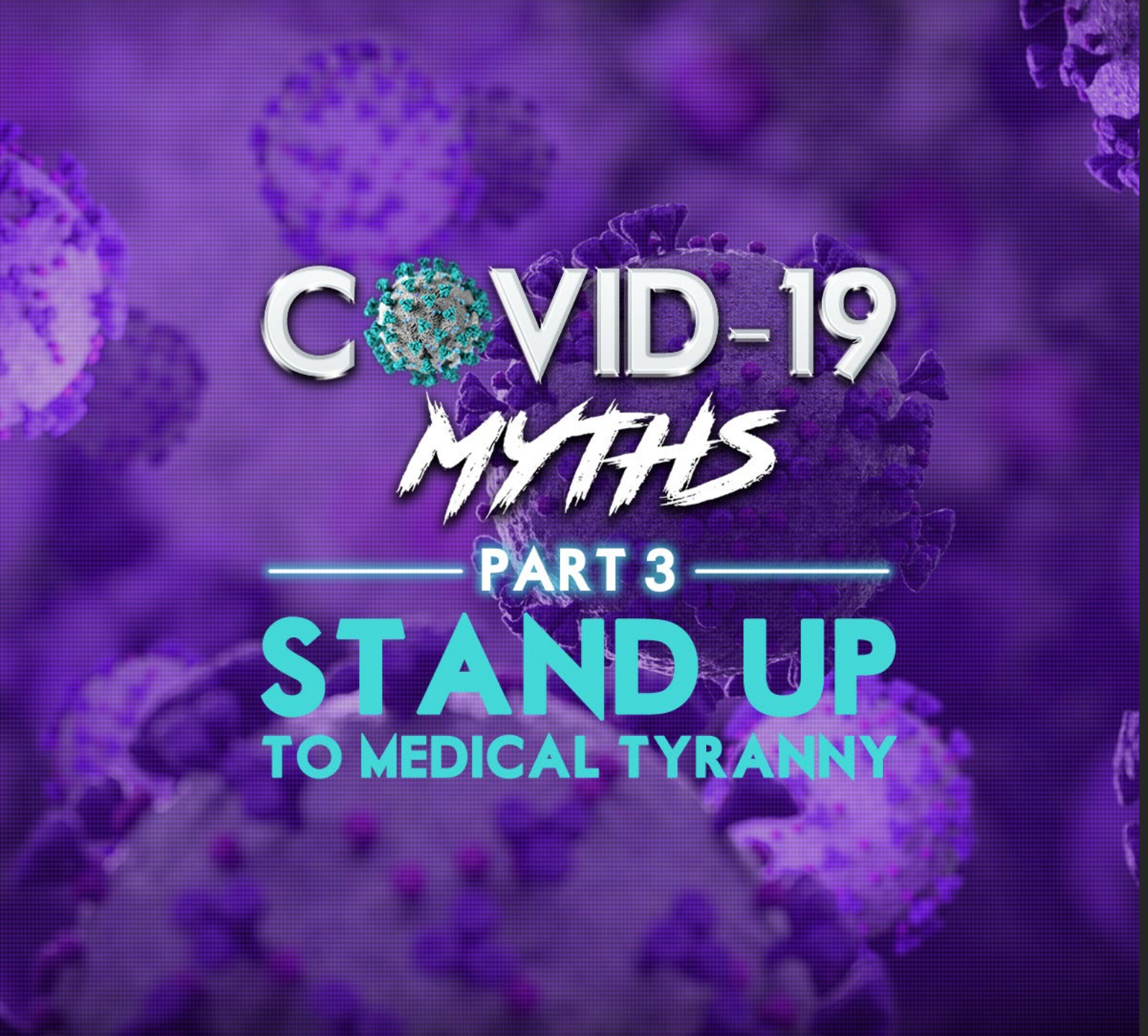


ANDREW
KAUFMAN, MD

SEPTEMBER 18, 2021

The Nuremberg Code (1947)

Permissible Medical Experiments

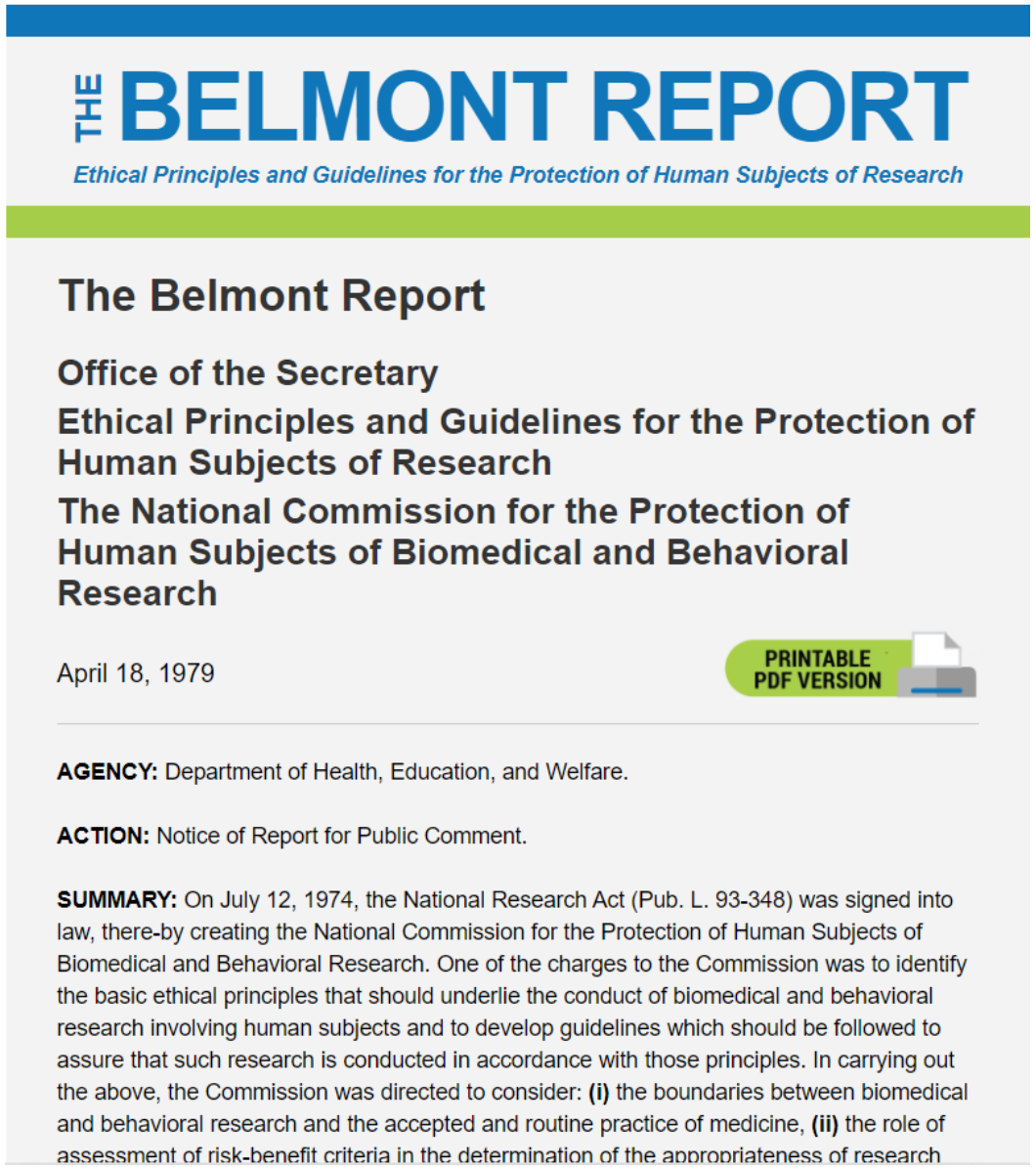
The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior from of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
   The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.

by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

British Medical Journal 313(7070):1445-75, 1996.



THE BELMONT REPORT

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The Belmont Report

Office of the Secretary

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

PRINTABLE PDF VERSION

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research

- Origin – Nuremberg Code
- Practice vs. Research
- Ethical Principles
  - Respect for Persons
  - Beneficence
- Informed Consent
- Comprehension
- Voluntariness
- Systematic Assessment of Risks and Benefits

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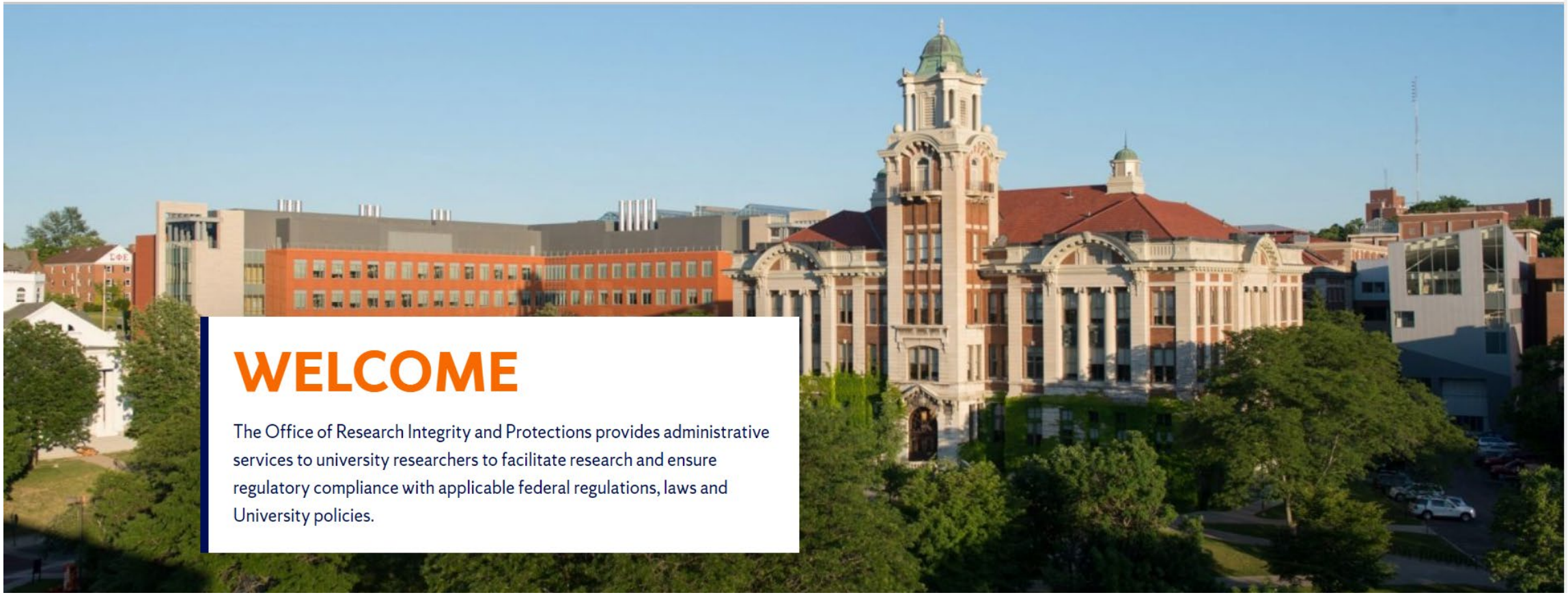
Financial Conflict of Interest (FCOI) | Announcements and News | Resuming Face-to-Face Human Participant Research



WELCOME

The Office of Research Integrity and Protections provides administrative services to university researchers to facilitate research and ensure regulatory compliance with applicable federal regulations, laws and University policies.

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

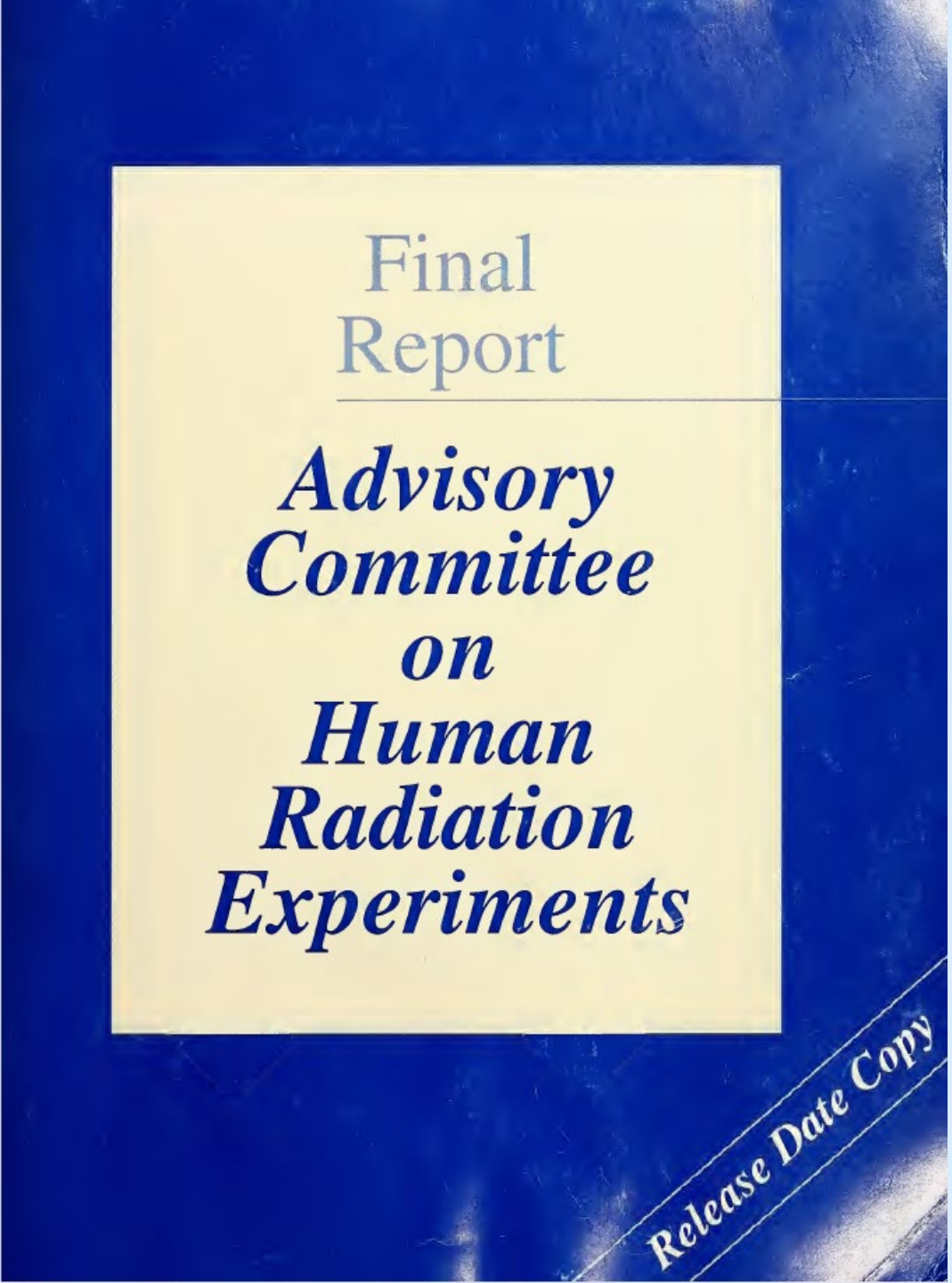
Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,

TUSKEGEE SYPHILIS STUDY 1932-1972

Herman Shaw (Tuskegee Study survivor) with President Clinton, May 16, 1997

- 399 illiterate, poor, rural black men w syphilis and 201 controls
- Make sure they never get treatment (later denied penicillin)
- Didn't know they had syphilis or what study was about
- Subjects died younger than controls
- Violated Nuremberg and Helsinki: No Informed Consent given
- Originally run by US Public Health Service, later CDC
- Complicit with study: Surgeon General(s), American Heart Association, US Public Health Service, CDC, Macon County Medical Society (Alabama)
- In 1958, each given $25.00 for 25 years participation
- In 1974, each subject awarded $37,500.00 for each living survivor in out of court settlement with US government



Hanford Green Run Experiment

- December 2, 1949
- GE, DoD, and Atomic Energy Commission
- Release radiation into atmosphere
  - Radioactive Iodine-131 (324 times as much as Three Mile Island) – 7,780 Curies
  - Radioactive Xenon-133 – 20,000 Curies
- Near Spokane, Washington
- Classified until 1986
- Purpose of study unknown

FDA EUA AUTHORIZED

U.S. FOOD & DRUG ADMINISTRATION

August 5, 2020

To: Manufacturers of Surgical Masks;
Health Care Personnel;
Hospital Purchasing Departments;
Authorized Distributors and Authorized Importers; and
Any Other Stakeholders

The U.S. Food and Drug Administration (FDA) is issuing this Emergency Use Authorization (EUA) in response to concerns relating to the insufficient supply and availability of disposable, single-use surgical masks[1,2] (hereafter also referred to as "surgical masks") for use in healthcare settings by health care personnel (HCP)[3] as personal protective equipment (PPE)[4] to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of authorized surgical masks as described in the Scope of Authorization (Section II) of this letter for use in healthcare settings by HCP as PPE during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of these authorized surgical masks for use in healthcare settings by HCP to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID-19 pandemic.[7,8]

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[6] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations*

Emergency Use Authorization of Medical Products and Related Authorities

Guidance for Industry and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats

January 2017

Procedural
OMB Control No. 0910-0595
Expiration Date 08/31/2022
See additional PRA statement in section IX of this guidance.

addition to the manufacturer's labeling, appropriate information with respect to the product, such as that provided in the brief Fact Sheet described above.[44]

b. Information for Recipients

Although informed consent as generally required under FDA regulations[45] is not required for administration or use of an EUA product, section 564 does provide EUA conditions to ensure that recipients are informed about the MCM they receive under an EUA. For an unapproved product (section 564(e)(1)(A)(ii)) and for an unapproved use of an approved product (section 564(e)(2)(A)), the statute requires that FDA ensure that recipients are informed to the extent practicable given the applicable circumstances:

- That FDA has authorized emergency use of the product;
- Of the significant known and potential benefits and risks associated with the emergency use of the product, and of the extent to which such benefits and risks are unknown;
- That they have the option to accept or refuse the EUA product and of any consequences of refusing administration of the product;[46] and
- Of any available alternatives to the product and of the risks and benefits of available

COVID Mandates

- Not lawful
- Not beneficial
- Violates international treaties, Federal and Sate law, criminal laws, research policies
- Exemptions
  - Asking for permission
  - Agree to mandate
- Do NOT use attorneys
- Boycotts – can be powerful, need widespread participation
- Lawful remedies

SOLUTIONS IN LAW:

STAND UP TO COVID TYRANNY!

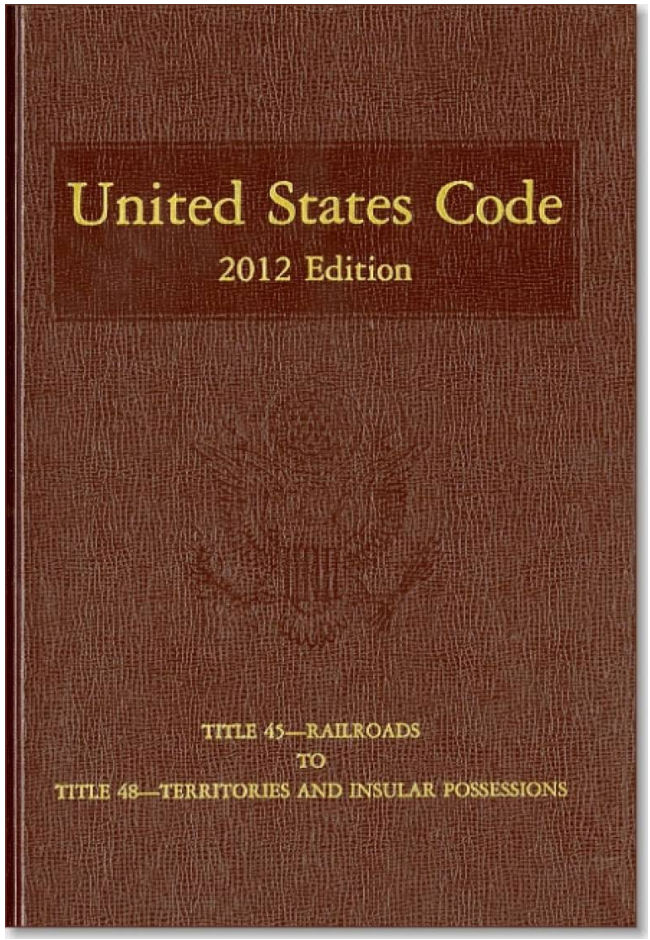
...with Alphonse Faggiolo

MEDICAMENTUM
AUTHENTICA


DO WHAT IS
RIGHT,
NOT WHAT IS
EASY

ALPHONSE'S PROCESS

1. Attempt to work, receive service, enter store, etc. and be denied service or fired.
2. Send affidavit requesting relief. Include facts and relevant law (Constitution, Federal, State, local).
3. If no response…File professional complaints, grievances, and criminal charges (State and Federal)
4. If no response…File pro se Federal lawsuit Title 42, §1983



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LII > U.S. Code > Title 42 > CHAPTER 21 > SUBCHAPTER I > **§ 1983**

42 U.S. Code § 1983 - Civil action for deprivation of rights

U.S. Code | Notes | State Regulations

prev | next

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia.

(R.S. § 1979; Pub. L. 96–170, § 1, Dec. 29, 1979, 93 Stat. 1284; Pub. L. 104–317, title III, § 309(c), Oct. 19, 1996, 110 Stat. 3853.)

- "We the people…secure the Blessings of Liberty to ourselves and our Posterity…"
- 1st Amendment – "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."
- 14th Amendment – "nor shall any State deprive any person of life, liberty, or property, without due process of the law; nor deny to any person within its jurisdiction the equal protection of the laws."

What is a Place of Public Accommodation?

USC 42 §12181

(7)PUBLIC ACCOMMODATION The following private entities are considered public accommodations for purposes of this subchapter, if the operations of such entities affect commerce—

(A)an inn, hotel, motel, or other place of lodging, except for an establishment located within a building that contains not more than five rooms for rent or hire and that is actually occupied by the proprietor of such establishment as the residence of such proprietor;

(B)a restaurant, bar, or other establishment serving food or drink;

(C)a motion picture house, theater, concert hall, stadium, or other place of exhibition or entertainment;

(D)an auditorium, convention center, lecture hall, or other place of public gathering;

(E)a bakery, grocery store, clothing store, hardware store, shopping center, or other sales or rental establishment;

(F)a laundromat, dry-cleaner, bank, barber shop, beauty shop, travel service, shoe repair service, funeral parlor, gas station, office of an accountant or lawyer, pharmacy, insurance office, professional office of a health care provider, hospital, or other service establishment;

(G)a terminal, depot, or other station used for specified public transportation;

(H)a museum, library, gallery, or other place of public display or collection;

(I)a park, zoo, amusement park, or other place of recreation;

(J)a nursery, elementary, secondary, undergraduate, or postgraduate private school, or other place of education;

(K)a day care center, senior citizen center, homeless shelter, food bank, adoption agency, or other social service center establishment; and

(L)a gymnasium, health spa, bowling alley, golf course, or other place of exercise or recreation.

NYS Human Rights Law §292

9. The term "place of public accommodation, resort or amusement" shall include, regardless of whether the owner or operator of such place is a state or local government entity or a private individual or entity, except as hereinafter specified, all places included in the meaning of such terms as: inns, taverns, road houses, hotels, motels, whether conducted for the entertainment of transient guests or for the accommodation of those seeking health, recreation or rest, or restaurants, or eating houses, or any place where food is sold for consumption on the premises; buffets, saloons, barrooms, or any store, park or enclosure where spirituous or malt liquors are sold; ice cream parlors, confectionaries, soda fountains, and all stores where ice cream, ice and fruit preparations or their derivatives, or where beverages of any kind are retailed for consumption on the premises; wholesale and retail stores and establishments dealing with goods or services of any kind, dispensaries, clinics, hospitals, bath-houses, swimming pools, laundries and all other cleaning establishments, barber shops, beauty parlors, theatres, motion picture houses, airdromes, roof gardens, music halls, race courses, skating rinks, amusement and recreation parks, trailer camps, resort camps, fairs, bowling alleys, golf courses, gymnasiums, shooting galleries, billiard and pool parlors; garages, all public conveyances operated on land or water or in the air, as well as the stations and terminals thereof; travel or tour advisory services, agencies or bureaus; public halls, public rooms, public elevators, and any public areas of any building or structure. Such term shall not include kindergartens, primary and secondary schools, high schools, academies, colleges and universities, extension courses, and all educational institutions under the supervision of the regents of the state of New York; any such kindergarten, primary and secondary school, academy, college, university, professional school, extension course or other education facility, supported in whole or in part by public funds or by contributions solicited from the general public; or any institution, club or place of accommodation which proves that it is in its nature distinctly private. In no event shall an institution, club or place of accommodation be considered in its nature distinctly private if it has more than one hundred members, provides regular meal service and regularly receives payment for dues, fees, use of space, facilities, services, meals or beverages directly or indirectly from or on behalf of a nonmember for the furtherance of trade or business. An institution, club, or place of accommodation which is not deemed distinctly private pursuant to this subdivision may nevertheless apply such selective criteria as it chooses in the use of its facilities, in evaluating applicants for membership and in the conduct of its activities, so long as such selective criteria do not constitute discriminatory practices under this article or any other provision of law. For the purposes of this section, a corporation incorporated under the benevolent orders law or described in the benevolent orders law but formed under any other law of this state or a religious corporation incorporated under the education law or the religious corporations law shall be deemed to be in its nature distinctly private.

Definition of Disability
USC Title 42 §12102

(1) Disability
The term "disability" means, with respect to an individual

(A) a physical or mental impairment that substantially limits one or more major life activities of such individual;
(B) a record of such an impairment; or
(C) being regarded as having such an impairment (as described in paragraph (3)).

(2) Major Life Activities

(A) In general
For purposes of paragraph (1), major life activities include, but are not limited to, caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working.
(B) Major bodily functions
For purposes of paragraph (1), a major life activity also includes the operation of a major bodily function, including but not limited to, functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.

(3) Regarded as having such an impairment
For purposes of paragraph (1)(C):
(A) An individual meets the requirement of "being regarded as having such an impairment" if the individual establishes that he or she has been subjected to an action prohibited under this chapter because of an actual or perceived physical or mental impairment whether or not the impairment limits or is perceived to limit a major life activity.
(B) Paragraph (1)(C) shall not apply to impairments that are transitory and minor. A transitory impairment is an impairment with an actual or expected duration of 6 months or less.

§12182. Prohibition of discrimination by public accommodations

(a) General rule

No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.

(b) Construction

(1) General prohibition

(A) Activities

(i) Denial of participation

It shall be discriminatory to subject an individual or class of individuals on the basis of a disability or disabilities of such individual or class, directly, or through contractual, licensing, or other arrangements, to a denial of the opportunity of the individual or class to participate in or benefit from the goods, services, facilities, privileges, advantages, or accommodations of an entity.

§12182. Prohibition of discrimination by public accommodations

(a) General rule

No individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.

(b) Construction

(2) Specific prohibitions

(A) Discrimination

For purposes of subsection (a) of this section, discrimination includes

(i) the imposition or application of eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any goods, services, facilities, privileges, advantages, or accommodations, unless such criteria can be shown to be necessary for the provision of the goods, services, facilities, privileges, advantages, or accommodations being offered;

§12182. Prohibition of discrimination by public accommodations

For purposes of subsection (a) of this section, discrimination includes

(ii) a failure to make reasonable modifications in policies, practices, or procedures, when such modifications are necessary to afford such goods, services, facilities, privileges, advantages, or accommodations to individuals with disabilities, unless the entity can demonstrate that making such modifications would fundamentally alter the nature of such goods, services, facilities, privileges, advantages, or accommodations;

Article 5 – Autonomy and individual responsibility

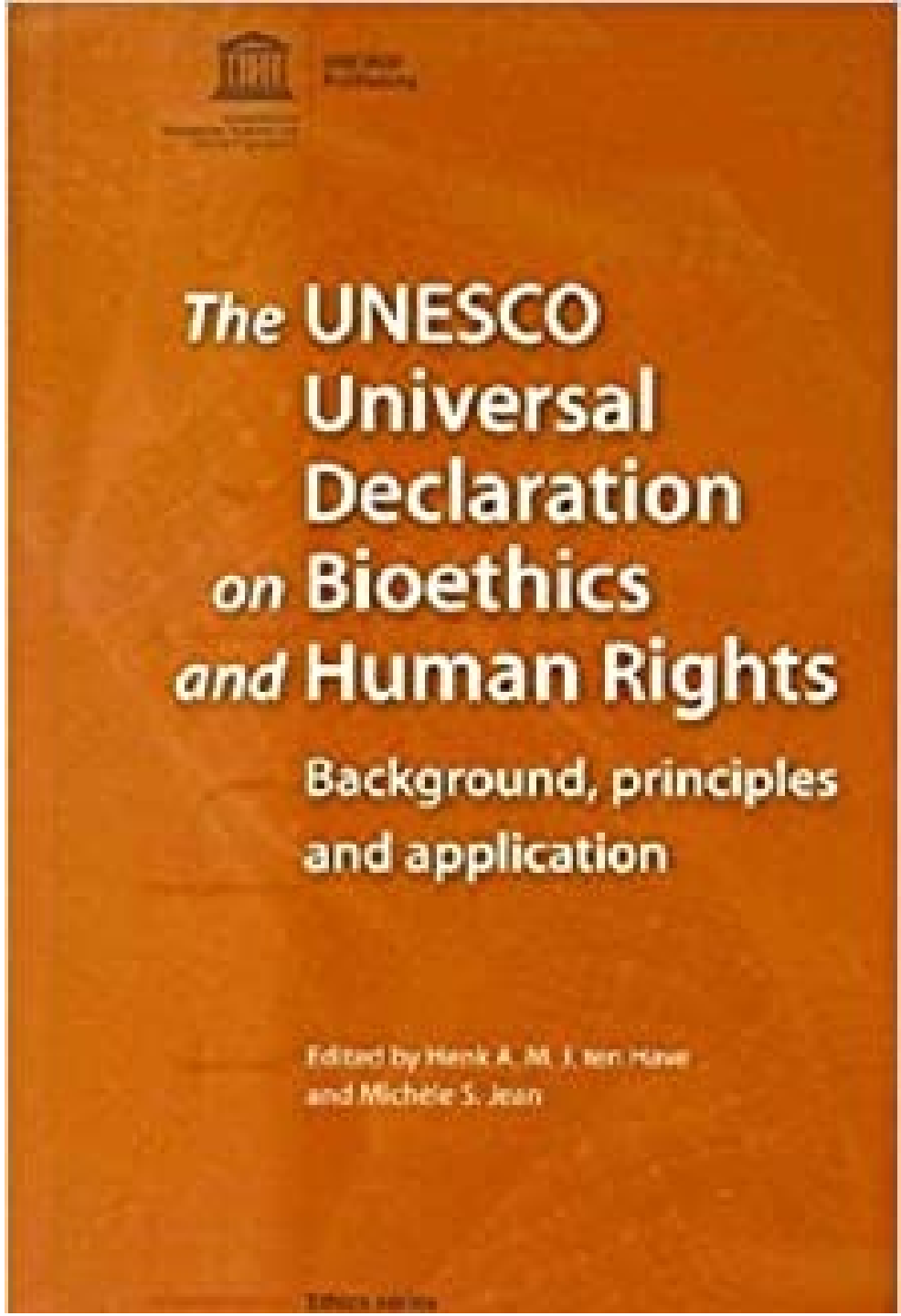
The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.



- § 135.60 Coercion in the third degree.

A person is guilty of coercion in the third degree when he or she compels or induces a person to engage in conduct which the latter has a legal right to abstain from engaging in, or to abstain from engaging in conduct in which he or she has a legal right to engage, or compels or induces a person to join a group, organization or criminal enterprise which such latter person has a right to abstain from joining, by means of instilling in him or her a fear that, if the demand is not complied with, the actor or another will:

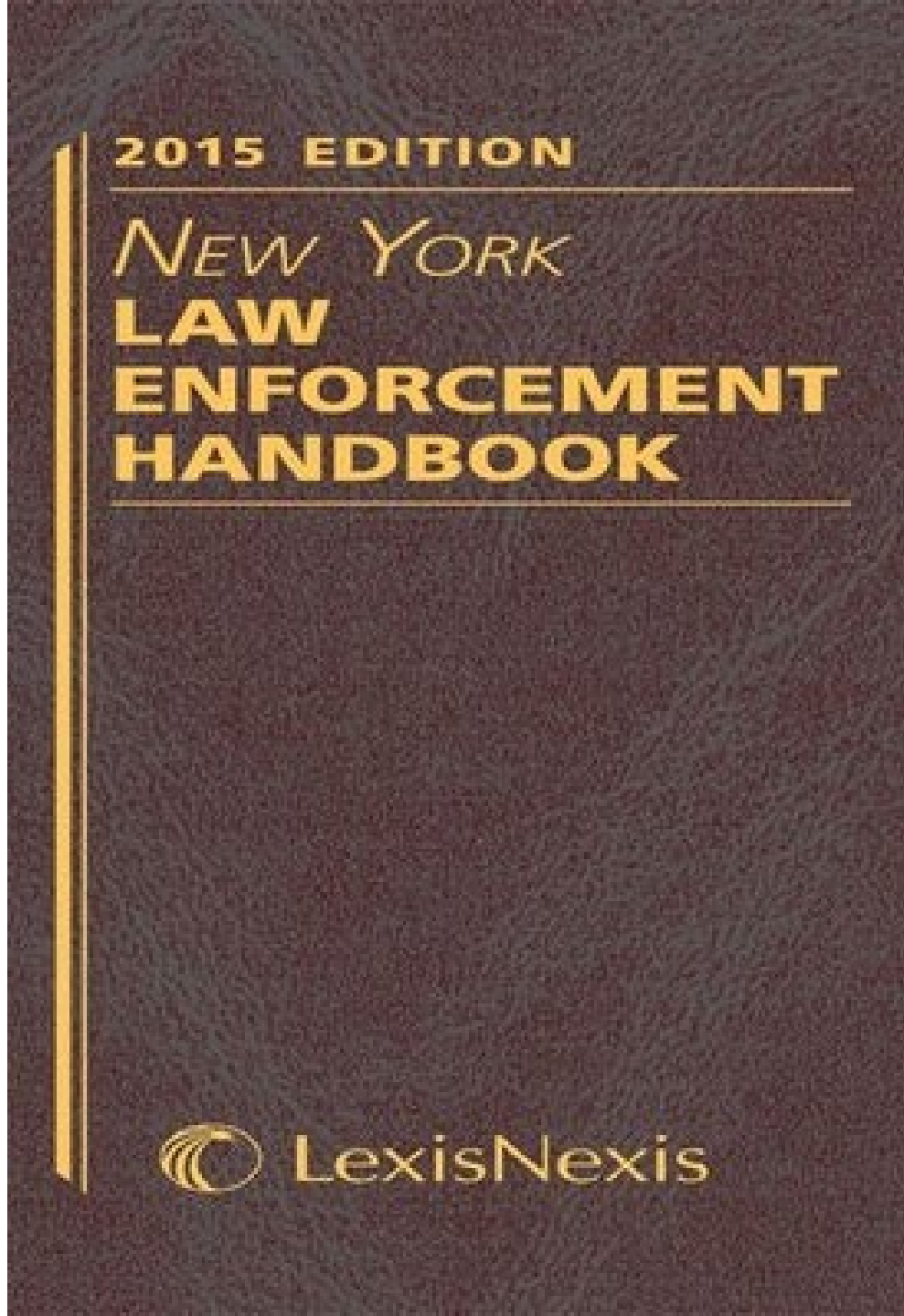
1. Cause physical injury to a person; or

4. Accuse some person of a crime or cause criminal charges to be instituted against him or her; or

5. Expose a secret or publicize an asserted fact, whether true or false, tending to subject some person to hatred, contempt or ridicule

9. Perform any other act which would not in itself materially benefit the actor but which is calculated to harm another person materially with respect to his or her health, safety, business, calling, career, financial condition, reputation or personal relationships.

Coercion in the third degree is a class A misdemeanor.



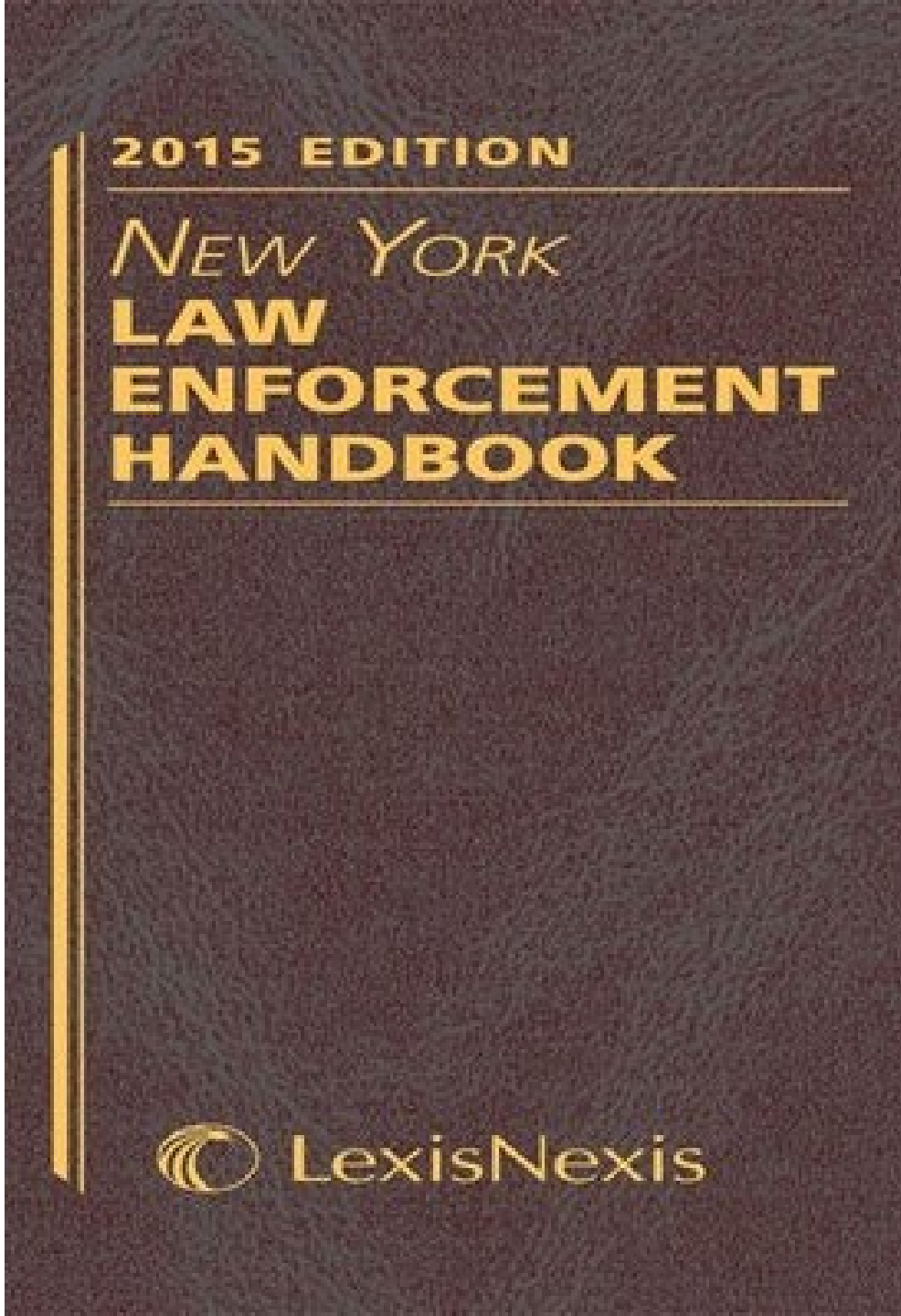
§ 121.11 Criminal obstruction of breathing or blood circulation.

A person is guilty of criminal obstruction of breathing or blood circulation when, with intent to impede the normal breathing or circulation of the blood of another person, he or she:

a. applies pressure on the throat or neck of such person; or

b. blocks the nose or mouth of such person.

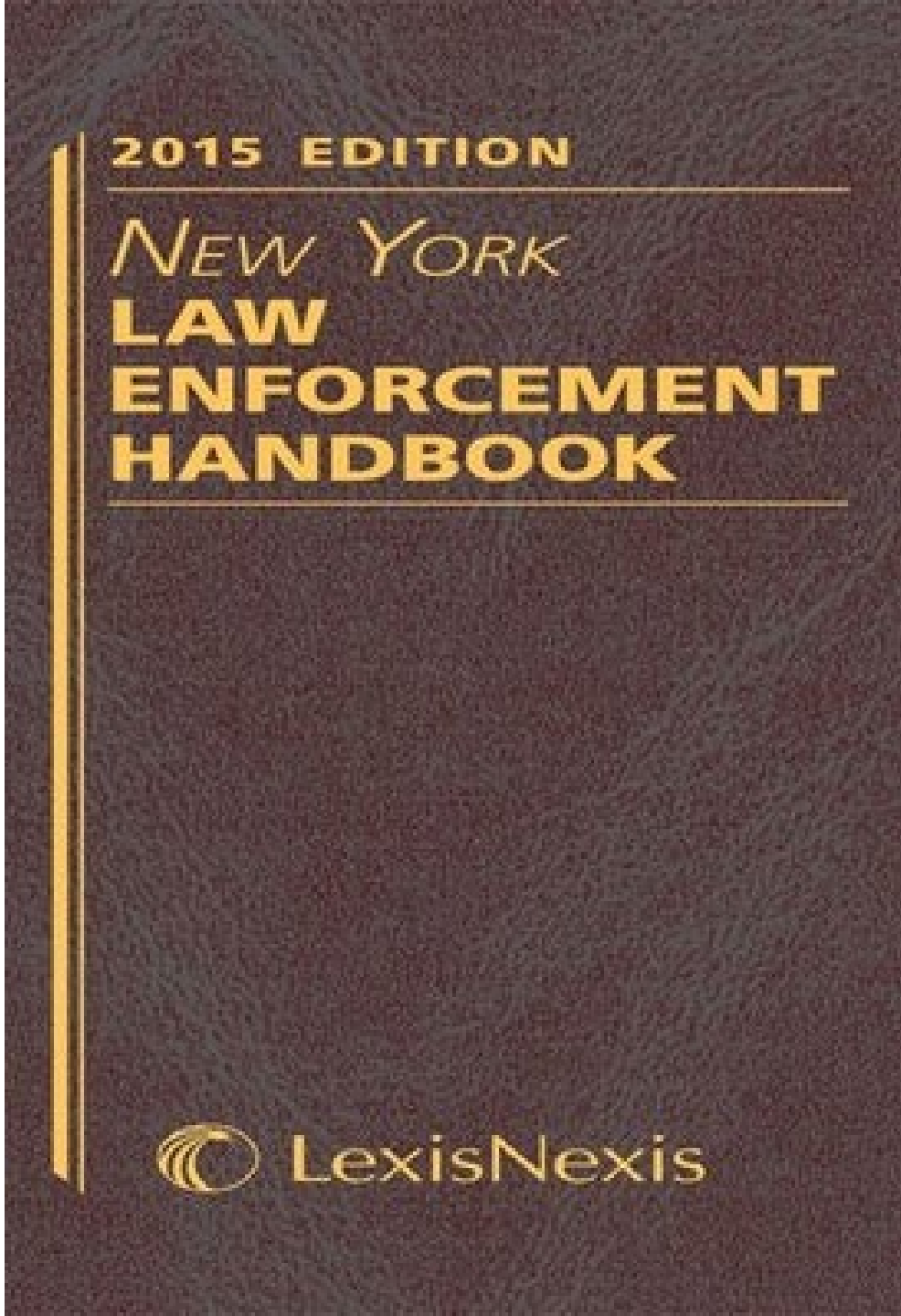
Criminal obstruction of breathing or blood circulation is a class A misdemeanor.



§ 6512. Unauthorized practice a crime.

1. Anyone not authorized to practice under this title who practices or offers to practice or holds himself out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who practices any profession as an exempt person during the time when his professional license is suspended, revoked or annulled, or who aids or abets an unlicensed person to practice a profession, or who fraudulently sells, files, furnishes, obtains, or who attempts fraudulently to sell, file, furnish or obtain any diploma, license, record or permit purporting to authorize the practice of a profession, shall be guilty of a class E felony.

2. Anyone who knowingly aids or abets three or more unlicensed persons to practice a profession or employs or holds such unlicensed persons out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who knowingly aids or abets three or more persons to practice any profession as exempt persons during the time when the professional licenses of such persons are suspended, revoked or annulled, shall be guilty of a class E felony.



18 U.S.C. § 242 - DEPRIVATION OF RIGHTS UNDER COLOR OF LAW

Whoever, under color of any law, statute, ordinance, regulation, or custom, willfully subjects any person in any State, Territory, Commonwealth, Possession, or District to the deprivation of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States, or to different punishments, pains, or penalties, on account of such person being an alien, or by reason of his color, or race, than are prescribed for the punishment of citizens, shall be fined under this title or imprisoned not more than one year, or both; and if bodily injury results from the acts committed in violation of this section or if such acts include the use, attempted use, or threatened use of a dangerous weapon, explosives, or fire, shall be fined under this title or imprisoned not more than ten years, or both; and if death results from the acts committed in violation of this section or if such acts include kidnapping or an attempt to kidnap, aggravated sexual abuse, or an attempt to commit aggravated sexual abuse, or an attempt to kill, shall be fined under this title, or imprisoned for any term of years or for life, or both, or may be sentenced to death.


START

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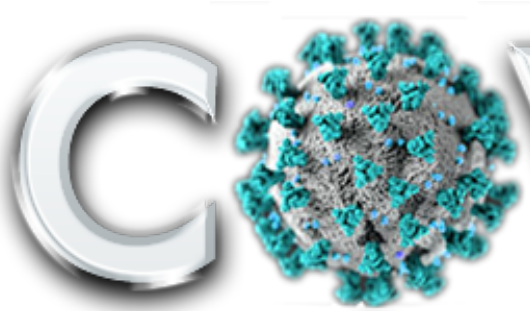
IVERMECTIN: The True Story

Andrew Kaufman, MD

September 18, 2021



COVID-19 MYTHS

PART 3

IVERMECTIN

- Is it safe?
- Is it effective?
- Exactly what is it effective for?
- What is atypical pneumonia?
- What are natural ways to support healing of atypical pneumonia?

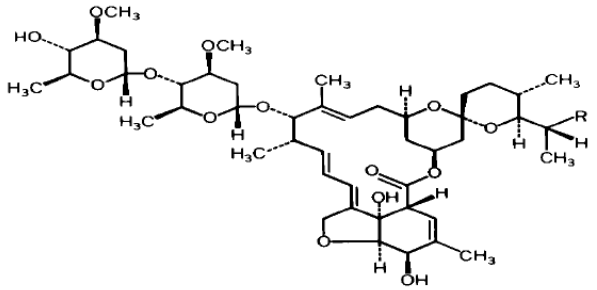
TABLETS

STROMECTOL®

(IVERMECTIN)

DESCRIPTION

STROMECTOL* (Ivermectin) is a semisynthetic, anthelmintic agent for oral administration. Ivermectin is derived from the avermectins, a class of highly active broad-spectrum, anti-parasitic agents isolated from the fermentation products of *Streptomyces avermitilis.* Ivermectin is a mixture containing at least 90% 5-*O*-demethyl-22,23-dihydroavermectin A_{1a} and less than 10% 5-*O*-demethyl-25-de(1-methylpropyl)-22,23-dihydro-25-(1-methylethyl)avermectin A_{1a}, generally referred to as 22,23-dihydroavermectin B_{1a} and B_{1b}, or H_2B_{1a} and H_2B_{1b}, respectively. The respective empirical formulas are $C_{48}H_{74}O_{14}$ and $C_{47}H_{72}O_{14}$, with molecular weights of 875.10 and 861.07, respectively. The structural formulas are:



Component B_{1a}, R = C_2H_5 Component B_{1b}, R = CH_3

Ivermectin is a white to yellowish-white, nonhygroscopic, crystalline powder with a melting point of about 155°C. It is insoluble in water but is freely soluble in methanol and soluble in 95% ethanol

Am. J. Trop. Med. Hyg., 98(2), 2018, pp. 382–388
doi:10.4269/ajtmh.17-0042

Serious Neurological Adverse Events after Ivermectin—Do They Occur beyond the Indication of Onchocerciasis?

Rebecca E. Chandler*
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Abstract. Serious neurological adverse events have been reported from large scale community-based ivermectin treatment campaigns against *Onchocerciasis volvulus* in Africa. The mechanism of these events has been debated in the literature, largely focusing on the role of concomitant infection with *Loa loa* versus the presence of mdr-1 gene variants in humans allowing ivermectin penetration into the central nervous system. A case series of serious neurological adverse events occurring with the use of ivermectin outside of the onchocerciasis indication has been identified in VigiBase, an international database of suspected adverse drug reactions. Forty-eight cases have been reported from multiple countries in which ivermectin has been prescribed for multiple indications; clinical review excluded 20 cases with more probable explanations or other exclusion criteria. Within the remaining 28 cases, there is supportive evidence for a causative role of ivermectin including presence of the drug in brain tissue in one case and recurrence of symptoms on repeated exposure in three cases. This series suggests that serious neurological adverse events observed with the use of ivermectin in the treatment of onchocerciasis may not be entirely explained by concomitant high burden loiasis infections. By comparison with the extensive post marketing experience with ivermectin in the successful treatment of parasitic infections, the number of reported cases suggests that such events are likely rare. However, elucidation of individual-level risk factors could contribute to therapeutic decisions that can minimize harms. Further investigation into the potential for drug–drug interactions and explorations of polymorphisms in the mdr-1 gene are recommended.

Ivermectin, 'Wonder drug' from Japan: the human use perspective

By Andy CRUMP[*1] and Satoshi ŌMURA[*1,†]

(Contributed by Satoshi ŌMURA, M.J.A.)

Abstract: Discovered in the late-1970s, the pioneering drug ivermectin, a dihydro derivative of avermectin—originating solely from a single microorganism isolated at the Kitasato Intitute, Tokyo, Japan from Japanese soil—has had an immeasurably beneficial impact in improving the lives and welfare of billions of people throughout the world. Originally introduced as a veterinary drug, it kills a wide range of internal and external parasites in commercial livestock and companion animals. It was quickly discovered to be ideal in combating two of the world's most devastating and disfiguring diseases which have plagued the world's poor throughout the tropics for centuries. It is now being used free-of-charge as the sole tool in campaigns to eliminate both diseases globally. It has also been used to successfully overcome several other human diseases and new uses for it are continually being found. This paper looks in depth at the events surrounding ivermectin's passage from being a huge success in Animal Health into its widespread use in humans, a development which has led many to describe it as a "wonder" drug.

Keywords: avermectin, ivermectin, mode of action, onchocerciasis, lymphatic filariasis, drug

American Journal of Therapeutics 28, e299–e318 (2021)

OPEN

Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19

Pierre Kory, MD,[1]* Gianfranco Umberto Meduri, MD,[2] Joseph Varon, MD,[3] Jose Iglesias, DO,[4] and Paul E. Marik, MD[5]

Background: After COVID-19 emerged on U.S shores, providers began reviewing the emerging basic science, translational, and clinical data to identify potentially effective treatment options. In addition, a multitude of both novel and repurposed therapeutic agents were used empirically and studied within clinical trials.

Areas of Uncertainty: The majority of trialed agents have failed to provide reproducible, definitive proof of efficacy in reducing the mortality of COVID-19 with the exception of corticosteroids in moderate to severe disease. Recently, evidence has emerged that the oral antiparasitic agent ivermectin exhibits numerous antiviral and anti-inflammatory mechanisms with trial results reporting significant outcome benefits. Given some have not passed peer review, several expert groups including Unitaid/World Health Organization have undertaken a systematic global effort to contact all active trial investigators to rapidly gather the data needed to grade and perform meta-analyses.

Data Sources: Data were sourced from published peer-reviewed studies, manuscripts posted to preprint servers, expert meta-analyses, and numerous epidemiological analyses of regions with ivermectin distribution campaigns.

Therapeutic Advances: A large majority of randomized and observational controlled trials of ivermectin are reporting repeated, large magnitude improvements in clinical outcomes. Numerous prophylaxis trials demonstrate that regular ivermectin use leads to large reductions in transmission. Multiple, large "natural experiments" occurred in regions that initiated "ivermectin distribution" campaigns followed by tight, reproducible, temporally associated decreases in case counts and case fatality rates compared with nearby regions without such campaigns.

Conclusions: Meta-analyses based on 18 randomized controlled treatment trials of ivermectin in COVID-19 have found large, statistically significant reductions in mortality, time to clinical recovery, and time to viral clearance. Furthermore, results from numerous controlled prophylaxis trials report significantly

Clinical Infectious Diseases

MAJOR ARTICLE

Ivermectin for the Treatment of Coronavirus Disease 2019: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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Background. We systematically assessed benefits and harms of the use of ivermectin (IVM) in patients with coronavirus disease 2019 (COVID-19).

Methods. Published and preprint randomized controlled trials (RCTs) assessing the effects of IVM on adult patients with COVID-19 were searched until 22 March 2021 in 5 engines. Primary outcomes were all-cause mortality rate, length of hospital stay (LOS), and adverse events (AEs). Secondary outcomes included viral clearance and severe AEs (SAEs). The risk of bias (RoB) was evaluated using the Cochrane Risk of Bias 2.0 tool. Inverse variance random effect meta-analyses were performed, with quality of evidence (QoE) evaluated using GRADE methods.

Results. Ten RCTs (n = 1173) were included. The controls were the standard of care in 5 RCTs and placebo in 5. COVID-19 disease severity was mild in 8 RCTs, moderate in 1, and mild and moderate in 1. IVM did not reduce all-cause mortality rates compared with controls (relative risk [RR], 0.37 [95% confidence interval, .12–1.13]; very low QoE) or LOS compared with controls (mean difference, 0.72 days [95% confidence interval, −.86 to 2.29 days]; very low QoE). AEs, SAEs, and viral clearance were similar between IVM and control groups (low QoE for all outcomes). Subgroups by severity of COVID-19 or RoB were mostly consistent with main analyses; all-cause mortality rates in 3 RCTs at high RoB were reduced with IVM.

Conclusions. Compared with the standard of care or placebo, IVM did not reduce all-cause mortality, LOS, or viral clearance in RCTs in patients with mostly mild COVID-19. IVM did not have an effect on AEs or SAEs and is not a viable option to treat patients with COVID-19.

Keywords. ivermectin; SARS-CoV-2; COVID-19; mortality; meta-analysis.

American Journal of Therapeutics 28, e434–e460 (2021)

OPEN

Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines

Andrew Bryant, MSc,[1]* Theresa A. Lawrie, MBBCh, PhD,[2]
Therese Dowswell, PhD,[2] Edmund J. Fordham, PhD,[2]
Scott Mitchell, MBChB, MRCS,[3] Sarah R. Hill, PhD,[1] and
Tony C. Tham, MD, FRCP[4]

Background: Repurposed medicines may have a role against the SARS-CoV-2 virus. The antiparasitic ivermectin, with antiviral and anti-inflammatory properties, has now been tested in numerous clinical trials.

Areas of uncertainty: We assessed the efficacy of ivermectin treatment in reducing mortality, in secondary outcomes, and in chemoprophylaxis, among people with, or at high risk of, COVID-19 infection.

Data sources: We searched bibliographic databases up to April 25, 2021. Two review authors sifted for studies, extracted data, and assessed risk of bias. Meta-analyses were conducted and certainty of the evidence was assessed using the GRADE approach and additionally in trial sequential analyses for mortality. Twenty-four randomized controlled trials involving 3406 participants met review inclusion.

Therapeutic Advances: Meta-analysis of 15 trials found that ivermectin reduced risk of death compared with no ivermectin (average risk ratio 0.38, 95% confidence interval 0.19–0.73; n = 2438; I^2 = 49%; moderate-certainty evidence). This result was confirmed in a trial sequential analysis using the same DerSimonian–Laird method that underpinned the unadjusted analysis. This was also robust against a trial sequential analysis using the Biggerstaff–Tweedie method. Low-certainty evidence found that ivermectin prophylaxis reduced COVID-19 infection by an average 86% (95% confidence interval 79%–91%). Secondary outcomes provided less certain evidence. Low-certainty evidence suggested that there may be no benefit with ivermectin for "need for mechanical ventilation,"

Main authors on the review, Maria Popp and Stephanie Weibel said: “The lack of good quality evidence on efficacy and safety of ivermectin arises from a study pool that consists mainly of small, insufficiently powered RCTs with overall limited quality regarding study design, conduct and reporting. Current evidence does not support using ivermectin for treating or preventing of COVID-19 unless they are part of well-designed randomized trials.”

Cochrane Infectious Diseases

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New Cochrane Review: Ivermectin for preventing and treating COVID-19

Ivermectin, a drug used to treat parasites such as scabies in humans and intestinal helminths in cattle, was screened in 2020 for activity against COVID-19. Laboratory tests suggested a weak effect on SARS-CoV-2 virus in a test tube but did not seem feasible in humans as the doses needed would be large. However, small early trials suggested large effects on mortality, and this has led to some advocacy groups lobbying for its widespread introduction worldwide.

Researchers from the **CEOsys project** collaborated with the LSTM-based Cochrane Infectious Disease Group (**CIDG**) to carry out a systematic review, **published today on the Cochrane Library**, to explore the effects of ivermectin in preventing and treating COVID-19 infection.

The review authors included 14 randomized controlled trials with 1678 participants. Treatment of mild to moderate COVID-19 patients was investigated in 13 studies comparing ivermectin with placebo or with no treatment in addition to comparable usual care in the study arms. Only one study investigated prevention of SARS-CoV-2 infection and compared ivermectin to no treatment. The review looked at the effects of ivermectin on the number of deaths, whether the patient’s condition worsened or improved, and unwanted effects.

The Cochrane review cannot confirm whether ivermectin (administered in hospital or as an outpatient) compared with placebo or usual care, leads to more or fewer deaths after one month, whether it improves or worsens patients’ condition, increases or decreases unwanted side effects, nor whether it increases or reduces negative COVID-19 tests 7 days after treatment. Likewise, the review cannot confirm whether or not ivermectin prevents SARS-CoV-2 infection or reduces number of deaths after high-risk exposure.

Main authors on the review, Maria Popp and Stephanie Weibel said: “The lack of good quality evidence on efficacy and safety of ivermectin arises from a study pool that consists mainly of small, insufficiently powered RCTs with overall limited quality regarding study design, conduct and

Chapter 11
Parasitic Diseases of the Lung

Danai Khemasuwan, Carol Farver and Atul C. Mehta

Introduction

Parasitic infection can be categorized into helminthic and protozoal infections. Although, there is a decreasing trend of parasitic infection worldwide due to improved socioeconomic conditions and better hygiene practices, the urbanization of the cities around the world, global climate changes, international traveling, and increasing numbers of immunocompromised individuals have expanded the population who is vulnerable to parasitic diseases [1]. The diagnosis of parasitic diseases of the respiratory system is relatively difficult because clinical manifestations and radiologic findings are non-specific. Therefore, high index of suspicion, travel history, and a detailed interrogation of personal hygiene are crucial for diagnosis of parasitic lung diseases. The helminthes can affect respiratory system in different phases of their life cycle. In this chapter, we discuss the clinical manifestations, radiographic, bronchoscopic and pathologic findings, and management of several helminthic and protozoal lung diseases. The term "pneumatodes" has been used to represent the group of parasites that affect airways and lungs. Some of the unique presentations of each parasite are also addressed which may be helpful to pulmonologist in managing these uncommon diseases (Tables 11.1 and 11.2).

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A.C. Mehta et al. (eds.), *Diseases of the Central Airways*,
Respiratory Medicine, DOI 10.1007/978-3-319-29830-6_11

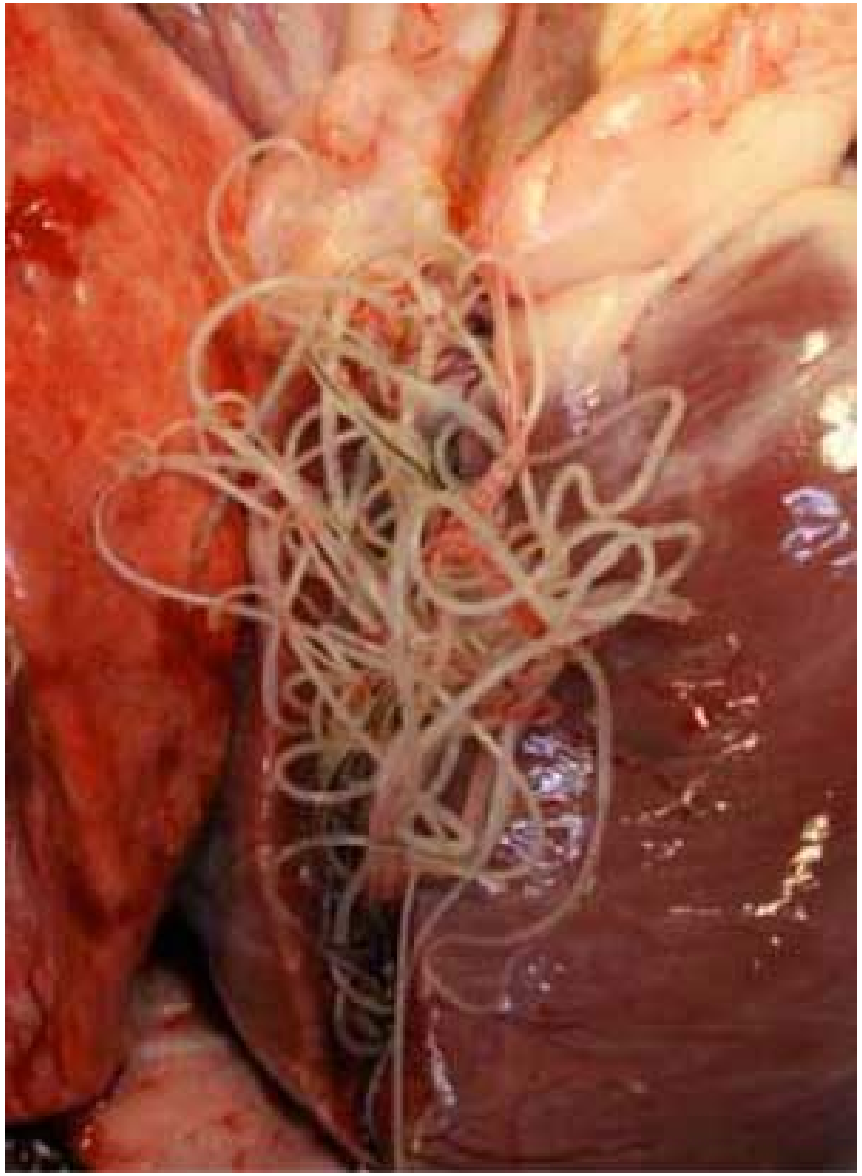

Table 11.2

Main features of parasitic diseases of lung

Parasite	Infective form	Endemic area	Mode of transmission	Pulmonary presentation	Bronchoscopic evaluation	Treatment
Nematodes						
Ascariasis (*Ascaris lumbricoides*)	Eggs and larva	Asia, Africa, and South America	Ingestion	Eosinophilic pneumonia, cough, wheezing, dyspnea	Presence of parasite in the airways	Mebendazole and albendazole
Hookworm (*Ancyclostoma duodenale*) (*Necator americanus*)	Larva	Tropical and subtropical areas	Skin penetration	Eosinophilic pneumonia, cough, wheezing, dyspnea, alveolar hemorrhage	Presence of hookworm in sputum, a marked eosinophil predominance from BAL	Mebendazole and albendazole
Strongyloidiasis (*Strongyloides stercoralis*)	Filariform larvae	Tropical and subtropical areas	Skin penetration	Eosinophilic pneumonia, cough, wheezing, dyspnea, hyperinfection syndrome	Bloody bronchoalveolar lavage (BAL) and presence of parasite from BAL under microscopic examination	Ivermectin and albendazole
Syngamosis	Eggs or adult worms	Asia, Africa, and South America	Ingestion	Foreign body-like lesion in bronchus nocturnal cough	Presence of parasite in the airways	Removal via bronchoscopy

Table 11.2

Main features of parasitic diseases of lung

larynges)						
Dirofilariasis (*Dirofilaria immitis*)	Larva	Tropical and subtropical areas	Mosquito-borne infection	Cough, chest pain, fever, dyspnea, mild eosinophilia, and lung nodules	Surgical lung biopsy	None (self-limited)
Tropical pulmonary eosinophilia (*Brugia malayi*) (*Wuchereria bancrofti*)	Larva	Tropical and subtropical areas (South and Southeast Asia)	Mosquito-borne infection	Eosinophilic pneumonia, cough, wheezing, dyspnea, restrictive pattern on spirometry, decreased diffusion lung capacity	BAL shows eosinophils more than 50 % of the total cells	Diethylcarbamazine (DEC)
Visceral larva migrans (*Toxocara canis*) (*Toxocara catis*)	Larva	Worldwide	Ingestion	Eosinophilic pneumonia, episodic wheezing	N/A	Diethylcarbamazine (DEC)
Trichinella infection (*Trichinella spiralis*)	Larva	Worldwide	Ingestion	Cough, pulmonary infiltrates, dyspnea is due to respiratory muscles involvement	N/A	Mebendazole
Trematodes						
Schistosomiasis (*Schistosoma* spp)	Cercarial larvae	East Asia, South America, sub-Saharan Africa	Skin penetration	Pulmonary hypertension, and Katayama fever	An eosinophil predominance from BAL in the absence of parasites	Praziquantel
Paragonimiasis	Metacercaria	Southeast Asia,	Ingestion of	Fever, cough, hemoptysis,	Bronchial stenosis due to	Praziquantel and

Table 11.2

Main features of parasitic diseases of lung

(*Toxocara catis*)						
Trichinella infection (*Trichinella spiralis*)	Larva	Worldwide	Ingestion	Cough, pulmonary infiltrates, dyspnea is due to respiratory muscles involvement	N/A	Mebendazole
Trematodes						
Schistosomiasis (*Schistosoma* spp)	Cercarial larvae	East Asia, South America, sub-Saharan Africa	Skin penetration	Pulmonary hypertension, and Katayama fever	An eosinophil predominance from BAL in the absence of parasites	Praziquantel
Paragonimiasis (*Paragonimus* spp)	Metacercaria (infective larvae)	Southeast Asia, South America, Africa	Ingestion of infested crustaceans	Fever, cough, hemoptysis, chest pain, and pleural effusion	Bronchial stenosis due to mucosal edema and mucosal nodularity	Praziquantel and triclabendazole
Cestodes						
Hydatid disease (*Echinococcus granulosus*)	Eggs	Worldwide (esp. Middle East)	Ingestion	Chest pain, cough, hemoptysis, pleural lesion, expectoration of cyst contents, and hypersensitivity reaction	Bronchoscopic examination reveals sac-like cyst in the airway	Surgical removal of cysts, followed by mebendazole and albendazole
Mesomycetozoea						
Rhinosporidiosis (*Rhinosporidium seeberi*)	Spores	South Asia	Ingestion of contaminated water	Strawberry-like, nasopharyngeal polyps, epistaxis, nasal congestion	Bronchoscopy revealed pinkish mulberry-like rhinosporidiosis mass in the airway	Therapeutic bronchoscopy and dapsone

HOW MUCH HUMAN HELMINTHIASIS IS THERE IN THE WORLD?

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The impact of Norman Stoll's presidential address to the American Society of Parasitologists in Boston at Christmas time in 1946 has been and continues to be immense. Since its publication in 1947, have any helminthologists not read it? Have any parasitology text books not cited it since then? Does any parasitology course today not refer students to it? Despite our expanding knowledge of DNA, molecular biology, and immunology and the application of mathematical techniques to our understanding of epidemiology and helminth population biology, Stoll's appraisal of the wormy world still excites and challenges our imaginations.

A measure of the influence of Stoll's paper is the fact that we regularly use the title of "This Wormy World" as we seek to draw attention to the global public health significance of human helminth infections. CRC Press reprinted the paper (renamed as "The Wormy World") and supplied a commentary in each of a series of volumes dealing with zoonoses (CRC, 1982). The World Health Organization used the same title for an issue of its official magazine (WHO, 1984) and recently *Parasitology Today* devoted an issue to revisiting the subject of "This Wormy World" in which Bundy (1997a) explained why Stoll's paper has been supremely important in directing our approach to the study and management of human helminth infections and colleagues evaluated the current status of several major helminthiases. Only last year, Bundy and de Silva (1998) again wrote about this wormy world, this time with themes of optimism and encouragement over prospects for control.

In this article, I have sought to place Stoll's evaluation of human helminthiasis in a contemporary setting. I have tried to address some of the questions he asked and to review aspects of current progress in the control of human helminthiasis. Most of all, I hope this paper will be seen as a tribute to Stoll's inspirational leadership and will serve as a reminder of our need to tackle what he saw as an "unremittingly corrosive" burden of disease.

ESTIMATES OF CURRENT NUMBERS OF HUMAN HELMINTH INFECTIONS

Three hundred and forty-two species of helminths have been

minth infections; then as now, it was no easy task to es
the number of multiple infections.

Estimates of likely numbers of human cases of infec
a variety of helminths that may cause serious diseas
sented in Table II. This information has been gleane
eral sources that are cited in the table. Stoll, by cc
all the estimates in his table himself, and he was
the weaknesses in his methodology. Readers of
ticle should still be cautious over accepting th
the numbers in Table II. Most estimates ter
the extrapolation of prevalence surveys to a
In this regard, sample size is crucial; a pre
from a survey involving 100 people is n
of 10% from a survey of 1,000 people
effort has been made to select the subj
to give more reliable results than tho
hospitals where the subjects had r
that they harbored a particular inf
nological problems with data se
infrastructures and lack of resou
may be all that are available
population that did not partic
over the number of cases a
nematodes in the Pacific
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in the world for lymp
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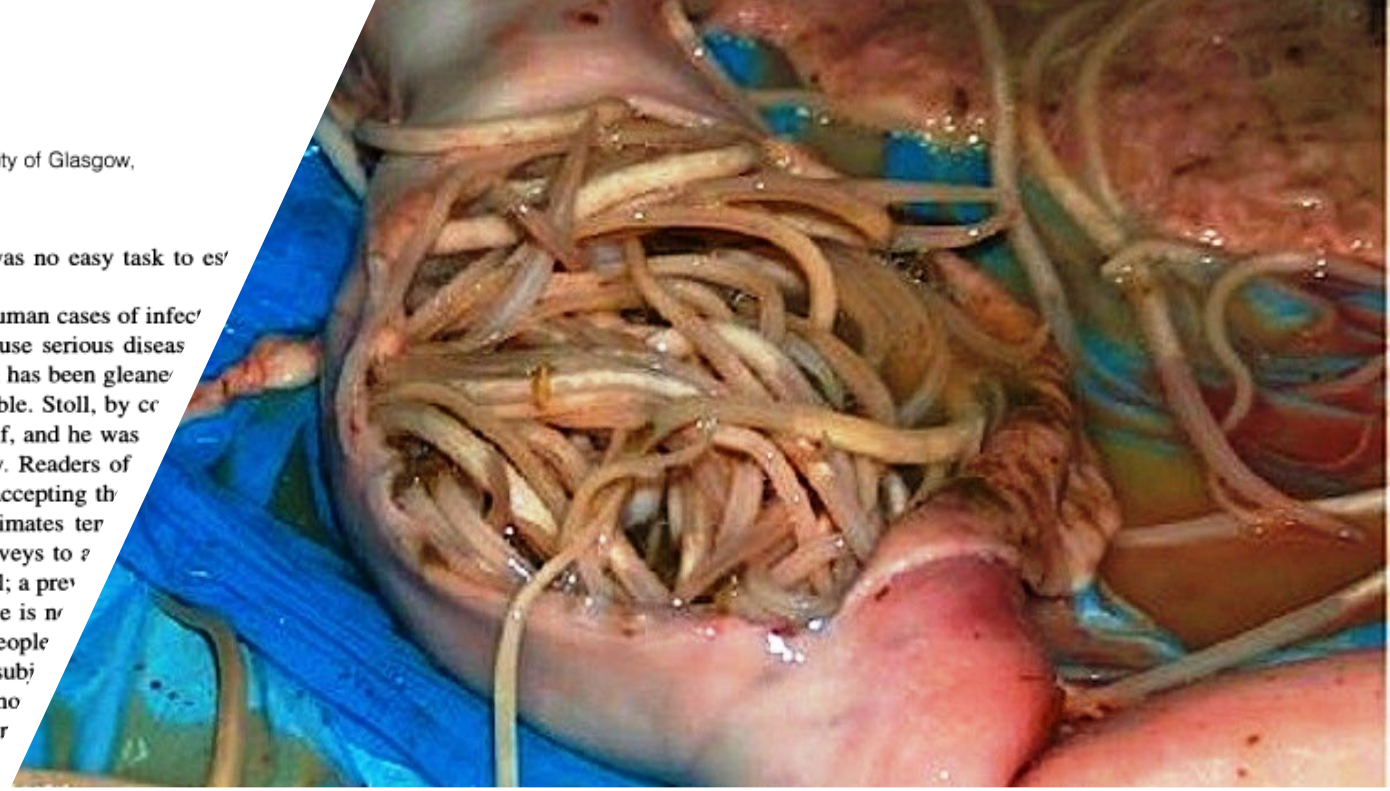

TABLE I. Helminths recorded from human hosts* (Coombs and Crompton, 1991).

	Number
Taxonomic group	
Acanthocephala	7
Nematoda	138
Nematomorpha	24
Platyhelminthes	173
Digenea	113
Eucestoda	57
Turbellaria	3
Number of species	342
Helminth site	
Alimentary tract	197
Cavities, organs and tissues	107
Circulatory system	21
Skin and tissues	56

* The host status of humans is often difficult to determine. The records deal with established human host-helminth relationships and diverse spurious or accidental infections (see Orihel and Ash, 1995).

americanus			
Ascaris lumbricoides	1,472.00	Worldwide; developing countries	Chan et al., 1994 (Crompton, 1988, 1989; Peng et al., 1998)
Brugia malayi and *Brugia timori*	13.00	E. Indonesia islands; Philippines; S.E. Asia; Southern China and India	Michael et al., 1996 (WHO, 1992; Michael and Bundy 1997; Ottesen et al., 1997)
Clonorchis sinensis	7.01	China; Korea; Taiwan; Vietnam	WHO, 1995a (Cross, 1991)
Diphyllobothrium latum	9.00	Worldwide; where certain raw fish is eaten	Sturchler, 1988
Dracunculus medinensis	0.08	Sub-Saharan Africa; Yemen	WHO, 1998b
Echinococcus granulosus and *Echinococcus multilocularis*	2.70	Worldwide; *E. multilocularis* in lats 70° and 30° north	Craig et al., 1996
Echinostoma ilocanum and related species	0.15	Philippines; Thailand	WHO, 1995a (Cross, 1991)
Fasciola gigantica and *Fasciola hepatica*	2.40	China; Egypt; Europe; Iran; S. America	WHO, 1995a (Chen and Mott, 1990; Mas-Coma, 1998)
Fasciolopsis buski	0.21	Bangladesh; Cambodia; China; India; Indonesia; Laos; Thailand; Vietnam	WHO, 1995a (Cross, 1991)
Heterophyes heterophyes and related species	0.24	Egypt; Iran; Korea	WHO, 1995a (Cross, 1991)
Hymenolepis nana	75.00	Americas; Australia; developing countries	Sturchler, 1988
Loa loa	13.00	West and central Sub-Saharan Africa	Pinder, 1988 (Sturchler, 1988)
Metagonimus yokogawi and related species	0.66	Korea and S.E. Asia	WHO, 1995a (Cross, 1991)
Onchocerca volvulus	17.66	Central and S. America; Sub-Saharan Africa; Yemen	Molyneux and Davies, 1997 (WHO, 1995b)
Opisthorchis viverrini and *Opisthorchis felineus*	10.33	Kazakhastan; Laos; Thailand; Ukraine	WHO, 1995a (Cross, 1991)
Paragonimus westermani and related species	20.68	China; Ecuador; Korea; Laos; Peru	WHO, 1995a
Schistosoma haematobium	113.88	Africa; E. Mediterranean region	
Schistosoma intercalatum	1.73	Few countries in Sub-Saharan Africa	Based on Doumenge et al., 1987 and Utros-


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