Mayor and Council of City of Vancouver
City Hall
453 West 12th Avenue
Vancouver, BC V5Y 1V4

October 14th, 2019

Re: Changing Animal Testing Protocols – New Innovations

Dear Mayor Stewart and Council:

I write today to ask Council NOT to allow rezoning for animal laboratories at the new St. Paul's Hospital Medical Hospital. There is a better way!

As you are aware, science and technology are progressing at lightning speed and, in the many areas, that means that our present methods and methodology need to be revised.

For decades, animals have been used in medical laboratories and subjected to all kinds of horrendous experiments in the hopes of finding cures for diseases in humans. Millions of animals have been subjected to pain and death and our society still has no cures for major illnesses such as cancer, diabetes, heart and high blood pressure conditions. In fact, hundreds of the drugs that were tested on animals and given approval for use in humans have had to be withdrawn from the marketplace, citing negative consequences for humans that were not discovered in clinical trials using animals. Just a few of these examples are listed in the links below:

(Printed copies of all the articles for the links below are attached.)

https://en.wikipedia.org/wiki/List_of_withdrawn_drugs

https://prescriptiondrugs.procon.org/view.resource.php?resourceID=005528

More and more, the medical community has been refining medical care to see if drugs and treatments can be customized for individual patients for a more personalized approach, using their own blood and stem cells. Medical ideas such as "regenerative medicine, tissue engineering and gene therapy offer the opportunity to treat and cure many of today's intractable afflictions." (Feb. 26/14 - from Biomedicines - US National Library Medicine, National Institutes of Health).

"According to the U.S. Food and Drug Administration, 9 out of 10 drugs that pass animal tests fail in humans because they don't work or are dangerous. With this acknowledgement, various agencies, such as the Environmental Protection Agency and National Institutes of Health, have made efforts to reduce the use of animal testing." (July 24/16 - from "Human on a Chip Technology"
- https://www.newsobserver.com/news/technology/article91642877.html)

The article below is on innovative technology from the University of Pennsylvania's School of Engineering and Applied Science.

https://medium.com/penn-engineering/penn-engineerings-blinking-eye-on-a-chip-used-for-disease-modeling-and-drug-testing-b98392ece6cf

The new St. Paul's complex is going to be the latest in design and materials, with state of the art facilities. The motto on its own website is "The future of health care in BC starts at the new St. Paul's". If that's true, then it is

time for St. Paul's (and the City of Vancouver) to move with the changing times and engage the cutting edge, innovative testing protocols that are progressing in the marketplace. If you ARE building for the future, then embrace the future and offer our citizens the benefits of the latest advances in technology.

https://helpstpauls.com/newstpauls?gclid=CjwKCAjwnrjrBRAMEiwAXsCc4_EpgilxuB4JZ857OIoPki7tHOV5axl_aLnvTcZlmn4DoCZJ6HK1iRoCpNEQAvD_BwE

I hope St. Paul's and City Council will lead the way and be an example for other cities. I oppose animal testing.

Sincerely,

s.22(1) Personal and Confidential

Mrs. Lana Simon

s.22(1) Personal and Confidential

WIKIPEDIA

List of withdrawn drugs

Drugs or medicines may be **withdrawn** from commercial markets because of risks to patients, but also because of commercial reasons (e.g. lack of demand and relatively high production costs). Where risks or harms is the reason for withdrawal, this will usually have been prompted by unexpected adverse effects that were not detected during Phase III clinical trials, i.e. they were only made apparent from postmarketing surveillance data collected from the wider community over longer periods of time.

This list is not limited to drugs that were ever approved by the FDA. Some of them (lumiracoxib, rimonabant, tolrestat, ximelagatran and ximelidine, for example) were approved to be marketed in Europe but had not yet been approved for marketing in the US, when side effects became clear and their developers pulled them from the market. Some drugs in this list (e.g. LSD) were never approved for marketing in the US or Europe.

Contents

Significant withdrawals

1

Drug name	Withdrawn	Country	Remarks
Adderall XR	2005	Canada	Risk of stroke[1] The ban was later lifted because the death rate among those taking Adderall XR was determined to be no greater than those not taking Adderall.
Alatrofloxacin	2006	Worldwide	Serious liver injury leading to liver transplant or death.[2]
Alclofenac	1979	UK	Vasculitis[3]
Alpidem (Ananxyl)	1995	Worldwide	Not approved in the US, withdrawn in France in 1994[4] and the rest of the market in 1995 because of rare but serious hepatotoxicity.[3][5]
Alosetron (Lotronex)	2000	US	Serious gastrointestinal adverse events; ischemic colitis; severe constipation.[2] Reintroduced 2002 on a restricted basis
Althesin (=Alphaxolone amineptine + Alphadolone)	1984	France, Germany, UK	Anaphylaxis.[3]
Amineptine (Survector)	1999	France, US	Hepatotoxicity, dermatological side effects, and abuse potential.[6] Reason:
Aminopyrine	1999	France, Thailand	risk of agranulocytosis and severe acne.[3]
Amobarbital	1980	Norway	Risk of overdose.[3]
Amoproxan	1970	France	Dermatologic and ophthalmic toxicity.[3]
Anagestone acetate	1969	Germany	Animal carcinogenicity.[3]
Antrafenine	1984	France	Unspecific experimental toxicity.[3]
Aprotinin (Trasylol)	2008	US	Increased risk of death.[2]
Ardeparin (Normiflo)	2001	US	Not for reasons of safety or efficacy.[7]
Astemizole (Hismanal)	1999	US, Malaysia, Multiple Nonspecified Markets	Fatal arrhythmia[2][3]
Azaribine	1976	US	Thromboembolism.[3]
Bendazac	1993	Spain	Hepatotoxicity.[3]
Benoxaprofen	1982	Germany, Spain, UK, US	Liver and kidney failure; gastrointestinal bleeding; ulcers.[2][3]
Benzarone	1992	Germany	Hepatitis.[3]
Benziodarone	1964	France, UK	Jaundice.[3]
Beta-ethoxy-lacetanilanide	1986	Germany	Renal toxicity, animal carcinogenicity.[3]
Bezitramide	2004	Netherlands	Risk of fatal overdose[8]
Bithionol	1967	US	Dermatologic toxicity.[3]

Drug name	Withdrawn	Country	Remarks
Broazolam	1989	UK	Animal carcinogenicity.[3]
Bromfenac	1998	US	Severe hepatitis and liver failure (requiring transplantation).[2]
Bucetin	1986	Germany	Kidney damage[3]
Buformin	1978	Germany	Metabolic toxicity.[3]
Bunamiodyl	1963	Canada, UK, US	Nephropathy.[9]
Butamben (Efocaine) (Butoforme)	1964	US	Dermatologic toxicity; psychiatric Reactions.[3]
Canrenone	1986	Germany	Animal Carcinogenicity.[3]
Cerivastatin (Baycol, Lipobay)	2001	US	Risk of rhabdomyolysis[2]
Chlormadinone (Chlormenadione)	1970	UK, US	Animal Carcinogenicity.[3]
Chlormezanone (Trancopal)	1996	European Union, US, South Africa, Japan	Hepatotoxicity & Steven-Johnson Syndrome [3]
Chlorphentermine	1969	Germany	Cardiovascular Toxicity.[3]
Cianidanol	1985	France, Germany, Spain, Sweden	Hemolytic Anemia.[3]
Cinepazide	1988	Spain	Agranulocytosis.[10][11]
Cisapride (Propulsid)	2000	US	Risk of fatal cardiac arrhythmias[2]
Clioquinol	1973	France, Germany, UK, US	Neurotoxicity.[3]
Clobutinol	2007	Germany	Ventricular arrhythmia, QT-prolongation.[12]
Cloforex	1969	Germany	Cardiovascular toxicity.[3]
Clomacron	1982	UK	Hepatotoxicity.[3]
Clometacin	1987	France	Hepatotoxicity.[3]
Co-proxamol (Distalgesic)	2004	UK	Risk of overdose
Cyclobarbital	1980	Norway	Risk of overdose[3]
Cyclofenil	1987	France	Hepatotoxicity.[3]
Dantron	1963	Canada, UK, US	Mutagenic.[13] withdrawn from general use in UK but permitted in terminal patients
Dexfenfluramine	1997	European Union, UK, US	Cardiotoxic[3]
Propoxyphene (Darvocet/Darvon)	2010	Worldwide	Increased risk of heart attacks and stroke.[14]
Diacetoxydiphenolisatin	1971	Australia	Hepatotoxicity.[3]
Diethylstilbestrol	1970s	US	Carcinogen
Difemerine	1986	Germany	Multi-Organ toxicities.[3]
Dihydrostreptomycin	1970	US	Neuropsychiatric reaction.[3]

Drug name	Withdrawn	Country	Remarks
Dilevalol	1990	UK	Hepatotoxicity.[3]
Dimazole (Diamthazole)	1972	France, US	Neuropsychiatric reaction.[3]
Dimethylamylamine (DMAA)	1983	US	Voluntarily withdrawn from market by Lily.[15]:12 Reintroduced as a dietary supplement in 2006;[15]:13 and in 2013 the FDA started work to ban it due to cardiovascular problems[16]
Dinoprostone	1990	UK	Uterine hypotonus, fetal distress.[3]
Dipyrone (Metamizole)	1975	UK, US, Others	Agranulocytosis, anaphylactic reactions.[3]
Dithiazanine iodide	1964	France, US	Cardiovascular and metabolic reaction.[3]
Dofetilide	2004	Germany	Drug interactions, prolonged QT.[12]
Drotrecogin alfa (Xigris)	2011	Worldwide	Lack of efficacy as shown by PROWESS-SHOCK study[17][18][19]
Ebrotidine	1998	Spain	Hepatotoxicity.[3]
Efalizumab (Raptiva)	2009	Germany	Withdrawn because of increased risk of progressive multifocal leukoencephalopathy[12]
Encainide	1991	UK, US	Ventricular arrhythmias.[2][3]
Ethyl carbamate	1963	Canada, UK, US,	Carcinogen.[20]
Etretinate	1989	France	Teratogen.[2][3]
Exifone	1989	France	Hepatotoxicity.[3]
Fen-phen (popular combination of fenfluramine and phentermine)	1997		Cardiotoxicity
Fenclofenac	1984	UK	Cutaneous reactions; animal carcinogenicity.[3]
Fenclozic acid	1970	UK, US	Hepatotoxicity.[3]
Fenfluramine	1997	European Union, UK, US, India, South Africa, others	Cardiac valvular disease, pulmonary hypertension, cardiac fibrosis.[3][21]
Fenoterol	1990	New Zealand	Asthma mortality.[3]
Feprazone	1984	Germany, UK	Cutaneous reaction, multiorgan toxicity.[3]
Fipexide	1991	France	Hepatotoxicity.[3]
Flosequinan (Manoplax)	1993	UK, US	Increased mortality at higher doses; increased hospitalizations.[2][3]
Flunitrazepam	1991	France	Abuse.[3]
Flupirtine	2018	European Union	Liver toxicity.[22]

Drug name	Withdrawn	Country	Remarks
Gatifloxacin	2006	US	Increased risk of dysglycemia.[2]
Gemtuzumab ozogamicin (Mylotarg)	2010	US	No improvement in clinical benefit; risk for death.[2]
Glafenine	1984	France, Germany	Anaphylaxis.[3]
Grepafloxacin (Raxar)	1999	Withdrawn Germany, UK, US others	Cardiac repolarization; QT interval prolongation.[2]
Hydromorphone (Palladone, extended release version)	2005		High risk of accidental overdose when extended release version (Palladone) administered with alcohol. Standard hydromorphone is sold in most of the world including the US
Ibufenac	1968	UK	Hepatotoxicity, jaundice.[3]
Indalpine	1985	France	Agranulocytosis.[3]
Indoprofen	1983	Germany, Spain, UK	Animal carcinogenicity, gastrointestinal toxicity.[3]
Iodinated casein strophantin	1964	US	Metabolic reaction.[3]
Iproniazid	1964	Canada	Interactions with food products containing tyrosine.[23]
Isaxonine phosphate	1984	France	Hepatotoxicity.[3]
Isoxicam	1983	France, Germany, Spain, others	Stevens johnson syndrome.[3]
Kava Kava	2002	Germany	Hepatotoxicity.[12]
Ketorolac	1993	France, Germany, others	Hemorrhage, renal Failure.[3]
L-tryptophan	1989	Germany, UK	Eosinophilic myalgia syndrome.[3] Still sold in the US
Levamisole (Ergamisol)	1999	US	Still used as veterinary drug and as a human antihelminthic in many markets; listed on the WHO List of Essential Medicines. In humans, it was used to treat melanoma before it was withdrawn for agranulocytosis.[24][25][26]
Levomethadyl acetate	2003	US	Cardiac arrhythmias and cardiac arrest.[2]
Lumiracoxib (Prexige)	2007–2008	Worldwide	Liver damage
Lysergic acid diethylamide (LSD)	1950s–1960s		Marketed as a psychiatric drug; withdrawn after it became widely used recreationally. Now illegal in most of the world.
Mebanazine	1975	UK	Hepatotoxicity, drug intereaction.[3]
Methandrostenolone	1982	France, Germany, UK, US, others	Off-label abuse.[3]
Methapyrilene	1979	Germany, UK, US	Animal carcinogenicity.[3]
Methaqualone	1984	South Africa (1971), India (1984), United Nations (1971–1988)	Withdrawn because of risk of addiction and overdose[27][28]

Drug name	Withdrawn	Country	Remarks
Metipranolol	1990	UK, others	Uveitis.[3]
Metofoline	1965	US	Unspecific experimental toxicity.[3]
Mibefradil	1998	European Union, Malaysia, US, others	Fatal arrhythmia, drug interactions.[2][3]
Minaprine	1996	France	Convulsions.[3]
Moxisylyte	1993	France	Necrotic hepatitis.[3]
Muzolimine	1987	France, Germany, European Union	Polyneuropathy.[3]
Natalizumab (Tysabri)	2005–2006	US	Voluntarily withdrawn from US market because of risk of Progressive multifocal leukoencephalopathy (PML). Returned to market July, 2006.
Nefazodone	2007	US, Canada, others	Branded version withdrawn by originator in several countries in 2007 for hepatotoxicity. Generic versions available.[29]
Nialamide	1974	UK, US	Hepatotoxicity, drug intereaction.[3]
Nikethamide	1988	multiple markets	CNS Stimulation.[3]
Nitrefazole	1984	Germany	Hepatic and hematologic toxicity.[3]
Nomifensine	1981–1986	France, Germany, Spain, UK, US, others	Hemolytic Anemia, hepatotoxicity, serious hypersensitive reactions.[2][3]
Oxeladin	1976	Canada, UK, US (1976)	Carcinogen.[30]
Oxyphenbutazone	1984–1985	UK, US, Germany, France, Canada	Bone marrow suppression, Stevens–Johnson syndrome.[3][31][32]
Oxyphenisatin (Phenisatin)		Australia, France, Germany, UK, US	Hepatotoxicity.[3]
Ozogamicin	2010	US	No improvement in clinical benefit; risk for death; veno-occlusive disease.[2]
Pemoline (Cylert)	1997	Canada, UK	Withdrawn from US in 2005. Hepatotoxicity[33] Reason:hepatotoxicity.[3]
Pentobarbital	1980	Norway	Risk of fatal overdose[3]
Pentylenetetrazol	1982	US	Withdrawn for inability to produce effective convulsive therapy, and for causing seizures.
Pergolide (Permax)	2007	US	Risk for heart valve damage.[2]
Perhexiline	1985	UK, Spain	Neurologic and hepatic toxicity.[3]
Phenacetin	1975	Canada	An ingredient in "A.P.C." tablet; withdrawn because of risk of cancer and kidney disease[34] Germany Denmark, UK, US, others Reason: nephropathy.[3]

Drug name	Withdrawn	Country	Remarks
Phenformin and Buformin	1977	France, Germany US	Severe lactic acidosis[3]
Phenolphthalein	1997	US	Possible carcinogen.[35]
Phenoxypropazine	1966	UK	Hepatotoxicity, drug intereaction.[3]
Phenylbutazone	1985	Germany	Off-label abuse, hematologic toxicity.[3]
Phenylpropanolamine (Propagest, Dexatrim)	2000	Canada, US	Hemorrhagic stroke.[36][37]
Pifoxime (=Pixifenide)	1976	France	Neuropsychiatric reaction.[3]
Pirprofen	1990	France, Germany, Spain	Liver toxicity.[3][10]:223
Prenylamine	1988	Canada, France, Germany, UK, US, others	Cardiac arrythmia[38] and death.[3]
Proglumide	1989	Germany	Respiratory reaction.[3]
Pronethalol	1965	UK	Animal carcinogenicity.[3]
Propanidid	1983	UK	Allergy.[3]
Proxibarbal	1998	Spain, France, Italy, Portugal, Turkey	Immunoallergic, thrombocytopenia.[3]
Pyrovalerone	1979	France	Abuse.[3]
Rapacuronium (Raplon)	2001	US, multiple markets	Withdrawn in many countries because of risk of fatal bronchospasm[2]
Remoxipride	1993	UK, others	Aplastic anemia.[3]
rhesus rotavirus vaccine-tetravalent (RotaShield)	1999	US	Withdrawn due to risk of intussusception[39]
Rimonabant (Acomplia)	2008	Worldwide	Risk of severe depression and suicide[12]
Rofecoxib (Vioxx)	2004	Worldwide	Withdrawn by Merck & Co. Risk of myocardial infarction and stroke[2]
Rosiglitazone (Avandia)	2010	Europe	Risk of heart attacks and death. This drug continues to be available in the US
Secobarbital		France, Norway, others.	Risk of overdose[3]
Sertindole	1998	European Union	Arrhythmia and sudden cardiac death[3][40]
Sibutramine (Reductil/Meridia)	2010	Australia,[41] Canada,[42] China,[43] the European Union (EU),[44] Hong Kong,[45] India,[46] Mexico, New Zealand,[47] the Philippines,[48] Thailand,[49] the United Kingdom,[50] and the United States[51]	Increased risk of heart attack and stroke.[2]
Sitaxentan	2010	Germany	Hepatotoxicity.[12]

Drug name	Withdrawn	Country	Remarks
Sorivudine	1993	Japan	Drug interaction and deaths.[52]
Sparfloxacin	2001	US	QT prolongation and phototoxicity.[2]
Sulfacarbamide	1988	Germany	Dermatologic, hematologic and hepatic reactions.[3]
Sulfamethoxydiazine	1988	Germany	Unknown.[3]
Sulfamethoxypyridazine	1986	UK	Dermatologic and hematologic reactions.[3]
Suloctidil	1985	Germany, France, Spain	Hepatotoxicity.[3]
Suprofen	1986–1987	UK, Spain, US	Kidney damage.[2][3]
Tegaserod (Zelnorm)	2007	US	Risk for heart attack, stroke, and unstable angina.[2] Was available through a restricted access program until April 2008.
Temafloxacin	1992	Germany, UK, US, others	Low blood sugar; hemolytic anemia; kidney, liver dysfunction; allergic reactions[2][3]
Temafloxacin	1992	US	Allergic reactions and cases of hemolytic anemia, leading to three patient deaths.[2] (http://www.fda.gov/bbs/topics/NEWS/NEW00279.html)
Temazepam (Restoril, Euhypnos, Normison, Remestan, Tenox, Norkotral)	1999	Sweden, Norway	Diversion, abuse, and a relatively high rate of overdose deaths in comparison to other drugs of its group. This drug continues to be available in most of the world including the US, but under strict controls.
Terfenadine (Seldane, Triludan)	1997–1998	France, South Africa, Oman, others, US	Prolonged QT interval; ventricular tachycardia[2][3]
Terodiline (Micturin)	1991	Germany, UK, Spain, others	Prolonged QT interval, ventricular tachycardia and arrhythmia.[3]
Tetrazepam	2013	European Union	Serious cutaneous reactions.[53]
Thalidomide	1961	Germany	Withdrawn because of risk of teratogenicity;[54] returned to market for use in leprosy and multiple myeloma under FDA orphan drug rules
Thenalidine	1963	Canada, UK, US	Neutropenia[3][55]
Thiobutabarbitone	1993	Germany	Kidney injury.[3]
Thioridazine (Melleril)	2005	Germany, UK	Withdrawn worldwide due to severe cardiac arrhythmias[56][57]
Ticrynafen (Tienilic acid)	1980	Germany, France, UK, US others	Liver toxicity and death.[3]
Tolcapone (Tasmar)	1998	European Union, Canada, Australia	Hepatotoxicity[3]
Tolrestat (Alredase)	1996	Argentina, Canada, Italy, others	Severe hepatotoxicity[3]

Drug name	Withdrawn	Country	Remarks
Triacetyldiphenolisatin	1971	Australia	Hepatotoxicity.[3]
Triazolam	1991	France, Netherlands, Finland, Argentina, UK others	Psychiatric adverse drug reactions, amnesia.[3][58]
Triparanol	1962	France, US	Cataracts, alopecia, ichthyosis.[3]
Troglitazone (Rezulin)	2000	US, Germany	Hepatotoxicity[2]
Trovafloxacin (Trovan)	1999–2001	European Union, US	Withdrawn because of risk of liver failure[2][3]
Valdecoxib (Bextra)	2004	US	Risk of heart attack and stroke.[2]
Vincamine	1987	Germany	Hematologic toxicity.[3]
Xenazoic acid	1965	France	Hepatotoxicity.[3]
Ximelagatran (Exanta)	2006	Germany	Hepatotoxicity[12]
Zimelidine	1983	Worldwide	Risk of Guillain–Barré syndrome, hypersensitivity reaction, hepatotoxicity[3][59][60] banned worldwide.[61]
Zomepirac	1983	UK, Germany, Spain, US	Anaphylactic reactions and non-fatal allergic reactions, renal failure[2][3]

See also

- Adverse drug reaction
- Adverse events
- European Medicines Agency
- Food and Drug Administration

References

1. Branch, Government of Canada, Health Canada, Public Affairs, Consultation and Communications. "Health Canada – Home Page" (http://www.hc-sc.gc.ca/english/protection/warnings/2005/2005_01.html). Archived (https://web.archive.org/web/20050628074032/http://www.hc-sc.gc.ca/english/protection/warnings/2005/2005_01.html) from the original on 28 June 2005. Retrieved 28 November 2016.
2. Qureshi, ZP; Seoane-Vazquez, E; Rodriguez-Monguio, R; Stevenson, KB; Szeinbach, SL (July 2011). "Market withdrawal of new molecular entities approved in the United States from 1980 to 2009". *Pharmacoepidemiology and Drug Safety*. **20** (7): 772–7. doi:10.1002/pds.2155 (https://doi.org/10.1002%2Fpds.2155). PMID 21574210 (https://www.ncbi.nlm.nih.gov/pubmed/21574210).
3. Fung, M.; Thornton, A.; Mybeck, K.; Wu, J. H.-h.; Hornbuckle, K.; Muniz, E. (1 January 2001). "Evaluation of the Characteristics of Safety Withdrawal of Prescription Drugs from Worldwide Pharmaceutical Markets-1960 to 1999". *Therapeutic Innovation & Regulatory Science*. **35** (1): 293–317. doi:10.1177/009286150103500134 (https://doi.org/10.1177%2F009286150103500134).
4. "WHO Drug Information Vol. 8, No. 2, 1994, page 64" (http://whqlibdoc.who.int/druginfo/DRUG_INFO_8_2_1994.pdf) (PDF). Archived (https://web.archive.org/web/20120303224305/http://whqlibdoc.who.int/druginfo/DRUG_INFO_8_2_1994.pdf) (PDF) from the original on 3 March 2012. Retrieved 28 November 2016.

Last updated on: 1/30/2014 | Author: ProCon.org

FDA-Approved Prescription Drugs Later Pulled from the Market

Below are the 35 drugs we could find that have been recalled from the US market since the 1970s, some that had been in use since the 1930s. A sample of advertisements for only some of the drugs are included because there is a scarcity of ads for withdrawn drugs online due to manufacturers removing ads for withdrawn drugs as part of the agreement to no longer market the drugs.

According to the FDA, a "drug is removed from the market when its risks outweigh its benefits. A drug is usually taken off the market because of safety issues with the drug that cannot be corrected, such as when it is discovered that the drug can cause serious side effects that were not known at the time of approval." The FDA also takes into account the number of people taking a drug being considered for removal so as to not harm those patients.

2

1. Accutane (Isotretinoin)

on the market for **27** YEARS

1982 to June 2009

Use: Acne
Manufacturer: Hoffman-La Roche

Cause for recall:
increased risk of birth defects, miscarriages, and premature births when used by pregnant women; inflammatory bowel disease; suicidal tendencies

Over 7,000 lawsuits were filed against the manufacturer over the side effects including a $10.5 million verdict and two $9 million verdicts.

2. Baycol (Cerivastatin)

on the market for **3** YEARS

1998 to Aug. 2001

Use: Cholesterol reduction
Manufacturer: Bayer A.G.

Cause for recall:
rhabdomyolysis (breakdown of muscle fibers that results in myoglobin being released into the bloodstream) which led to kidney failure; 52 deaths (31 in the US) worldwide; 385 nonfatal cases with most requiring hospitalization; 12 of the deaths were related to taking this drug in combination with gemfibrozil (Lopid)

3. Bextra (Valdecoxib)

on the market for

3.3

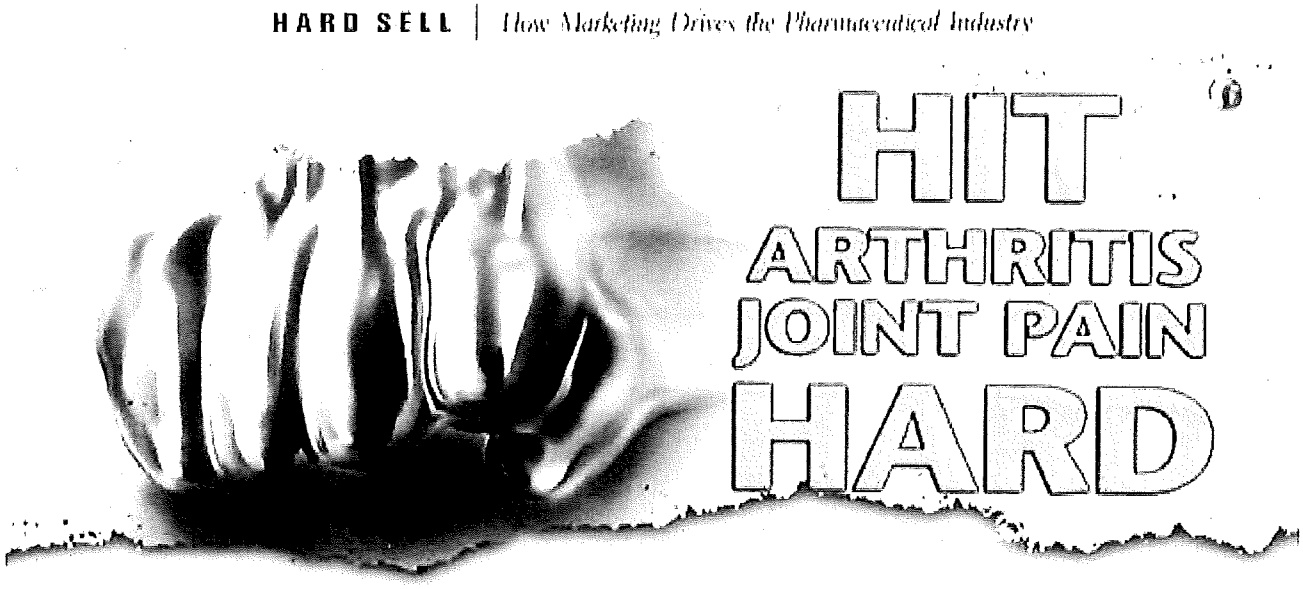
YEARS

Nov. 20, 2001 to Apr. 7, 2005

Use: NSAID (pain relief)
Manufacturer: G.D. Searle & Co.

Cause for recall:
serious cardiovascular adverse events (like death, MI, stroke); increased risk of serious skin reactions (like toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme); gastrointestinal bleeding

The FDA determined that Bextra showed no advantage over other NSAID pain relievers on the market.



The ad illustrated above is for Bextra in a September issue of the Journal of the American Medical Association.

Bernadette Tansey, "Hard Sell: How Marketing Drives the Pharmaceutical Industry/The Side Effects of Drug Promotion/Aggressive Ads for Painkillers Left More Patients Exposed to Risk," www.sfgate.com, Feb. 27, 2005

4. Cylert (Pemoline)

on the market for

30

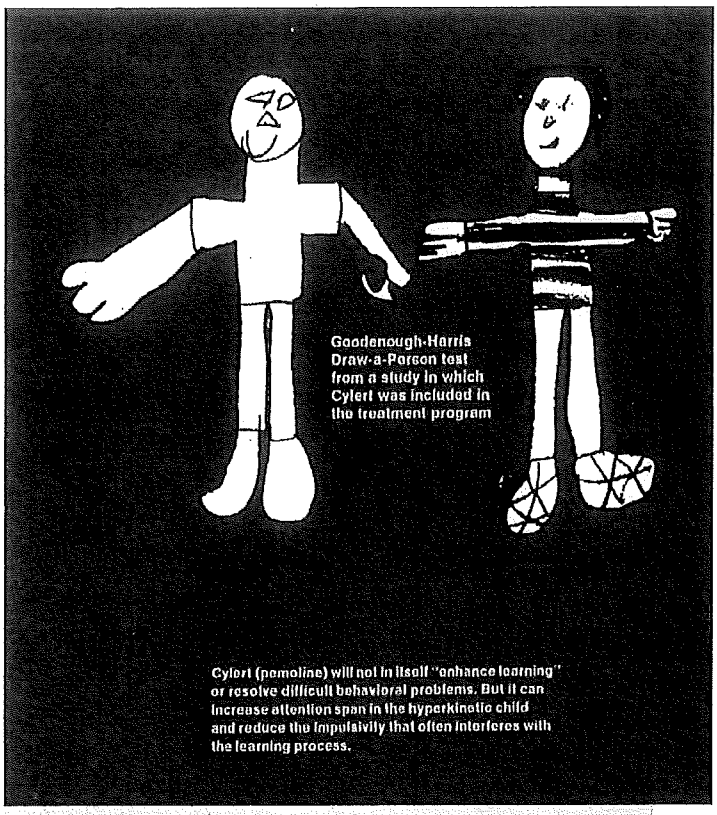
YEARS

1975 to Oct. 2010

Use: Central nervous system stimulant to treat ADHD/ADD
Manufacturer: Abbott Laboratories

Cause for recall:
liver toxicity

The FDA added a box warning to Cylert in 1999, alerting doctors and patients to the potential of liver damage.



Cylert®
(pemoline)

offers these benefits in a treatment program for MBD

- Single daily dose administration
- Minimal cardiovascular effects
- Mean dosage in long-term studies remained remarkably constant

EFFICACY

Multi-clinic study[1,2]
21 investigators from 10 states and two provinces in Canada took part in the clinical studies.

Double-blind, placebo control
413 patients were randomly assigned to Cylert or placebo groups. 238 patients met all criteria for evaluation of efficacy.

Psychological test results
Children on Cylert had significantly higher scores statistically than those on placebo on these psychological tests:

- The Wechsler Intelligence Scale for Children (WISC) and its performance IQ Sub-Component
- The Wide Range Achievement Test (WRAT) (reading and arithmetic)
- The Lincoln-Oseretsky Motor Performance Test Factor II

Overall results
Approximately two out of three patients were significantly improved by treatment with Cylert as reflected by global ratings.

1. Conners, C. K., ed., *Clinical Use of Stimulant Drugs in Children*, Excerpta Medica, 1974, p. 93
2. Page, J. G., et al., J. Learning Disabilities, 7:498, Oct., 1974.

SAFETY

Multi-clinic study (9 weeks)
safety data analyzed on 407 patients
There was no significant difference between Cylert and placebo groups in:

- Blood pressure
- Laboratory tests
- Pulse
- Neurological status

Insomnia and anorexia were the most frequently seen side effects and often improved with continuation of treatment or reduction of dosage.

Mean weight loss of 1.1 lbs. was demonstrated in the Cylert group during early weeks of treatment; long-term studies have shown that by 3-6 months, most children return to the normal rate of weight gain for their age group.

Long-term study on Cylert
up to 3 years and continuing
Mean dosage . . . remained remarkably constant.
Blood pressure . . no significant changes attributed to Cylert.
Pulse rate . . . . . no significant changes attributed to Cylert.

Laboratory examination—mild to moderate increase in transaminase (SGOT and SGPT) levels in 1-2% of patients (no clinical symptoms); levels returned to normal on withdrawal of medication.

No clinically significant abnormalities in the other tests.

Please see last page of this advertisement for Prescribing Information.

Importance of single daily dosage to the child, the parents and the teacher

For the child		For the adults
No drug in child's possession while at school	⟷	Control of medication remains with parents
Avoids situation in which child is repeatedly singled out as being "different"	⟷	Obviates need for nurse or teacher to supervise taking of mid-day doses
Helps prevent possible variations in effect caused by missed, forgotten or delayed doses	⟷	Helps assure that the prescribed dosage is being given each day

Cylert (pemoline), alone among CNS stimulants used to treat MBD, is inherently long-acting, permitting once-daily dosage.

Cylert can be taken with meals

You can prescribe Cylert a.o., p.c., or with meals. Although the speed of absorption is slightly slowed by food, the total absorption is not affected.

Dosage and administration

Cylert is given as a single oral dose each morning.

The recommended starting dose is 37.5 mg. per day. This daily dosage should be gradually increased at one-week intervals using increments of 18.75 mg. until the desired clinical response is obtained.

The mean daily effective dose ranges from 56.25 to 75 mg. per day. The maximum recommended daily dose of Cylert is 112.5 mg.

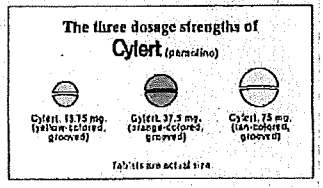
Using the recommended schedule of dose titration, significant benefits may not be seen until the third or fourth week of drug therapy. Side effects may be seen prior to optimum clinical results.

When not to use Cylert

Cylert should not be used for (and will not be effective in) simple cases of overactivity in school-age children.

Neither should it be used in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis.

The physician should rely on a complete history of the child and a thorough description of symptoms from both parents and teacher before postulating a diagnosis of MBD.



Cylert (PEMOLINE)

Prescribing Information

Description: Cylert (pemoline) is a white, tasteless, odorless powder which is relatively insoluble (less than 1 mg/ml) in water, chloroform, ether, acetone, and benzene. In 95% ethyl alcohol, the solubility of pemoline is 2.2 mg/ml.

Actions: Cylert (pemoline) is a central nervous system stimulant. The pharmacologic activity of pemoline is similar to that of other known stimulants but with minimal sympathomimetic effects. Pemoline is structurally dissimilar from the amphetamines and methylphenidate. Although the exact mode of pharmacodynamic action is undetermined in man, pemoline has been reported to increase the rate of synthesis of dopamine in rat brain.

In human subjects, Cylert produces peak blood levels within 2-4 hours. The serum half-life is approximately 12 hours. Multiple dose studies in adults at several dose levels indicate that serum levels plateau in approximately three days. Cylert and its metabolites are primarily excreted by the kidneys with approximately 75% of an oral dose appearing in the urine within a 24-hour period. Approximately 43% of pemoline is excreted unchanged. Metabolites include pemoline dione, conjugated pemoline and mandelic acid.

Cylert (pemoline) has a gradual onset of action in children with minimal brain dysfunction. Using the recommended schedule of dosage titration, significant clinical benefit may not be evident until the third or fourth week of drug administration.

Indications: MINIMAL BRAIN DYSFUNCTION IN CHILDREN—as adjunctive therapy to other remedial measures (psychological, educational, social).

Special Diagnostic Considerations:

Specific etiology of minimal brain dysfunction (MBD) is unknown, and there is no single diagnostic test. Adequate diagnosis includes the use not only of medical but of psychological, educational, and social resources.

Characteristics commonly reported include: A chronic history of moderate to severe hyperactivity, short attention span, distractibility, emotional lability, and impulsivity. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present. The diagnosis of MBD must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with MBD. In the primary therapy of MBD, appropriate educational placement is essential and psychosocial intervention is generally necessary. When these measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis.

Contraindications: Cylert (pemoline) is contraindicated in patients with known hypersensitivity or idiosyncrasy to the drug. (See PRECAUTIONS)

Warnings: Cylert is not recommended for children under six years of age since safety and efficacy in this age group have not yet been established.

Since Cylert (pemoline) and its metabolites are excreted primarily by the kidneys, caution should be observed in administering the drug to children with significantly impaired renal function.

Sufficient data on safety and efficacy of Cylert administration for periods beyond two years duration in children with minimal brain dysfunction are not yet available. Although a definite causal relationship has not been established, some temporary suppression of predicted growth pattern (i.e., weight and/or height) has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

Drug Interactions: Interactions between Cylert and other drugs have not been studied in humans. As with most other drugs, concurrent administration with other agents, especially drugs with central nervous system activity, should be carefully monitored.

[redacted]

Drug Dependence: Studies of the drug abuse potential of Cylert (pemoline) in primates have not demonstrated a potential for self-administration. However, the pharmacologic similarities between Cylert and other CNS stimulants with known abuse liability suggest that drug dependence of the stimulant type might occur. There have been isolated reports of transient psychotic symptoms in adults following long-term misuse of pemoline taken orally in excessive quantities. Therefore, caution should be observed in emotionally unstable patients considered to have a psychological potential for drug dependence.

Precautions: Delayed hypersensitivity reactions involving the liver have been reported in 1-2% of the patients receiving Cylert usually after several months of therapy. No clinical symptomatology has been observed, but mild to moderate increases in transaminase (SGOT and SGPT) levels have occurred in these cases. These effects appear to be completely reversible when drug treatment is discontinued. Transaminase levels should be determined periodically during therapy with Cylert to detect any such reactions.

Adverse Reactions: The most frequently reported adverse reaction with Cylert is insomnia. Insomnia has been observed prior to optimum therapeutic response and in the majority of cases was transient in nature or responded to dosage reduction. Anorexia with weight loss during the first few weeks of therapy has also been reported. With continuing therapy, a return to a normal weight curve usually occurred within three to six months. Other adverse reactions reported include stomachache, skin rash, irritability, mild depression, nausea, dizziness, headache, drowsiness, and hallucinations. Mild adverse reactions appearing early in treatment often remit with continuing therapy. If adverse reactions are of a significant or protracted nature, dosage reduction or discontinuation should be considered.

Dosage and Administration: Cylert (pemoline) is administered as a single oral dose each morning. The recommended starting dose is 37.5 mg per day. This daily dosage should be gradually increased at one week intervals using increments of 18.75 mg until the desired clinical response is obtained. The mean daily effective dose ranges from 56.25 to 75 mg per day. The maximum recommended daily dose of pemoline is 112.5 mg.

Clinical improvement with Cylert is gradual. Using the recommended schedule of dosage titration, significant benefit may not be evident until the third or fourth week of drug administration. Drug administration should be interrupted occasionally to determine if behavioral symptoms sufficient to require continuing therapy recur.

Overdosage: Cylert overdosage has been reported to produce symptoms of tachycardia, hallucinations, agitation, or restlessness. The treatment of acute massive overdosage with pemoline is essentially the same as that for overdosage with any drug having CNS stimulatory effects. Management is largely symptomatic and may include induction of emesis, gastric lavage or other measures as appropriate.

How Supplied: Cylert (pemoline) is supplied as monogrammed, grooved tablets in three dosage strengths:

18.75 mg. tablets (yellow-colored) in bottles of 100 (NDC 0074-6025-13)

37.5 mg. tablets (orange-colored) in bottles of 100 (NDC 0074-6057-13)

75 mg. tablets (tan-colored) in bottles of 100 (NDC 0074-6073-13)

ABBOTT LABORATORIES
North Chicago, IL 60064 [illegible]

Abbott Laboratories, "Cylert," American Journal of Diseases of Children, www.bonkersinstitute.org, 1976

5. Darvon & Darvocet

(Propoxyphene)

on the market for

55

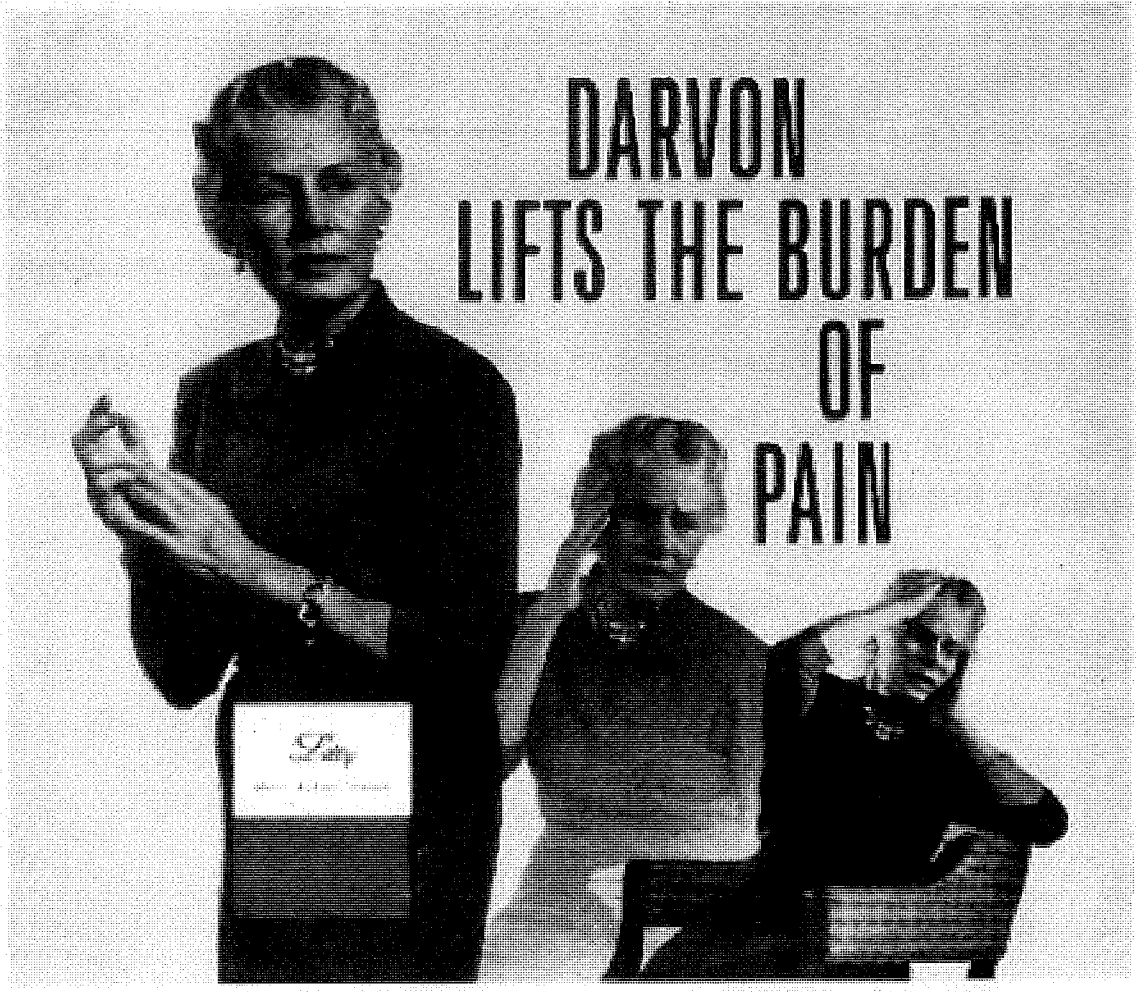
YEARS

1955 to
Nov. 19, 2010

Use: Opioid pain reliever
Manufacturer: Xanodyne

Cause for recall:
serious toxicity to the heart; between 1981 and 1999 there were over 2,110 deaths reported

The UK banned Darvon and Darvocet in 2005. The FDA was petitioned in 1978 and again in 2006 to ban the drug by the group Public Citizen.



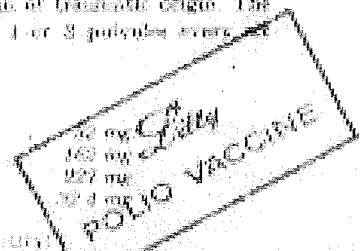
A non-narcotic analgesic with the potency of codeine

DARVON (Darvon Propoxyphene Hydrochloride, Lilly) is equally as potent as codeine yet is much better tolerated. You will find it helpful in any condition associated with pain. Because Darvon is non-narcotic, it lends to use in chronic conditions requiring long-term therapy. Side effects are minimal. The usual adult dosage: 32 mg every four hours to 65 mg. every six hours as needed. Available in 32 mg. and 65 mg. pulvules.

DARVON COMPOUND (Darvon Propoxyphene and Acetylsalicylic Acid Compound, Lilly) combines the analgesic and anti-inflammatory benefits of "A.S.A. Compound" with the additive properties of Darvon. Thus, it is useful in relieving pain associated with rheumatic or arthritic disease, such as neuralgia, sciatica, or arthritis, as well as acute pain of traumatic origin. The usual adult dose is 1 or 2 pulvules every four hours as needed.

Each Pulvule Darvon Compound provides:

Darvon
Acetylsalicylic
"A.S.A." Acetylsalicylic Acid Lilly
Caffeine



Christian Sinclair, "Are You Glad Darvocet Got Pulled by the FDA? Are You Sure?," www.pallimed.org, Nov. 30, 2010

6. DBI (Phenformin)

on the market for

19

YEARS

1959 to Nov. 1978

Use: antidiabetic
Manufacturer: Ciba-Geigy

Cause for recall:
lactic acidosis (low pH in body tissues and blood and a buildup of lactate) in patients with diabetes

7. DES (Diethylstibestrol)

on the market for

31

YEARS

1940 to 1971

Use: synthetic estrogen to prevent miscarriage, premature labor, and other pregnancy complications
Manufacturer: Grant Chemical Co.

Cause for recall:

clear cell adenocarcinoma (cancer of the cervix and vagina), birth defects, and other developmental abnormalities in children born to women who took the drug while pregnant; increased risk of breast cancer, higher risk of death from breast cancer; risk of cancer in children of mothers taking the drug including raised risk of breast cancer after age 40; increased risk of fertility and pregnancy complications, early menopause, testicular abnormalities; potential risks for third generation children (the grandchildren of women who took the drug) but they are unclear as studies are just beginning

Studies in the 1950s showed the drug was not effective at preventing miscarriages, premature labor, or other pregnancy complications.

— in either high or low dosage[3,4,5]

(Each **des**PLEX tablet starts with 25 mg. of diethylstilbestrol, U.S.P., which is then ultramicronized to smooth and accelerate absorption and activity. A portion of this ultramicronized diethylstilbestrol is even included in the tablet coating *to assure prompt help in emergencies.* **des**PLEX tablets also contain vitamin C and certain members of the vitamin B complex to aid detoxification in pregnancy and the effectuation of estrogen.)

For further data and a generous trial supply of **des**PLEX, write to:
Medical Director

REFERENCES
1. Canario, E. M., et al.: Am. J. Obst. & Gynec. 65:1298, 1953.
2. Gilman, L., and Koplowitz, A.: N. Y. St. J. Med. 50:2823, 1950.
3. Karnaky, K. J.: South. M. J. 45:1166, 1952.
4. Peña, E. F.: Med. Times 82:921, 1954; Am. J. Surg. 87:95, 1954.
5. Ross, J. W.: J. Nat. M. A. 43:20, 1951; 45:223, 1953.

GRANT CHEMICAL COMPANY, INC., Brooklyn 26, N.Y.

Barbara Hammes and Cynthia Laitman, "Pharmaceutical Company Advertisement for DES by the Grant Chemical Company, Brooklyn, NY, Printed in the *American Journal of Obstetrics & Gynecology* in 1957," *Journal of Midwifery and Women's Health*, www.medscape.com, 2003

8. Duract (Bromfenac)

on the market for
1
YEAR
July 1997 to
June 26, 1998

Use: Pain killer
Manufacturer: Wyeth-Ayerst Laboratories

Cause for recall:
4 deaths; 8 patients requiring liver transplants; 12 patients with severe liver damage

Duract was labeled for maximum use of 10 days but patients often received/took more than 10 days worth of pills; all cases of death and liver damage involved patients taking pills for longer than 10 days.

9. Ergamisol (Levamisole)

on the market for **11 YEARS**

May 8, 1989 to 2000

Use: Worm infestation; colon and breast cancers; rheumatoid arthritis
Manufacturer: Janssen Pharmaceutica

Cause for recall:
neutropenia (a type of low white blood cell count), agranulocytosis (a type of low white blood cell count), and thrombotic vasculopathy (blood clots in blood vessels) which results in retiform purpura (a purple discoloration of the skin that can sometimes require reconstructive surgery)

Levamisole is still used to treat animals with worm infestations in the US. It is also being found in street cocaine as an adulterant to increase euphoric qualities.

10. Hismanal (Astemizole)

on the market for **11 YEARS**

1988 to
Aug. 13, 1999

Use: Antihistamine
Manufacturer: Janssen Pharmaceutica

Cause for recall:
slowed potassium channels in the heart that could cause torsade de pointes (TdP; a heart condition marked by a rotation of the heart's electrical axis) or long QT syndrome (LQTS; prolonged QT intervals)

11. Lotronex (Alosetron)

on the market for

0.8

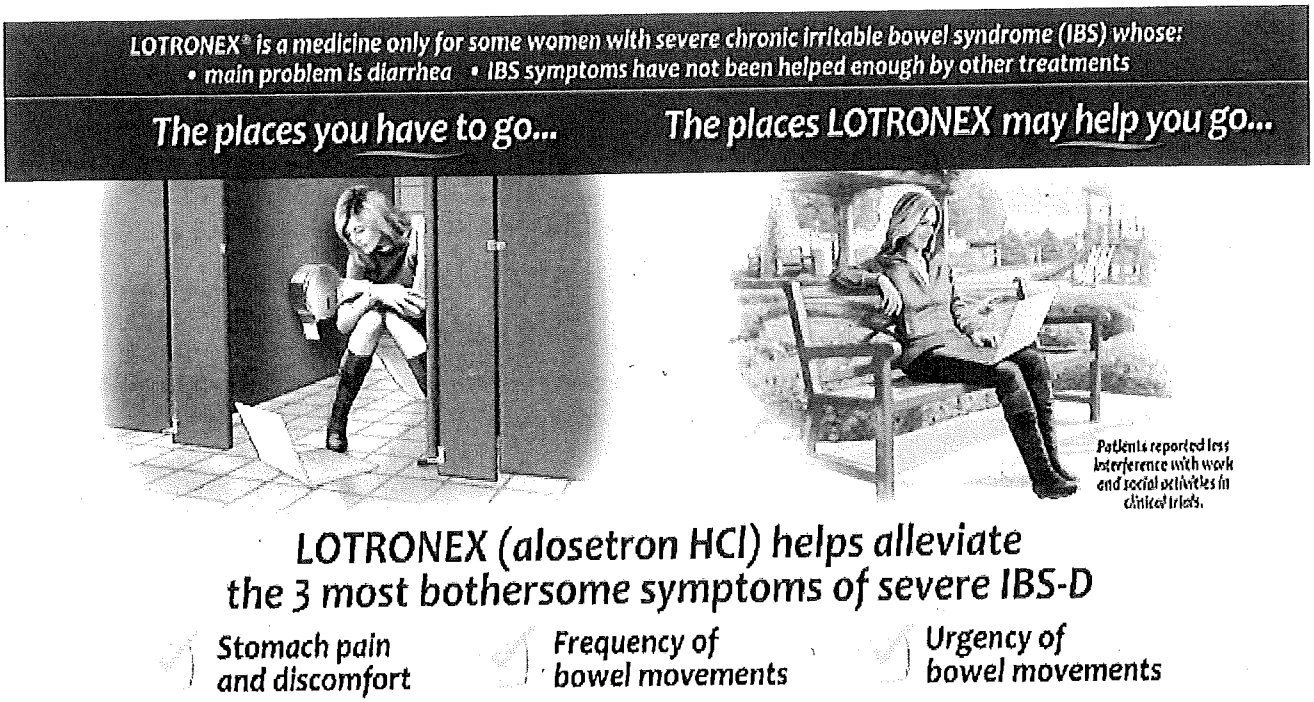
YEAR

Feb. 9, 2000 to Nov. 28, 2000

Use: Irritable bowel syndrome (IBS) in women
Manufacturer: Prometheus Laboratories, Inc.

Cause for recall:
49 cases of ischemic colitis (inflammation and injury of the large intestine); 21 cases of severe constipation (10 requiring surgery); 5 deaths; mesenteric ischemia (inflammation and injury of the small intestine)

Lotronex was reintroduced to the US market in 2002 with restricted indication.



Irritable Bowel Syndrome Self Help and Support Group, "Lotronex," www.ibsgroups.org (accessed Jan. 6, 2014)

12. Meridia (Sibutramine)

on the market for **13 YEARS**
Nov. 1997 to Oct. 2010

Use: Appetite Suppressant
Manufacturer: Knoll Pharmaceuticals

Cause for recall:
increased cardiovascular and stroke risk

FDA reviewer Dr. David Graham listed Meridia with Crestor, Accutane, Bextra, and Serevent as drugs whose sales should be limited or stopped because of their danger to consumers in Sep. 30, 2004 testimony before a Senate committee, calling the drugs "another Vioxx."

13. Merital & Alival (Nomifensine)

on the market for **3 YEARS**
1982 to 1985

Use: Antidepressant
Manufacturer: Hoechst AG (now Sanofi-Aventis)

Cause for recall:
haemolytic anemia; some deaths due to immunohemolytic anemia

14. Micturin (Terodiline)

on the market for **2 YEARS**
Aug. 1989 to Sep. 13, 1991

Use: Bladder incontinence
Manufacturer: Forest Labs

Cause for recall:
QT prolongation and potential for cardiotoxicity

15. Mylotarg (Gemtuzumab Ozogamicin)

on the market for **10 YEARS**
May 2000 to June 21, 2010

Use: Acute myeloid leukemia (AML, a bone marrow cancer)
Manufacturer: Wyeth

Cause for recall:
increased risk of death and veno-occlusive disease (obstruction of veins)

16. Omniflox (Temafloxacin)

on the market for **0.3 YEAR**

Jan. 31, 1992 to June 5, 1992

Use: Antibiotic for pneumonia, bronchitis, and other respiratory tract infections; prostatitis and other genitourinary tract infections; skin ailments.
Manufacturer: Abbot Laboratories

Cause for recall:
3 deaths; severe low blood sugar; hemolytic anemia and other blood cell abnormalities; kidney disfunction (half of the cases required renal dialysis); allergic reactions including some causing life-threatening respiratory distress

17. Palladone (Hydromorphone hydrochloride, extended-release)

on the market for **0.5 YEAR**

Jan. 2005 to July 13, 2005

Use: Narcotic painkiller
Manufacturer: Purdue Pharma

Cause for recall:
high levels of palladone could slow or stop breathing, or cause coma or death; combining the drug with alcohol use could lead to rapid release of hydromorphone, in turn leading to potentially fatally high levels of drugs in the system

18. Permax (Pergolide)

on the market for **19 YEARS**

1988 to Mar. 29, 2007

Use: Parkinson's disease
Manufacturer: Valeant

Cause for recall:
valve regurgitation (a condition that causes the valves to not close tightly, which allows blood to flow backward over the valve) in the mitral, tricuspid, and aortic heart valves, which can result in shortness of breath, fatigue, and heart palpitations

Permax is still available in the U.S. for veterinary use, specifically for pituitary pars intermedia hyperplasia or equine Cushing's Syndrome (ECS) in horses.

19. Pondimin (Fenfluramine)

on the market for **24 YEARS**

1973 to
Sep. 15, 1997

Use: Appetite suppressant
Manufacturer: Wyeth-Ayerst

Cause for recall:
30% of patients prescribed the drug had abnormal echocardiograms; 33 cases of rare valvular disease in women; 66 additional reports of heart valve disease

Pondimin is better known as "Fen-Phen" when prescribed with Phentermine.

20. Posicor (Mibefradil)

on the market for

1

YEAR

June 1997 to
June 1998

Use: Calcium channel blocker (used to treat hypertension)
Manufacturer: Roche Laboratories

Cause for recall:
fatal interactions with at least 25 other drugs (ex: common antibiotics, antihistamines, and cancer drugs) including astemizole, cisapride, terfenadine, lovastatin, and simvastatin

Posicor was found by the FDA to offer no significant benefit over other anti-hypertensive or antianginal drugs, which made the risks of drug interactions "unreasonable." Patients immediately switching from Posicor to another calcium channel blocker were at increased risk of going into shock within 12 hours of the drug switch.

21. Propulsid (Cisapride)

on the market for **7** YEARS

1993 to July 14, 2000

Use: Severe nighttime heartburn associated with gastroesophageal reflux disease (GERD)
Manufacturer: Janssen Pharmaceutica

Cause for recall:
more than 270 cases of serious cardiac arrythmias (including ventricular tachycardia, ventricular fibrillation, torsades de pointes, and QT prolongation) reported between July 1993 and May 1999, with 70 being deaths.

Propulsid is also banned in India (2011) and available for limited use in Europe. It is still available for use in animals in the US and Canada.

22. PTZ & Metrazol

(Pentylenetetrazol)

on the market for **48** YEARS

1934 to 1982

Use: Convulsive therapy for schizophrenia and other psychiatric conditions
Manufacturer: not known

Cause for recall:
uncontrollable seizures; pulled muscles; fractured bones; spine fractures in as many as 42% of patients

23. Quaalude [Marketed as: Optimal, Sopor, Parest, Somnafac, and Bi-Phetamine T] (Methaqualone)

on the market for

23

YEARS

1962 to 1985

Use: Sedative and hypnotic
Manufacturer: William H. Rorer Inc. & Lemmon Company

Cause for recall:
mania; seizures; vomiting; convulsions; death

Methaqualone was originally tested in India as a malaria treatment (it was ineffective). The drug is now a schedule 1 drug in the United States (like heroin, marijuana, and LSD).

A good morning after a sleep-through night

That's how a patient feels after a restful night's sleep provided by Quāālude-300 (methaqualone).

He wakes up alert and ready to face the demands of the day (Quāālude patients usually awaken easily and without evidence of "hangover")... because he slept well all night (Quāālude usually helps produce 6 to 8 hours of restful sleep)... and he didn't have to lie awake for a long period of time before he went to sleep (Quāālude can induce sleep in 10 to 30 minutes). Now the physician has one less tired, sleepy and apprehensive patient to contend with.

Non-barbiturate Quāālude-300 is chemically unrelated to other sedative-hypnotics. Its therapeutic value has been established in controlled clinical studies and by wide usage of methaqualone throughout the world.

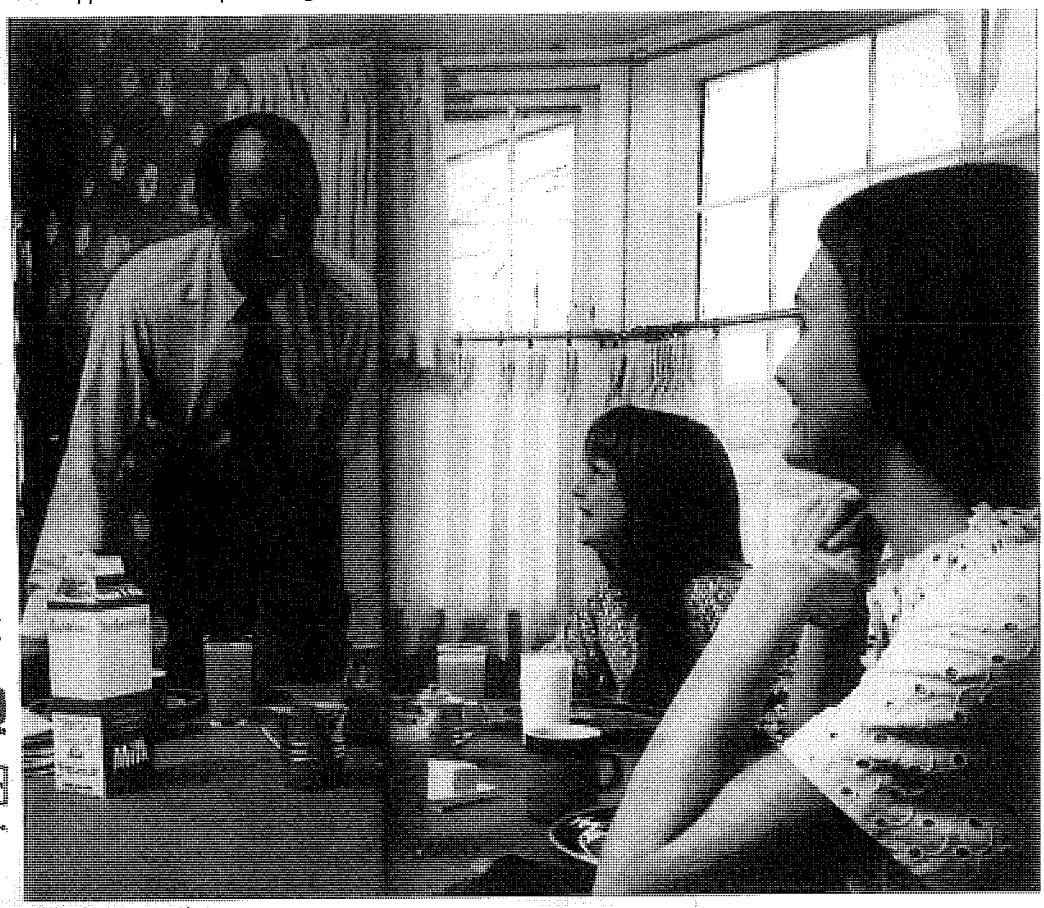
Side effects reported have been mild, transient, and have often proved to be statistically insignificant when compared to placebo effects. (See brief summary on last page of advertisement.)

For these reasons, maybe the prescribing physician sleeps a little better, too.

a non-barbiturate
Quāālude®-300
300 mg. tablets
(methaqualone)

WILLIAM H. RORER, INC.
Fort Washington, Pa. 19034

For additional prescribing information, please turn page.



A good morning after a sleep-through night

Sleeping and awakening with Quāālude®-300 (methaqualone) can be a pleasant experience—patients enjoy a sleep-through night, usually without "drugged" after-effects in the morning.

Quāālude is chemically unrelated to barbiturates and glutethimide.

Side effects reported have been mild, transient, and often statistically insignificant when compared to placebo effects. (See *Adverse Reactions* section below.)

Patients appreciate this gentle way to sleep:
sleep usually within 10-30 minutes
sleep duration—6-8 hours
the awakening—pleasantly alert—usually no "hung-over" feeling

Quāālude®-300
300 mg. tablets
(methaqualone) a non-barbiturate

Brief Summary
of Prescribing Information

Indications:
Sleep. Daytime sedation.

Usual Adult Dose:
For sleep, 150-300 mg. at bedtime. For patients previously on other hypnotics, 300 mg. for five to seven nights. *For sedation*, 75 mg. t.i.d. or q.i.d. Not recommended in children. Dosage should be individualized for aged, debilitated or highly agitated patients.

Overdosage:
Acute overdosage may result in delirium and coma, with restlessness and hyperpnea, progressing to convulsions. Evacuate gastric contents, maintain adequate ventilation and support blood pressure, if necessary. Dialysis may be helpful. Analeptics are contraindicated. Succinylcholine accompanied by assisted respiration has been proposed for prolonged convulsions. Overdoses of methaqualone appear to be less often associated with cardiac or respiratory depression than are overdoses of oral barbiturates, but shock and respiratory arrest may occasionally occur.

Contraindications:
Contraindicated in women who are or may become pregnant; or patients with known hypersensitivity.

Warnings:
Take hypnotic dose only at bedtime. Not recommended in children. Warn patient on Quāālude against driving a car or operating dangerous machinery. Care needed when administered with other sedative, analgesic or psychotropic drugs or alcohol because of possible additive effects. Pending longer clinical experience, Quāālude should not be used continuously for periods exceeding three months. *Psychological dependence* occasionally occurs. *Physical dependence* rarely reported. However, caution needed with addiction-prone patients.

Precautions:
Use with caution and prescribe small quantities in patients with anxiety states where impending depression or suicidal tendencies exist. Give in reduced doses, if at all, in patients with impaired hepatic function.

Adverse Reactions:
Neuropsychiatric: headache, hangover, fatigue, dizziness, torpor, transient paresthesia of the extremities. An occasional patient has experienced restlessness or anxiety. *Hematologic:* aplastic anemia possibly related to methaqualone has been very rarely reported. *Gastrointestinal:* dry mouth, anorexia, nausea, emesis, epigastric discomfort, diarrhea. *Dermatologic:* diaphoresis, bromhidrosis, exanthema. Urticaria has been particularly well documented.

Supplied:
Quāālude-150 (150 mg. white, scored tablets). Quāālude-300 (300 mg. white, scored tablets).

Consult complete literature before prescribing.

WILLIAM H. RORER, INC.
Fort Washington, Pa. 19034

Res Obscura, "From Quacks to Quaaludes: Three Centuries of Drug Advertising," www.resobscura.blogspot.nl, June 11, 2012

24. Raplon (Rapacuronium)

on the market for **2 YEARS** 1999 to Mar. 27, 2001

Use: Non-polarizing neuromuscular blocker (used in anesthesia
Manufacturer: Organon Inc.

Cause for recall:
bronchospasms and unexplained deaths

25. Raptiva (Efalizumab)

on the market for **6 YEARS** 2003 to Apr. 8, 2009 (completely withdrawn by June 8, 2009)

Use: Psoriasis
Manufacturer: Genentech

Cause for recall:
progressive multifocal leukoencephalopathy (PML; a rare and usually fatal disease that causes inflammation or progressive damage of the white matter in multiple locations of the brain)

26. Raxar (Grepafloxacin)

on the market for
2
YEARS
1997 to
Nov. 1, 1999

Use: Antibiotic for bacterial infections
Manufacturer: Glaxo Wellcome

Cause for recall:
cardiac repolarization; QT interval prolongation; ventricular arrhythmia (torsade de pointes)

27. Redux (Dexfenfluramine)

on the market for
1
YEAR
1996 to Sep. 15, 1997

Use: Appetite suppressant
Manufacturer: Wyeth-Ayerst

Cause for recall:
30% of patients prescribed the drug had abnormal echocardiograms; 33 cases of rare valvular disease in women; 66 additional reports of heart valve disease

Redux is better known as "Fen-Phen" when prescribed with Phentermine.

28. Rezulin (Troglitazone)

on the market for

3.25

YEARS

Jan. 29, 1997 to Mar. 21, 2000

Use: Antidiabetic and anti-inflammatory
Manufacturer: Parke-Davis/Warner Lambert (now Pfizer)

Cause for recall:
at least 90 liver failures; at least 63 deaths

About 35.000 personal injury claims were filed against the manufacturer (Pfizer).

29. Selacryn (Tienilic acid)

on the market for

3

YEARS

May 2, 1979 to 1982

Use: blood pressure
Manufacturer: SmithKline

Cause for recall:
hepatitis; 36 deaths; at least 500 cases of severe liver and kidney damage

Anphar Labs (which developed the drug in France and sold rights to sell in US to SmithKline) sent a report to SmithKline in Apr. 1979 (translated in May 1979 to English from French) stating Selacryn damaged livers. On Dec. 13, 1984, SmithKline Beckman plead guilty to "14 counts of failing to file reports with the drug agency of adverse reactions to Selacryn and 20 counts of falsely labeling the drug with a statement that there was no known cause-and-effect relationship between Selacryn and liver damage"

30. Seldane (Terfenadine)

on the market for

13

YEARS

1985 to
Feb. 1, 1998

Use: Antihistamine
Manufacturer: Hoechst Marion Roussel (now Sanofi-Aventis)

Cause for recall:
life-threatening heart problems when taken in combination with other drugs (specifically erthromycin (an antibiotic) and ketoconazole (an antifungal)

Seldane was not considered an imminent threat. The FDA pulled Seldane from the market because Allegra and Allegra D were produced by the same company and were deemed safer by the FDA.

31. Trasylol (Aprotinin)

on the market for

15 (48)

YEARS

1993 (but used since the 1960s) to Nov. 5, 2007 (marketing suspension request to phase it out of the market);
May 14, 2008 (manufacturer announced complete removal from market)

Use: antifibrinolytic to reduce blood loss during surgery
Manufacturer: Bayer

Cause for recall:
increased chance of death, serious kidney damage, congestive heart failure, and strokes

On Feb. 8, 2006, the FDA issued a public heath advisory to surgeons who perform heart bypasses, alerting them of possible fatal side effects.

32. Vioxx (Rofecoxib)

on the market for

5.3

YEARS

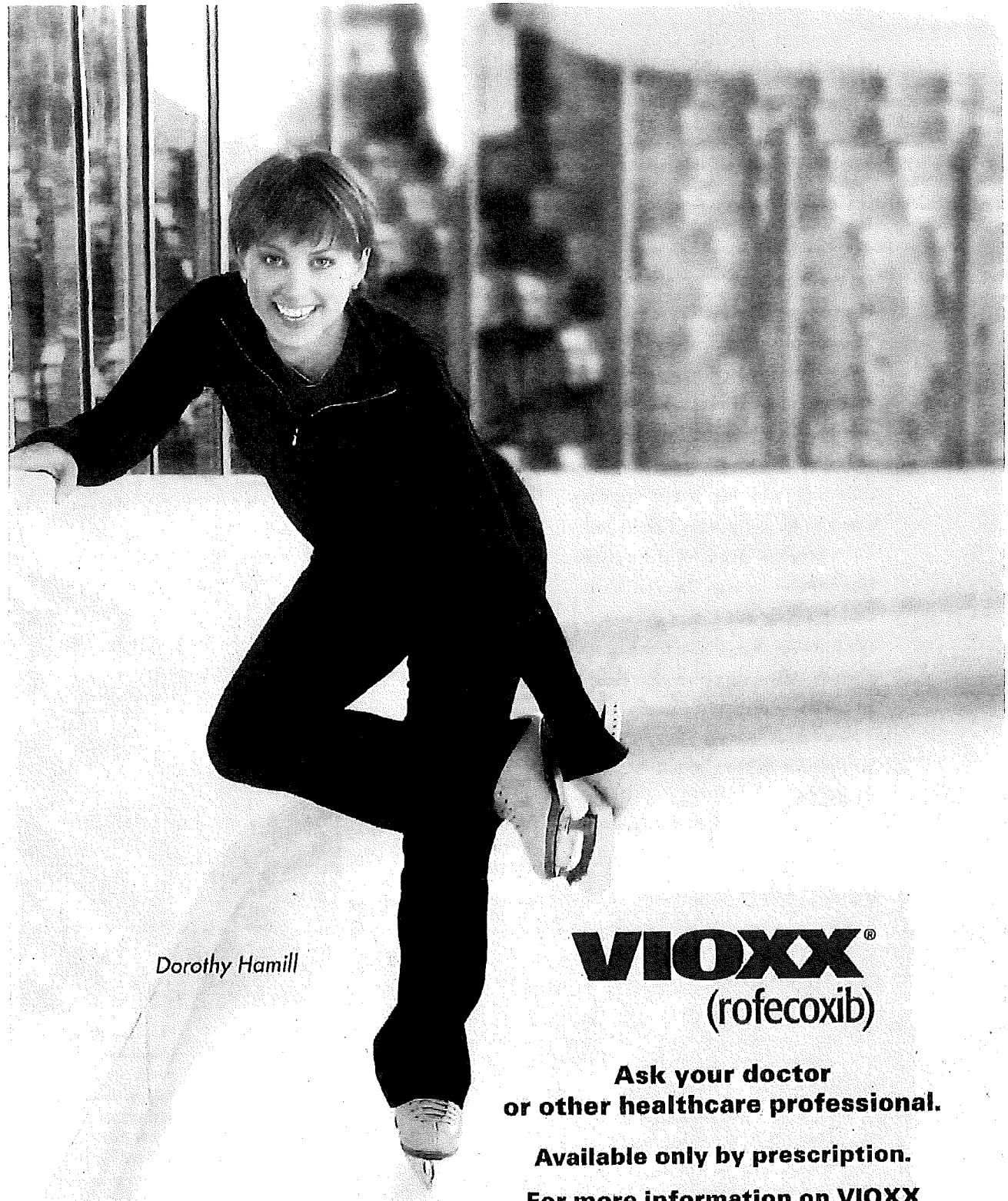
May 20, 1999 to Sep. 30, 2004

Use: NSAID (pain relief)
Manufacturer: Merck

Cause for recall:

increased risk of heart attack and stroke; linked to about 27,785 heart attacks or sudden cardiac deaths between May 20, 1999 and 2003

Ads for Vioxx features Olympic gold medalists Dorothy Hamill and Bruce Jenner. Vioxx was prescribed to more than 20 million people.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Today's Seniors Network, "This Is Patient Education?," www.todayssenioronsnetwork.com (accessed Jan. 7, 2014)

33. **Xigris** (Drotrecogin alfa (activated))

on the market for **10** YEARS
Nov. 2001 to Oct. 25, 2011

Use: Severe sepsis and septic shock
Manufacturer: Eli Lilly & Company

Cause for recall:
no survival benefit

34. **Zelmid** (Zimelidine)

on the market for **0** YEARS
1982 to 1982 (withdrawn by the FDA before being released in the US market)

Use: Anti-depressant
Manufacturer: Astra AB (now AstraZeneca)

Cause for recall:
Guillain–Barré syndrome; higher risk of suicide

35. **Zelnorm** (Tegaserod maleate)

on the market for **4.6** YEARS

The News&Observer

SCITECH

'Human on a chip' technology could replace animal testing

By Patricia Torres

(SAN JOSE) MERCURY NEWS

JULY 24, 2016 09:41 PM, UPDATED JULY 25, 2016 03:23 PM

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Heather Enright, a biologist at Lawrenc uses a monitor and a microscope this month to look at a computer chip that ns, part of the "Human on a Chip" research in Livermore, Calif. PHOTOS BY *NS LIVERMORE, CALIF.*

Hoping to make the lab rat a thing of the past, scientists at Lawrence Livermore National Laboratory are testing technology that replicates vital human tissues on microchips.

Animal rights advocates are encouraged that the technology may one day end experiments on mice, rats, snakes and other animals used to test products and develop drugs in laboratories around the world.

The "Human on a Chip" program shifts the experiments from living animals to the lab by replicating cells of human organs and tissues, exposing them to chemicals and using electrical signals to measure the response.

While labs and university researchers in other parts of the United States are using similar technology to test different organs of the body, scientists at Lawrence Livermore are focusing on four vital body functions: the central nervous system, peripheral nervous system, blood-brain barrier and heart.

3

The chips allow scientists, for example, to measure how certain body parts react to caffeine, heart medicine or other more dangerous toxins. In one early experiment, scientists applied capsaicin, the chemical that makes peppers hot, to cells of the peripheral nervous system and were able to measure a response.

The cells can survive and function on chips for several weeks in some cases, so many different kinds of experiments can be done to measure how exposure to drugs or chemicals affects cells and to evaluate cell recovery, with no human or animal test subjects necessary.

Lawrence Livermore gets its human tissues from AnaBios Corp., a San Diego company. The tissues are derived from organ donors, and unlike tissues grown from stem cells, these are mature and can provide a more reliable response to stimuli.

Still under testing and far from being widely used, the process also has the ability to speed up development of medical countermeasures to toxins and provide more accurate data than animal testing does.

"Animal testing can be more complicated and costly, whereas these chips can be much more reliable" said Kris Kulp, a lab scientist who is part of the project.

According to the U.S. Food and Drug Administration, 9 out of 10 drugs that pass animal tests fail in humans because they don't work or are dangerous. With this acknowledgment, various agencies, such as the Environmental Protection Agency and National Institutes of Health, have made efforts to reduce the use of animal testing.

Last month, President Barack Obama signed an updated Toxic Substances Control Act, originally approved in 1976, that includes a provision calling for restrictions on animal testing.

"We are familiar with this new direction that science is taking, and we're very excited about the possibility that it can replace animals in chemical testing, drug development and other areas," said Kathy Guillermo, vice president of laboratory investigations for People for the Ethical Treatment of Animals.

Joyce Tischler, general counsel for Animal Legal Defense Fund, said her group is excited about alternatives to animal testing.

"This also means that the science, environmental and animal welfare communities are all on the same page, which is to protect human life from chemicals and diseases," Tischler said. "We would just like to see it without the use of live animals."

More than 100 million animals are killed in experiments each year in the United States, according to the Laboratory Animal Resource Center at the University of California at San Francisco.

Lawrence Livermore Lab is spending nearly $2 million a year on the project, called iCHIP (in-vitro Chip-based Human Investigational Platform), which is now in its third year, said Elizabeth Wheeler, principal investigator.

The bulk of the chemicals used at Lawrence Livermore come from the Forensics Science Center, one of two U.S. labs certified for identifying chemical warfare agents. The U.S. Army in 2013 used the "Human on a Chip" technology to test chemicals used in warfare.

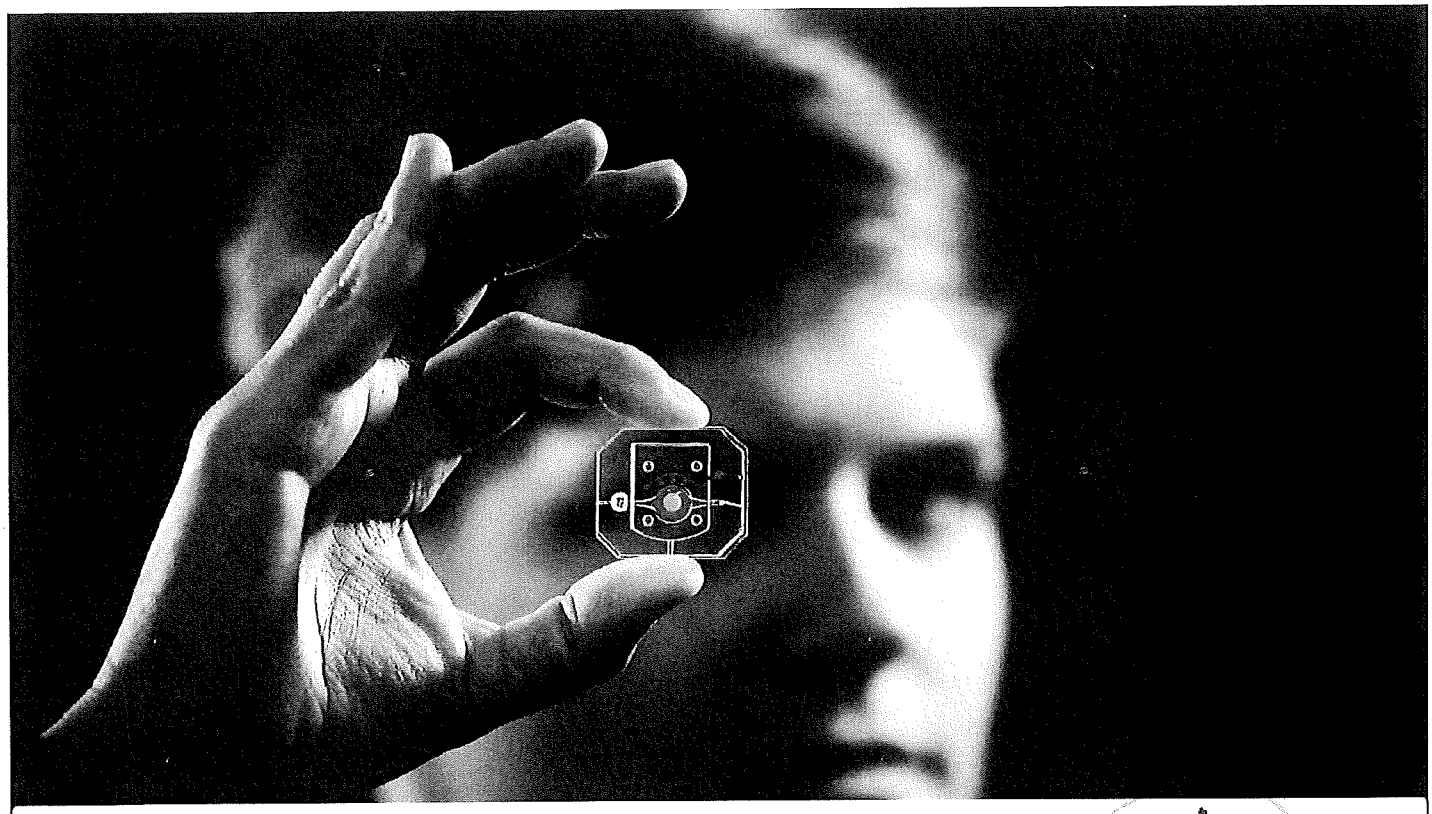
Wheeler said her group has no plans, nor is it legally allowed, to experiment with warfare agents.

She said the long-term goal is to collaborate with other research centers studying the technology on other parts of the body.

"We hope to integrate them all together and re-create the human body and the reactions it has to link multiple chips to capture interactions between different organs," Wheeler said.

Penn Engineering's Blinking Eye-on-a-Chip Used for Disease Modeling and Drug Testing

Penn Engineering Follow
Aug 5 · 7 min read



Rachel Young, a graduate student in Huh's lab, holds up the new eye-on-a-chip device. The latest iteration of the lab's eye-on-a-chip has a mechanical eyelid to simulate blinking, and was used to test an experimental drug for dry eye disease. By incorporating human cells into an engineered scaffolding, the eye-on-a-chip has many of the benefits of testing on living subjects, while minimizing risks and ethical concerns.

By Lauren Salig

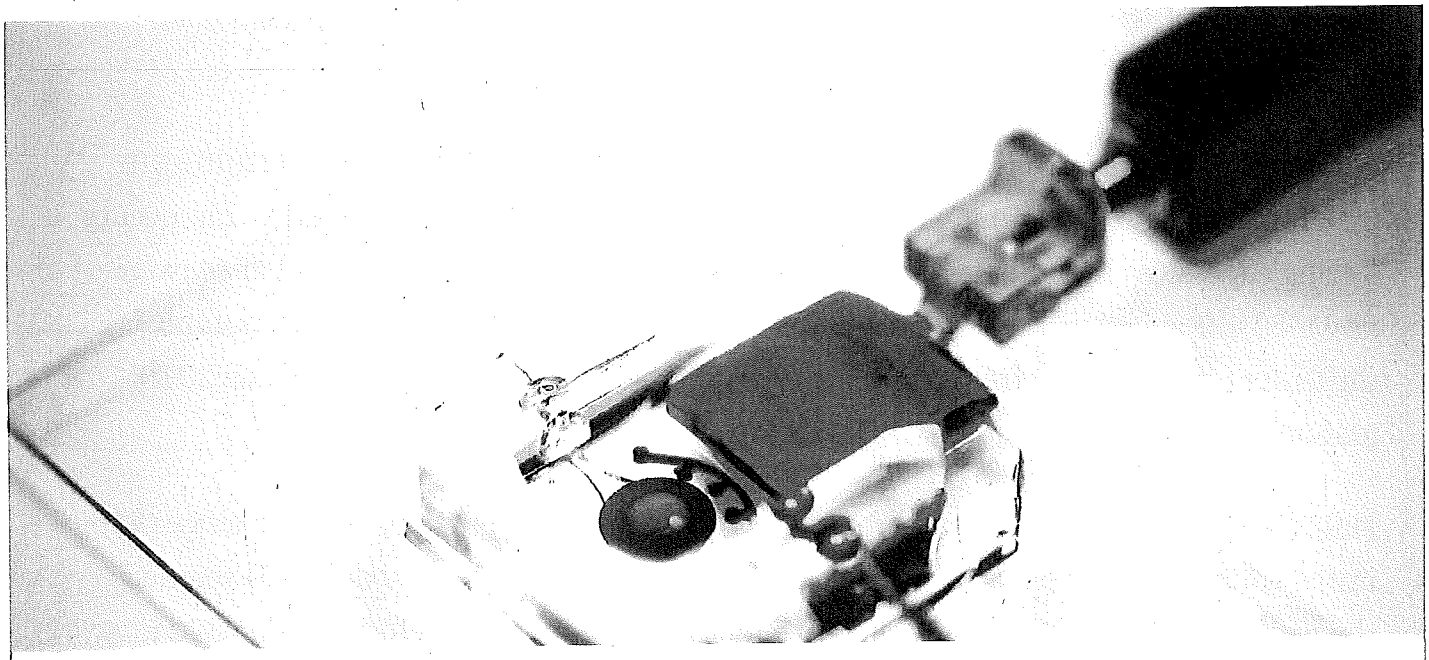
People who spend eight or more hours a day staring at a computer screen may notice their eyes becoming tired or dry, and, if those conditions are severe enough, they may eventually develop dry eye disease (DED). DED is a common disease with shockingly few FDA-approved drug options, partially because of the difficulties of modeling the complex pathophysiology in human eyes. Enter the blinking eye-on-a-chip: an artificial human eye replica constructed in the laboratory of Penn Engineering researchers.

This eye-on-a-chip, complete with a blinking eyelid, is helping scientists and drug developers to improve their understanding and treatment of DED, among other potential uses. The research, published in *Nature Medicine*, outlines the accuracy of the eye-on-a-chip as an organ stand-in and demonstrates its utility as a drug testing platform.

They collaborated with Vivian Lee, Vatinee Bunya and Mina Massaro-Giordano from the Department of Ophthalmology in Penn's Perelman School of Medicine, as well as with Vivek Shenoy, Eduardo D. Glandt President's Distinguished Professor in Penn Engineering's Department of Materials Science and Engineering. Other collaborators included Woo Byun, Andrei Georgescu and Yoon-suk Yi, members of Huh's lab, and Farid Alisafaei, a member of Shenoy's lab.

Huh's lab specializes in creating organs-on-a-chip that provide microengineered *in vitro* platforms to mimic their *in vivo* counterparts, including lung and bone marrow proxies launched into space this May to study astronaut illness. The lab has spent years fine-tuning its eye-on-a-chip, which earned them the 2018 Lush Prize for its promise in animal-free testing of drugs, chemicals, and cosmetics.

In this study, Huh and Seo focused on engineering an eye model that could imitate a healthy eye and an eye with DED, allowing them to test an experimental drug without risk of human harm.



The Huh lab's eye-on-a-chip attached to a motorized, gelatin-based eyelid. Blinking spreads tears over the corneal surface, and so was a critical aspect to replicate in the researchers' model of dry eye disease. cells. The cells of the cornea grow on the inner circle of scaffolding, dyed yellow, and the cells of the conjunctiva grow on the surrounding red circle. Artificial tears are supplied by a tear duct, dyed blue.

To construct their eye-on-a-chip, Huh's team starts with a porous scaffold engineered with 3D printing, about the size of a dime and the shape of a contact lens, on which they grow human eye cells. The cells of the cornea grow on the inner circle of scaffolding, dyed yellow, and the cells of the conjunctiva, the specialized tissue covering the white part of human eyes, grow on the surrounding red circle. A slab of gelatin acts as the eyelid, mechanically sliding over the eye at the same rate as human blinking. Fed by a tear duct, dyed blue, the eyelid spreads artificial tear secretions over the eye to form what is called a tear film.

"From an engineering standpoint, we found it interesting to think about the possibility of mimicking the dynamic environment of a blinking human eye. Blinking serves to spread tears and generate a thin film that keeps the ocular surface hydrated. It also helps form a smooth refractive surface for light transmission. This was a key feature of the ocular surface that we wanted to recapitulate in our device," says Huh.

For people with DED, that tear film evaporates faster than it's replenished, resulting in inflammation and irritation. A common cause of DED is the reduced blinking that occurs during excessive computer usage, but people can develop the disease for other reasons as well. DED affects about 14 percent of the world's population but has been notably difficult to develop new treatments for, with 200 failed clinical drug trials since 2010 and only two currently available FDA-approved drugs for treatment.

Huh's lab has been considering the drug-testing potential of organs-on-a-chip since their initial conceptualization, and, because of its surface-level area of impact, DED seemed the perfect place to start putting their eye model to the test. But before they started a

mechanisms that underlie the development and progression of DED. First, as water evaporates from the tear film, salt concentration increases dramatically, resulting in hyperosmolarity of tears. And second, with increased tear evaporation, the tear film becomes thinner more rapidly and often ruptures prematurely, which is referred to as tear film instability. The question was: Is our model capable of modeling these core mechanisms of dry eye?"

The answer, after much experimentation, was yes. The team evoked DED conditions in their eye-on-a-chip by cutting their device's artificial blinking in half and carefully creating an enclosed environment that simulated the humidity of real-life conditions. When put to the test against real human eyes, both healthy and with DED, the corresponding eye-on-a-chip models proved their similarity to the actual organ on multiple clinical measures. The eyes-on-a-chip mimicked actual eyes' performance in a Schirmer strip, which tests liquid production; in an osmolarity test, which looks at tear film salt content; and in a keratography test, which evaluates the time it takes for a tear film to break up.

Having confirmed their eye-on-a-chip's ability to mirror the performance of a human eye in normal and DED-inducing settings, Huh's team turned to the pharmaceutical industry to find a promising DED drug candidate to test-drive their model. They landed on an upcoming drug based on lubricin, a protein primarily found in the lubricating fluid that protects joints.

"When people think of DED, they normally treat it as a chronic disease driven by inflammation," says Huh, "but there's now increasing evidence suggesting that mechanical forces are important for understanding the pathophysiology of DED. As the tear film becomes thinner and more unstable, friction between the eyelids and the ocular surface increases, and this can damage the epithelial surface and also trigger adverse biological responses such as inflammation. Based on these observations, there is

By comparing the testing results of their models of a healthy eye, an eye with DED, and an eye with DED plus lubricin, Huh and Seo were able to further scientists' understanding of how lubricin works and show the drug's promise as a DED treatment.

Similarly, the process of building a blinking eye-on-a-chip pushed forward scientists' understanding of the eye itself, providing insights into the role of mechanics in biology. Collaborating with Shenoy, director of the Center for Engineering MechanoBiology, the team's attention was drawn to how the physical blinking action was affecting the cells they cultivated to engineer an artificial eye on top of their scaffolding.

"Initially, the corneal cells start off as a single layer, but they become stratified and form multiple layers as a result of differentiation, which happens when these cells are cultured at the air-liquid interface. They also form tight cell-cell junctions and express a set of markers during differentiation," Huh says. "Interestingly, we found out that mechanical forces due to blinking actually help the cells differentiate more rapidly and more efficiently. When the corneal cells were cultured under air in the presence of blinking, the rate and extent of differentiation increased significantly in comparison to static models without blinking. Based on this result, we speculate that blink-induced physiological forces may contribute to differentiation and maintenance of the cornea."

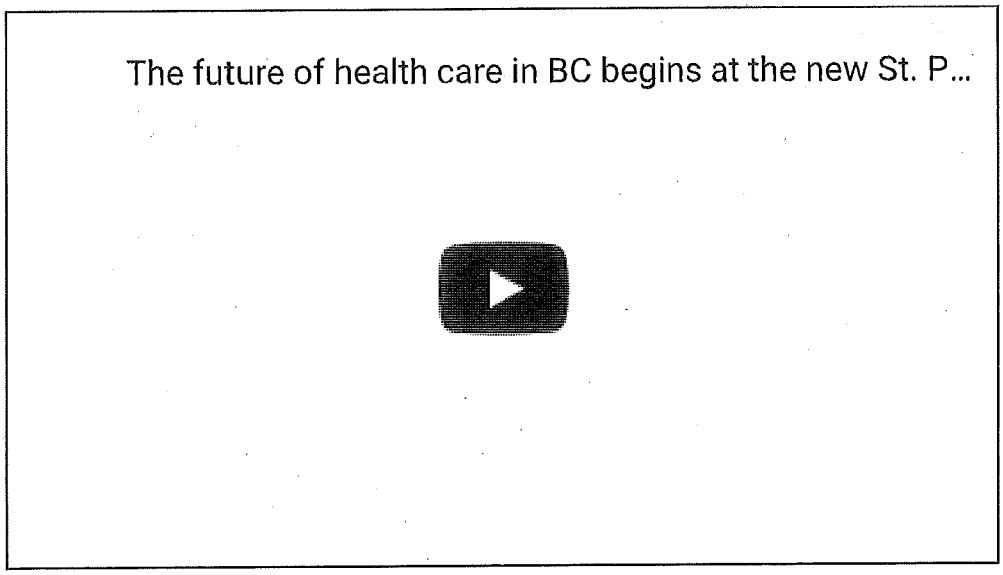
In other words, human cornea cells growing on the scientists' scaffold more quickly became specialized and efficient at their particular jobs when the artificial eyelid was blinking on top of them, suggesting that mechanical forces like blinking contribute significantly to how cells function. These types of conceptual advances, coupled with drug discovery applications, highlight the multifaceted value that engineered organs-on-a-chip can contribute to science.

Huh and Seo's eye-on-a-chip is still just dipping its toes into the field of drug testing, but this first step is a victory that represents years of work refining their artificial eye to reach this level of accuracy and utility.

"We are particularly proud of the fact that our work offers a great and rare example of interdisciplinary efforts encompassing a broad spectrum of research activities from design and fabrication of novel bioengineering systems to *in vitro* modeling of complex human disease to drug testing," says Huh. "I think this is what makes our study unique and representative of innovation that can be brought about by organ-on-a-chip technology."

This work was supported by the National Institutes of Health through grants 1DP2HL127720–0, R01EY026972 and K08EY025742–01, the National Science Foundation through grants CMMI:15–48571, and Research to Prevent Blindness.

Health Dry Eyes Bioengineering Engineering Science



The future of health care in BC starts at the new St. Paul's.

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On Friday, February 15, it was announced that the business plan for the new St. Paul's was approved by the provincial government. This $1.9 billion project will be the largest hospital redevelopment in BC's history. St. Paul's Foundation wants to make sure that the community – here in Vancouver and around British Columbia – is aware of the project's benefits and how it will help to transform care in this province.

St. Paul's is a world-renowned success story, with a culture of compassion, a history of putting people first, and a track record of ground breaking research for more than a century. It is a vital part of British Columbia's health care system offering specialized care not available anywhere else in the province. With the new St. Paul's we have a once-in-a-lifetime opportunity to deliver patient-centred care in state-of-the-art facilities using the latest technology and supported by leading-edge research, medical education and innovation.

For background information on the new St. Paul's project visit thenewstpauls.ca

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Pacific Animal Foundation

A Network of Caring in the Urban Wilderness

Mayor and Council of City of Vancouver
City Hall
453 West 12th Avenue
Vancouver, BC V5Y 1V4

October 17, 2019

Dear Mayor Stewart and Vancouver Council:

Re: A Changing Paradigm – Moving away from Animal Testing

I am writing today, as President of Pacific Animal Foundation, a registered Canadian charity, to bring to Council's attention, several websites and articles that indicate substantial progression in the area away from using animals in testing for medical research. A direct quote from the following article states:

"However, the 21st Century has already seen the development of a wide range of non-animal methods incorporating complex cell cultures, organs-on-a-chip and computer modelling. These methods are more relevant to human biology and are already enabling the replacement of animals as the default option in life science, particularly in the areas of toxicology and regulatory testing, but also in biomedical research.

This recently published study says the time has now come to prioritise the Replacement of animals used for scientific purposes, over refinement and reduction strategies."

Moving beyond the Three Rs in Biomedical Research – European Union Science Hub -

https://ec.europa.eu/jrc/en/science-update/moving-beyond-three-rs-biomedical-research

Johns Hopkins University, world renowned medical facility, is, in fact, America's first research university (1876) and home to nine world-class academic divisions working together as one university. The university established the Bloomberg School of Public Health - Center for Alternatives to Animal Testing.

http://caat.jhsph.edu/

http://caat.jhsph.edu/about/index.html

Many countries, including Canada, now have national Centers for Alternatives to Animal Testing including Canada and are adopting the 3R's in medical research. The Canadian Centre in Canada is located at the University of Windsor, Ontario and is found at the following website:

http://www.uwindsor.ca/ccaam/

And a recent TEDx talk is found at the following link which I would urge you to watch:

https://www.youtube.com/watch?time_continue=14&v=6O6kOcZH_mg

The technological advances are moving at a tremendous rate and the focus is leading in the direction of human-based cell modelling, and organ on a chip solutions as a means of better understanding answers and refining custom medical care for humans.

https://newfrontiersin3d.com/

Daily, there are more advances and emerging technologies which will assist the medical community in their quest for disease treatments.

St. Paul's Hospital claims on its new website: **"The future of health care in BC starts at the new St. Paul's"** and, if that is to be true, then the hospital MUST move forward with the changing times and paradigm and away from animal testing for research.

https://helpstpauls.com/newstpauls?gclid=Cj0KCQjwoqDtBRD-ARIsAL4pviBd0301aBYVysWPheZGbvBzws0qvcyGPYAp2FRwkTdXbVyoGt_ApAwaAt3OEALw_wcB

I strongly urge the Mayor and Council to reject any approval for animal laboratory facilities for testing of animals at the new St. Paul's Hospital in Vancouver ! They need to head into the future.

Thank you for your time and attention.

Sincerely,

s.22(1) Personal and Confidential

Lana Simon, Director
Pacific Animal Foundation
www.pacificanimal.org

BRILL *Over three centuries of scholarly publishing*

Animal Experimentation: Working Towards a Paradigm Change

Editors: Kathrin Herrmann and Kimberley Jayne

Animal experimentation has been one of the most controversial areas of animal use, mainly due to the intentional harms inflicted upon animals for the sake of hoped-for benefits in humans. Despite this rationale for continued animal experimentation, shortcomings of this practice have become increasingly more apparent and well-documented. However, these limitations are not yet widely known or appreciated, and there is a danger that they may simply be ignored. The 51 experts who have contributed to *Animal Experimentation: Working Towards a Paradigm Change* critically review current animal use in science, present new and innovative non-animal approaches to address urgent scientific questions, and offer a roadmap towards an animal-free world of science.

Readership

This volume is intended not only for fellow scholars and scientists, but for the interested public, campaigners, students, academics, researchers, regulators and industry.

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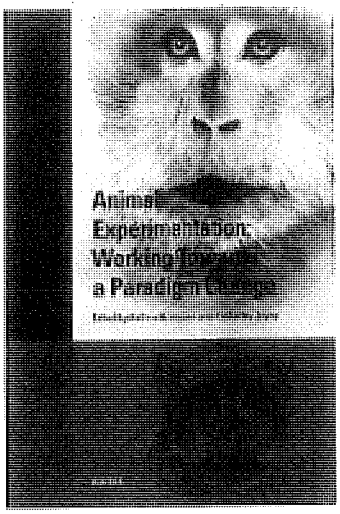

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English (en)

EU Science Hub

loving beyond the Three Rs in Biomedical Research

EP
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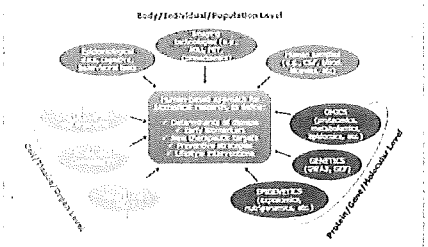
A new study co-authored by the JRC prioritises human relevant methods and the replacement of animal models in omedical research.



(https://ec.europa.eu/jrc/sites/jrcsh/files/styles/normal-responsive/public/moving_beyond_the_three_rs.png?itok=u5Qif787)
Schematic view of how human-based models/tools, technological approaches and readouts can be applied in biomedical
©Herrmann, Pistollato, Stephens

is year marks the 60th anniversary of the Three Rs, ned at promoting the 'Replacement' of animal use in ience, the 'Reduction' of the number of animals used r experiment, and the 'Refinement' of experimental ocedures to minimise suffering and improve welfare. ese principles were first described in 1959 by the UK ientists Russell and Burch ttps://books.google.it/books/about/The_principles_o numane_experimental_te.html? =j75qAAAAMAAJ&redir_esc=y)and have contributed nsiderably ever since to progressing humane research methods and excellence in ience.

wever, the 21st Century has already seen the development of a wide range of non-imal methods incorporating complex cell cultures, organs-on-a-chip and computer odelling. These methods are more relevant to human biology and are already enabling e replacement of animals as the default option in life science, particularly in the areas toxicology and regulatory testing, but also in biomedical research.

is recently published study ttps://www.altex.org/index.php/altex/article/view/1301)says the time has now come prioritise the Replacement of animals used for scientific purposes, over refinement d reduction strategies.

e emerging paradigm in research likely foreshadows an era in which the Three Rs are creasingly perceived as a solution to a receding problem.

eplacing animal experimentation in biomedical research

the European Union, basic and applied research accounts for about two-thirds of the imals used in science (https://eur-lex.europa.eu/legal-content/EN/TXT/?i=CELEX:52013DC0859). To date however, replacement of animal methods with man-based models has been mainly discussed in the context of regulatory toxicology d chemical safety. This can be linked to several factors including the relatively limited mber of standard studies performed and significant public concern over this use of imals.

)reover, biomedical research is traditionally more diverse and decentralised compared toxicity testing, encouraging originality and combinations of both animal and non-imal approaches, despite the limited capacity of current preclinical animal models to curately predict the safety and efficacy of new drugs.

·omoting Human Relevance in Biomedical Research

oritizing animal-free methods of high human relevance is a sensible way to avoid the ıited translational value of animal models of human biology.

ın-animal approaches and technologies, such as patient-derived cells and biological mples, large clinical data repositories, computational and imaging tools, machine ırning and micro-dosing approaches, are already enabling scientists to incorporate man relevance as a primary design criterion of biomedical research models and proaches.

ıch a human-oriented perspective is particularly relevant to the study of chronic, generative, non-communicable diseases, which are characterized by complex :eractions between environmental and genetic factors.

is important to prioritize human relevant methods and the replacement of animal ɔdels in biomedical research in order to deepen our understanding of human thologies and increase the likelihood of success in the development of drugs that are ıly effective in humans.

ıcreasing Awareness, Dissemination and Education on Non-ıimal Approaches

ıowledge sharing through education and training is pivotal to increase the awareness currently available animal-free methods.

e JRC's EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) ttps://ec.europa.eu/jrc/en/eurl/ecvam) has recently coordinated a study ttps://ec.europa.eu/jrc/en/science-update/education-and-training-3rs)to review ailable education and training resources that support the 3Rs approach.

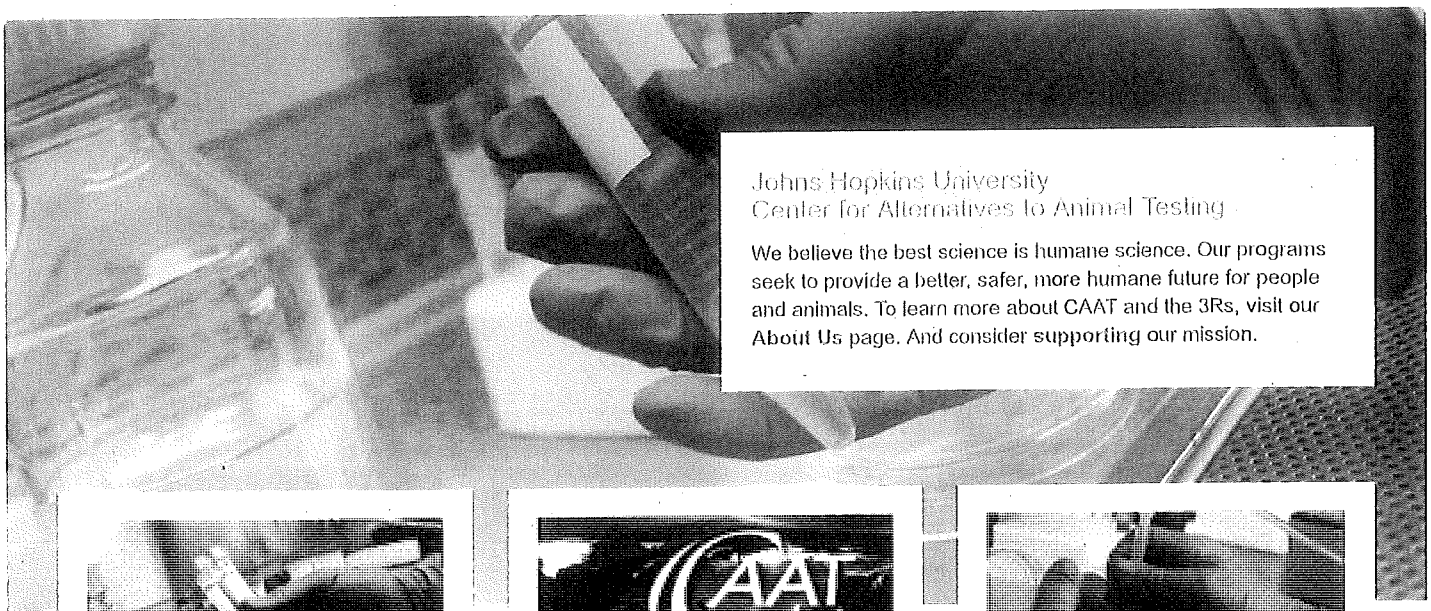
IRL ECVAM is also collaborating with Directorate General for Environment (DG ENV) in initiative (https://ec.europa.eu/jrc/en/science-update/calls-experts-training-tools-:ernatives-animal-testing)aimed at engaging experts to design and produce eLearning ɔdules to provide interactive instruction to students and professionals involved in lab imal use.

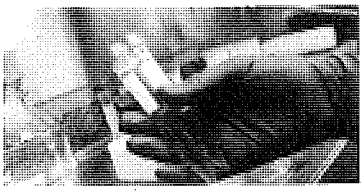
reach early career scientists, the JRC organised Summer Schools ttps://ec.europa.eu/jrc/en/event/conference/jrc-summer-school-non-animal-proaches-science) on non-animal approaches in science in 2017 and 2019. Similar tivities and initiatives are ongoing in the USA and in Canada.

ɐad more in:

:rrmann K, Pistollato F, Stephens ML. Beyond the 3Rs: Expanding the use of human-evant replacement methods in biomedical research ttps://www.altex.org/index.php/altex/article/view/1301). ALTEX. 2019;36(3):343-2.

)I: 10.14573/altex.1907031





CAAT News and Upcoming Events

News and upcoming events sponsored by CAAT, CAAT-Europe, and the Transatlantic Think Tank for Toxicology (t^4).

Sign up for our CAATwalk Newsletter for the latest news about our activities! View the latest CAATwalk Newsletter (October 11, 2019)

Postdoc Position Available
In the Developmental Neurotoxicology (autism), 3D organoid models, high-content imaging, CRISPR/Cas9 gene editing.
Details

Upcoming Events

JHU Exposome Collaborative Launch Event
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Keynote Talk: On the Replacement of Animal Testing: Yesterday, Today, and Tomorrow
Michael Balls, Emeritus Professor, Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK
Wednesday, November 20, 2019 • 4-5pm
Johns Hopkins Bloomberg School of Public Health
Event will be livestreamed here

60 Years of the 3Rs—Lessons Learned and the Road Ahead
November 22, 2019

CAAT-Europe

CAAT and CAAT-Europe promise sound scientific synergy involving experts from both sides of the Atlantic to promote the implementation of human-relevant alternative approaches, the advancement of research, and the dissemination of the 3Rs.

ALTERTOX Academy Training: PBPK Modeling and Quantitative In Vitro-In Vivo Extrapolation
October 3-4, 2019
Wageningen, Netherlands

Altertox Academy: 2019 Hands-on Training Courses

CAAT-Europe is housed at the University of Konstanz, Germany.

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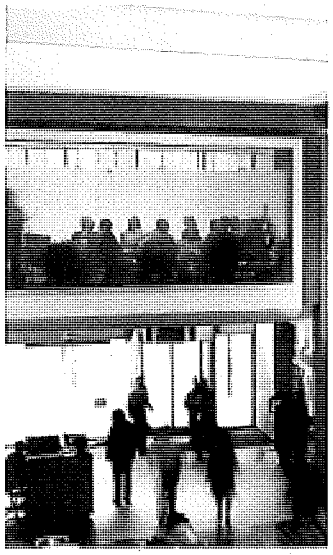
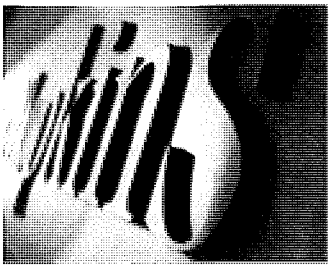
About Us: Center for Alternatives to Animal Testing

CAAT **CAAT- Europe**

The Johns Hopkins Center for Alternatives to Animal Testing (CAAT), founded in 1981, is part of the Johns Hopkins University Bloomberg School of Public Health, with a European branch (CAAT-Europe) located at the University of Kostanz, Germany.





We promote humane science by supporting the creation, development, validation, and use of alternatives to animals in research, product safety testing, and education. We seek to effect change by working with scientists in industry, government, and academia to find new ways to replace animals with non-animal methods, reduce the numbers of animals necessary, or refine methods to make them less painful or stressful to the animals involved.

Information about **CAAT-Europe** can be found here.

Information about the **Transatlantic Think Tank of Toxicology (t^4)** can be found here.

Vision/Mission Statement
History
Timeline
Achievements
Advisory Board
Programs
Staff
Sponsors
CAAT Brochure (2.2 MB PDF)

We also have a website devoted to 3Rs and alternatives news and information—Altweb: The Global Clearinghouse for Information on Alternatives to Animal Testing.

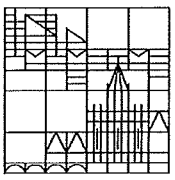
And our official journal, *ALTEX: Alternatives to Animal Experimentation*, can be found here.

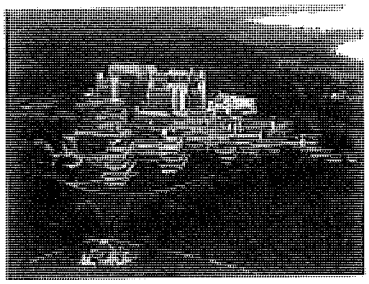
You can follow CAAT on Facebook and Twitter, too, or visit our YouTube channel.

This page is also now available in Ukrainian.

CAAT-Europe, housed at the University of Konstanz, coordinates transatlantic activities to promote education in humane science and will participate in and/or coordinate publicly and privately funded European projects. Dr. Thomas Hartung serves as program liaison representing Johns Hopkins, and Dr. Marcel Leist serves as the University of Konstanz liaison. Thomas Hartung is also a Professor for Pharmacology and Toxicology at Konstanz. Furthermore, Alexander Burkle (Molecular Toxicology) and Daniel Dietrich (Human and Environmental Toxicology) of Konstanz are members of CAAT-Europe.

Universität Konstanz





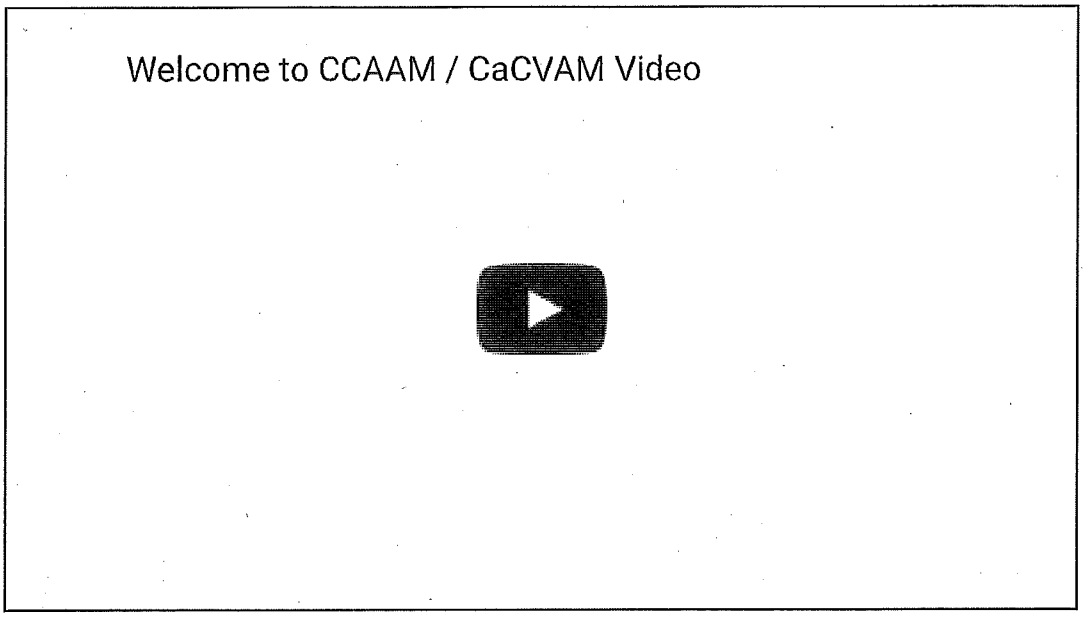
CAAT -Europe plans to develop a joint education program between the Johns Hopkins School of Public Health and the University of Konstanz. This program will include e-courses, CAAT's existing certificate program on humane science, a student exchange, and collaboration in the International Graduate School (International Research Training Group— IRTG 1331— Konstanz, Germany and Zürich, Switzerland "Cell-based Characterization of Disease Mechanisms in Tissue Destruction and Repair.")

Goals of CAAT-Europe:

Establish a CAAT EU faculty and advisory board composed of sponsor representatives and prominent academics from Europe
Establish a competence base of European experts available for project work
Participate in the Transatlantic Think Tank for Toxicology (t^4) devoted to conceptual work for the paradigm shift in toxicology
Coordinate a series of information days on relevant developments from the US in Europe, a reciprocal of the program already established by CAAT in the US
Set up transatlantic consortia for international research projects on alternative methods
Support ALTEX as the official journal of CAAT, EUSAAT, and t^4.
Develop strategic projects with sponsors to promote humane science and new toxicology

CAAT-Europe at the University of Konstanz
University of Konstanz
POB 600
78457 Konstanz
Germany
Phone: +49 7531 882233
Fax: +49 7531 884156
Contact: Giorgia Pallocca
email: caat-eu-2@uni-konstanz.de

Welcome to CCAAM / CaCVAM



The Canadian Centre for Alternatives to Animal Methods (CCAAM) and the Canadian Centre for the Validation of Alternative Methods (CaCVAM) aim to develop, validate, and promote non-animal, human biology-based platforms in biomedical research, education, and chemical safety testing.

Experimental animals continue to serve as the gold standard in biomedical research today, but many breakthroughs in research labs do not make it into our clinics—95% of drugs tested to be safe and effective in animals fail in human clinical trials. Similarly, for evaluating the safety of chemicals, the legacy animal-based methods are not sufficiently reliable to accurately predict adverse outcomes on human health and the environment.

From the Americas to the Far East, countries across the globe have already established national centres dedicated to non-animal alternatives and approved legislation to shift away from animal testing, but Canada has lagged behind, until now—our Centre is the first-of-its-kind in Canada.

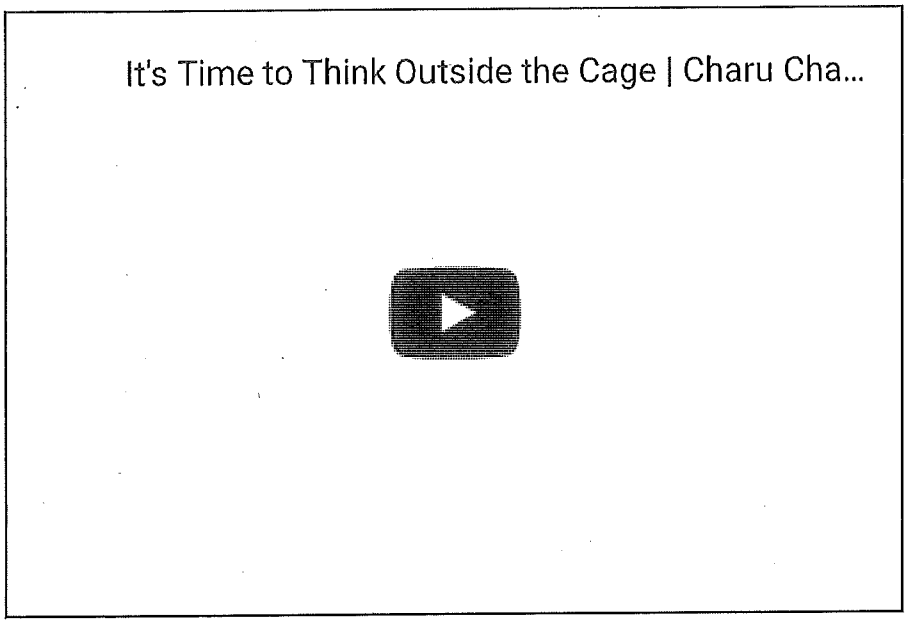
We promote a paradigm shift in which human biology serves as the gold standard.

Time to change the gold standard.

Time to place Canada on the map.

We are deeply grateful to Eric and Dana Margolis for their incredibly generous gift that will transform CCAAM/CaCVAM:
http://www.uwindsor.ca/dailynews/2018-10-29/largest-research-donation-uw...

TEDx talk by Dr. Charu Chandrasekera, executive director of CCAAM/CaCVAM "**It's time to think outside the cage**"



New Frontiers in 3D Cell Technologies

A full-day scientific symposium to discuss practical applications for transformative 3D cell and organ-on-a-chip technologies

April 25, 2019 • MIT Samberg Center • Cambridge, MA USA

JOIN US (/REGISTER/)

Are you ready for the future of preclinical drug testing?

Organ on a chip systems | scalable 3D disease modeling platforms | animal testing alternatives | highly predictive drug safety screening

Join the conversion. Help shape the future.

The 2019 New Frontiers in 3D Technologies conference brings together pharma and biotech thought-leaders, research scientists, and regulatory experts for an exclusive one-day conference on applications for innovative new 3D cell technologies for drug efficacy and safety testing.

- Learn about practical applications for the latest generation of 3D *in vitro* models that have successfully transitioned from R&D evaluations to indispensable for everyday use in industry
- Discuss 3D technology trends and real-world implementation challenges
- Discover disease modeling platforms, assay strategies, and readout techniques that could transform how your organization does drug discovery and development
- Debate how best to apply emerging tools for organ-on-a-chip systems.
- Network with influencers in the fields of metabolic disease, oncology, and toxicology
- Share how you are applying 3D cell-based technology in your work by submitting an abstract for a poster or oral presentation.

LEARN MORE (/PROGRAM/)

REGISTER (/REGISTER/)

ORGAN-ON-A-CHIP
SOLUTIONS

HUMAN DISEASE MODELING

ALTERNATIVES TO ANIMAL TESTING

DRUG SAFETY SCREENING

Featured Speakers

This year's program includes talks by innovators in 3D cell technologies from Novo Nordisk, GC Therapeutics, Takeda Pharmaceuticals, and the Broad Institute of Harvard and the Massachusetts Institute of Technology.

Matthias von Herrath, MD

Vice President and Head of the Novo Nordisk Diabetes R&D Center and Professor at the La Jolla Institute for Immunology.

Parastoo Khoshakhlagh, PhD

CEO and co-founder of GC Therapeutics (GCTx)

Matthew Wagoner, PhD

Associate Director of Mechanistic and Investigative toxicology, Takeda Pharmaceuticals

Anne Carpenter, PhD

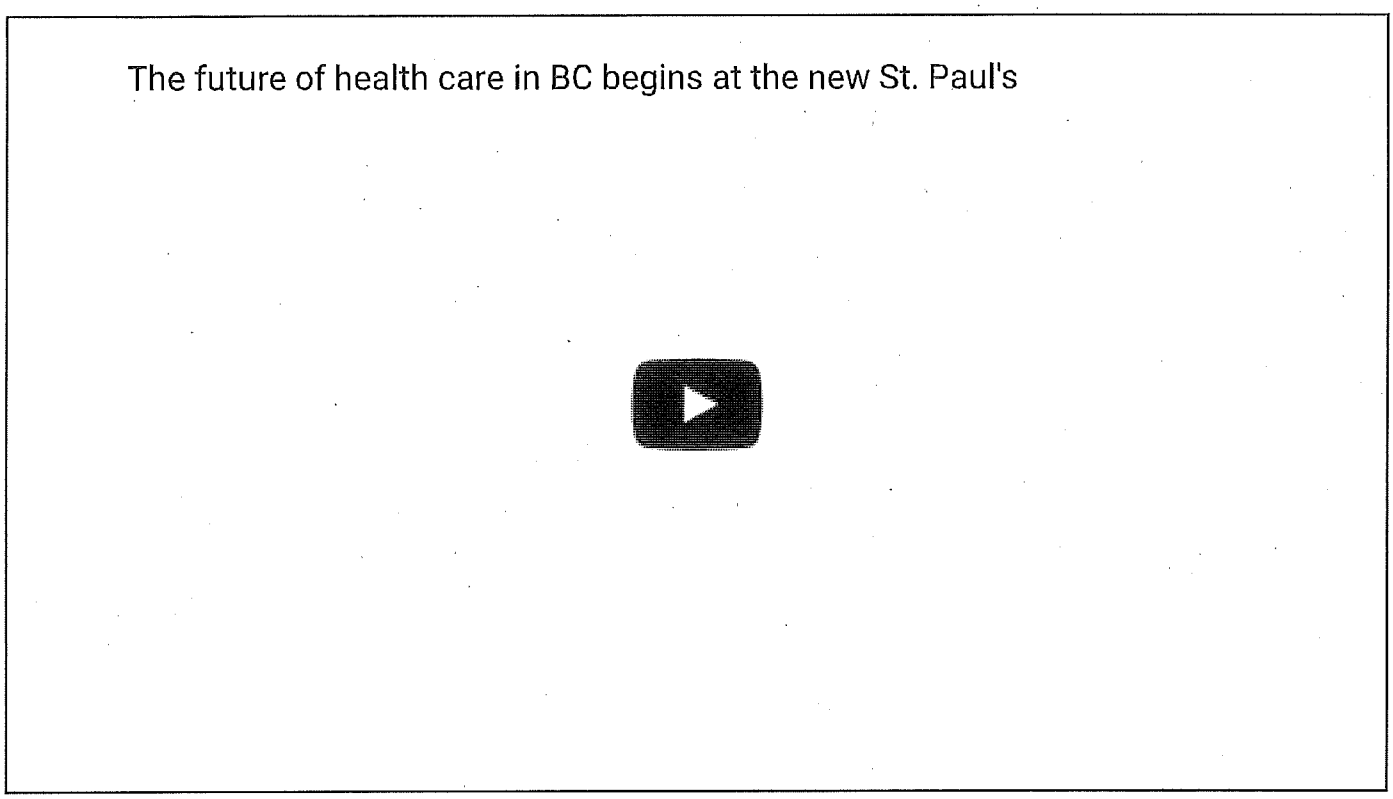
Institute Scientist and Merkin Fellow at the Broad Institute of Harvard and MIT

VIEW CONFERENCE AGENDA (/PROGRAM/)

Call for Abstracts

New Frontiers in 3D invites scientists, bioengineers, academic researchers, and innovation leaders to subm
3D Cell Technology for consideration for poster and oral presentations at ou

SUBMIT ABSTRACT (/REGISTER)



The future of health care in BC starts at the new St. Paul's.

LEARN MORE DONATE NOW

On Friday, February 15, it was announced that the business plan for the new St. Paul's was approved by the provincial government. This $1.9 billion project will be the largest hospital redevelopment in BC's history. St. Paul's Foundation wants to make sure that the community – here in Vancouver and around British Columbia – is aware of the project's benefits and how it will help to transform care in this province.

St. Paul's is a world-renowned success story, with a culture of compassion, a history of putting people first, and a track record of ground breaking research for more than a century. It is a vital part of British Columbia's health care system offering specialized care not available anywhere else in the province. With the new St. Paul's we have a once-in-a-lifetime opportunity to deliver patient-centred care in state-of-the-art facilities using the latest technology and supported by leading-edge research, medical education and innovation.

For background information on the new St. Paul's project visit thenewstpauls.ca

Dragnea, Irina

From: Nellie Enright s.22(1) Personal and Confidential
Sent: Friday, October 18, 2019 5:30 PM
To: Public Hearing
Subject: Spam: Concerned for unusual treatment towards innocent animals

I am against these unnecessary so-called laboratory examinations. their torture institutions and nothing more. 30 years can go by and there are no new advances. You're stealing people's money. And torturing our animals. Unnecessarily.

Dragnea, Irina

From: rosalee trimble s.22(1) Personal and Confidential
Sent: Friday, October 18, 2019 7:57 PM
To: Public Hearing

I am totally opposed to any kind of animal testing at St Paul's Hospital. What a cruel and horrifying thing it is to test on our animal friends. NEVER let this happen in our society today-- PLEASE!

Dragnea, Irina

From: Anne Birthistle s.22(1) Personal and Confidential
Sent: Friday, October 18, 2019 8:06 PM
To: Public Hearing
Subject: St Paul's Rezoning

Please note the urgent concerns of the ADAV Society regarding lack of sustainability and environmental harm of animal research laboratories and attenuating waste materials. Council is requested to investigate fully the environmental impact of such facilities before permits are considered.
Modern technological improvements are replacing animal research methods and this progress must be evaluated more closely if Vancouver is to stay on the cutting edge of biomedical research and training.

Sincerely,

Boards of Directors
ADAV Society of B C and
BC Foundation for NonAnimal Research

ASent from my iPad

Dragnea, Irina

From: Clo Leone s.22(1) Personal and Confidential
Sent: Friday, October 18, 2019 8:26 PM
To: Public Hearing
Subject: Animal testing at St. Paul's Hospital

I am opposed to animal testing at the new St. Paul's Hospital.

Clo Leone
s.22(1) Personal and Confidential

Dragnea, Irina

From: Suzanne Goodwin s.22(1) Personal and Confidential
Sent: Friday, October 18, 2019 11:57 PM
To: Public Hearing
Subject: St. Paul's Hospital rezoning

I am opposed to any and all animal testing, use, confinement or experimentation at the new St. Paul's Hospital.

Sincerely,
Suzanne Goodwin

Sent from my iPhone

Dragnea, Irina

From: Gerald Martin s.22(1) Personal and Confidential
Sent: Saturday, October 19, 2019 2:01 AM
To: Public Hearing
Subject: St. Paul's animal experimentation lab proposal

I fervently and humbly ask that the proposal to allow an animal experimental lab to the new St. Paul's.

In today's world, there is no real need to have such a facility, even aside from the fact that the animals suffer horrendously and unnecessarily. And that, I hold, is something we do not have the ethical and moral right to do. As a so called civilized society it behooves us to embrace the concept of guardianship, rather than exploitation.

It is also understood that new and non intrusive ways are coming more and more to the forefront. For an introduction, I ask that you take the time to watch this TED talk, presented by Charu Chandrasekera of the University of Windsor. It runs for 14:21 minutes and is both informative and educational for all of us.

Here is the url: https://www.youtube.com/watch?v=6O6kOcZH_mg&fbclid=IwAR1Qcf-bHPIwnUxT7xaY6dP19_I6Lqe4VWxkUCZmuVxaKPFbHf5pII2YEHM

Thank you for your indulgence.

Respectfully,
Gerald Martin

Sent from Mail for Windows 10

Dragnea, Irina

From: Nellie Enright s.22(1) Personal and Confidential
Sent: Friday, October 18, 2019 5:32 PM
To: Public Hearing

I'm totally against this unusual treatment towards animals. Unnecessary and unrewarding. 30 years can go by with no new advances. Their torture chambers nothing more. Disgusting. I'm not for this and I want the council to know it. Many many people are not for this. It's barbaric. It's old let's come up with something new and effective. This is not it. They all should be shut down.
My name is Nellie Enright Brida,
New Jersey USA

Dragnea, Irina

From: PATRICIA KENDALL s.22(1) Personal and Confidential
Sent: Saturday, October 19, 2019 1:57 PM
To: Public Hearing
Subject: Rezoning Application for 1002 Station St and 250-310 Prior St

Public Hearing written submission by Patricia Kendall, Vancouver, BC

Constitution of Providence Health Care Society – No Authority to Construct or Operate Research Facilities

In my letter to Council dated September 17, 2019 (available under "News" on the Rezoning for the Animals website www.rezoningforanimals.com), I advised the City that the Constitution of the Providence Health Care Society does **not** permit it to establish research facilities. The establishment of research facilities by the Society would be unlawful – outside its legal authority.

Despite this, the Rezoning for the Animals group assures the City that it will not, post-zoning, bring legal action on this issue provided the rezoning bylaw (and an accompanying *Land Title Act*, section 219 covenant) ensure that animal experimentation may not take place within the hospital research laboratories.

Dragnea, Irina

From: PATRICIA KENDALL s.22(1) Personal and Confidential
Sent: Saturday, October 19, 2019 2:09 PM
To: Public Hearing
Subject: Rezoning Application for 1002 Station St and 250-310 Prior St

Public Hearing written submission by Patricia Kendall, Vancouver, BC

Constitution of Providence Health Care Society Requires Compassion to Animals

In my letter to Council dated September 26, 2019 (available under "News" on the Rezoning for the Animals website www.rezoningforanimals.com), I advised the City that the Constitution of the Providence Health Care Society does **not** permit it to be in any way involved with cruel experimentation on animals.

The Constitution of the Society requires it to comply with the following:

- respect the sacredness of all aspects of life
- compassionate research
- nurture love and compassion

The Constitution also requires it to carry out its purposes in accordance with the teachings, canons and ethics of the Roman Catholic Church. This means no act of cruelty toward any creature.

Dragnea, Irina

From: Helen Prynn s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 6:03 AM
To: Public Hearing
Subject: St. Paul's Hospital Rezoning

Dear Sir/ Madam,

I am writing to you because I am strongly opposed to animal testing at the new St. Paul's Hospital. Nowadays, the horrific conditions and suffering of animals used in experiments have been widely documented as has been its limited effectiveness for human medical advances. It's almost 2020 and there are sophisticated, human-relevant alternatives to animal testing (which will become more advanced in the upcoming years) that can be used instead. Surely, a hospital built in 2020s deserves a drug testing facility reflecting these facts.

many thanks for your time and attention to this matter,

Helen

Dragnea, Irina

From: Bc. Michaela Skokanová s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 6:22 AM
To: Public Hearing
Subject: Animal testing at St. Paul's Hospital

Hello,
I oppose to animal testing so I'd like to let you know the St. Paul's Hospital really should not do that because it is an inhumane unnecessary throw-back.
Thank you for acknowledging this and holding an open forum for the citizens.
Sincerely,
M. Skokanova

Dragnea, Irina

From: Timea Sarina s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 8:37 AM
To: Public Hearing
Subject: NO ANIMAL TESTING!

I am opposed to animal testing at the new St. Paul's Hospital. That is something unacceptable!

Timea Sarina

Dragnea, Irina

From: pradmin s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 11:00 AM
To: Public Hearing
Subject: Opposed to Animal Testing at St. Paul's Hospital

Re: Patricia Kendall: Ban animal testing at the new St. Paul's Hospital

A fine piece by Ms Kendall acknowledging the failure of the 'animal testing model'.

The dubious ethics of experimenting on Peter (mice, cats, dogs, humans in 3rd world countries etc) to benefit Paul notwithstanding, one really should wonder why the expensive, wonderful work done by these smart medical research guys over decades and decades still hasn't produced cures for the major diseases mentioned in the article. After all, if we actually run out of diseases, wouldn't we also run out of grant money and bring to a grinding halt all the industries that depend on such finances?

No. Forbid change to the pecuniary status quo! Healthy people in a healthy society is just too damaging to these businesses. Lifestyle changes such as plant-based diets exercise go a long way towards creating that healthy society, but is the death knell for those who profit from sick people.

So banning animal testing (at St Paul's Hospital and everywhere else) is definitely a step in the right direction and will hopefully be followed up with banning many other iniquities that are supported by a generally unsuspecting and unquestioning population which is pummeled into thinking that the various medical industries actually have their best interests at heart.

Prad Basu
Shawnigan Lake, BC

Dragnea, Irina

From: Ondřej Máca s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 12:50 PM
To: Public Hearing
Subject: No animal testing

I am opposed to animal testing at the new St. Paul's Hospital.

Ondřej Máca

Dragnea, Irina

From: Colins Amandah s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 1:44 PM
To: Public Hearing
Subject: Public hearing animal testing new St Paul's Hospital

I am opposed to animal testing at the new St. Paul's Hospital.
YIKES!
It is horrendous...animals are sentient beings deserving respect NOT torture. Humans Sadly Rationalize Away the Rights of Other Species.

Sincerely,
Amandah Colins
Vancouver, BC

Dragnea, Irina

From: Travels with TJ s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 2:17 PM
To: Public Hearing
Subject: Stop Animal testing

STOP ANIMAL TESTING!!!!

Sent from my iPhone

Dragnea, Irina

From: Microsoft.com Team s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 2:41 PM
To: Public Hearing
Subject: No to animal testing

Hell no . I am against the testing

Dragnea, Irina

From: Microsoft.com Team s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 2:42 PM
To: Public Hearing

I am NOT in favor of testing at Saint pauls

Dragnea, Irina

From: haley millwater s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 2:56 PM
To: Public Hearing

I am vehemently opposed to animal testing at the new St. Paul's hospital. Please do not take part in the cruel and unnecessary torture of innocent animals. It is more evident than ever that sickening animals of a different species does not help us cure illnesses in our own. Additionally, the proof is overwhelming that animals suffer in the ways we do. Animal testing is scientifically and ethically indefensible and there is no place for this in a civilized society. Please see this issue with empathy.

Dragnea, Irina

From: Crystal R-L s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 5:11 PM
To: Public Hearing
Subject: Animal testing

There is ABSOLUTELY NO EXCUSE for animal testing. Please do not allow this cruel heartless practice to continue. If you have any light in your soul.

Dragnea, Irina

From: Del-Rae Croteau s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 5:35 PM
To: Public Hearing
Subject: RE: Animal testing @ St. Pauls Hospital

Hi there,

My name is DelRae and I am opposed to any form of animal testing. It is completely cruel!
No animal should have to undergo product testing, ever. If you want to test! Look for voluntary humans!

Thank you for your time,

DelRae Croteau

Sent from my Samsung Galaxy smartphone.

Dragnea, Irina

From: s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 5:49 PM
To: Public Hearing
Subject: St. Paul's Hospital Rezoning (Public Hearing October 22, 2019)

Dear Mayor Stewart and Councillors,

In this, my submission to the Public Hearing concerning St. Paul's Hospital Rezoning, I would like to explain why I am opposed to animal experimentation. It has a 95% failure rate.
If I were asked to invest in a company with such a poor level of success, barely 5%, I would suspect my financial advisor's motive. And yet decades of research on non-human species have failed to help find cures for human diseases. The chief beneficiaries have been mice and other animals experimented on in laboratories. Clearly, experimentation on animals is a poor investment for human health.

In 2017 W5 produced an undercover documentary showing what tortures beagles and a little monkey suffered at the hands of ITR Technologies in Quebec. The beagles were being prepared to inhale a foreign substance. One of the dogs resisted and was slapped many times for not cooperating with his torturer. I cannot erase from my memory what agony was being inflicted on the monkey.

The W5 documentary led me to buy a must-read book by doctors Ray and Jean Greek, called *Sacred Cows and Golden Geese.* It is a well-documented exposé of what drives research on animals in laboratories: vested interests. Research using live animals has become systemic in hospital, university, and private laboratories. It's the way things have always been done, and it's a big industry that pays for overhead and salaries. It's now an open secret that experiments on live animals result in finding cures for animals, but not for humans.

Recently I watched "It's Time to Think Outside the Cage" (TEDX talk) by Dr. Charu Chandrasekera. She is the Executive Director of the Canadian Centre for Alternatives to Animal Methods and the Canadian Centre for the Validation of Alternative Methods, University of Windsor, Ontario. Her talk, available online, explores what alternatives are available which actually show a promise of success for humans.

Despite its decades of failures, research on animals in laboratories continues, but it is becoming a sunset industry whose lights will be turned off by the coming generation of young medical researchers. That is why I am asking Vancouver Council to rule on the side of good science and refuse to pass a rezoning bylaw that would permit more futile experimentation on live animals in the new Hospital.

Much of my knowledge about research using animals has come from online sources. To my surprise, even the W5 undercover documentary is still on the internet. Near the end of that video, the Executive Director of the Canadian Council on Animal Care, Louise Desjardins, was asked if CCAC had ever revoked a laboratory's license after their inspection. She could

not recall that ever happening. Elsewhere I read that in the 49 years since the Canadian Council on Animal Care was founded, no license has ever been revoked or suspended. I firmly believe that the CCAC's actual purpose is to protect institutions which experiment on live animals. The CCAC's assurances that animals are being treated according to industry standards are accepted by a public accustomed to respect professionals in medicine without question. The same can be said of the fancifully named Canadian Council on Animal Care.

In general, people want to believe animals do not suffer unduly in laboratories, but not a single person to whom I emailed the W5 documentary link would watch the film. Instinctively they feared seeing animals in severe pain. The usual excuse was that they loved animals, so they could not watch footage where they are made to suffer. Besides, they would not be able to sleep if they watched W5. Of course, they were right about the sleep part because I viewed it.

In reading the information offered on the Rezoning for the Animals link, I also stumbled upon a letter on the internet which was hand-delivered to you on June 13, 2019. Its author is Patricia Kendall, a retired municipal lawyer. As you have the letter, I need not comment on the points it raised. However, the legal procedure errors that are in the rezoning application are either sloppy work by the person who prepared it, or – a darker thought – the sloppiness is intended to hide information from Vancouver Council and the public. I therefore endorse the request for a re-submitted rezoning application followed by a public meeting.

In closing, I once more urge Vancouver Council to help the new St. Paul's Hospital become a leader in modern medical research. By definition modern excludes outdated and wasteful animal model experiments.

Thank you,
Helen Schiele

October 20, 2019

Dragnea, Irina

From: s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 7:22 PM
To: Public Hearing

Hello,
I find it completely disgusting that there is even any consideration for animal testing. We as humans, Canadians, etc know better then this!

Sincerely,
Trevor

Dragnea, Irina

From: Anita s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 7:47 PM
To: Public Hearing
Subject: Animal testing at St Paul's

Hello
I am opposed to animal testing at the new location of St Paul's hospital.

Anita Aleksejev
Vancouver BC
Sent from my iPhone

Dragnea, Irina

From: brittany goldhawke s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 7:56 PM
To: Public Hearing
Subject: Re: St. Paul's hospital , rezoning for the animals

I am emailing in regards to the potential animal testing to occur at St. Paul's hospital. I am appalled that animal testing would be considered an option in our City. I am completely against any and all animal testing, and will not advocate for any hospital that tortures any animals, it is barbaric, it is unnecessary, and is ineffective in treating human disease. This hospital must not be allowed to perform such testing on innocent and sentient beings.

Thank you
Brittany Goldhawke

Sent from my iPhone

Dragnea, Irina

From: Serena GalbraithHriech s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 8:41 PM
To: Public Hearing
Subject: STOP ANIMAL TESTING

Its 2019 we shouldn't even have to be discussing this! I am opposed to animal testing at the new st. Paul's hospital.

Dragnea, Irina

From: Kim burgham s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 9:58 PM
To: Public Hearing
Subject: animal testing

In this day and age, i would have thought you would know better.
Please STOP
Kim Burgham,
Vancouver , B.C.

Dragnea, Irina

From: Ed Sadler s.22(1) Personal and Confidential
Sent: Sunday, October 20, 2019 11:21 PM
To: Public Hearing

Animal experimentation at St. Pauls should never be on the table. It is cruel, outdated and it does not work. We now have computer models that are more accurate reps than animal tests are. Mayor and council, please read these science based articles on the uselessness of animal testing.

https://www.huffpost.com/entry/animal-experimentation_b_3676678
https://www.huffpost.com/entry/animal-testing-diseases_b_3813856
https://www.huffpost.com/entry/why-animal-experimentatio_b_3997568

Thanks for reading and considering being compassionate towards animals that deserve a life.

Ed Sadler
s.22(1) Personal and Confidential

Dragnea, Irina

From: Nick Jukes, s.22(1) Personal and Confidential
Sent: Monday, October 21, 2019 7:20 AM
To: Public Hearing
Cc: s.22(1) Personal and Confidential
Subject: St. Paul's Hospital - rezoning

To Mayor Kennedy Stewart and Vancouver City Council members,

As s.22(1) Personal and Confidential and as a regular visitor to Vancouver, this is a message regarding the rezoning of St. Paul's Hospital for its new site.

Please use all of the Council's powers to help ensure that the Hospital is blocked from performing animal experimentation within training, research and applied research.

As you may be aware from the news internationally, from scientific reports and studies, and from online resources such as our own Alternatives and Studies databases at interniche.org, there are many exciting and innovative developments in non-animal methods for medical research and testing, and for surgical training, with increasing evidence of their enhanced relevance and reliability.

It would be a shame if Vancouver weren't able to maintain its status as socially progressive, and instead aligned itself with older methods that lack validation and ignored the exciting advances in both science and training. Please choose innovative and humane approaches, which will be to everyone's benefit.

Yours sincerely,

Nick Jukes

****

Nick Jukes
s.22(1) Personal and Confidential

****

Dragnea, Irina

From: Debra Milenk s.22(1) Personal and Confidential
Sent: Monday, October 21, 2019 12:00 PM
To: Public Hearing
Subject: Against Animal Testing

I am opposed to the Animal Testing at the New St Pauls Hospital

Regards Debra Milenk

s.22(1) Personal and Confidential

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Sent from Mail for Windows 10

Dragnea, Irina

From: Vanessa Anderson s.22(1) Personal and Confidential
Sent: Monday, October 21, 2019 1:13 PM
To: Public Hearing
Subject: Animal testing at new St. Paul's hospital

I am very hopeful we can eliminate animal testing. Please

Dragnea, Irina

From: Karen Stiewe s.22(1) Personal and Confidential
Sent: Monday, October 21, 2019 1:23 PM
To: Public Hearing
Subject: No animal testing laboratory at St. Paul's Hospital

Dear Mayor and Councilors:

I was disturbed to hear that the City is considering the rezoning of St. Paul's hospital to allow for an animal testing laboratory.
This action would result in a regressive, archaic and backward outcome. My father was a successful kidney transplant recipient there.

Experiments based on animal models seldom provide cures for human beings, in fact 95% of the time, cures found in animal testing do NOT extrapolate to cures for human beings. This would result in a total waste of precious resources, feeding a flawed and costly scientific system that many scientists now question.

Not only are resources wasted, but animal experimentation is cruel. Secrecy and security behind laboratory doors prevent the public from knowing the shocking treatment of innocent and sentient beings. It is NOT a "necessary evil". Modern and human relevant scientific technologies are available and advancing to replace irrelevant and cruel animal testing models. This is the way of the future and the path I hope you choose to support.

I implore you to watch the CTV News W-5 investigative undercover video depicting the treatment of animals at the Montreal ITR Lab (International Toxicology Research). Every week protesters gather there aiming to shut the laboratory down. I have no doubt the same protests will occur at St. Paul's. More and more, undercover videos and the media are exposing the truth behind animal testing laboratory doors.

https://www.ctvnews.ca/w5/undercover-investigation-reveals-what-goes-on-inside-montreal-animal-research-lab-1.3320123

Karen Stiewe