dysfunction, gastrointestinal bleeding)⁷⁸⁸</p> <p>Breastfeeding: Do not use in nursing mothers [Facts and Comparisons]⁷⁸⁹</p>
Odomzo®			(See Sonidegib)
Ofloxacin		10/20/00	(See Fluoroquinolones)
Ogen®		10/20/00	(See Estropipate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Omeprazole	73590-58-6	06/28/00	Category C [Briggs 4th] ⁷⁹⁰ Breastfeeding: Contraindicated [Briggs 1997] ⁷⁹¹
Oncovin®			(See Vincristine sulfate)
Oral contraceptives	---		Category X [Briggs 4th] ⁷⁹² Breastfeeding: Compatible (rare breast enlargement; decrease in milk production and protein content [AAP] ⁷⁹³
Oretic®		10/20/00	(See Hydrochlorothiazide)
Oretonmethyl®		10/17/00	(See Methyltestosterone)
Ortho-Cyclen®			(See Norgestimate/ethinyl estradiol)
Ortho-Dienestrol®		10/17/00	(See Dienestrol)
Ortho-Est®		10/20/00	(See Estropipate)
Ortho-Novum 1/35®		10/20/00	(See NORETHINDRONE/ETHINYL estradiol)
Ortho-Novum 1/50®		10/20/00	(See NORETHINDRONE/MESTRANOL)
Ortho-Tri-Cyclen®			(See Norgestimate/ethinyl estradiol)
Ovcon®		10/20/00	(See NORETHINDRONE/ETHINYL estradiol)
Ovral®		10/20/00	(See Norgestrel/ethinyl estradiol)
Oxandrin®		10/17/00	(See Anabolic steroids) (Oxandrolone)
Oxandrolone		10/17/00	(See Anabolic steroids)
Oxazepam		10/17/00	(See Benzodiazepines)
Oxazolidinedione anticonvulsants (paramethadione, trimethadione)	---	07/10/00	Category X [Schardein] ⁷⁹⁴
Oxsoralen®		10/20/00	(See Methoxsalen)
Oxymetholone	434-07-1	03/10/00	Category X (can cause fetal harm) ⁷⁹⁵ Breastfeeding: Discontinue ⁷⁹⁶ (Also see Anabolic steroids)
Oxytetracycline	79-57-2		Category D [Briggs 4th] ⁷⁹⁷ (use in the last half of pregnancy may permanently discolor the teeth of the fetus) ⁷⁹⁸ Breastfeeding: See Tetracycline hydrochloride (present in human milk) ⁷⁹⁹

Drug/Substance	CAS Number	Date Added	Comments/Notes
Oxytetracycline hydrochloride (internal use)	2058-46-0	06/30/95	(See Oxytetracycline)
Paclitaxel	33069-62-4	03/10/00	Category D (can cause fetal harm) ⁸⁰⁰ Breastfeeding: Discontinue ⁸⁰¹
L-PAM		10/20/00	(See Melphalan)
Pamelor®			(See Nortriptyline)
Paradione®		10/20/00	(See Oxazolidinedione anticonvulsants)) (Paramethadione)
Paradione®		10/20/00	(See Paramethadione)
Paramethadione	115-67-3	06/30/95	Category D [Briggs 4th] ⁸⁰² (fetal methadione syndrome [PMID 50427] ⁸⁰³ [PMID 412416] ⁸⁰⁴) (See also Oxazolidinedione anticonvulsants)
Paraplatin®	41575-94-4		(See Carboplatin)
Parlodel®		10/17/00	(See Bromocriptine)
Paroxetine	78246-49-8	11/01/20 17	Anencephaly, atrial septal defects, right ventricular outflow tract obstruction cardiac defects, gastroschisis, and omphalocele [BMJ]. ⁸⁰⁵
Paxipam®		10/20/00	(See Halazepam)
PBZ®		10/20/00	(See Tripeleppamine)
PCP	60124-79-0		(See Phencyclidine)
Pelamine®		10/20/00	(See Tripeleppamine)
Penetrex®			(See Enoxacin)
dl-Penicillamine	52-66-4		(See Penicillamine)
Penicillamine (dl-Penicillamine)	52-66-4		Category X (except in treatment of Wilson's Disease or certain cases of cystinuria) ^{806, 807} Category D [Briggs 5th] ⁸⁰⁸ (in treatment of Wilson's Disease and certain cases of cystinuria) ^{809, 810} Breastfeeding: Contraindicated ^{811, 812}
Pentobarbital sodium	57-33-0	06/30/95	Category D (can cause fetal damage and withdrawal symptoms) ⁸¹³ Breastfeeding: With caution (small amounts excreted in milk) ⁸¹⁴ (See also Barbiturates)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Pentostatin	53910-25-1	03/10/00	Category D [Facts and Comparisons] ⁸¹⁵ (can cause fetal harm) ⁸¹⁶ Breastfeeding: Discontinue ⁸¹⁷ [Facts and Comparisons] ⁸¹⁸
Pertix®		10/20/00	(See Menadione)
Phenacemide	63-98-9	06/30/95	Category D [Facts and Comparisons] ⁸¹⁹ Breastfeeding: Discontinue [Facts and Comparisons] ⁸²⁰
Phencyclidine	60124-79-0		Category X [Briggs 4th] ⁸²¹ (hallucinogen with no legitimate use) Breastfeeding: Contraindicated [AAP] ⁸²²
Phenindione	83-12-5	06/30/00	Category D [Briggs 4th] ⁸²³ Breastfeeding: Contraindicated (increased prothrombin and partial thromboplastin time in one infant; not use in United States) [AAP] ⁸²⁴
Phenobarbital	50-06-6		Category D [Briggs 4th] ⁸²⁵ (manufacturer notes Category C) ⁸²⁶ Breastfeeding: With caution; ⁸²⁷ should not be given (sedation, infantile spasms after weaning from milk containing phenobarbital, one reported case of methemoglobinemia [AAP] ⁸²⁸ (See also Barbiturates)
Phenprocoumon	435-97-2	06/30/95	Category D [Briggs 4th] ⁸²⁹ (may cause fetal harm, including CNS malformations and hearing disorder [PMID 8147045]) ⁸³⁰ Breastfeeding: Avoid [Briggs 4th] ⁸³¹
Phenurone®			(See Phenacemide)
L-Phenylalanine mustard		10/20/00	(See Melphalan)
Phenylbutazone	50-33-9	07/10/00	Category C [Briggs 4th] ⁸³² Category D if used in the third trimester [Briggs 4th] ⁸³³ Breastfeeding: Compatible [AAP] ⁸³⁴ (excreted in breast milk [Briggs 4th]) ⁸³⁵

Drug/Substance	CAS Number	Date Added	Comments/Notes
Phenytoin	57-41-0		Category D [Briggs 6 th] ⁸³⁶ (possible fetal hydantoin syndrome) ⁸³⁷ Breastfeeding: Not recommended (secreted in low concentrations in human milk), ⁸³⁸ usually compatible (one case of methemoglobinemia reported [AAP] ⁸³⁹)
Phenytoin sodium	630-93-3		(See Diphenylhydantoin)
Pindione [®]		10/20/00	(See Phenindione)
Piperazine estrone sulfate	7280-37-7		(See Estropipate)
Pipobroman	54-91-1	06/30/94	(Antimetabolite) Animal data: Developmental: [PMID 4504975] ⁸⁴⁰ Breastfeeding: Contraindicated [Briggs 1997] ⁸⁴¹
Platinol [®] -AQ			(See Cisplatin)
Plicamycin	18378-89-7	09/30/94	Category X (may cause fetal harm) ⁸⁴² Breastfeeding: Discontinue ⁸⁴³
Potassium iodide	7681-11-0		Category D (can cause fetal harm) ⁸⁴⁴ Breastfeeding: Compatible [AAP] ⁸⁴⁵ (excreted in breast milk, may cause skin rash and thyroid suppression in the infant) ⁸⁴⁶
Povidone-iodine	25655-41-8		Category D [Briggs 4 th] ⁸⁴⁷ (do not use vaginally or in broken skin during pregnancy, may be used as a surgical prep for C-section; ⁸⁴⁸ can cause fetal harm [PMID 7431610]) ⁸⁴⁹ Breastfeeding: Compatible [AAP] ⁸⁵⁰ do not use vaginally or in broken skin (can cause fetal harm) ⁸⁵¹
Pravachol [®]			(See Pravastatin sodium)
Pravastatin sodium	81131-70-6	03/10/00	Category X ⁸⁵² Breastfeeding: Contraindicated (small amount excreted in human milk) ⁸⁵³
Premarin [®]			(See Conjugated estrogens)
Prilosec [®]		10/20/00	(See Omeprazole)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Primidone	125-33-7		<p>Category D [Briggs 4th]⁸⁵⁴ (minor dysmorphic features—possibly a “fetal primidone syndrome” [PMID 9434858],⁸⁵⁵ neonatal hemorrhage; prophylactic vitamin K₁ advised for one month prior to and during delivery)⁸⁵⁶</p> <p>Breastfeeding: Discontinue nursing in the presence of undue somnolence and drowsiness in nursing newborns⁸⁵⁷ (appears in breast milk in substantial quantities [Facts and Comparisons]),⁸⁵⁸ use with caution (sedation, feeding problems [AAP]⁸⁵⁹)</p>
Prinivil®			(Lisinopril) (See ACE Inhibitors)
Procarbazine	671-16-9		(See Procarbazine hydrochloride)
Procarbazine hydrochloride	366-70-1	06/30/95	<p>Male: Azoospermia⁸⁶⁰</p> <p>Category D (can cause fetal harm)⁸⁶¹</p> <p>Breastfeeding: Do not nurse⁸⁶²</p>
Progesterone	57-83-0	07/10/00	(See Hydroxyprogesterone)
Propecia®			(See Finasteride)
Propylthiouracil	51-52-5	06/30/95	<p>Category D (can cause fetal harm)⁸⁶³</p> <p>Breastfeeding: Contraindicated (excreted in human milk)⁸⁶⁴</p>
Proscar®		10/20/00	(See Finasteride)
Prosom®		10/20/00	(See Estazolam)
Provera®		10/20/00	(See Medroxyprogesterone acetate)
Prozac®			(See Fluoxetine)
PTU		10/20/00	(See Propylthiouracil)
Purinethol®			(See Mercaptopurine)
Pyrimethamine	58-14-0	03/10/00	<p>Category C (concurrent administration of folic acid strongly recommended when used for the treatment of toxoplasmosis during pregnancy; teratogenic in rats)⁸⁶⁵</p> <p>Breastfeeding: Discontinue (excreted in human milk)⁸⁶⁶</p>

Drug/Substance	CAS Number	Date Added	Comments/Notes
Quazepam	36735-22-5	03/10/00	Category X [Facts and Comparisons] ⁸⁶⁷ [USPDI] ⁸⁶⁸ Breastfeeding: See Benzodiazepines
Quinine	130-95-0		(See Quinine sulfate)
Quinine sulfate			Category X ⁸⁶⁹ (uterine contraction activity with doses higher than recommended, malformations with large doses) [Facts and Comparisons] ⁸⁷⁰ Breastfeeding: With caution (excreted in breast milk in small amounts), ⁸⁷¹ infants with G-6-PD should not breastfeed [Briggs 1997] ⁸⁷²
Radioactive sodium		06/28/00	Breastfeeding: Contraindicated [Briggs 1997] ⁸⁷³ (radioactivity in milk present 96 hours [AAP] ⁸⁷⁴)
Restoril®		10/17/00	(See Temazepam)
Retinoic acid	302-79-4		Category C (applied to skin) [Facts and Comparisons] ⁸⁷⁵ Pregnancy: Oral (internal) exposure teratogenic (Retinoic acid embryopathy [PMID 3162101] ⁸⁷⁶ [PMID 1438063]) ⁸⁷⁷ Breastfeeding: With caution [Facts and Comparisons] ⁸⁷⁸ (See also Isotretinoin , Tretinoin)
Retinol	68-26-8	06/30/95	(See Vitamin A)
Retinyl esters			(See Vitamin A)
Ribavirin	36791-04-5	09/30/94	Category X (may cause fetal harm) ⁸⁷⁹ Breastfeeding: Discontinue ⁸⁸⁰
Rocaltrol®		10/17/00	(See Calcitriol)
Rohypnol®			(See Flunitrazepam)
Randomycin®		10/20/00	(See Methacycline hydrochloride)
RU-486®		10/20/00	(See Mifepristone)
Rubella vaccine, live			Contraindicated (Category C) ⁸⁸¹ Breastfeeding: With caution (live virus secreted in milk and may be transmitted to breast-fed infant) ⁸⁸²
Sandimmune®		10/17/00	(See Cyclosporin)
L-Sarcosylsin		10/20/00	(See Melphalan)
Secobarbital	309-43-3	06/30/95	(See Barbiturates)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Seconal®		10/17/00	(See Barbiturates) (Secobarbital)
Selective serotonin reuptake inhibitors (SSRIs)		09/28/2009	Septal heart defects with sertaline and citalopram (but not other SSRIs) [PMID 19776103] ⁸⁸³
Septra®			(See Sulfonamides)
Serax®		10/17/00	(See Benzodiazepines) (Oxazepam)
Sertaline	79617-96-2	09/28/2009	Septal heart defects [PMID 19776103] ⁸⁸⁴
Simvastatin	79902-63-9	06/07/00	Category X ⁸⁸⁵ [Briggs 6 th] ⁸⁸⁶ (skeletal abnormalities in animals) [Facts and Comparisons] ⁸⁸⁷ Breastfeeding: Contraindicated ⁸⁸⁸
Smallpox vaccine		07/10/00	Category X [Schardein] ⁸⁸⁹
Sonidegib	1218778-77-8	07/28/2015	Potential risk for severe birth defects or death to fetuses. Embryo-fetal death or severe birth defects when administered to a pregnant woman. In animal reproduction studies, oral administration of sonidegib during organogenesis at doses below the recommended human dose of 200 mg resulted in embryotoxicity, fetotoxicity, and teratogenicity in rabbits. Teratogenic effects observed included severe midline defects, missing digits, and other irreversible malformations [FDA]. ⁸⁹⁰
Sodium (radioactive)		06/28/00	(See Radioactive sodium)
Sodium iodide	7681-82-5		(See Iodine)
Sodium iodide ¹²⁵			(See Iodine¹²⁵)
Sodium iodide ¹³¹			(See Iodine¹³¹)
Sonidegib	1218778-77-8		
Soriatane®		11/20/2000	(See Acitretin)
Stanozolol	10418-03-8	06/08/00	Category X (can cause fetal harm) ⁸⁹¹ Breastfeeding: Discontinue ⁸⁹²
Streptomycin	57-92-1	06/07/00	(See Streptomycin sulfate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Streptomycin sulfate	3810-74-0	06/30/95	Category D (can cause fetal harm) ⁸⁹³ Breastfeeding: Discontinue ⁸⁹⁴ (See also Aminoglycosides)
Streptozocin (streptozotocin)	18883-66-4	03/10/00	Category D ⁸⁹⁵ Breastfeeding: Discontinue ⁸⁹⁶
Styptobion®		10/20/00	(See Menadione)
Sulfamethoxazole			(See Sulfonamides)
Sulfonamides	---		Contraindicated (Category C) (may cause kernicterus) ⁸⁹⁷ Breastfeeding: Contraindicated (excreted in milk and may cause kernicterus) ⁸⁹⁸
Sulindac	38194-50-2	03/10/00	(See NSAIDs) Not recommended ⁸⁹⁹ Breastfeeding: Should not be undertaken ⁹⁰⁰
Supprelin®			(See Histrelin acetate)
Synarel®			(See Nafarelin acetate)
Synkavite®		10/20/00	(See Menadione)
Tabloid®			(See Thioguanine)
TACE®			(See Chlorotrianisene)
Tamoxifen citrate	54965-24-1	06/30/95	Category D (may cause fetal harm) ⁹⁰¹ Breastfeeding: Discontinue ⁹⁰²
Tapazole®			(See Methimazole)
Technitium ⁹⁹			Category X Breastfeeding: Contraindicated [Briggs 1997] ⁹⁰³ (radioactivity in milk for 15 hours to 3 days [AAP] ⁹⁰⁴)
Tegison®		10/20/00	(See Etretinate)
Tegretol®		10/17/00	(See Carbamazepine)
Temazepam	846-50-4	06/30/95	Category X (contraindicated) ⁹⁰⁵ Breastfeeding: With caution ⁹⁰⁶ (See also Benzodiazepines)
Teniposide	29767-20-2		Category D (may cause fetal harm) ⁹⁰⁷ Breastfeeding: Discontinue ⁹⁰⁸
Tenoretic®			(See Atenolol and Chlorothiazide) (Atenolol and Hydrochlorothiazide)
Tenormin®			(See Atenolol)
Terramycin®			(See Oxytetracycline)
Tesanone®		10/17/00	(See Testosterone)
Testandro®		10/17/00	(See Testosterone)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Testoderm®			(See Testosterone)
Testosterone	58-22-0	06/07/00	Category X (may cause fetal harm) ⁹⁰⁹ Breastfeeding: Contraindicated ⁹¹⁰
Testosterone cypionate	58-20-8	06/30/95	Contraindicated (may cause virilization of the external genitalia of the female fetus) ⁹¹¹ Breastfeeding: Contraindicated ⁹¹²
Testosterone enanthate	315-37-7	06/30/95	Category X (contraindicated, may cause virilization of the external genitalia of the female fetus) ⁹¹³ Breastfeeding: Discontinue ⁹¹⁴
Testosterone propionate		10/17/00	(See Testosterone)
Testred®		10/17/00	(See Methyltestosterone)
Tetracycline	60-54-8		(See Tetracycline hydrochloride)
Tetracycline hydrochloride (internal use)	64-75-5	06/30/95	Category D [Briggs 6 th] ⁹¹⁵ (may cause fetal harm) ⁹¹⁶ Breastfeeding: Compatible [AAP] ⁹¹⁷ (present in the milk of lactating women, ⁹¹⁸ but negligible absorption by infant [Briggs 4 th]) ⁹¹⁹
Tequin®			(See Gatifloxacin)
Thalidomide	50-35-1	06/30/95	Category X (may cause fetal harm) ⁹²⁰ Males: Contraindicated in males having intercourse with fertile females without barrier protection (i.e., males must use latex condoms to prevent exposing pregnant or potentially pregnant females to thalidomide in semen) ⁹²¹ Breastfeeding: Discontinue ⁹²²
Thalomid®			(See Thalidomide)
Thioguanine	154-42-7	06/30/95	Category D (may cause fetal harm) ⁹²³ Breastfeeding: Discontinue ⁹²⁴
Thioplex®			(See Thiotepa)
Thiotepa	52-24-4		Category D (can cause fetal harm) ⁹²⁵ Breastfeeding: Discontinue ⁹²⁶
Thiouracil	141-90-2	07/10/00	(See Propylthiouracil)
Thyreostat®		10/20/00	(See Methylthiouracil)
Tobramycin	32986-56-4		(See Tobramycin sulfate)
Tobramycin sulfate	49842-07-1	06/30/95	Category D ⁹²⁷ (See Aminoglycosides)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Topiramate	97240-79-4	02/26/2014	Category D (cleft lip and/or palate) [Janssen] Low birth weight (PMID 24463659) ⁹²⁸
Toxol®			(See Paclitaxel)
Tranxene®		10/17/00	(See Benzodiazepines) (Chlorazepate)
Tretinoin	302-79-4		(See Isotretinoin)
Triazolam	28911-01-5	06/30/95	Category X ⁹²⁹ Breastfeeding: Not recommended ⁹³⁰ (See also Benzodiazepines)
Tridione®		10/20/00	(See Oxazolidinedione anticonvulsants) (Trimethadione)
Tridione®		10/20/00	(See Trimethadione)
Trilostane	13647-35-3	06/30/95	Fertility: Reversible gonadal function [USPDI] ⁹³¹ Category X (reduces circulating progesterone, produces cervical dilation, may terminate pregnancy) [USPDI] ⁹³² Breastfeeding: Problems have not been documented [USPDI] ⁹³³
Trimethadione	127-48-0	06/30/95	Category D [Briggs 4th] ⁹³⁴ (fetal trimethadione syndrome [PMID 50427]). ⁹³⁵ growth retardation, microcephaly, cleft lip/palate, unusual facies, cardiovascular malformations [PMID 9434858]) ⁹³⁶ (See Oxazolidinedione anticonvulsants)
Trimetrexate glucuronate	82952-64-5	03/10/00	Category D (can cause fetal harm) ⁹³⁷ Breastfeeding: Discontinue ⁹³⁸
Tripelennamine	91-81-6		Category B [Briggs 4th] ⁹³⁹ Breastfeeding: Contraindicated [Briggs 4th] ⁹⁴⁰ (excreted in breast milk [Facts and Comparisons]) ⁹⁴¹
Tromexane®			(See Ethyl biscoumacetate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Uracil mustard	66-75-1	06/30/95	Male: Azoospermia [USPDI] ⁹⁴² Female: Amenorrhea [USPDI] ⁹⁴³ Pregnancy: Avoid [USPDI] ⁹⁴⁴ Breastfeeding: Not recommended (risks of adverse effects, mutagenicity, carcinogenicity) [USPDI] ⁹⁴⁵
Uramustine®		10/20/00	(See Uracil mustard)
Urofollitropin	26995-91-5	06/30/95	Category X (may cause fetal harm) ⁹⁴⁶ Breastfeeding: With caution ⁹⁴⁷
Urolene Blue®		10/20/00	(See Methylene blue)
Vaccine (live measles)			(See Measles vaccine, live)
Vaccine (live mumps)			(See Mumps vaccine, live)
Valium®			(See Diazepam)
Valproate sodium	1069-66-5	06/30/95	Category X (can produce teratogenic effects) ⁹⁴⁸ , decreased cognitive functioning at age 3 years [PMID 19369666] ⁹⁴⁹ and at age 6 years [FDA]. ⁹⁵⁰ Breastfeeding: Consider discontinuing nursing (excreted in breast milk) ⁹⁵¹
Valproic acid	99-66-1		Category X [Briggs 6 th] ⁹⁵² (may produce teratogenic effects) ⁹⁵³ and decreased IQ at age 6 years [FDA]. ⁹⁵⁴ Breastfeeding: With caution (excreted in breast milk) ⁹⁵⁵
Vasotec®		10/17/00	(See Enalapril)
Velban®			(See Vinblastine sulfate)
VePesid®		10/20/00	(See Etoposide)
Vercite®			(See Pipobroman)
Vercyte®		10/20/00	(See Pipobroman)
Versanoin®		10/20/00	(See Tretinoin)
Versed®		10/17/00	(See Midazolam)
Vibramycin®			(See Doxycycline)
Vibra-tabs®			(See Doxycycline)
Vinblastine	865-21-4		(See Vinblastine sulfate)
Vinblastine sulfate	143-67-9	06/30/95	Category D (can cause fetal harm) ⁹⁵⁶ Breastfeeding: Discontinue ⁹⁵⁷
Vincristine	57-22-7		(See Vincristine sulfate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Vincristine sulfate	2068-78-2	06/30/95	Category D (can cause fetal harm) ⁹⁵⁸ Breastfeeding: Discontinue ⁹⁵⁹
Virilon®		10/20/00	(See Methyltestosterone)
Virilon®			(See Testosterone cypionate)
Vistide®			(See Cidofovir)
Vitamin A	68-26-8		Category A Category X (if used in does above the RDA [Briggs 4th], ⁹⁶⁰ may cause fetal harm; safety of amounts exceeding 6,000 Units of Vitamin A daily during pregnancy has not been established) ⁹⁶¹ Essential for normal reproduction (US RDA = 8,000 IU; Institute of Medicine advocates an RDA = 2667 IU in pregnant females [Institute of Medicine]) ⁹⁶² Breastfeeding: US RDA of 5,000 Units is recommended for nursing mothers ⁹⁶³
Vitamin A acid		10/20/00	(See Tretinoin)
Vitamin D ₂			(See Ergocalciferol)
Vitamin D ₃			(See Cholecalciferol)
VP-16-213		10/20/00	(See Etoposide)
Vumon®			(See Teniposide)
Warfarin	81-81-2	06/30/95	Category X (may cause fatal fetal hemorrhage <i>in utero</i> or birth malformations) ⁹⁶⁴ (See Dicumarol) Breastfeeding: Compatible [AAP], ⁹⁶⁵ no restrictions (appears in human milk in an inactive form) ⁹⁶⁶
Winstrol®			(See Stanozolol)
Xanax®		10/17/00	(See Alprazolam)
Yellow fever vaccine		07/10/00	Category D [Schardein] ⁹⁶⁷
Zanosar®			(See Streptozocin)
Zesteril®			(Lisinopril) (See ACE Inhibitors)
Zocor®		10/20/00	(See Simvastatin)
Zoladex®			(See Goserelin acetate)

Drug/Substance	CAS Number	Date Added	Comments/Notes
Zoloft®	79617-96-2	09/28/20 09	Septal heart defects [PMID 19776103] ⁹⁶⁸
Zonisamide	68291-97-4	02/26/20 14	Teratogenic in multiple animal species [Rxlist] ⁹⁶⁹ Low birth weight (PMID 24463659) ⁹⁷⁰ Breastfeeding: excreted in human milk [Rxlist] ⁹⁷¹

(IX) OCCUPATIONAL BIOLOGICAL REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

A) INTRODUCTION

Biologic ReproDev hazards include microorganisms (including bacteria, protozoa, viruses, and fungi), vaccines, and hyperpyrexia—fever greater than 102.2°F or 39°C—a possible response to infection or vaccination.^{iv} Although numerous biological hazardous agents exist, many of these are transmitted only under unusual circumstances, or are a risk primarily in specialized occupations (e.g., veterinary medicine, laboratory medicine, meat processing and packaging, hunting). In addition, agents that cause adverse fetal effects indirectly have been omitted (e.g., bacterial infections that may result in spontaneous abortions due to sepsis). The listed biologic hazards produce adverse ReproDev effects through transmission from the mother to the fetus during pregnancy, or to the neonate during delivery or shortly after birth. Many of these agents are associated with health care, day care, or school settings. However, any given agent may not carry the same degree of risk of transmission in all settings. Accordingly, the clinician should assess a given worker’s risk from biologic hazards through a review of his/her status, the frequency and duration of exposure, and current exposure control methods including personal protective equipment.

Prevention of infection is accomplished by prevention of exposure, or through immunization or acquired immunity where applicable. Proper engineering controls, work practices, and personal protective equipment must be used. Worker education on ReproDev hazards and preventive protective practices is essential.

Table 11 – Occupational Biological Reproductive and Developmental Hazards List

Category	Agent or Disease	Notes
Bacteria	Brucellosis	<i>Brucella</i> species (<i>b. abortus</i> , <i>b. melitensis</i> , <i>b. suis</i> , <i>b. canis</i>) Clinically symptomatic disease (not just exposure to or sub-clinical infection with <i>brucella</i>) has been associated with first trimester spontaneous abortion, third trimester fetal death and pre-term labor, although brucellosis is not commonly the reproductive hazard to humans that it is to animals, possibly due to the absence of erythritol in the human placenta [PMID 11283806], ⁹⁷² [PMID 11770592], ⁹⁷³ [PMID 10909521]. ⁹⁷⁴ Congenital brucellosis [PMID 17597440] ⁹⁷⁵

^{iv} This is not to imply that hyperpyrexia is only due to infections. For example, elevated body temperature has been associated with use of hot tubs.

Category	Agent or Disease	Notes
	Ehrlichiosis	Human granulocytic ehrlichiosis [PMID 9691104]. ⁹⁷⁶ Treatment with tetracycline or doxycycline (preferably [PMID 4180868 , ⁹⁷⁷ NEJM]), ⁹⁷⁸ both potentially harmful, or rifampin [PMID 9675481] ⁹⁷⁹ may need to be considered.
	Group B Streptococcus	Early-onset (neonatal) group B streptococcus [MMWR] ⁹⁸⁰
	Invasive <i>Hemophilus influenzae</i>	Increased susceptibility to invasive <i>H. influenzae</i> during pregnancy, fetal loss and premature birth [PMID 24643602] ⁹⁸¹
	Leprosy	Mycobacteria leprae Hansen's Disease. Fetal and placental infection is rare, ⁹⁸² but transmission from an infected, untreated mother to infant is not uncommon ⁹⁸³ (apparently from skin-to-skin or droplet transmission). ⁹⁸⁴
	Listeriosis	Listeria monocytogenes Granulomatosis infantisepticemia, spontaneous abortion [PMID 15824987], ⁹⁸⁵ stillbirth [PMID 12437035], ⁹⁸⁶ premature labor [PMID 18646305], ⁹⁸⁷ chorioamnionitis with multiple placental abscesses [PMID 12389339] ⁹⁸⁸ Listeriosis symptoms during pregnancy may mimic those of influenza and coincide with bacteremic phase of infection. Management of pregnant women with febrile illness may include blood cultures to rule out listeriosis [MMWR]. ⁹⁸⁹
	Lyme disease	<i>Borrelia burgdorferi</i> [PMID 2423719] ⁹⁹⁰ Timely maternal antibiotic treatment appears to eliminate risks to the fetus of adverse Lyme disease sequelae [PMID 10666804] ⁹⁹¹ [PMID 8362948]. ⁹⁹²

Category	Agent or Disease	Notes
	Relapsing fever	<p><i>Borrelia hermsii</i>, transmitted by the soft tick <i>Ornithodoros hermsi</i> [PMID 15004063]⁹⁹³</p> <p>High perinatal mortality, premature delivery, spontaneous abortion [PMID 9351408],⁹⁹⁴ [PMID 3416842]⁹⁹⁵</p>
	Syphilis	<p>Severe infection may cause fetal demise with hydrops; mild infection may cause detectable abnormalities of skin, teeth, and bones [PMID 921549]⁹⁹⁶</p> <p>High risk of spontaneous abortion, stillbirth, or infected infant when untreated maternal infection occurs at any time during pregnancy; recognizable features of congenital syphilis rarely occur before 16th week of gestation [PMID 6551148]⁹⁹⁷</p>
	Tuberculosis	(TB)
	Typhoid fever	<p>Spontaneous abortion, premature delivery [PMID 3832761]⁹⁹⁸</p> <p>Neonatal typhoid (intrauterine transmission from an infected mother) [PMID 7808844]⁹⁹⁹</p>
Protozoa	Leishmaniasis	<p><i>Leishmania donovani</i></p> <p>Visceral leishmaniasis or Kala Azar</p> <p>Transplacental transmission may occur in asymptomatic women [PMID 10545591]¹⁰⁰⁰</p>
	Malaria	<p><i>Plasmodium vivax</i>, <i>P. ovale</i>, <i>P. falciparum</i>, <i>P. malariae</i></p> <p>Prophylactic antimalarials may pose some risk, but it is generally felt that their use is preferred to the risk to the fetus and mother of contracting malaria.</p>

Category	Agent or Disease	Notes
	Toxoplasmosis	<p>Domestic cats are a potential source. Risk dependent on gestational age at the time of maternal seroconversion: intracranial hyperechogenic foci or calcifications and ventricular dilatation (generally bilateral and symmetrical), intrahepatic densities, increased thickness and hyperdensity of the placenta, ascites, pericardial and pleural effusions, cerebral palsy, microcephaly, bilateral blindness, hydrocephalus, epilepsy [PMID: 1566716].¹⁰⁰¹</p> <p>Pregnant women who become infected during pregnancy are generally treated immediately with spiramycin.</p>
	Trypanosomiasis	<p><i>Trypanosoma cruzi</i> American trypanosomiasis or Chagas' disease May infect the placenta with or without fetal transmission (congenital trypanosomiasis) [PMID 3938649]¹⁰⁰²</p>
Virus	Coxsackievirus	<p>First & second trimesters: Low risk of transmission; certain strains associated with prematurity, congenital abnormalities, spontaneous abortion Term: Some risk of transmission and severely infected infant [PMID 6551148]¹⁰⁰³</p>

Category	Agent or Disease	Notes
	Cytomegalovirus	Human herpesvirus 5 Sensoryneural hearing loss & vestibular disorders [PMID 26347442] ¹⁰⁰⁴ Maternal viremia can result in transplacental infection (placental cytotrophoblasts are permissive to CMV replication); congenital infection from antepartum cervical/vaginal viral shedding is thought to be rare. Postnatal infection can occur via intrapartum exposure to cervical/vaginal viral shedding or via consumption of infected breast milk and is unlikely to cause severe disease in healthy full-term neonates. Clinical findings in symptomatic newborns include small for gestational age, microcephaly, ventriculomegaly, chorioretinitis, jaundice, hepatosplenomegaly, thrombocytopenia, and petechiae. The mortality rate among symptomatic newborns is approximately 5 percent, and 50 to 60 percent of survivors develop serious long-term neurologic morbidity [PMID: 8160023]. ¹⁰⁰⁵
	Ebola virus	Spontaneous abortions & stillbirth among pregnant women with Ebola Hemorrhagic Fever ¹⁰⁰⁶ [PMID 9988157] ¹⁰⁰⁷ Labor and Delivery has high risk of exposure to bodily fluids, including amniotic fluid [PMID 28383378] ¹⁰⁰⁸
	Echovirus	Term: High risk of transmission and severely infected infant [PMID 6551148] ¹⁰⁰⁹
	Hepatitis B virus	First & second trimesters: Some risk of transmission; Third trimester: High risk of transmission; High risk of transmission from asymptomatic HBeAg carrier mothers; Some risk of transmission from HBsAg carrier (HBeAg negative) mothers [PMID 6551148] ¹⁰¹⁰

Category	Agent or Disease	Notes
	Hepatitis E virus	Maternal and fetal death, abortion, premature delivery, neonatal mortality [PMID 11307901], ¹⁰¹¹ [PMID 7959147], ¹⁰¹² icteric and anicteric hepatitis, hypothermia, hypoglycemia [PMID 7723501] ¹⁰¹³
	Human immunodeficiency virus	HIV, AIDS
	Human parvovirus B19	Erythema infectiosa or Fifth disease, fetal anemia, fetal hydrops, death ¹⁰¹⁴
	Human T-cell leukemia virus type 1	Possible transmission from breastfeeding [PMID 2512396] ¹⁰¹⁵ Intra-uterine infection [PMID 2332671] ¹⁰¹⁶
	Influenza H1N1	Spontaneous abortion, premature rupture of membranes [MMWR] ¹⁰¹⁷ Fetal distress, premature delivery, emergency cesarean delivery, fetal death [PMID 20498414] ¹⁰¹⁸
	Lymphocytic choriomeningitis virus	Congenital hydrocephalus, microcephaly, macrocephaly, intracranial calcifications, chorioretinitis, hydrops [PMID 11004296], ¹⁰¹⁹ [PMID 11438904], ¹⁰²⁰ [PMID 662624] ¹⁰²¹ A potential risk for those handling rodents [MMWR]. ¹⁰²²
	Mumps virus	Mumps orchitis uncommonly may cause sterility
	Poliovirus	Early pregnancy: prematurity, low birth weight, stillbirth, spontaneous abortion; Term: Some risk of transmission and severely infected infant [PMID 6551148] ¹⁰²³

Category	Agent or Disease	Notes
	Rubella virus	<p>German measles</p> <p>Congenital rubella syndrome may include: heart malformations (patent ductus arteriosus, intraventricular septal defect, and pulmonic stenosis), ocular lesions (cataracts, microphthalmos, and chorioretinitis), CNS abnormalities (mental retardation, microcephaly, and deafness), malformation of bone metaphyses, hepatosplenomegaly, thrombocytopenia, interstitial pneumonitis, myocarditis, thrombocytopenic purpura, small size, and subacute sclerosing panencephalitis, a rare complication. Diabetes mellitus may be a late complication.¹⁰²⁴</p>
	Varicella/herpes zoster virus	<p>human herpesvirus 3, congenital varicella if infected in first trimester, neonatal varicella if infected near delivery (5 days before to 2 days after delivery)¹⁰²⁵</p>
	West Nile Virus	<p>Developmental (chorioretinitis, temporal and occipital white-matter loss) [MMWR]¹⁰²⁶</p> <p>Breastfeeding has been associated with seropositivity, and virus has been identified in human breast milk [MMWR],¹⁰²⁷ MMWR¹⁰²⁸</p>
	Zika Virus	<p>Congenital Zika Syndrome^{1029,1030} (microcephaly,¹⁰³¹ decreased brain tissue and subcortical calcifications, eye abnormalities including macular scarring and retinal pigment changes, congenital contractures, such as clubfoot or arthrogryposis, and hypertonia, and may include microphthalmos and macular chorioretinal atrophy,¹⁰³² and dysphagia¹⁰³³)</p>

Category	Agent or Disease	Notes
Vaccine	Mumps	Live attenuated vaccine—avoid pregnancy for 30 days after vaccination [CDC] ¹⁰³⁴ (some authorities recommend avoiding pregnancy for 3 months) Category C [Briggs 6th] ¹⁰³⁵
	Rubella	Live attenuated vaccine—avoid pregnancy for 3 months after vaccination [CDC]. ¹⁰³⁶ “No cases of congenital rubella syndrome or abnormalities attributable to a rubella vaccine virus infection have been observed in infants born to susceptible mothers who received rubella vaccine during pregnancy” [MMWR 1994]. ¹⁰³⁷ “No evidence indicates that administration of rubella-containing vaccine virus to a pregnant woman presents a risk for her fetus, although such a risk cannot be excluded on theoretical grounds” [CDC]. ¹⁰³⁸
	Vaccinia	Category X [Briggs 6th] ¹⁰³⁹ Fetal vaccinia (developmental) (very rare) Reported in women vaccinated in all three trimesters [MMWR] ¹⁰⁴⁰
	Varicella/herpes zoster virus vaccine	Category C (contraindicated during pregnancy) ¹⁰⁴¹ Avoid pregnancy for 3 months following vaccination ¹⁰⁴² Live attenuated vaccine. It is indicated for young adults not previously infected, especially HCWs and close contacts of immunocompromised persons. It produces detectable varicella antibodies in 97% of recipients and reduces the likelihood of clinical illness by 70% after exposure. No immune globulins, including varicella-zoster immune globulin, should be given within 5 mo before or 2 mo after vaccination. This vaccine may be given concomitantly with measles-mumps-rubella. Recipients should avoid salicylates for 6 wk because of the possibility of Reye's syndrome. ¹⁰⁴³

Category	Agent or Disease	Notes
	Venezuelan equine encephalitis TC-83 vaccine	Category X [Briggs 6 th] ¹⁰⁴⁴ Live attenuated vaccine—avoid pregnancy for in the immediate future after vaccination [Briggs 6 th] ¹⁰⁴⁵
	Yellow fever	Live attenuated vaccine Category D [Briggs 6 th] ¹⁰⁴⁶ (contraindicated in pregnancy except if exposure is unavoidable) (administer if a pregnant female must travel to endemic areas [MMWR 1994]) ¹⁰⁴⁷
Miscellaneous	Hyperpyrexia [PMID 4014176] ¹⁰⁴⁸	Effect of infection or immunization that can be a related ReproDev hazard
	Fava beans	Breastfeeding: Hemolysis in patient with G-6-PD deficiency [AAP] ¹⁰⁴⁹
	Aflatoxin	Growth faltering [PMID 17576701] ¹⁰⁵⁰ (mycotoxins have been detected in human milk [PMID 18338407]), ¹⁰⁵¹ limited evidence for IUGR [PMID 2741679], ¹⁰⁵² [PMID 9814089] ¹⁰⁵³
Biologicals not commonly encountered	Biowarfare agents (potential)	Q-fever Lassa fever (fetal and neonatal loss)[PMID 3139220] ¹⁰⁵⁴

(X) OCCUPATIONAL PHYSICAL REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

Table 12 – Occupational Physical Reproductive and Developmental Hazards List

AGENT	DATE ADDED
Altitude	06/24/2003
Excessive heat (thermal stress)	06/30/1995
Heavy lifting	
Impact	
Ionizing radiation	06/30/1995
Noise	
Postures, such as standing in military formations (attention or parade rest), and other prolonged periods without movement)	
Respirator use	
Shift work	
Vibration	01/24/2000

A) ALTITUDE

High altitudes (8,000 feet or more above sea level) have been associated with diminished birth weight (approximately 25 grams or more decrease per 1,000 feet increase in elevation) and with preeclampsia and gestational hypertension [[PMID 10329872](#),¹⁰⁵⁵ [PMID 12700368](#)].¹⁰⁵⁶ Aircraft flight at high altitude is accompanied by a decrease in partial pressure of oxygen and by increased exposure to cosmic radiation [[PMID 12107289](#),¹⁰⁵⁷ [PMID 12455507](#)].¹⁰⁵⁸ The level (or dose) of those stresses is related to the duration of the flight [[PMID 11973496](#)].¹⁰⁵⁹ Physical exertion during initial exposure to high altitude may present increased risk of adverse health effects. Initial (short-term, i.e., 4 to 5 days, rather than a few hours or the duration of a flight) exposures to high altitude should be limited to 8,250 feet (2,500 meters) [[PMID 8888456](#)].¹⁰⁶⁰

B) PHYSICAL EXERTION – GENERAL

Normal physiological changes in pregnancy result in increased resting heart rate, respiratory tidal volume, and oxygen debt incurred by performing a given task. However, physical activity in pregnancy has minimal risks and has been shown to benefit most women, although some modification to exercise routines may be necessary because of these normal anatomic and physiologic changes and fetal requirements. Women with uncomplicated pregnancies should be encouraged to engage in aerobic and strength-conditioning exercises before, during, and after pregnancy.

Obstetric care providers should carefully evaluate women with medical or obstetric complications before making recommendations on physical activity participation during pregnancy. Although frequently prescribed, bed rest is only rarely indicated and, in most cases, allowing ambulation should be considered. Regular physical activity during pregnancy improves or maintains physical fitness, helps with weight management, reduces the risk of gestational

diabetes in obese women, and enhances psychologic well-being. An exercise program that leads to an eventual goal of moderate-intensity exercise for at least 20–30 minutes per day on most or all days of the week should be developed with the patient and adjusted as medically indicated [[PMID 26595585](#)].¹⁰⁶¹

Although the healthy pregnant worker generally will be able to do most of her work up until the time of delivery,¹⁰⁶² some reduction in exertion requirements may be needed in the last trimester. The American Medical Association Guidelines for Continuation of Various Levels of Work During Pregnancy was published in 1984 and gives general guidance for physical work restrictions based on the week of gestation. NIOSH has published and revised guidelines that take into account horizontal reach, vertical height, and frequency-duration pattern.¹⁰⁶³ NLE Calc is an app based on the Revised NIOSH Lifting Equation.¹⁰⁶⁴ Recommendations regarding limitations on physically strenuous work **must be individualized**¹⁰⁶⁵ because physical capabilities vary greatly among women. Limitations should reflect the percent of maximal exertion required to complete the task before pregnancy. In general, a maximum pre-pregnancy load should be decreased by 20-25 percent during the third trimester. At no time during the pregnancy should the physical demands be increased over what the employee was accustomed to before becoming pregnant. Excessive or chronic fatigue should be avoided.

Guidelines can be summarized as follows.¹⁰⁶⁶

- General office work, standing intermittently, stooping or bending below knee level 2 or fewer times per hour, going up stairs less than 4 times per shift, and repetitive lifting of up to 24 lbs. can be continued throughout pregnancy.
- Standing for more than 30 minutes at a time can be continued up to the 8th month.
- Stooping and bending below knee level more than 2 times per hour, going up stairs 4 or more times per shift, and vertical climbing (e.g., ladders) less than 4 times per shift can be continued until the 7th month.
- Standing for more than 4 hours can be continued until into the 6th month.

Stooping and bending below knee level more than 10 times per hour and vertical climbing 4 or more times per shift can be continued until the 5th month. Generally, the medical professional best suited to make a determination regarding work load restrictions/allowances during pregnancy is a person knowledgeable in the woman's' medical status, pregnancy status, and job requirements. Often, this determination should be made by more than one medical or health professional working in concert with the woman's' supervisory chain of command or authority. The overall requirements of the job (with respect to physical effort, frequency, duration, and the availability of spontaneous at lib rest periods) and ongoing obstetrical evaluation of each worker must be considered in periodically making recommendations for restrictions on exertion as the pregnancy progresses. The pregnant worker's physical capabilities and the possibility of work limitation(s) should be addressed at each appointment with a HCP. A written medical recommendation should be provided by the HCP managing the pregnancy.

C) LIFTING

There are two primary concerns regarding lifting in pregnancy: protecting the worker from injury (primarily back injury), and protecting the pregnancy until term. It is biologically plausible that heavy physical exertion may have an influence on the course and outcome of pregnancy. The epidemiologic evidence is strongest for possibly increasing the risk of preterm delivery. Although not supported by all studies [[PMID 2617257](#)],¹⁰⁶⁷ the risk of impeded fetal growth or spontaneous abortion appears to be associated with maternal heavy lifting in the occupational setting [[PMID 3806263](#)],¹⁰⁶⁸ although bending, rather than lifting itself, may be the main cause [[PMID 8282467](#)].¹⁰⁶⁹ It can, however, be recommended that female workers avoid extremely heavy physical exertion (close to the individual's maximal capacity). The AMA 1999 "Report of the Council On Scientific Affairs" recommendations include "minimizing heavy lifting."¹⁰⁷⁰

Specific lifting restrictions should be individualized as described in the preceding paragraph. NIOSH Publications *Work Practices Guide for Manual Lifting*¹⁰⁷¹ and [Applications Manual for the Revised NIOSH Lifting Equation](#)¹⁰⁷² provide guidance only for workers in general and do not provide specific recommendations for pregnant women. Lifting involving awkward body mechanics (such as lifting during advanced pregnancy, in confined spaces, lifting large objects, lifting while twisting or using one hand or pushing, lifting unstable objects, high speed lifting, lifting on a slippery or uneven floor) are not covered by the NIOSH guidelines, and additional restrictions should be considered [[PMID 23467051](#)].^{1073,1074}

Based on the general guidelines given above, if a woman was able to perform a non-maximal effort task to which she is accustomed prior to pregnancy, then she will likely be able to continue that task during an uncomplicated pregnancy at least up to the third trimester. The worker and her supervisors should be advised that changes in lifting biomechanics occur as the pregnant abdomen increases the horizontal distance away from the axial skeleton at which objects must be held. Additional training may be required.

Additional restrictions in the third trimester of pregnancy include limiting or prohibiting work requiring balance (climbing ladders) and lifting weights that are bulky or awkward or that approach the woman's maximal (prior to pregnancy) lifting capacity. As pregnancy progresses, it is wise to reduce the physical workload and ensure rest periods of adequate frequency and duration. In late pregnancy, a pregnant woman should not do any task that may require a Valsalva (bearing down) maneuver.

D) RESPIRATOR USE IN PREGNANCY

Pregnancy is a common disqualifying reason in physicals done to clear workers for respirator use [[PMID 10086199](#)],¹⁰⁷⁵ although there is little support for this in the scientific literature. The type of respirator (e.g., simple dust mask or solvent-exposure canister), size and habitus of the pregnant worker, and stage of pregnancy (e.g., 3 months or 8 months gestation) are all factors that may be considered.

E) SHIFT WORK AND EXTENDED HOURS OF DUTY

Based on animal studies, it is thought that the biological rhythms of the unborn child follow those of the mother. Time shifts experienced by shift workers lead to disruption of their biological rhythms with varying degrees of associated fatigue and health complaints, such as general malaise and gastrointestinal disorders [[PMID 2203158](#)].¹⁰⁷⁶ Most “swing shift” and “graveyard shift” workers experience some degree of sleep deprivation and disruption of their normal biological rhythm. Workers with young children at home are particularly apt to be sleep deprived. Studies of workers in general have found increased fatigue after about nine hours of duty as evidenced by performance deficits and decreased alertness.

The degree of risk to pregnancy outcome from extended hours and shift work is not known. It is prudent at this time, and required for Navy servicewomen in the last trimester ([OPNAVINST 6000.1D](#)),¹⁰⁷⁷ to limit the number of total hours worked per week to 40, unless longer hours are requested by the employee and approved by her HCP. Shift work, especially rotating shift work, should be considered an added stressor for the pregnancy. Overtime work in conjunction with shift work should be avoided during pregnancy [[PMID 2203158](#)].¹⁰⁷⁸

F) PSYCHOLOGICAL AND PERCEIVED STRESS

A study using questionnaire data found that women undergoing fertility treatments who perceived their job as more demanding were less likely to conceive, and that likelihood to deliver after fertility treatment was associated with less working hours [[PMID 16404210](#)].¹⁰⁷⁹

G) HEAT STRESS (ENVIRONMENTAL CONDITIONS) AND HEAT STRAIN (PHYSIOLOGIC RESPONSE)

1) Effects on Fertility

Men who work in hot environments may have an associated lowering of sperm counts [[PMID 9756281](#)].¹⁰⁸⁰ This reversible effect may result in infertility until the heat exposure ceases and the sperm count is restored to normal levels. Male workers should be advised of this potential heat effect upon sperm counts. An appropriate specialist should evaluate men who have been trying unsuccessfully to father children. If a low sperm count is determined to be the cause of infertility in a man who works in a hot environment, temporary reassignment to a job without heat stress should be considered.

2) Effects on Pregnancy

Physiological changes that occur in pregnancy make the pregnant worker more susceptible to the effects of heat stress. The plasma volume increases and causes a relative anemia; the resting heart rate increases, and the cardiac output increases with much of the increase shunted to the placenta. There is also a 10-15 mm Hg fall in diastolic blood pressure. Uterine enlargement encroaches on the inferior vena cava and slows venous return from the lower extremities. Together, these cardiovascular changes increase the risk of heat syncope or fainting—and the associated risk of injury to the woman or the developing fetus. Varicosities of the lower extremity may be aggravated. Pedal edema is common in the last trimester and is aggravated by heat stress conditions. A decrease in appetite may occur with exposure to heat

and lead to poor weight gain. The extra weight of the pregnant abdomen increases metabolic load resulting in increased generation of heat and an increased oxygen debt incurred from physical exertion. Finally, the fetal temperature is about 0.5°C higher than normal maternal temperature. This adds to the increased thermal load of pregnancy. Other sources of heat that contribute to a “heat stress environment” include fever [[PMID 4014176](#)]¹⁰⁸¹ and hot tub or hot bath use [[PMID 1640616](#)],¹⁰⁸² in addition to occupational heat exposure. High-risk pregnancies (specifically, hypertensive patients) have significantly increased uterine vascular resistance during short-term heat exposure. Thus, safe short-term heat stress in uncomplicated pregnancies may be detrimental in high-risk pregnancies [[PMID 7993506](#)].¹⁰⁸³

3) Effects on Development

Few studies specifically address the epidemiological relationship between heat exposure and pregnancy outcome. Evidence from animal studies clearly indicates that elevation of core body temperature of sufficient degree and duration during specific gestational age intervals induces spontaneous abortion, fetal malformations, and postnatal developmental abnormalities. (For example, intrauterine growth retardation in lambs is a known effect of heat stressing pregnant ewes [[PMID 2030175](#)].)¹⁰⁸⁴ Human studies of pregnancy complicated by significant febrile episodes (maternal core temperature > 38.9°C—such as during influenza) at different stages of pregnancy suggest an association with adverse developmental outcomes,¹⁰⁸⁵ including neural tube defects [[PMID 6446171](#)].¹⁰⁸⁶ However, other human studies have failed to show any significant increase in specified developmental abnormalities.¹⁰⁸⁷

The American Conference of Governmental Industrial Hygienists (ACGIH) TLVs, NIOSH recommended exposure limits (RELs), and the Navy Physiological Heat Exposure Limits (PHELs) curves take into account the wet bulb globe temperature (WBGT) index and metabolic heat produced by work. However, these exposure limits apply to healthy, non-pregnant individuals and specifically do not apply to pregnant women. There is no accepted heat exposure standard to follow during pregnancy. NIOSH suggests that it is “prudent to monitor the body temperature of a pregnant worker exposed to total heat loads above the REL, every hour or so to ensure that the body temperature^v does not exceed 39°–39.5°C (102°–103°F) during the first trimester of pregnancy.”¹⁰⁸⁸ However, measuring core temperatures hourly during work may be difficult or impossible, and using a cut-off value of 102° may not be adequately protective. Clearly, maximum allowable WBGT levels for physical exertion must be lower and work times must be reduced for pregnant women in hot environments. As in all heat stress exposures, adequate replacement of lost fluids is essential. Supervisors must be especially responsive to early signs and/or symptoms of heat exhaustion in pregnant women (confusion, agitation, dizziness, visual disturbances, numbness, weakness, muscle cramping, involuntary muscle contractions, swelling/edema, nausea, vomiting, abdominal cramping, and uncontrollable shivering). (NOTE: The Navy uses an aspirated wet bulb in the determination of the WBGT index; the ACGIH and NIOSH recommended criteria use a natural wet bulb, which has no fan-

^v Core body temperature is usually assessed by somewhat “invasive” means, such as measuring rectal, vaginal, or esophageal temperature (but not by measuring oral temperature). The modern tympanic thermometer is a practical method for this application. (*Footnote not in original quoted text*)

assisted air movement across the wick. Care should be employed when using these criteria, especially when using different criteria and Navy-specific WBGT index meters.)

Standing times should also be reduced. [OPNAVINST 6000.1D](#) exempts pregnant women from standing at parade rest or at attention for longer than 15 minutes.¹⁰⁸⁹ In hot conditions, this time should be decreased and, preferably, standing at attention should be allowed only momentarily.

The HCP should issue medical recommendations for decreased working hours and exertion for pregnant women with complaints of excessive fatigue, swelling of the feet and ankles, lightheadedness, and poor appetite. Pregnant women should not be required to do work during their pregnancy that is more demanding than that to which they were accustomed to before pregnancy. Abrupt increases in environmental temperatures will increase the metabolic demands of physical activity for all workers. In order to avoid increasing the metabolic requirements for the pregnant worker, the exertion and/or the hours of work required should be appropriately decreased for work that must be done in hot environments. In most instances, proper administrative actions should be the result of close coordination between the managing HCP and the professional OH staff.

H) SOUND AND VIBRATION

1) Fetal Sound Exposure

Environmental or workplace sound is transmitted to the fetus through body tissues and uterine fluids, and probably within the fetus by bone conduction [[PMID 8944295](#)].¹⁰⁹⁰ Sound intensity in amniotic fluid was found to be about 4000 times less than at a sound source in air 2 cm from the abdomen [[PMID 1547171](#)].¹⁰⁹¹ Low frequency noise poses the greatest risk since it penetrates to the fetal cochlea more effectively than high frequencies. Most studies suggest attenuation at the cochlea of about 10 to 20 dB for frequencies less than 250 Hz, and over 40 dB at 2000 Hz [[PMID 8899910](#)].¹⁰⁹² However, one study reported sound enhancement at 125 Hz [[PMID 1635729](#)].¹⁰⁹³ Based on animal (sheep) data, sound levels within the uterus resulting from direct physical contact with a sound source decrease as the point of contact moves away from the abdomen [[PMID 3394740](#)].¹⁰⁹⁴ If a pregnant woman leans against a noise source with her abdomen, her fetus would be exposed to a greater sound level than if she leans against the same sound source with her shoulder.

While a fetus may be vulnerable to loud noise, the mother may have decreased hearing while she is pregnant; one study found a significant decrease in hearing levels for 125, 250 and 500 Hz, beginning in the first trimester and increasing in the second and third trimesters, and returning to normal in the post-partum period [[PMID 11535140](#)].¹⁰⁹⁵ Whether this would result in the mother being less likely to avoid loud sounds during pregnancy is unclear.

2) Fetal Sound Response

The fetal cochlea first demonstrates consistent auditory responsiveness in the 20th week of gestation. There have been no indications of behavioral auditory responses before 19 weeks gestation.¹⁰⁹⁶ Fetal effects of sound may vary with gestational age. Mammalian studies

indicate increased susceptibility to damage from sound during the final functional and structural stages of development in young animal cochleas.¹⁰⁹⁷ While there are no data for humans, children in utero could theoretically suffer hearing loss at lower sound levels and after a shorter duration of sound exposure than mature adults. The current auditory risk criteria were formulated for non-pregnant adults.¹⁰⁹⁸

3) Sound Exposure Effects

According to the American Academy of Pediatrics, studies suggest exposure to excessive noise during pregnancy may result in high-frequency hearing loss in newborns, and may be associated with prematurity and intrauterine growth retardation [[PMID 9836852](#)].¹⁰⁹⁹ Studies linking maternal sound exposure during pregnancy to increased incidence of hearing loss in neonates and young children are inconclusive due to inability to control all variables [[PMID 3788986](#)].¹¹⁰⁰ After the development of the fetal ear (mid-pregnancy), the fetus is able to perceive, and even respond to, external sounds. Sound attenuation from external air to within the uterus has been demonstrated [[PMID 1635729](#)].¹¹⁰¹ Exact levels of attenuation have differed (and one study even suggested low frequency sound level augmentation within the uterus), but high frequency sound levels (those thought to pose the most significant hazard to adult hearing) are consistently diminished more than low frequency. Concern remains, however, as to whether maternal exposure to high sound levels, even of low frequencies, may be harmful to the hearing of the fetus, because the fetus cannot be protected (for example, by earplugs) from the direct effects of such sounds [[PMID 2237460](#)].¹¹⁰² A significantly increased rate of loss of hearing at 4000 Hz has been noted in children whose mothers were exposed to high sound levels with both low and high (rather than only high) frequency components. (However, other risk factors may have been confounders.) The same study identified a three-fold increase in childhood high-frequency hearing loss among children whose mothers were exposed to occupational sound levels of 85 to 95 dB compared to those whose mothers had lower occupational sound level exposures during pregnancy. The authors recommended setting a temporary 85 dBA 8 hour sound limit for pregnant women until further research verifies the safety of higher sound level exposures [[PMID 3788986](#)].¹¹⁰³ Some authors feel that any sustained exposure of the developing auditory system to high sound levels represents an increase in the risk of noise-induced hearing loss [[PMID 2237460](#)],¹¹⁰⁴ although this has not been proven in humans. At least one Navy medical officer has advised that pregnant women not be subjected to noise in excess of 90 dB for an 8 hour work day (Moore).¹¹⁰⁵ This is the guideline recommended for general consideration, and is without respect to maternal hearing protection, as neither ear plugs nor ear muffs offer any fetal hearing protection.^{vi} Currently, definitive cut-off levels of hazardous (or non-hazardous) sound remain not identified.

Low birth weight is the most common non-auditory consequence associated with maternal sound exposure; however, this finding is not consistent across studies summarized by Nurminen in 1995 [[PMID 8520958](#)].¹¹⁰⁶ There has been extended discussion of possible non-auditory consequences to maternal sound exposure, related to stress-induced increase of

^{vi} Providers may advise pregnant workers to be alert to noise beyond the workplace, as hazardous noise levels may be found outside the work or industrial setting.

catecholamine levels and placental vasoconstriction. Shift work in a “noisy” environment was associated with pregnancy-induced hypertension in one study [[PMID 2772574](#)].¹¹⁰⁷ Whether sound-related, stress-induced increases of catecholamine levels and placental vasoconstriction are causally related to preterm births is unproven [[PMID 8520958](#)].¹¹⁰⁸ In one study of sound exposure during the first trimester of pregnancy, there was no association with selected structural malformations in infants (orofacial cleft or structural defect of the central nervous system, skeleton, or heart and great vessels) [[PMID: 2772573](#)].¹¹⁰⁹

4) Combined Fetal Exposures to Noise and Toxicants

Whether maternal occupational exposure to noise in combination with exposure to other occupational hazards poses an increased risk of fetal ototoxicity (i.e., an additive or synergistic response) has not been established. Data from studies investigating human populations exposed to both noise and industrial chemicals have been felt to be inadequate for assessing the combined effects of noise and chemical exposures on hearing [[PMID 9284647](#)].¹¹¹⁰ In most cases, exposure to chemical toxicants would be the primary concern. Non-occupational exposures are likely also to have a role, as prenatal maternal smoking has been associated with hearing loss in adolescents [[PMID 23788030](#)].¹¹¹¹

5) Vibration Effects

While not specifically “noise-related”, vibration has also been explored as a possible reproductive or developmental hazard. There is currently no conclusive evidence that whole body vibration poses maternal or fetal risk.¹¹¹² Segmental vibration of the maternal abdomen, such as would be caused by vibrating tools or objects contacting the abdomen, has been documented in mammalian (sheep) studies to alter fetal sleep [[PMID 7963297](#)].¹¹¹³

6) Maternal Noise and Vibration Exposure Guidelines

The ACGIH Physical Agents TLV Committee has noted that an 8-hour TWA exposure of 115 dBC (as distinct from dBA) or a peak exposure of 155 dBC to the abdomen of a pregnant worker beyond the fifth month of pregnancy may cause hearing loss in the fetus.¹¹¹⁴ This peak level equates to noise exposures generated by discharging firearms with larger than a .22 caliber round.

The following recommendations are based on current knowledge. They are not requirements or regulations.

1. The ACGIH 115 dBC TWA and peak 155 dBC noise notations should be observed as exclusion criteria starting at 20 weeks gestation. Excluding pregnant women from discharging firearms after 20 weeks gestation would be consistent with those criteria.
2. Pregnant workers should be vigilant in wearing hearing protectors whenever environmental noise exceeds 84 dBA, to minimize potentially unhealthy maternal cardiovascular and endocrine effects on the growing fetus.
3. Extended exposures (more than 12 minutes) above 104 dBA should be avoided after 20 weeks gestation, even with the use of maternal hearing protection.

4. Impact/impulse noise exposure sufficient to require personal hearing protection should be avoided.
5. Although there is currently no conclusive data defining safe-for-the-fetus noise levels after 20 weeks gestation, it is prudent to avoid unnecessary exposure to loud sounds. It is recommended that for noise at levels of 84 dBA or higher, the potential for risk (as contrasted to the actual known risk) to fetal hearing should be discussed with the mother. The aforementioned exposure limit of 90 dB recommended by [Moore](#)¹¹¹⁵ provides good guidance and may be used as a starting point for those without specific expertise. **If there is a question, then a team approach with an OB/GYN, OEM, pediatrics, and IH may be needed.**
6. Consider job rotation after the twentieth week of pregnancy for women working around intense sound levels.¹¹¹⁶
7. Care should be taken to avoid contact between the abdomen and vibrating tools or objects.
8. Determination as to the advisability of continuing work at a given sound level is deferred to the attending physician.

I) IONIZING RADIATION

Exposure limits for ionizing radiation are contained in NAVMED P-5055 (Feb 2011),¹¹¹⁷ Radiation Health Protection Manual, and [10 CFR 20](#); pregnant females may not receive more than 500 mrem (i.e., 0.5 rem or 5 mSv) of ionizing radiation during the course of a pregnancy ([10 CFR 20.1208](#)),¹¹¹⁸ and may not receive more than 50 mrem/month during that time (NAVMED P-5055).¹¹¹⁹

(XI) SUMMARY TABLE AND MISCELLANEOUS REPRODUCTIVE AND DEVELOPMENTAL HAZARDS

A) SUMMARY OF REPRODEV HAZARDS

The following is a summary listing of the chemical, biological, and physical ReproDev hazards. It is taken entirely from the preceding tables, contains no details, and is given only to provide a concise list for use at worksites.

Chemical Agents

α-Naphthyl-N-methylcarbamate	DDT (p,p'-Dichlorodiphenyltrichloroethane)	Lead (Pb)
1,2-Dibromo-3-chloropropane	DEHP	Lindane
1,2-Dibromoethane	di(2-ethylhexyl) Phthalate (DEHP)	Mercury and mercury compounds
1,3-Butadiene	Dimethylaminopropionitrile (DMAPN)	Mercury, elemental
2,3,7,8-Tetrachlorodibenzo-p-dioxin	Dinocap (fungicide)	Mercury, inorganic
2,4-D	Dinoseb (herbicide)	Mercury, organic
2,4-Dichlorophenoxy acetic acid	Dioxin	Methyl benzimidazole-carbamate
2,4-Dinitrotoluene	Disodium cyanodithiomido-carbonate	Methyl Cellosolve acetate
2,6-Dinitrotoluene	Epichlorohydrin	Methyl isocyanate
2-Bromopropane	Ethanol	Methyl mercury
2-Ethoxyethanol	Ethyl alcohol	Methylene blue
2-Methoxyethanol	Ethyl carbamate	Methylmethane sulfonate
Acetaldehyde	Ethylene dibromide	Methylnitrosourea
Acetylaminofluorene	Ethylene glycol monoethyl ether	MIC
Alcohol	Ethylene glycol monomethyl ether	Mirex
Anesthetic gases	Ethylene glycol monomethyl ether acetate	Nickel
Antimony	Ethylene oxide	o,p'-DDT
Arsenic	Ethylene thiourea (Ethylenethiourea)	Oryzalin
Atrazine	EthylNitrosourea	Oxydemeton methyl
Benzene	Gasoline	p,p'-DDT
Benzimidazoles	Hexachlorobenzene	p,p'-Dichlorodiphenyl-trichloroethane
Bischloroethyl nitrosourea	Hexachlorocyclohexane (Lindane®)	PCBs
Butiphos	Hexamethylphosphoramide	Perchloroethylene (PCE)
Cadmium	Hexamethylphosphoric triamide	Phthalates
Carbarsone	HMPA	Polychlorinated biphenyls (PCBs)
Carbaryl	Iodides	Sevin®
Carbendazim	Iodine	TCDD
Carbon dioxide	Kepone®	TCE
Carbon disulfide		Tetrachloroethylene
Carbon monoxide		Tobacco smoke - environmental (secondary/passive)
Chlordecone		Toluene
Cigarette smoke		Toluene-2,4-diamine
Ciguatoxin		Toluenediamine
Cycloheximide		Trichlorfon
DBCP		Trichloroethylene (TCE)

Urethane (ethyl
carbamate - NOT
"polyurethane")

VCM

Vinyl chloride (monomer,
not polyvinyl chloride
or PVC)

Xylenes

Biological Agents

Aflatoxin
 Biowarfare agents
 Brucellosis
 Cocksackievirus
 Cytomegalovirus
 Ebola virus
 Echovirus
 Ehrlichiosis
 Fava beans
 Group B Streptococcus
 Hepatitis B virus
 Hepatitis E virus
 Human immunodeficiency virus
 Human parvovirus B19
 Human T-cell leukemia virus type 1
 Hyperpyrexia
 Influenza H1N1
 Invasive Hemophilus influenza
 Leishmaniasis
 Leprosy
 Listeriosis
 Lyme disease
 Lymphocytic choriomeningitis virus
 Malaria
 Mumps
 Mumps virus
 Poliovirus
 Relapsing fever
 Rubella
 Rubella virus
 Syphilis
 Toxoplasmosis
 Trypanosomiasis
 Tuberculosis
 Typhoid fever
 Vaccinia
 Varicella/herpes zoster virus

Varicella/herpes zoster virus vaccine
 Venezuelan equine encephalitis TC-83 vaccine
 West Nile Virus
 Yellow fever
 Zika Virus

Physical Agents

Altitude
 Excessive heat (thermal stress)
 Heavy lifting
 Impact
 Ionizing radiation
 Noise
 Postures, such as standing in military formations (attention or parade rest), and other prolonged periods without movement)
 Respirator use
 Shift work
 Vibration

B) OTHE REPRODEV HAZARDS

The following table is included separately for completeness. Hazards include certain drugs of abuse as well as other substances unlikely to be considered in routine workplace evaluation.

Table 13 – Miscellaneous Reprodev Hazards Not Generally Considered

Alcohol	64-17-5		(See Ethanol under Drug Hazards)
Aspartame	22839-47-0	07/05/00	Category B [Briggs 4th] ¹¹²⁰ Category C in women with phenylketonuria [Briggs 4th] ¹¹²¹ Breastfeeding: With caution if mother or infant has phenylketonuria [AAP] ¹¹²²
Cigarette smoking	---		(See Tobacco smoke (primary))
Cocaine	50-36-2	06/30/95	Category C [Briggs 4th] ¹¹²³ Category X if nonmedicinal use [Briggs 4th] ¹¹²⁴ (associated with fetal malformations, placental toxicity [PMID 9434858]) ¹¹²⁵ Breastfeeding: Adverse effects reported (may cause cocaine intoxication) [AAP] ¹¹²⁶
Ecstasy	ACX number X1008014-7		(MDMA or N-Methyl-3,4-methylenedioxyamphetamine) (See Amphetamines)
Ethanol	64-17-5		(See Ethanol under Drug Hazards)
Ethyl alcohol	64-17-5		(See Ethanol under Drug Hazards)
Fava beans	---	07/05/00	Breastfeeding: Hemolysis in patient with G-6-PD deficiency [AAP] ¹¹²⁷
Heroin	561-27-3		Pregnancy: Preterm birth [PMID 2304039], ¹¹²⁸ neonatal withdrawal [Williams] ¹¹²⁹ Breastfeeding: Contraindicated (tremors, restlessness, vomiting, poor feeding) [AAP] ¹¹³⁰ (excreted in milk [PMID 9363416]) ¹¹³¹
MDMA	ACX number X1008014-7		(Ecstasy or N-Methyl-3,4-methylenedioxyamphetamine) (See Amphetamines)
N-Methyl-3,4-methylenedioxyamphetamine	ACX number X1008014-7		(Ecstasy or MDMA) (See Amphetamines)

<p>Tobacco smoke (primary) (see Tobacco smoke - environmental for second hand tobacco)</p>	<p>---</p>	<p>06/30/95</p>	<p>Males: Decreased sperm concentration and motility [PMID 9051418]¹¹³² and percentage of sperm with normal morphology [PMID 1521002]¹¹³³</p> <p>Females: Decreased fertility [PMID 9829871],¹¹³⁴ decreased fecundity, early mean age of menopause [PMID 9434858]¹¹³⁵</p> <p>Pregnancy: IUGR [PMID 9131707]¹¹³⁶ [PMID 9434858]¹¹³⁷</p> <p>Increased blood pressure (which returns to normal within two years) [PMID 8648540]¹¹³⁸</p> <p>Retinal vascular abnormalities (which resolve by age 6 months) [PMID 10839873]¹¹³⁹</p> <p>Adverse lung function effects [PMID 9272918]¹¹⁴⁰</p> <p>Breastfeeding: Conflicting studies finding decreased [PMID 9457000]¹¹⁴¹ or increased [PMID 8067348]¹¹⁴² infant growth</p>
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(XII) OCCUPATIONAL EXPOSURES OF REPRODUCTIVE AND DEVELOPMENTAL CONCERN - SUPERVISOR'S AND WORKER'S STATEMENTS

Two forms (NAVMED 6260/8 and NAVMED 6260/9) have previously been used to help evaluate workers for potential ReproDev hazard exposures. At the time of this update, those forms have expired and are no longer valid. Until updated versions are released, locally developed forms may be used to assist in managing workers with occupational exposures of ReproDev concern. Any form developed locally should follow the appropriate guidelines for creating medical forms and to ensure the protections of personal identifiers and health information.

The necessity to maintain confidentiality in matters of personal health must be emphasized.

(XIII) FEDERAL AND NAVY REGULATIONS RELATED TO PREGNANCY

A) GENERAL PRINCIPLES

Federal regulations prohibit discrimination from employment on the basis of pregnancy, childbirth or related medical conditions [[29 CFR 1604.10](#)].¹¹⁴³ The principle is that women affected by pregnancy and related medical conditions must be treated the same as other applicants and employees on the basis of their ability or inability to work.

If an employee is temporarily unable to perform the functions of her job because of a pregnancy-related condition, the employer is required to treat her in the same manner as it treats other temporarily disabled employees, such as providing modified tasks, alternative assignments or disability leave.

An employer cannot refuse to hire a woman because of her pregnancy-related condition so long as she is able to perform the major functions necessary to the job.

A woman is protected against being fired or refused a job or promotion merely because of pregnancy. She usually cannot be forced to go on leave as long as she can work. If a worker is absent on leave because of pregnancy or related conditions, the employer must hold her job open for her return on the same basis as jobs held open for workers on sick or disability leave for other reasons.

B) REGULATIONS CONCERNING PREGNANT FEDERAL CIVIL SERVICE PERSONNEL

[29 CFR 1604.10, Employment Policies Relating to Pregnancy and Childbirth](#)¹¹⁴⁴ and [OPNAVINST 5100.23 series](#), Navy Safety and Occupational Health Program Manual CH1, 21 July 2011¹¹⁴⁵ pertain to Navy employees.

The Pregnancy Discrimination Act¹¹⁴⁶ clarifies employment practices related to pregnancy or related conditions. [29 CFR 1610 Appendix](#)¹¹⁴⁷ further clarifies and gives answers to questions about the Act.

If a worker requests a change of duties or assignments after consulting her personal physician, the employing agency should make a reasonable effort to accommodate her. The personal physician should give her a written statement indicating the medical necessity of the recommended limitations. The OEM physician will review the recommendation. The OEM physician may consult with the personal physician to mutually determine the appropriate work restrictions for the worker. (The worker's personal physician may require a signed release before discussing the case.)

C) REGULATIONS CONCERNING PREGNANT SERVICEWOMEN

[SECNAVINST 1000.10A](#)¹¹⁴⁸ and [OPNAVINST 6000.1D](#)¹¹⁴⁹ together provide comprehensive policy about issues related to pregnant servicewomen.

[OPNAVINST 6000.1D](#)¹¹⁵⁰ prohibits diving as part of physical training by pregnant servicewomen. [BUMEDINST 6200.15A, Suspension of Diving Duty During Pregnancy](#),¹¹⁵¹ provides guidance on suspension of diving duty of pregnant servicewomen.

(XIV) REFERENCES

For ease of use, references are given in their entirety each time they are listed, even when listed multiple times, and World Wide Web addresses are given in selected cases.

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