Toward a Medico-Legal Approach to Protecting the Public's Health

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Main Points

1. Chronic diseases concern both physicians and environmental health scientists.

2. Physicians provide an idea of precaution from which the law can learn: Primordial prevention.

3. Recent findings in environmental health concerning lifelong exposures increase the urgency legally to use primordial prevention to protect the public and workforce.

Ravages of Infectious Diseases

For centuries humans have been afflicted by infectious diseases, plagues, and pandemics.

In Developed Countries Public Health Actions Decreased Infectious Diseases

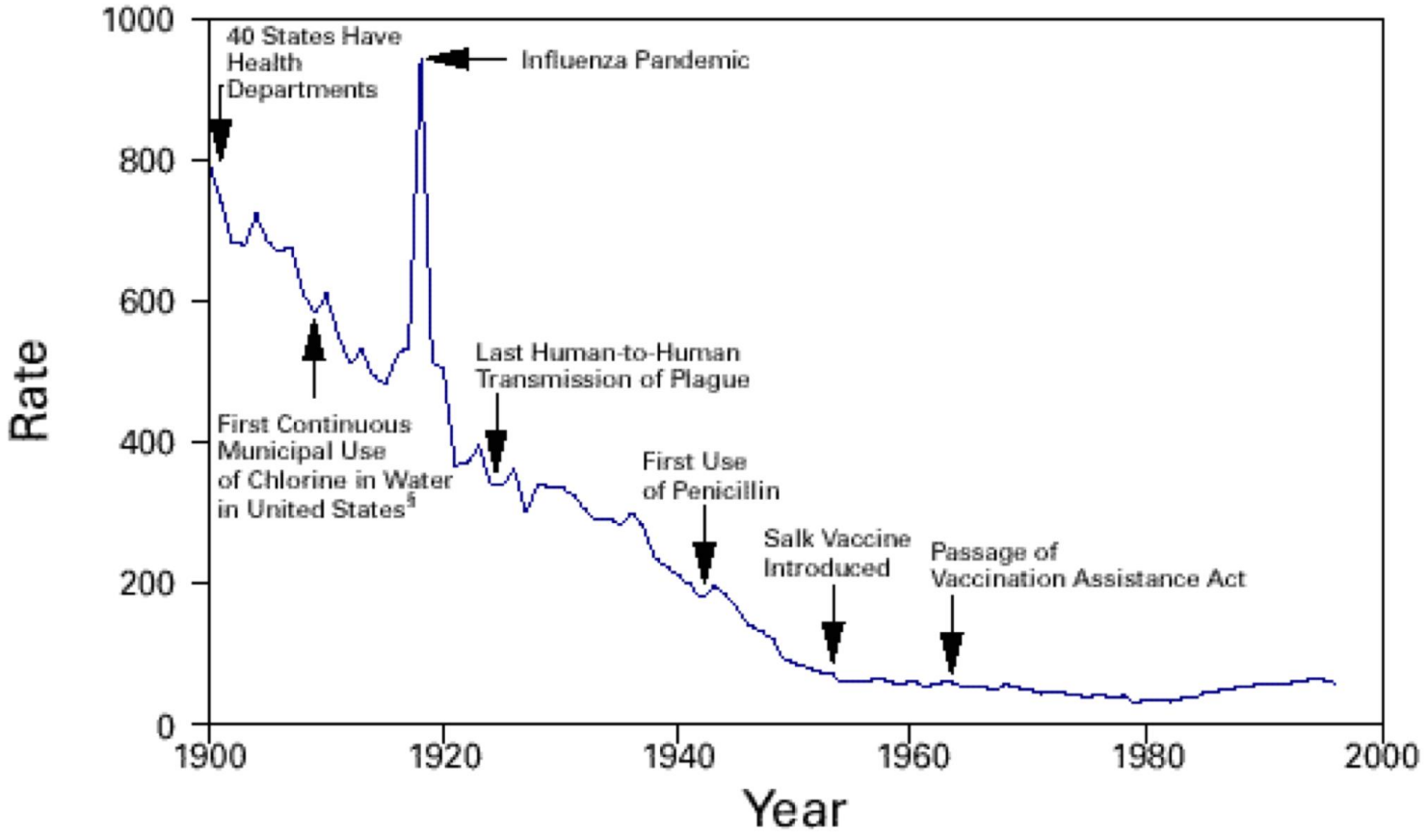
Collectively we cleaned up a polluted environment

Chlorinated drinking water

Introduced antibiotics

Discovered and used vaccines

FIGURE 1. Crude death rate* for infectious diseases — United States, 1900–1996†

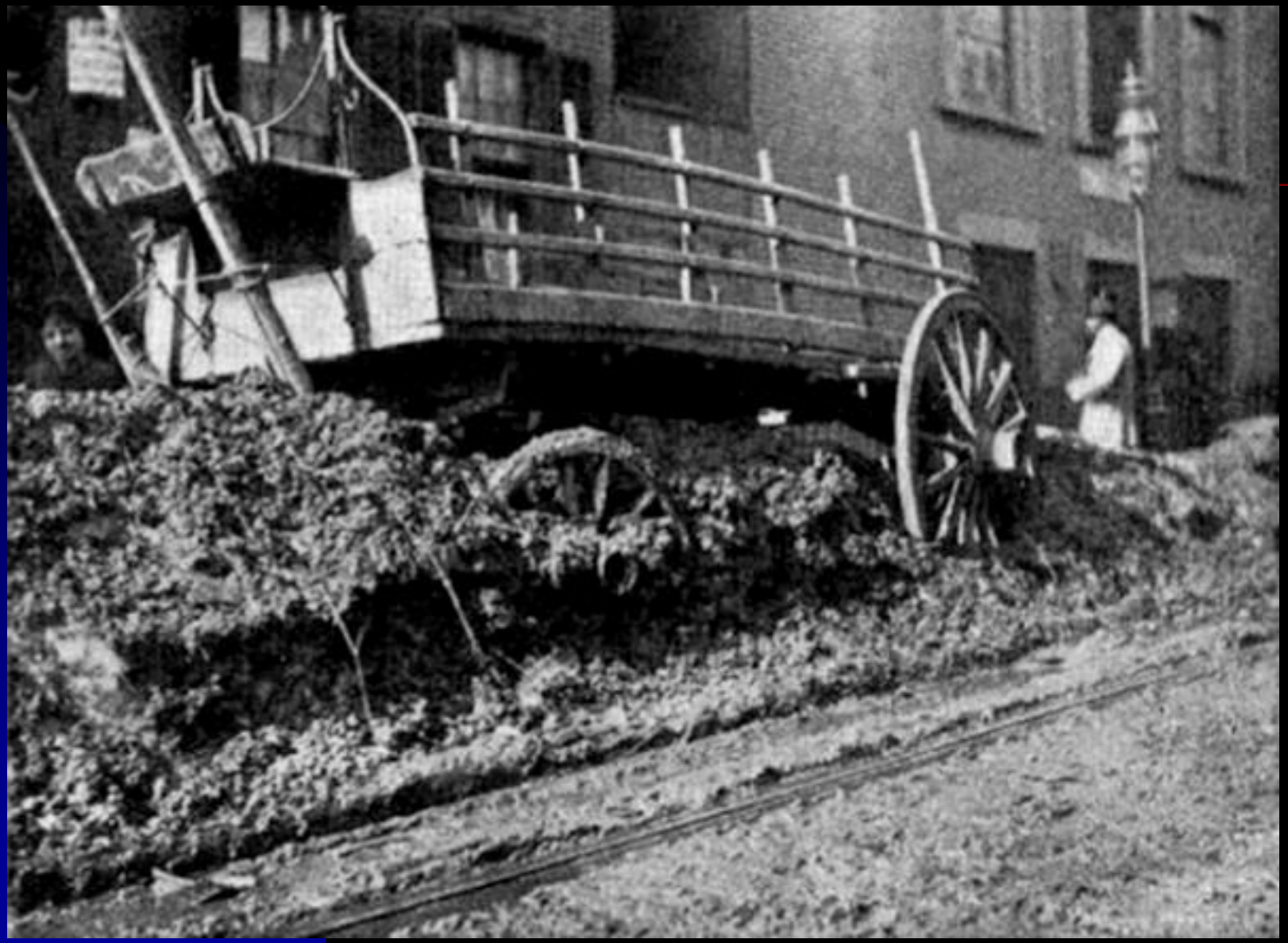


*Per 100,000 population per year.

†Adapted from Armstrong GL, Conn LA, Pinner RW. Trends in infectious disease mortality in the United States during the 20th century. JAMA 1999:281;61–6.

§American Water Works Association. Water chlorination principles and practices: AWWA manual M20. Denver, Colorado: American Water Works Association, 1973.

1926 New York Street,222. mtfca.com



A filthy New York City street in 1893; 2.5 million pounds/day

Sewage Entering the Delaware River, July 15, 1918.

Swimming in Delaware River Sewage (July 1918)
Department Historical Collection

Chronic Diseases

- Are now the leading causes of morbidity and mortality in developed countries. (James F. Fries, 1980; Bruce Lanphear, 2005; Barouki, et al., 2012; Dietert, Luebke, 2012)

Chronic Diseases Are

- “[W]idespread conditions that originate in early life and develop insidiously; the probability of their occurrence increases with age”.
- Of long duration and slow progression. (WHO)
- Cannot be prevented by vaccines.
- “Not communicable … and do not just disappear.” (http://www.medicinenet.com/script/main/art.asp?articlekey=33490)

Chronic Diseases

- Can result from bad luck, unfortunate genes, voluntary behavior, or *the actions of others*.
- Can interfere with life-long normal good health and flourishing.

Chronic Diseases of Concern to Physicians

Examples:

- Arteriosclerotic plaque increases the odds of acute thrombotic event or vascular insufficiency.
- Osteoarthritic bone spurs may be on x-rays for many years before pain or disability is noted in the joint.
- Glucose tolerance decreases gradually until sugar is excreted in the urine of the diabetic.
- Emphysema accelerates the loss of pulmonary reserve.
- The probability of neoplasms increases with age.

Chronic Diseases

Correctives:

- “Elimination of cigarette smoking greatly delays the … onset of symptoms of emphysema and reduces the probability of lung cancer.”
- “Treatment of hypertension retards development of certain complications in the arteries.”
- “Circumstantial evidence [suggests] that arteriosclerosis is retarded by weight reduction or exercise.” (Fries, 1980)

The Aim of the Physician and Personal Choices Should Be the “Compression of Morbidity”

- Approximate definition: there is greater success in postponing “the age of onset of chronic illness ... than the age at death and
- [squeezing] the most of the morbidity in life into a shorter period with less lifetime disability.” (Fries, et. al, 2011)

The Compression of Morbidity

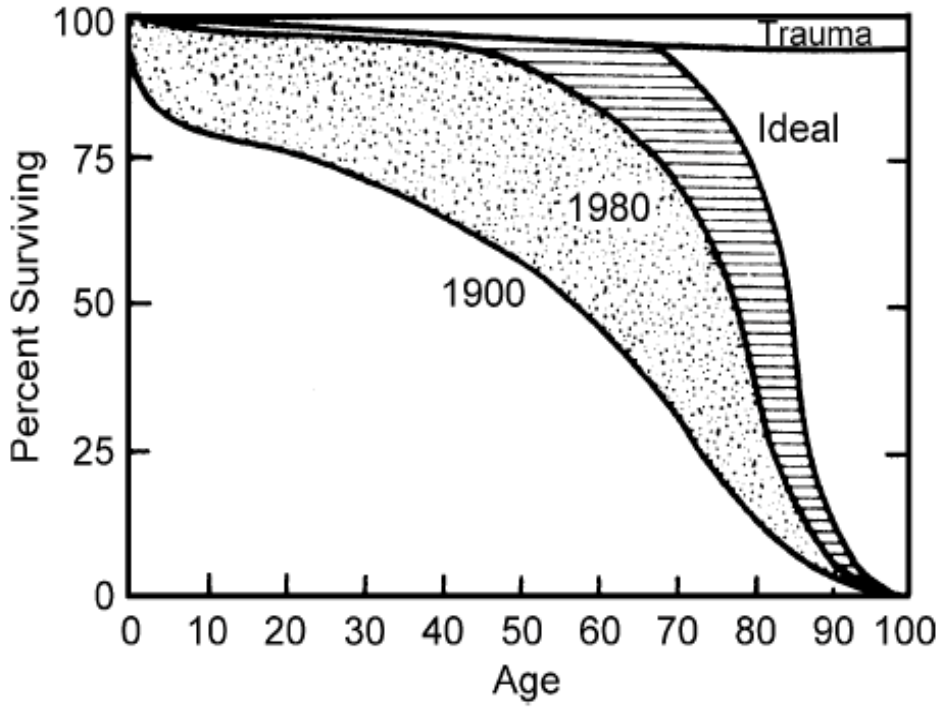


FIGURE 5. Ideal Survivorship Curve. Trauma plays a large and potentially reversible role. Chronic disease accounts for almost all of the approximately ten-year-wide area of premature death remaining over ages 60–90. Reprinted with permission from J.F. Fries and L.M. Crapo, *Vitality and Aging* (San Francisco: W.H. Freeman, 1981).

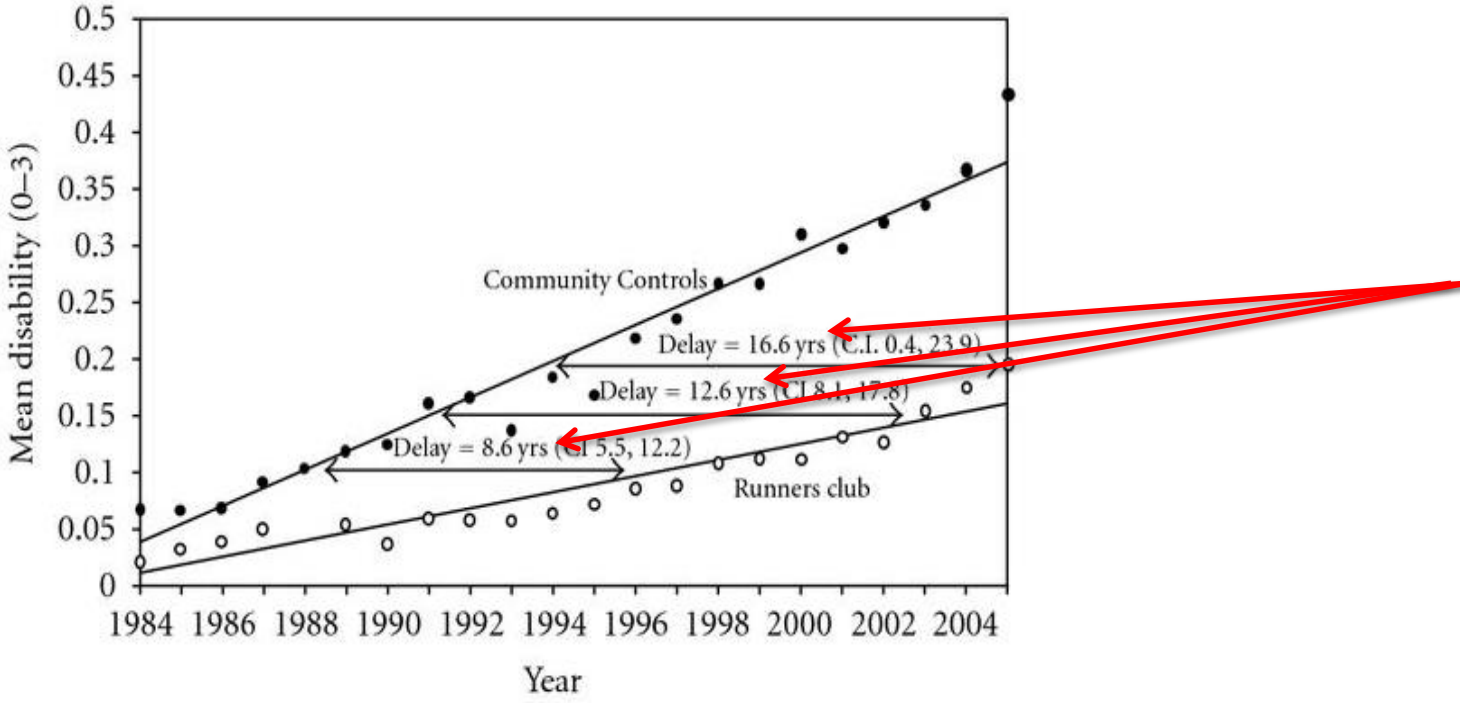
The Body “Rusts Out” Rather than “Wears Out.”

- Premature organ dysfunction, whether of muscle, heart, lung, or joint, is beginning to be conceived as stemming from disuse of the faculty, not overuse.

- Fries’ advice:
  - “Use it don’t lose it.”
  - “Run don’t rest.”

- “If loss of reserve function represents aging in some sense, then exercising an organ presents a strategy for modifying the aging process.” (Fries, 1980)

The Body "Rusts Out" Rather Than "Wears Out."

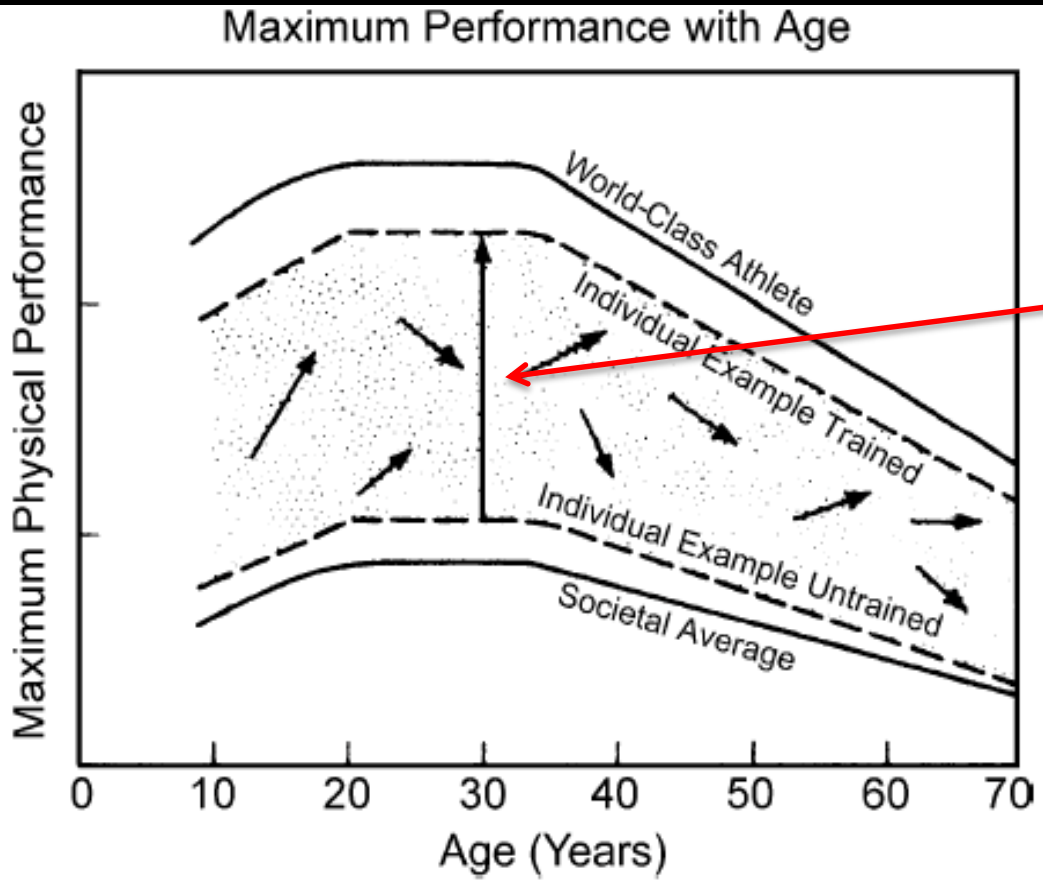


Morbidity Is Delayed Among exercisers

Figure 5: Disability progression—ages 58–79 years: Runners' Club and Community Controls. Progression of disability in Runner's Club and Community Control groups over 21 years from an average age of 58 is compared in the figure both with yearly disability values and statistically derived regression lines. The regression lines are derived from linear mixed models and adjusted for age, gender, BMI, smoking, and initial disability. Comparison of postponement of disability is represented by the absolute difference between the two groups in the time required to develop a given level of disability. The example shown is to reach Health Assessment Questionnaire (HAQ) Disability Index Scores of 0.10, 0.15, and 0.20. All differences are highly statistically different ($P < 0.001$). Lines continue to diverge with age. The postponement is 8.6 years between groups in reaching the .010 mark, 12.6 years to reach the 0.15 mark, and projected at 16.6 years for the HAQ level of 0.20. Consistent moderately active exercise postpones onset of disability for many years.

Fries, Bruce, Chakravarty, "Compression of Morbidity 1980–2011: A Focused Review of Paradigms and Progress," Journal of Aging Research, 2011)

The Plasticity of Aging



Maximum ***individual*** lifetime arc of good health

FIGURE 9. The Plasticity of Aging. Within the biological potential of the organism are multiple possible pathways to improvement of performance with age bounded by present performance and maximum potential performance. Reprinted with permission from J.F. Fries and L.M. Crapo, *Vitality and Aging* (San Francisco: W.H. Freeman, 1981).

Personal/Medical Protections vs Chronic Diseases

Medical/Personal	Primordial Prevention	Primary Prevention	Secondary Prevention	Tertiary Prevention
Lung disease, emphysema, COPD	Never smoke; don't begin	Quit smoking early in life	Reduce, quit smoking later if not earlier	Surgery, other treatment
Diabetes, atherosclerosis	Don't become obese	Reduce obesity/increase exercise	Reduce cholesterol, hypertension, time to first heart attack	Heart surgery, stints, statins
	Avoid sedentary behavior; exercise	Begin exercise	Begin exercise later if not earlier	Diabetes treatment
		Moderate other risks of chronic conditions		Total knee and hip replacements, cataract extractions
Liver disease, cirrhosis	Don't drink to excess/at all?	Quit the habit	Quit later if not earlier	

Two Takeaways from the Compression of Morbidity

- Each of us and our doctors have a role in reducing some chronic diseases in our lives:
  - Primordially prevent behaviors that lead to chronic diseases.
  - Adopt personal habits that forestall chronic diseases—"Use it, don't lose it!"
- Note the idea of "primordial prevention/precaution"—Don't engage in potentially harmful behavior; do engage in beneficial behavior.

Toxic Substances Also Contribute to Chronic Diseases

- This is clearly manifested by diseases that result from early life exposures, or
- The “developmental origins of disease.”
- Differences from Fries:
  - He is concerned with chronic diseases that develop mainly from voluntary choices and that can be ameliorated somewhat by choices and activities.
  - Neither is largely true of exposures to most toxicants, ignoring cigarette smoking and excessive drinking.

Toxic Substances Also Cause Chronic Diseases

- Neurological dysfunctions
- Immune system disorders
- Cancers
- Lung diseases
- Some coronary-artery diseases
- Some diabetes

A Justice Case for Preventing Chronic Diseases

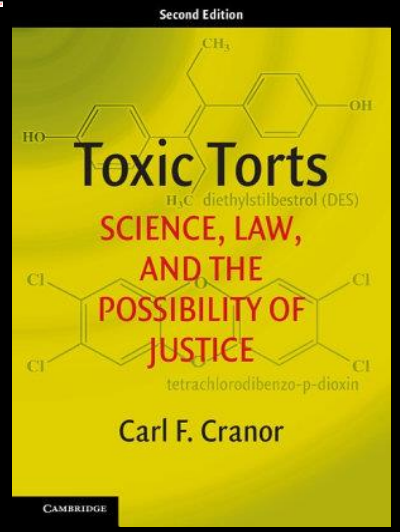
- Chronic diseases can cause substantial harm and arbitrarily interfere with opportunities for a flourishing normal life.

A Powerful Justice Principle-- *Fair Equality of Opportunity*— Identifies Important Justice Goals

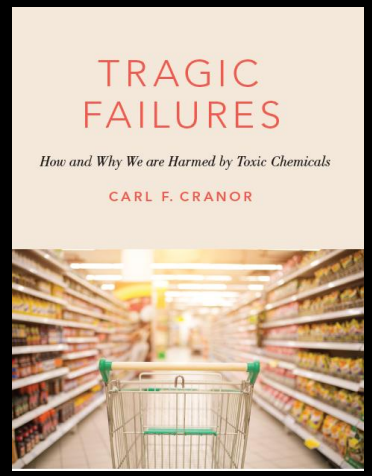
- Good health-*protection* and health-care institutions help counter diseases that frustrate life-long opportunities to:
  - Pursue careers or change them. (Rawls, 1971, 1999)
  - Develop life-plans, modify them, and pursue them beyond working years. (Daniels, 1981; Cranor, 2011, 2016)

At 47 Benzene-Caused Leukemia Undermined Brian Milward's Good Health and Opportunities

- His disease, chemotherapy, diabetes, and a rare bowel disorder left him at age 57, "with 'absolutely ridiculous' fatigue."
- His career and lifetime opportunities were greatly diminished:
  - He had to retire and take disability.
  - He can't do what he loves: repair race cars, work in his yard, play with his grandchildren. "It just sucks when you get a cancer like this." (Lombardi, Center for Public Integrity, 2014)



(Cambridge, 2016)



(Oxford, 2017)

Others Have An Arc of Good Health and Opportunities by Avoiding Serious Chronic Diseases

Oldest Woman to climb Kilimanjaro (86+)

Oldest Man to Climb Kilimanjaro (85+)

Oldest Man to Climb Mt. Everest (80)

Oldest Woman to Climb Mt. Everest (73+)

Lessons on Aging Well, From a 105-Year-Old Cyclist

Phys Ed

By GRETCHEN REYNOLDS FEB. 8, 2017

NY Times

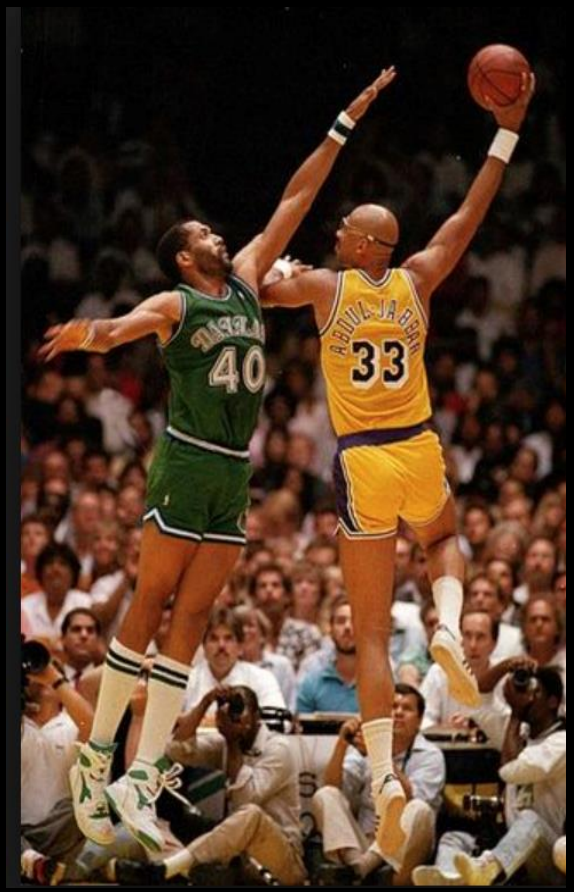
85-Year-Old Marathoner Is So Fast That Even Scientists Marvel

By JERÉ LONGMAN DEC. 28, 2016

NY Times

Others have an Arc of Good Health and Opportunities by Avoiding Serious Chronic Diseases

Diana Nyad, 64, completing 90 mile Cuba to Florida Swim



Retired professionally at 42

To Reduce Diseases that Curtail Fair Equality of Opportunity, Health Institutions Should

- *Prevent diseases* with preventive medicine and environmental health protections.
- *Treat diseases* that undermine persons' health; ensure access to medical care.
- *Maintain* the chronically ill as close to normal functioning as their ages and conditions allow by providing medical treatment and accommodations. (Daniels, 1981; Cranor, 2011, 2017)

The Law's Contribution

- Administrative health laws can prevent/reduce toxicity-caused chronic diseases.
- Personal injury (or the tort) law can support treatment and redress for diseases caused by others [not discussed].
- How well have these laws functioned?

Two Generic Strategies to *Prevent* Diseases from Chemical Creations

Postmarket laws

"Old" 1976 Toxic Substances Control Act (TSCA):

Chemical creations enter commerce with *no legally* required routine testing or approval (~90- 80% of chemical creations).

Authorize removal after risks/harms are shown.

Premarket laws

For drugs (1962) and pesticides (1968):

Laws *legally require routine* toxicity *testing & agency approval* prior to commercialization(~10-20% of chemical creations).

Authorize removal after risks/harms are shown.

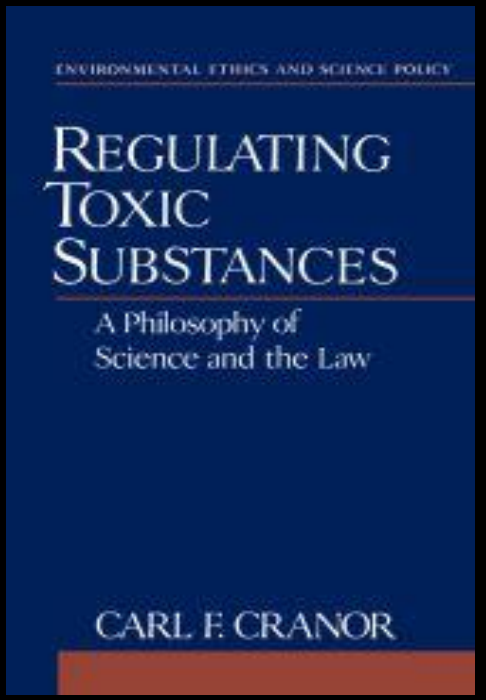
“Old” Postmarket TSCA (U.S. 1976)

- Grandfathered 62,000 general chemicals as safe.
- Permitted another 22,000 into commerce with little or no toxicity testing.

What Are Justice Aspects of the Science-Law Interaction in Postmarket Administrative Agencies?

- Rigid or mistaken scientific norms and slow action frustrated legal and health norms—e.g., low powered epidemiological studies (still an issue, 2017). (Cranor, et al., Amicus Brief, 4th Circuit Court of Appeals (2017); Neutra, Cranor, Gee, "The Use and Abuse of Bradford Hill in U.S. Toxic Tort Litigation" (2019))

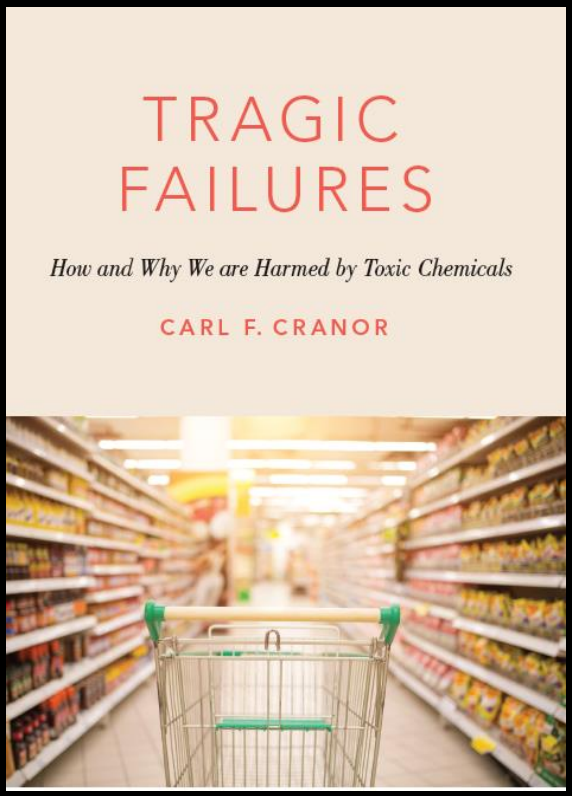
- Justice issue: With sufficient exposures sluggish regulation leads to more cancers/other diseases.



Oxford University Press, 1993, 1997

Injustice of Sluggish Protections: Hairdresser Sandy Guest's Death

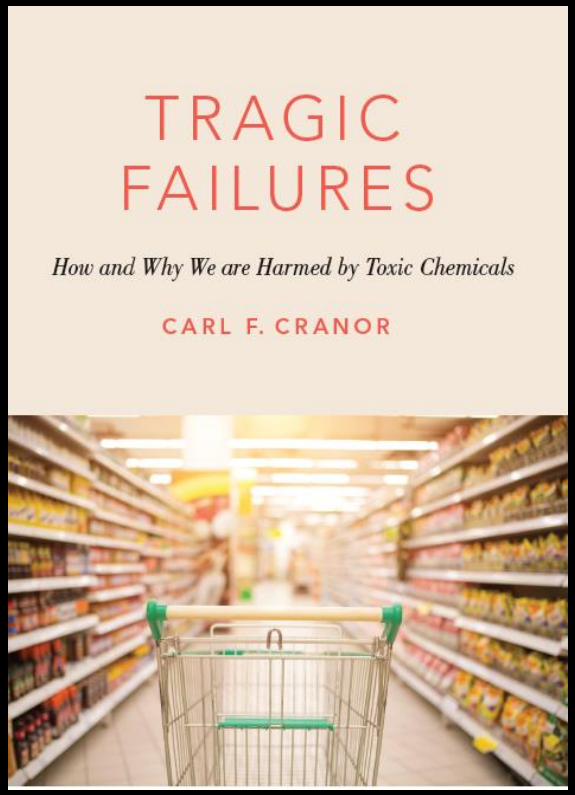
- She used Brazilian Blowout—"loaded with formaldehyde"—and died of leukemia at age 55. (Morris, 2015)
- 1981-2011: 17 studies revealed formaldehyde caused nasopharyngeal, sinonasal, and myeloid cancers; still no protections.
- Industry resistance and slow scientific review likely led to Guest's death.
- A company and administrative institutions failed her.



Oxford University Press, 2017

Injustices from Exposures to DuPont's C8 (PFOA) [Ingredient in Teflon, Gore-Tex]

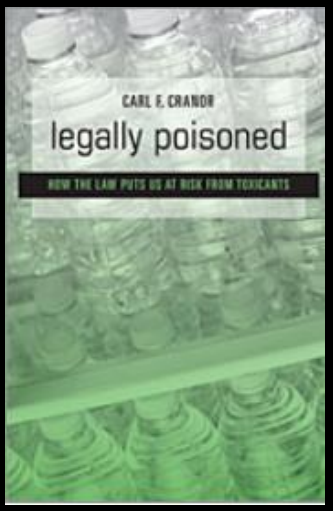
- Carla Bartlett's kidney cancer (C8 in drinking water)—$1.6 million. (2016)
- David Freeman's testicular cancer (C8 in water)—$5.6 million with punitive damages. (2017)
- Kenneth Vigneron, Sr.'s, testicular cancer (C8 in water)—$12.5 million with punitive damages. (2017)
- Wilbur Tennant's dead cattle (C8 in creek).
- DuPont settled for $671 million to cover damages affecting 3,550 plaintiffs and their communities. (2017)
- DuPont and administrative institutions failed them; the tort (personal injury) law redressed some harms.



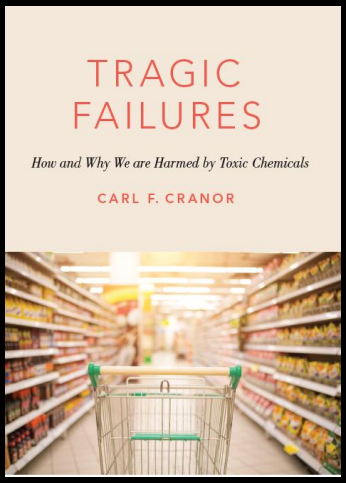
New Science—The "Developmental Origins of Disease"—Reveals Worse Shortcomings of Postmarket Laws (2007)

- Children are among the most vulnerable humans that are exposed to toxicants.

- How well do our laws protect them?
  (Cranor, 2008, 2008; Cranor, 2011; *Tragic Failures*, Ch. 2)



Harvard Press, 2011, 2013

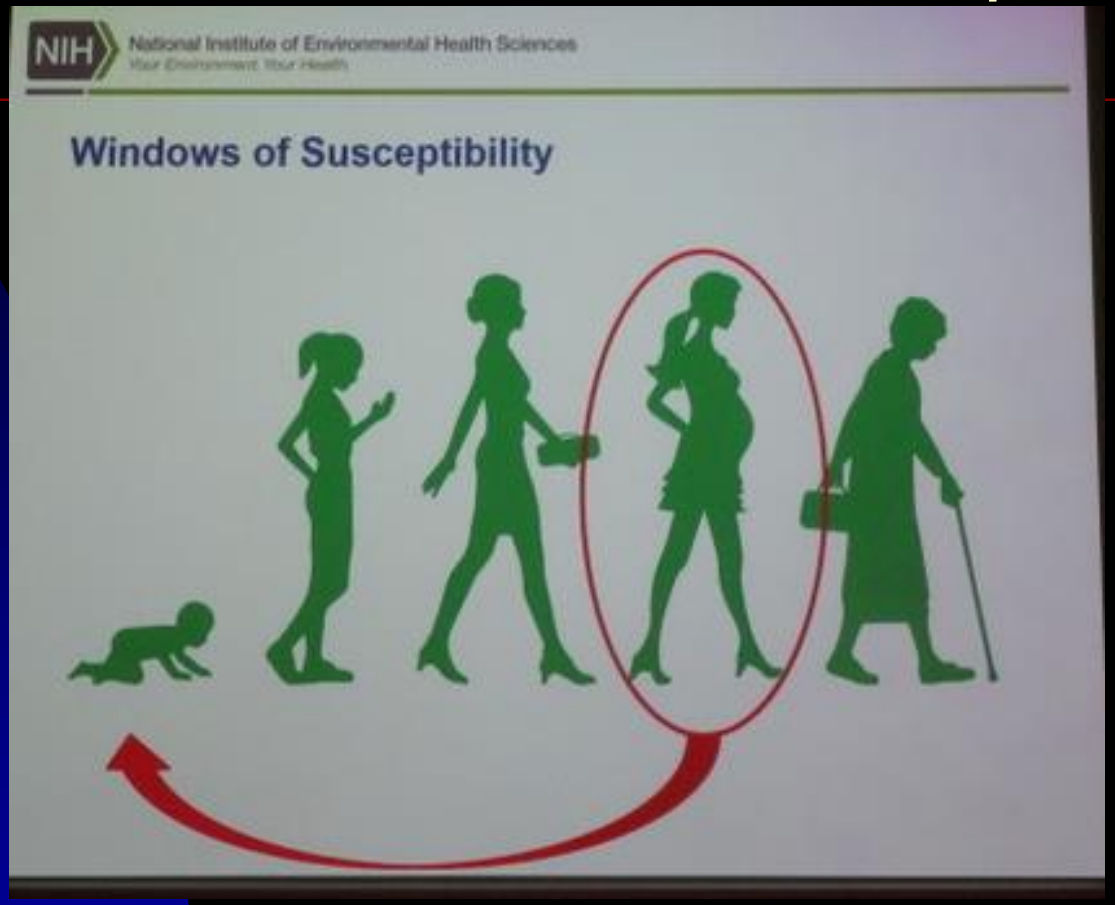


Oxford Press, 2017

What Is the Developmental Basis of Disease?

- Some chronic diseases originate from environmental insults during development and beyond—from embryos to fetuses to infants to teenagers (Cao, 2016), even to later life stages. (Heindel, 2018)
- Major mechanisms are epigenetic phenomena that turn genes on or off or alter protein regulation, but do not change DNA sequences. (Heindel, 2008)

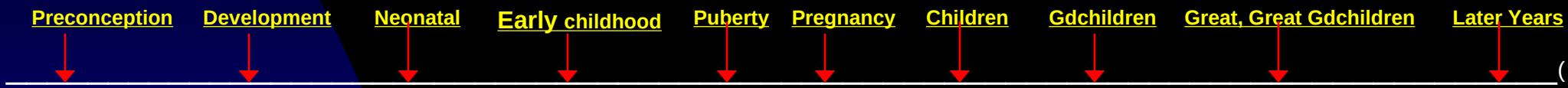
Timeline of Vulnerable Life Stages in a Person and Her Offspring



Preconception | Development | Neonatal | Early childhood | Puberty | Pregnancy | Children | Gdchildren | Great, Great Gdchildren | Later Years

(Heindel, 2018)

Timeline of Vulnerable Life Stages in a Person and Her Offspring

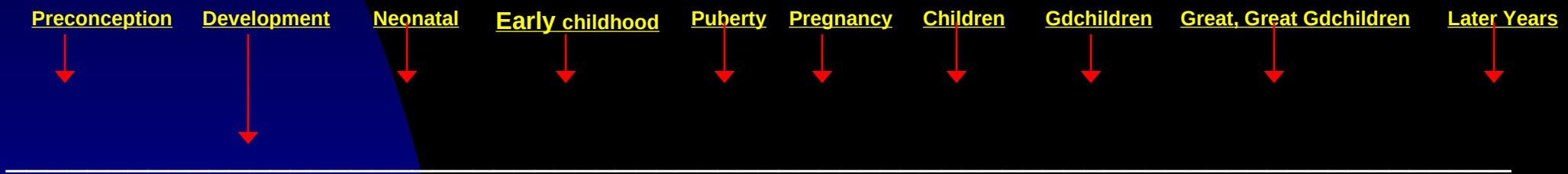


(Heindel, 2018)

- How many windows, what are they?
- What is the mechanism of sensitive windows outside of development?
- How do windows interact over the lifespan? (Heindel,Faroe Islands, 2018)

- Take home: We are not exposed at one specific life stage, but continually over a lifetime with different compounds—multiple lifetime exposures.

The Developmental Stage



(Heindel, 2018)

Developing Children Are Especially Vulnerable to Toxicants

- Are more susceptible to toxicants.
- Have greater exposures per body weight.
- Have lesser defenses.
- Have a longer lifespan for diseases to develop.
- Some adverse effects are irreversible.

Three Major Catastrophes Signaled These Findings

- *In utero* exposures to
  - MethylImercury
  - Thalidomide
  - Diethylstilbestrol

In utero Exposure to Methylmercury (1950s)

Sandra Bullock signs an autograph for Lisa Patrick, who suffers from Cerebral Palsy, and greets fans while at a red carpet premiere of her latest film, "The Blind Side," in New Orleans, Thursday, Nov. 19, 2009. AP Photo

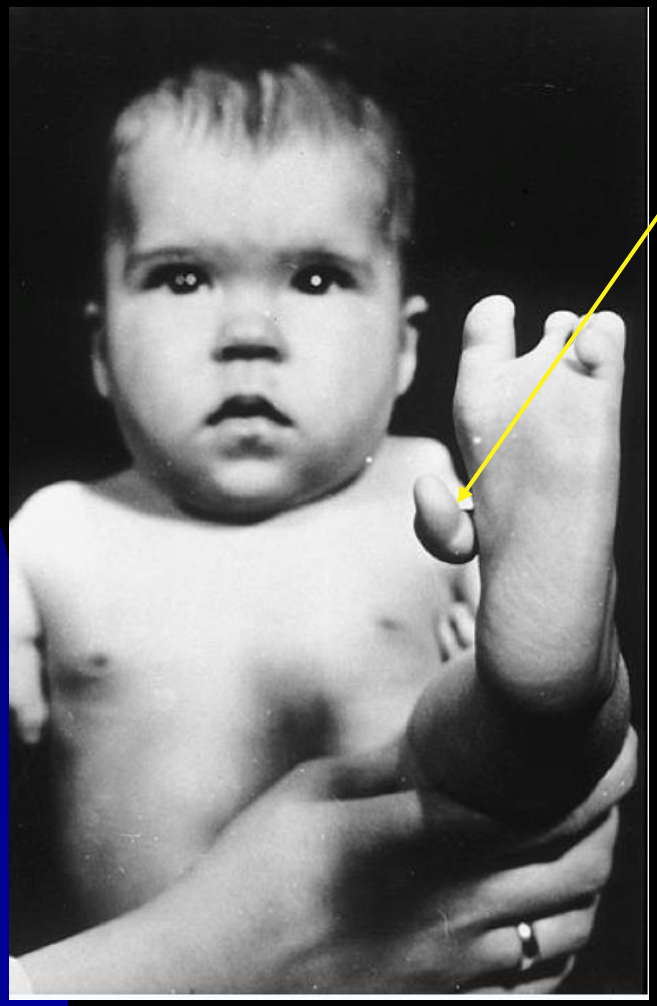
Methylmercury exposure *in utero at* Minimata Bay, Japan, induced cerebral palsy as well as

- mental retardation
- limb deformities
- constricted visual field
- sensory disturbance
- ataxia (poor muscle control)
- auditory disturbance
- disturbance of gait
- death.

- Cats having eaten contaminated fish "danced" strangely, jumped into the sea; birds fell from the sky. (Harada, 1995)

- 2,265 "official victims;" 10,000 compensated

First Trimester Ingestion of the Sedative Thalidomide (1960s)



National Cancer Institute, 1962

Thalidomide induced

- shortened limbs (affected 5k-7k children worldwide)

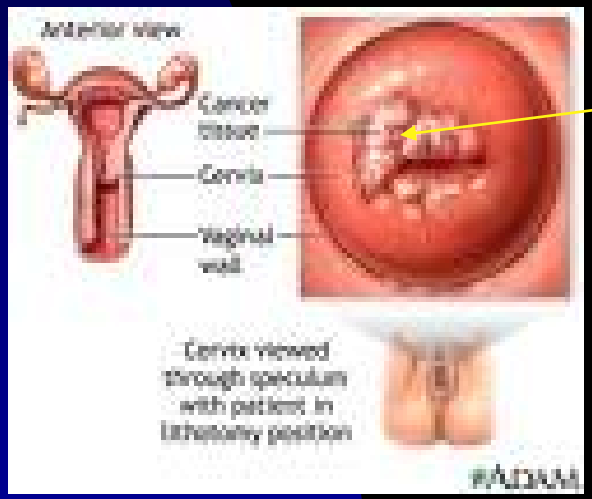
- no ears, deafness [subsequent retardation]
- no or small eyeballs
- spinal malformations
- congenital heart disease
- kidney abnormalities
- obstetrical problems (e.g., double vaginas)
- central nervous system problems, but often normal mentality
- autism (30 x higher)
- epilepsy, learning disorders
- death.

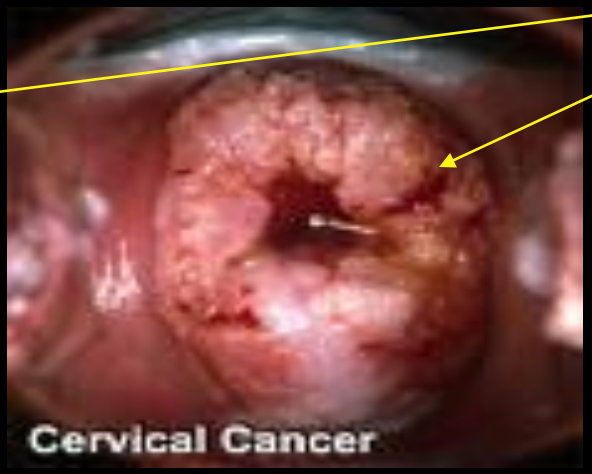
- 7k-8k were stillborn.

In utero Exposure to a Synthetic Estrogen (DES)

Diethylstilbestrol (DES) *in utero* induced cervical/vaginal cancer in daughters at age 20; 20 years later they were at increased risk of breast cancer.

DES mothers were also at increased risk of breast cancer.





Cancerous growth

Cedars Sinai Hospital, http://www.righthealth.com/Health/Photos%20Of%20Cervical%20Cancer-s?lid=goog-ads-sb-8536643334

We Are All Contaminated and Typically Over A Lifetime

- Up to 304+ manmade toxicants contaminate citizens. (CDC, 2017; Woodruff, et. al., 2011)
- Pregnant women can harbor 43+ toxicants shared with developing children *in utero*. (ACOG, 2013)
- Newborns have numerous toxicants in their bodies. (Fimrite, 2009)

Sources of Contamination

Everywhere, Everyday, and Everyone

Outdoor environment

Food supply

Workplace

Home/Indoor

Personal care products

Courtesy Tracey Woodruff, Obstetrics, UCSF

Routes of Contamination

- Ingestion
- Inhalation
- Absorption through the skin

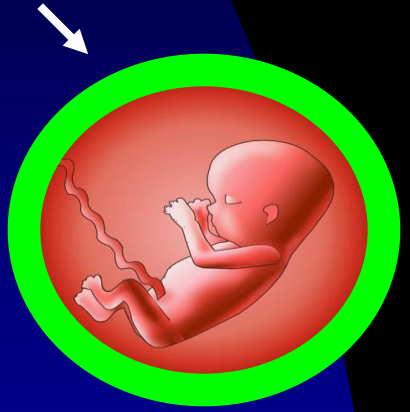
Women's Chemical Burden is Shared with Developing Fetuses and Newborns

- "[T]he vast majority of chemicals given a pregnant animal (or woman) reach the fetus in significant concentrations soon after administration." (Schardein, 2002)

- Plastic nanoparticles cross the placenta.
  (Wick, et al., 2010; 29 March 2010, EHN.org)

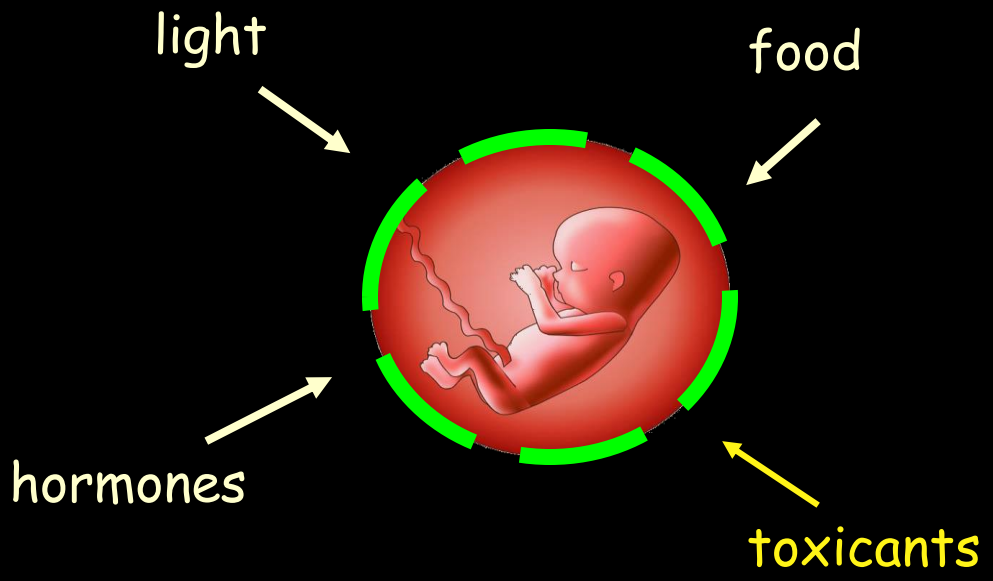
Development is a genetic program

1960s:
Perceived as comparatively impermeable (Needleman And Bellinger, 1995)



Mother is the fetal incubator

Development is an open system (developmental plasticity, ECO-DEVO)



Mother is the fetal environment

Courtesy
Ana Soto

Exquisite Sensitivity: Tiny Doses Can Pose Problems

- Mutagenic carcinogens—no threshold for toxicity.
  (David Eastmond, UCR Environmental Toxicology)
- Lead—no identified threshold for toxicity. (Lanphear, 2000, Canfield,2003; Bellinger & Needleman 2003, Goyer & Clarkson, 2006; Weaver & Silbergeld, 2007)
- Even substances that act via thresholds can produce linear effects in a large population. (Lutz, 1990)

Tiny Doses Can Pose Problems

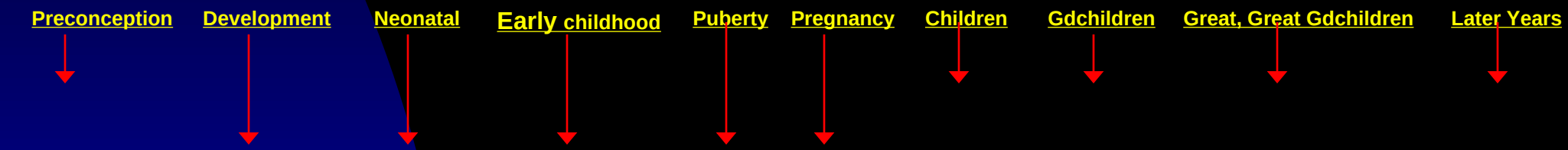
- A single Thalidomide pill caused malformations in at least one child. (Claudio, et. al., 2000)
- A single dose of valproic acid (anti-epileptic drug) *in utero* in animal studies can cause autism-like behavior. (Dufour-Rainfray, et. al., 2011).

Individual Genetic Variation Increases Vulnerability

- Susceptibility genes for
  - polycyclic aromatic hydrocarbons (by-products of combustion). (Perera, et. al.)
  - organophosphate pesticides. (Eskenazi, et. al., 2008)
  - methylmercury. (Julvez, et. al., 2013)

Numerous *Chronic Diseases* Arise from *In Utero,* Early Childhood, Teenage or Later Toxic Exposures

Timeline of Vulnerable Life Stages in a Person and Her Offspring



(Heindel, 2018)

- How many windows, what are they?
- How do windows interact over the lifespan? (Heindel, 2018)

The Annual Costs of *Neurodevelopmental* Diseases from Environmental Exposures (Excluding Lead)

Table 4. Estimated costs of neurobehavioral disorders of environmental origin, United States, 1997.

Lifetime costs per case of developmental disabilities	Mental retardation	Autism	Cerebral palsy
Physician visits	$17,127	—	$32,844
Prescription drugs	$3,121	—	$3,526
Hospitalization	$26,434	$4,437	$17,335
Assistive devices	$2,725	$116	$2,704
Therapy and rehabilitation	$11,577	$1,685	$14,421
Long-term care	$83,923	$32,846	$4,365
Home and auto modifications	$810	$571	$1,847
Special education services	$64,107	$72,399	$51,182
Home care	$907,742	$1,024,237	$882,932
Productivity losses due to morbidity	$563,869	$472,740	$467,753
Total lifetime costs per case	$1,680,000	$1,609,000	$1,479,000
Annual incident cases	44,190	4,698	11,614
Annual incident cases not attributable to lead	43,085	4,698	11,614
Total costs per annual cohort	$72.4 billion	$7.6 billion	$17.2 billion
Downward adjustment of costs for autism and cerebral palsy to account for co-existing mental retardation	—	–34%	–15%
	$72.4 billion	$5.0 billion	$14.6 billion
Total environmentally attributable costs of neurobehavioral disorders		$9.2 billion (range $4.6–18.4 billion)	

EAF estimated at 5, 10, or 20%.

Landrigan, et. al., *EHP* 2002

The Annual Costs of Lead-Caused Disorders

Table 1. Estimated costs of pediatric lead poisoning, United States, 1997.

EAF	=	100%
Main consequence	=	Loss of IQ over lifetime
Mean blood lead level in 1997 among 5-year-old children	=	2.7 µg/dL
A blood lead level of 1 µg/dL	=	Mean loss of 0.25 IQ points per child
Therefore, 2.7 µg/dL	=	Mean loss of 0.675 IQ points per child
Loss of 1 IQ point	=	Loss of lifetime earnings of 2.39%
Therefore, loss of 0.675 IQ points	=	Loss of 1.61% of lifetime earnings
Economic consequences		
For boys: loss of 1.61% × $881,027 (lifetime earnings) × 1,960,200	=	$27.8 billion
For girls: loss of 1.61% × $519,631 (lifetime earnings) × 1,869,800	=	$15.6 billion
Total costs of pediatric lead poisoning	=	$43.4 billion

Landrigan, et. al., *EHP* 2002

The Annual Costs of Asthma (Immune Disorders) Due to Environmental Origin

Table 2. Estimated costs of pediatric asthma of environmental origin, United States, 1997.

Medical and indirect costs	U.S. dollars
Hospital care	
Inpatient	634 million
Emergency room	323 million
Outpatient	154 million
Physicians' services	
Inpatient	54 million
Outpatient	625 million
Medications	2.81 billion
Subtotal: medical costs	4.6 billion
Indirect Costs	
School days lost	1.78 billion
Premature deaths	193 million
Subtotal: indirect costs	2.0 billion
Total costs of pediatric asthma	6.6 billion
EAF	30% (range 10–35%)
Environmentally attributable costs of pediatric asthma	2.0 billion (range $0.7–2.3 billion)

Landrigan, et. al., *EHP* 2002

Childhood (Life Long?) Cancers

- Most childhood cancers, begin in the womb, e.g., acute lymphoblastic (ALL) and acute myeloid childhood leukemias (AML) (Greaves & Wiemels, 2003; Smith, 2009;)
- Pesticide exposures are associated with ALL (11x) and AML (14x). (Ross, *et. al.*, 1994)
- Paternal and maternal exposures can elevate risks. (Ross, *et. al.*, 1994)

Secondary Diseases and *Treatment of Cancers* Add to Adverse Effects

- Secondary cancers/other diseases e.g., breast cancer, heart disorders, cognitive problems, diabetes, and infertility.
- Neurological problems, e.g., ADHD, reading, math difficulties, sometimes strokes.
- Failure to "thrive."
- Earlier mortality; accelerating the aging process. (McGinley, 2016)
- The disease and treatment-morbidities hamper opportunities.

The Annual Costs of Childhood Cancer Due to Environmental Origin

Table 3. Estimated costs of pediatric cancer of environmental origin, United States, 1997.

Costs	U.S. dollars
Medical costs (per primary case)	
Inpatient care	189,600
Outpatient care	20,400
Laboratory	263,200
Physicians' services	35,900
Subtotal: medical costs	509,000
Indirect morbidity costs (per primary case):	
Lost parental wages	13,500
Loss of IQ	60,500
Subtotal: indirect morbidity costs	74,000
Total morbidity costs per primary case	583,000
Morbidity costs of secondary cases[a]	40,000
Morbidity costs per case for primary and subsequent secondary cancer	623,000
Total annual morbidity costs of childhood cancer[b]	
Medical and indirect morbidity costs	4.8 billion
Costs of premature deaths	1.8 billion
Total morbidity costs	6.6 billion
Costs of environmentally attributable pediatric cancer	332 million (range 132–663 million)

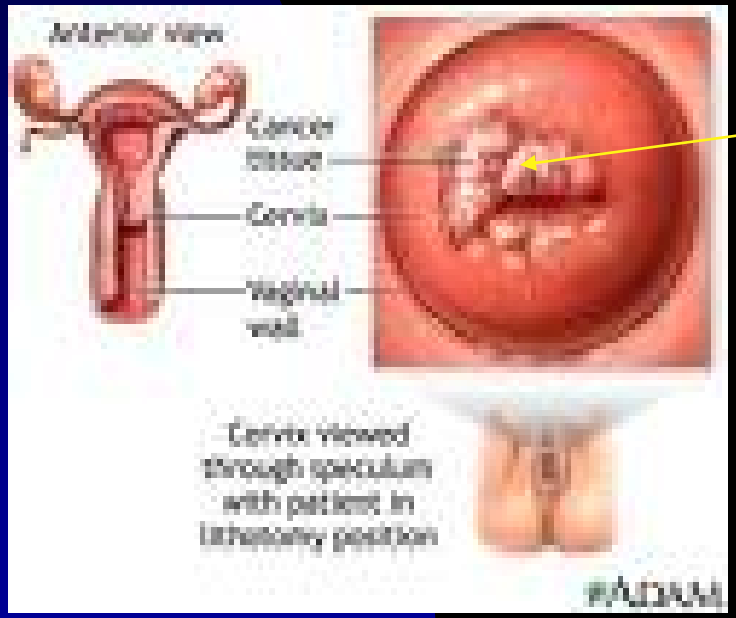
EAF calculated at 2, 5, and 10%.
[a]Present value of costs of second cases, 7.46% of above, excluding effects of radiation on IQ in second cancers. [b]Based on 7,722 new cases of childhood cancer per year.

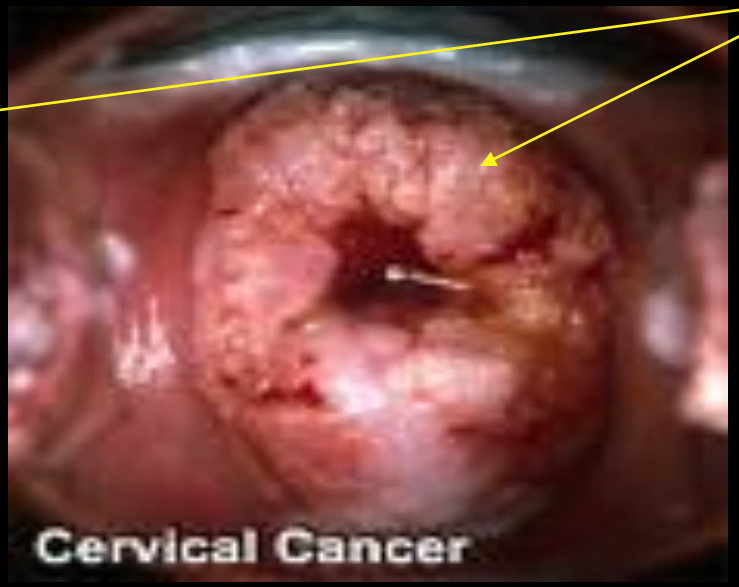
Landrigan, et. al., *EHP* 2002

Vaginal (Reproductive) Cancer from *in utero* Exposure

Diethylstilbestrol (DES) induced vaginal cancer in daughters about 20 years after exposure; 20 years later they were at increased risk of breast cancer.

DES mothers were also at increased risk of breast cancer.





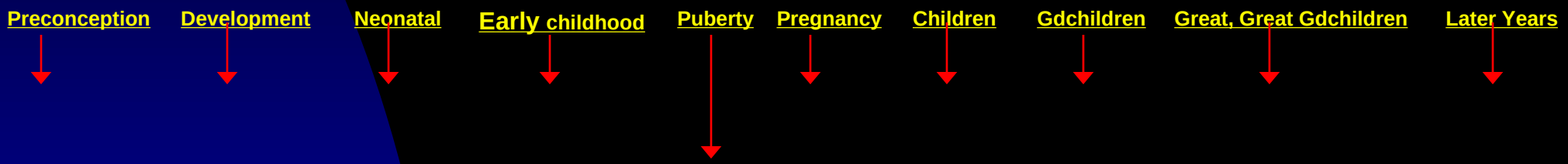
Cancerous growth

Cedars Sinai Hospital, http://www.righthealth.com/Health/Photos%20Of%20Cervical%20Cancer-s?lid=goog-ads-sb-8536643334

Breast Cancers:
Worse Effects in Children v. Adults at Same Dose

- Breast cancer risks are higher for teenage (or earlier) exposures than for adults to radiation (3-5X) and DDT (5x). (NAS 1990; Ronckers, 2004; Cohn, 2007).

The Developmental Stage



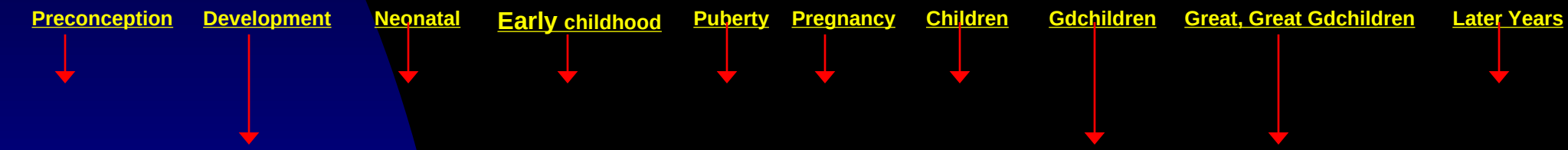
(Heindel, 2018)

Animal Data Show
Transgenerational Reproductive Disorders

- *In utero* toxic exposure when reproductive organs are developing causes transgenerational reproductive harm and some cancers in males and females alike through 4 generations.

(Anway, et al., 2006; Skinner, et. al., 2007, 2009; Manikkam, et. al. 2012; Nilsson, et al., Skinner, 2012)

Timeline of Vulnerable Life Stages in a Person and Her Offspring



(Heindel, 2018)

Obesity: A Chronic Condition Associated with Other Diseases

- type 2 diabetes and insulin resistance,
- coronary heart disease,
- high blood pressure and strokes,
- asthma and pulmonary problems,
- gall bladder and kidney diseases.
  (Newbold, et al., 2006)

Obesity

- A single dose of DES (or some other synthetic estrogens) is sufficient to cause obesity in mice.
  (Vom Saal, 2011)
- Not an energy imbalance

Obese Mouse; Normal Mouse

A single gene
methylated *in utero*
at one location (8 ppb)

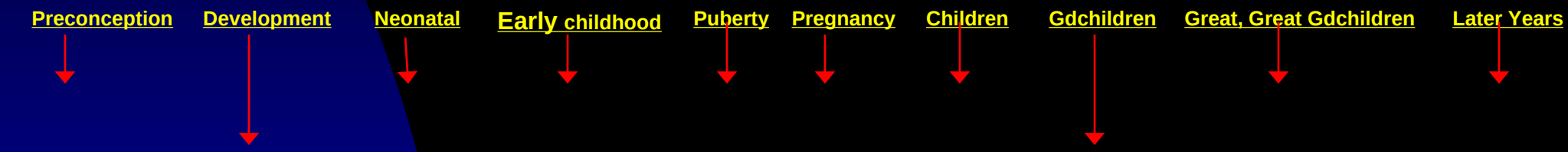
Same genome,
same diet,
same exercise,
different *in utero*
exposure to one dose
of a synthetic estrogen

Obesity

- Michael Skinner's lab identified transgenerational obesity (and other) effects from DDT at consumer exposures—in animal family lines (out to 4 generations).
(Skinner, Manikkam, et. al., 2013)

- His concern: DDT exposures 2 generations earlier may predispose people to obesity.

Timeline of Vulnerable Life Stages in a Person and Her Offspring



(Heindel, 2018)

“Contaminated Daddy” Factors

- Toxic contamination of males can produce miscarriages, along with prenatal or neonatal problems:

- Paxil, anesthetic gases, morphine, lead, mercury, pesticides, solvents, dyes, and paints.
(Anthes, *Miller-McCune*, 2010; Schulavitz, NYT, 2013)

“Contaminated Parents” Pose Occupational and Developmental Justice Issues

- Workers are “callously” unprotected. (Morris, 2015)
- “Yvette Flores’s body was a ‘toxic warehouse before [her son] Mark was conceived.’”
- Mark was born with “extensive cognitive impairment,” caused by *in utero* lead exposure. (Morris, 2015)

“Contaminated Parents:” Occupational and Developmental Issues

- Spectra-Physics and the Occupational Safety and Health Administration failed Yvette and Mark.
- Mark (now 36) has no ordinary opportunities; he cannot conduct daily living activities on his own.
- Justice requires increased (primordial?) occupational protections for adults *and their children*.

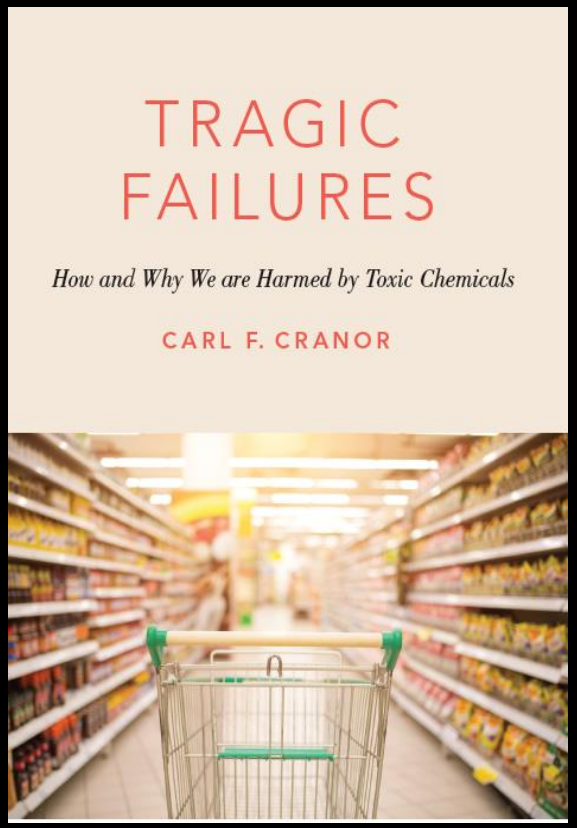
Yvette Flores brushes her son Mark’s hair at their home in San Jose, California, on Nov. 14, 2014.

Photo by Maryam Jameel/Center for Public Integrity

Brief Exposures Can Endure Biologically

- TINY, SOMETIMES *FLEETING* EXPOSURES CAN BECOME *BIOLOGICALLY EMBEDDED* IN INDIVIDUALS, IN THEIR CHILDREN, GRANDCHILDREN (MULTIGENERATIONAL), OR, WITH UNLUCKY TIMING IN GREAT GRANDCHILDREN AND BEYOND (TRANSGENERATIONAL), CAUSING ADVERSE EFFECTS.

What Should Be Done?



The Developmental Basis of Disease and Lifetime Exposures Show the Urgency to Change Legal Approaches

- This new science and our permeability to toxicants
  - Reveals the Inadequacy of legal protections from chronic diseases.
  - We cannot prevent permeability or developmental vulnerability.
- Laws preventing toxic exposures are the best approach.

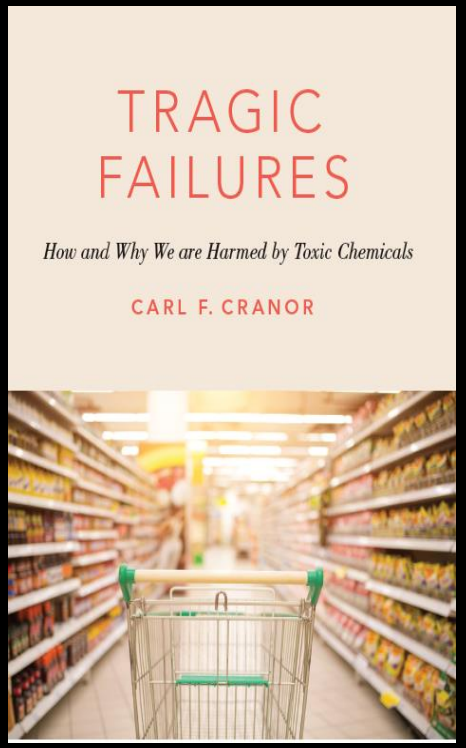
Legal Failures

Congress chose “Old” TSCA (1976) to regulate 80-90% of chemical creations with *postmarket* laws:

- 84,000 are in commerce with little toxicity data.
- They remain there until a health agency carries a difficult legal and scientific burden to reduce exposures.

Postmarket Laws Are Too Late to Protect Children and the Rest of US

- Are unjust; they
  - Cannot prevent chronic *diseases and morbidity* in children or adults.
  - Permit harm to children and adults
  - Undermine lifetime opportunities for some of us.



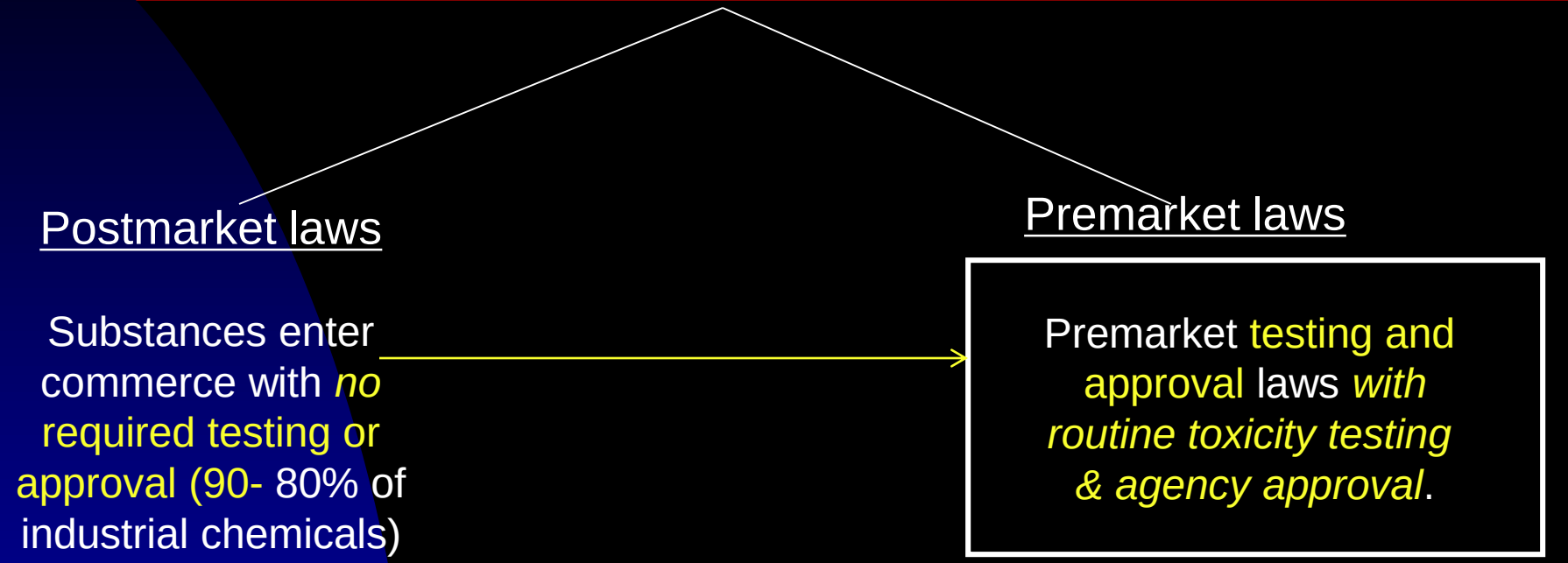
What Can Be Done about Toxicity-Induced Chronic Diseases?

- Vaccinations won't prevent them; antibiotics won't treat them.
- The law must primordially prevent toxic exposures and "clean up" toxicants as public health officials once cleaned up streets, sewage, water, and the air.
- We need legal changes and a political commitment to their implementation.

We Need *Primordial* Preventive Legal Protections

Medical/Personal	**Primordial Prevention**	**Primary Prevention**	**Secondary Prevention**	**Tertiary Prevention**
Lung disease, emphysema, COPD	Never smoke	Quit smoking early in life	Reduce, quit smoking later if not earlier	Surgery, other treatment
Diabetes, atherosclerosis	Never become obese	Reduce obesity/increase exercise	Reduce cholesterol, hypertension, time to first heart attack	Heart surgery, stints, statins
	Avoid sedentary behavior; exercise	Begin exercise	Begin exercise later if not earlier	Diabetes treatment
		Moderate other risks of chronic conditions		Total knee and hip replacements, cataract extractions
Liver disease, cirrhosis	Don't drink to excess/at all?	Quit the habit	Quit later if not earlier	
Legal/Institutional Responses	**Prevent initial exposures**-- Screen human created chemicals for toxicity with Premarket testing and scientific review laws—FDCA, New TSCA, pesticide laws	**Expeditiously reduce exposures** once they pose risks ---Use **postmarket regulatory actions** or postmarket correctives in premarket laws	**Sluggishly reduce exposures** once they pose risks --Use **postmarket regulatory actions** or postmarket correctives in premarket laws	**Remedy existing morbidities as best the law can** when they are caused by others' toxicants —Use the **tort (personal injury) law**

Generic Legal Strategies for Public Health Protections



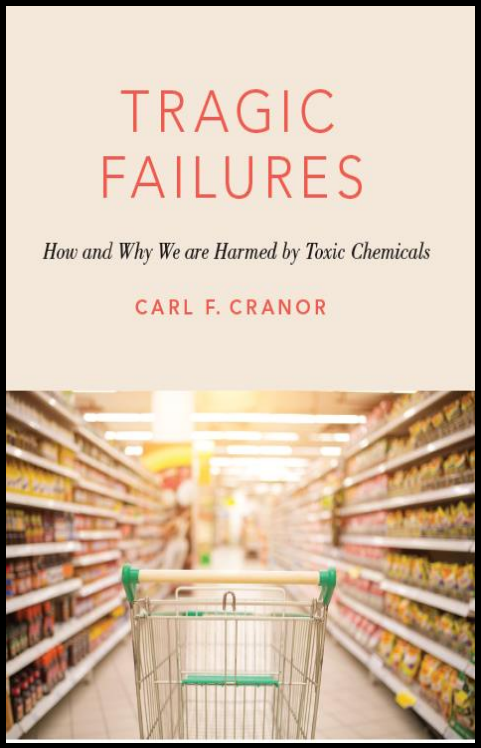
(Cranor & Eastmond, 2001; Cranor, 2006, 2011, 2016, 2017; Silbergeld, Cranor, Mandrioli, 2015)

Legal Failures

- Premarket testing and approval laws for pharmaceuticals and pesticides are better, but need improvement.
- They miss adverse effects; substances should be tested for developmental toxicity.
- The Food and Drug Administration: most drugs are not tested for children, yet are often prescribed. (FDA)

Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016)

- Congress enacted a “new” TSCA (June 2016) that
  - Requires EPA to “make an affirmative finding on the safety of a new chemical” before commercialization.
  - Seeks to protect “susceptible and highly exposed populations—pregnant women, children, and workers.”
  - Eases acquisition of needed data.
  - Provides aggressive legal timetables to reduce old toxicants.
  - But, the legacy of 84,000 untested substances is overwhelming—How many are “active” in commerce: 10,000, 20,000, 30,000 or more?



Some Conclusions:
A Step Toward Primordial Prevention

- Toxic contamination is unavoidable; no place to hide.
- Excellent premarket testing under “new” TSCA could prevent harm and contribute to an arc of good health.
- Removing existing toxicants will likely be slothful; they will linger for decades, some “forever,” (e.g., C8).

Some Conclusions: Possible Good News

- The Lautenberg Act would better serve justice if it were well- and efficiently-administered in the spirit of the law, and officials use science appropriate to the legal tasks.

Some Conclusions: Possible Bad News

- Will new chemicals be properly and broadly reviewed for safety--or will they receive a cursory review with little/no testing?
- The Bad News: Cursory reviews are apparently followed; since January 2017 the EPA has approved 600 new products to enter commerce, an unheard of rate and quite different from reviews of pharmaceuticals and pesticides.

Some Conclusions: We Can Do Better

- Collectively we can do much better.
- However, we need presidential administrations and EPA administrators committed to protecting the public's health.

Main Points

1. Chronic diseases concern both physicians and environmental health scientists.

2. Physicians provide an idea of precaution from which the law can learn: Primordial prevention.

3, Recent findings in environmental health concerning lifelong exposures increase the urgency legally to use primordial prevention to protect the public and workforce.

Thank you