

PERIODICAL REVIEW



A monthly review for readers of
Health Care Ethics USA

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AMA JOURNAL OF ETHICS

September 2021

From the Editor

How Differently Should the FDA Regulate Drugs and Devices?

Ariel Wampler, MD

Case and Commentary

How Should Clinicians and Organizations Assess Risks and Benefits of First-in-Human Implantation of Investigational Devices?

Beatrice L. Brown, MBE and Aaron S. Kesselheim, MD, JD, MPH

What Do Clinicians and Organizations Owe Patients with Recalled Implanted Devices or Materials?

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What Should Physician-Researchers Tell Patient-Subjects About Their Relationships with Industry?

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What Should Patients Be Told About Device Representatives' Roles at the Point of Surgical Care?

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AMA *Code of Medical Ethics*' Opinions Related to Implantable Devices

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What Should Cardiac Patients Know About Device Cybersecurity Prior to Implantation?

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FDA Device Oversight From 1906 to the Present

Anna Pisac and Natalia Wilson, MD, MPH

How Pseudoscience Generated US Material and Device Regulations

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Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?

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Is the FDA Failing Women?

Madris Kinard, MBA and Rita F. Redberg, MD, MSc

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AMERICAN JOURNAL OF BIOETHICS

September 2021

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Health Disparities, Systemic Racism, and Failures of
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Open Peer Commentaries

Making Culture a Verb: Implications for Health
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Materializing Systemic Racism, Materializing Health
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Grounding Medical Education in Health Equity: The
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Disability Cultural Competence for All as a Model

Rosemarie Garland-Thomson & Lisa I. Iezzoni

The Disruptive Power of Intersectionality

Jenny Kingsley, Emily R. Berkman & Sabrina F.
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Target Article

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September 2021

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Adults in Primary Care and Geriatrics Practices in the

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Literature Review

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Racial Disparity in Payments, Yield No Quality or

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Adam A. Markovitz, John Z. Ayanian, Anupama

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Marketplace Participation and Potential Financial

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Joachim O. Hero, Anna D. Sinaiko, Alon Peltz, Jon

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The Affordable Care Act Increased Medicaid

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Lindsey Rose Bullinger and Angélica Meinhofer

Privately Insured Transgender People Are at Elevated

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Landon Hughes, Theresa I. Shireman, and Jaclyn

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Food Insecurity Among Health Care Workers in the
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Mithuna Srinivasan, Xi Cen, Brandy Farrar, Jennifer

A. Pooler, and Talia Fish

National Trends in ED Visits, Hospital Admissions,

and Mortality for Medicare Patients During the

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Peter B. Smulowitz, A. James O'Malley, Hazar

Khidir, Lawrence Zaborski, J. Michael McWilliams,

and Bruce E. Landon

Vaccinations Against COVID-19 May Have Averted

Up to 140,000 Deaths in the United States

Sumedha Gupta, Jonathan Cantor, Kosali I. Simon,

Ana I. Bento, Coady Wing, and Christopher M.

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Equity and the Uneven Distribution of Federal

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Jason D. Buxbaum and Summer Rak

Myocardial Infarction Care Among the Elderly:
Declining Treatment with Increasing Age in Two
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John Hsu, Tor Iversen, Mary Price, Tron Anders
Moger, Delaney Tevis, Terje P. Hagen, and William
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Association Of Unemployment with Medicaid
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Paul R. Shafer, David M. Anderson, Rebecca
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The Concise Argument

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Unethical informed consent caused by overlooking
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Who will receive the last ventilator: why COVID-19
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Donna T Chen, Lois Shepherd, Jordan Taylor, Mary
Faith Marshall

Limits of remote working: the ethical challenges in
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Lisa Schölin, Moira Connolly, Graham Morgan,
Laura Dunlop, Mayura Deshpande, Arun Chopra

Feature Article

Novel drug candidates targeting Alzheimer's disease:
ethical challenges with identifying the relevant patient
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Erik Gustavsson, Pauline Raaschou, Gerd Lärffars,
Lars Sandman, Niklas Juth

US Sick Leave in Global Context: US Eligibility
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Jody Heymann, Aleta Sprague, Alison Earle, Michael
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'Long COVID': Making the Invisible Visible

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Commentary to 'Novel drug candidates targeting
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Join the Lone Kidney Club: incentivising live organ
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Are emotional support animals prosthetics or pets?

Body-like rights to emotional support animals

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Emotional support animals are not like prosthetics: a
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Military metaphors and pandemic propaganda:

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Zahra Khan, Yoshiko Iwai, Sayantani DasGupta

Red herrings, circuit-breakers and ageism in the COVID-19 debate

David R Lawrence, John Harris

Ethics Briefing

Medical ethics and law for doctors of tomorrow: the consensus statement restructured and refined for the next decade

Pirashanthie Vivekananda-Schmidt, Carwyn Hooper

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION

September 7, 2021

Original Investigation

Effect of Intravenous Fluid Treatment with a Balanced Solution vs 0.9% Saline Solution on Mortality in Critically Ill Patients: The BaSICS Randomized Clinical Trial

Fernando G. Zampieri, MD, PhD; Flávia R. Machado, MD, PhD; Rodrigo S. Biondi, MD; et al.

Effect of Slower vs Faster Intravenous Fluid Bolus Rates on Mortality in Critically Ill Patients: The BaSICS Randomized Clinical Trial

Fernando G. Zampieri, MD, PhD; Flávia R. Machado, MD, PhD; Rodrigo S. Biondi, MD; et al.

Effect of School Integrated Pest Management or Classroom Air Filter Purifiers on Asthma Symptoms in Students with Active Asthma: A Randomized Clinical Trial

Wanda Phipatanakul, MD, MS; Petros Koutrakis, PhD; Brent A. Coull, MD, PhD; et al.

Research Letter

Age-Dependent Neutralization of SARS-CoV-2 and P.1 Variant by Vaccine Immune Serum Samples
Timothy A. Bates, BSc; Hans C. Leier, BA; Zoe L. Lyski, MS; et al.

Long-term Symptoms After SARS-CoV-2 Infection in Children and Adolescents

Thomas Radtke, PhD; Agne Ulyte, MD, PhD; Milo A. Puhan, MD, PhD; et al.

Viewpoint

Aligning Payments, Services, and Quality in Primary Care

John H. Wasson, MD; Harold C. Sox, MD; Harold D. Miller

Enforcement of the Physician Payments Sunshine Act: Trust and Verify

Eli Y. Adashi, MD, MS; I. Glenn Cohen, JD

Cancer as a Global Health Priority

Satish Gopal, MD; Norman E. Sharpless, MD

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Drifting Over the Horizon: Navigating the End-of-Life Journey

David Allan Gruenewald, MD

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Does Crystalloid Composition or Rate of Fluid Administration Make a Difference When Resuscitating Patients in the ICU?

Michael J. Connor Jr, MD; Craig M. Coopersmith, MD

School Classrooms as Targets to Reduce Allergens and Improve Asthma

William W. Busse, MD; Daniel J. Jackson, MD

Review

Pancreatic Cancer: A Review

Wungki Park, MD; Akhil Chawla, MD; Eileen M. O'Reilly, MD

JAMA Insights

Cognitive Decline Associated with Anesthesia and Surgery in Older Patients

Susana Vacas, MD, PhD; Daniel J. Cole, MD; Maxime Cannesson, MD, PhD

JAMA Clinical Challenge

Inflammatory Myositis in a Patient with Melanoma
Mithu Maheswaranathan, MD; Michel G. Khouri, MD; Sophia C. Weinmann, MD

Medical News & Perspectives

Detecting Kids' Broken Hearts—Cardiac Screening Advised During Well-Child Visits

Anita Slomski

News From the JAMA Network

Most Fully Vaccinated Patients with Cancer Have SARS-CoV-2 Antibodies

Covering Tracheostomies Reduces Viral Spread to Health Care Staff

Novel Oral Drug Rapidly Treats Postpartum Depression

Guidelines for Lipid-Lowering Therapy Intensification Rarely Followed

News From the Food and Drug Administration

First Interchangeable Biosimilar Insulin Drug Is Approved

Testing Monoclonal Antibodies for Rabies Prophylaxis

Developing Partnerships to Streamline Global Food Safety

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Emoji for the Medical Community—Challenges and Opportunities

Debbie Lai, BA; Jennifer 8. Lee, BA; Shuhan He, MD

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Original Investigation

Effect of Camrelizumab vs Placebo Added to Chemotherapy on Survival and Progression-Free Survival in Patients with Advanced or Metastatic Esophageal Squamous Cell Carcinoma: The ESCORT-1st Randomized Clinical Trial
Huiyan Luo, MD, PhD; Jin Lu, BS; Yuxian Bai, MD; et al.

Effect of Urate-Elevating Inosine on Early Parkinson Disease Progression: The SURE-PD3 Randomized Clinical Trial

The Parkinson Study Group SURE-PD3 Investigators

Caring for the Critically Ill Patient - Effect of Low-Normal vs High-Normal Oxygenation Targets on Organ Dysfunction in Critically Ill Patients: A Randomized Clinical Trial

Harry Gelissen, MD, MBA; Harm-Jan de Grooth, MD, PhD; Yvo Smulders, MD, PhD; et al.

Poetry and Medicine

Sequelae

Nancy Naomi Carlson

JAMA Revisited

Public Health and Private Practice

JAMA Patient Page

Variants of SARS-CoV-2

Adam S. Luring, MD, PhD; Preeti N. Malani, MD, MSJ

Comment & Response

Age at Diabetes Onset and Subsequent Risk of Dementia

Half-Dose vs Stable-Dose Conventional Synthetic Disease-Modifying Antirheumatic Drugs and Disease Flare in Patients with Rheumatoid Arthritis

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Error in Letter to the Editor

Incorrect Classification of Pharmaceutical Agent
Incorrect Description in Patient Page

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Trends in Mortality From COVID-19 and Other Leading Causes of Death Among Latino vs White Individuals in Los Angeles County, 2011-2020
Paul Simon, MD; Alex Ho, MD; Megha D. Shah, MD; et al.

US Preventive Services Task Force

Recommendation Statement - Screening for Chlamydia and Gonorrhea: US Preventive Services Task Force Recommendation Statement
US Preventive Services Task Force

Evidence Report - Screening for Chlamydial and Gonococcal Infections: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

Amy Cantor, MD, MPH; Tracy Dana, MLS; Jessica C. Griffin, MS; et al.

Viewpoint

Making Vaccines Available to Other Countries Before Offering Domestic Booster Vaccinations

G. Owen Schaefer, DPhil; R. J. Leland, PhD; Ezekiel J. Emanuel, MD, PhD

Setting the Stage for the Next 10 Years of Health Care Payment Innovation

Bob Kocher, MD; Rahul Rajkumar, MD

Private Equity and Health Care Delivery: Value-Based Payment as a Guardrail?

Brian W. Powers, MD, MBA; William H. Shrank, MD, MSHS; Amol S. Navathe, MD, PhD

A Piece of My Mind

Preventing a Pandemic's Toll—We've Been Here Before

Abigail Zuger, MD

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Martin Urner, MD; Carolyn S. Calfee, MD, MAS; Eddy Fan, MD, PhD

Screening for Chlamydia and Gonorrhea

Jeanne Marrazzo, MD, MPH; Jodie Dionne-Odom, MD, MSPH

JAMA Guide to Statistics and Methods

Estimands, Estimators, and Estimates

Roderick J. Little, PhD; Roger J. Lewis, MD, PhD

JAMA Insights

Pulmonary Rehabilitation in 2021

Carolyn L. Rochester, MD; Martijn A. Spruit, PT, PhD; Anne E. Holland, PT, PhD

Medical News & Perspectives

Influenza's Unprecedented Low Profile During COVID-19 Pandemic Leaves Experts Wondering What This Flu Season Has in Store

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Original Investigation

Effect of Probiotics on Incident Ventilator-Associated Pneumonia in Critically Ill Patients: A Randomized Clinical Trial

Jennie Johnstone, MD, PhD; Maureen Meade, MD, MSc; François Lauzier, MD, MSc; et al.

News From the Centers for Disease Control and Prevention

Adolescent Myocarditis After COVID-19 Vaccination Is Rare

Severe Tuberculosis Surged After Shelter-in-Place Lifted

Biotech Innovations

SARS-CoV-2 Variant Antibodies Wane 6 Months After Vaccination

Potential New Immune-Checkpoint Inhibitor Partner for Lung Cancer

Point-of-Care SARS-CoV-2 Variant Diagnostic in Development

Poetry and Medicine

Taxonomy of the Oaks

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The Fad for Pseudoscience: Pertinent Queries and Musings

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Screening for Chlamydia and Gonorrhea

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Poloxamer 188 vs Placebo for Painful Vaso-occlusive Episodes in Children and Adults with Sickle Cell Disease

A Review of the Diagnosis and Management of Headache

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Percentage Incorrect in 2 Places

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Effect of Lower Tidal Volume Ventilation Facilitated by Extracorporeal Carbon Dioxide Removal vs Standard Care Ventilation on 90-Day Mortality in Patients with Acute Hypoxemic Respiratory Failure: The REST Randomized Clinical Trial

James J. McNamee, MB, ChB; Michael A. Gillies, MD; Nicholas A. Barrett, MB, ChB; et al.

Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke Among Patients at Low Surgical Risk

Raj R. Makkar, MD; Sung-Han Yoon, MD; Tarun Chakravarty, MD; et al.

Research Letter

Antibody Response After a Third Dose of the mRNA-1273 SARS-CoV-2 Vaccine in Kidney Transplant Recipients with Minimal Serologic Response to 2 Doses

Ilios Benotmane, MD; Gabriela Gautier, MD; Peggy Perrin, MD; et al.

Change in Saliva RT-PCR Sensitivity Over the Course of SARS-CoV-2 Infection

Zion Congrave-Wilson, MS; Yesun Lee, PhD; Jaycee Jumarang, MD; et al.

Special Communication

A Guideline for Reporting Mediation Analyses of Randomized Trials and Observational Studies: The AGReMA Statement

Hopin Lee, PhD; Aidan G. Cashin, PhD; Sarah E. Lamb, DPhil; et al.

Viewpoint

Confronting the Delta Variant of SARS-CoV-2, Summer 2021

Carlos del Rio, MD; Preeti N. Malani, MD, MSJ; Saad B. Omer, MBBS, PhD

Potential Implications of SARS-CoV-2 Delta Variant Surges for Rural Areas and Hospitals

Sameer S. Kadri, MD, MS; Steven Q. Simpson, MD

The Helping to End Addiction Long-term (HEAL) Initiative of the National Institutes of Health

Rebecca G. Baker, PhD; Walter J. Koroshetz, MD; Nora D. Volkow, MD

A Piece of My Mind

It Is What It Is

Meeta Prasad Kerlin, MD, MSCE

Editorial

Transcatheter Valve Replacement for Bicuspid Aortic Stenosis

Catherine M. Otto, MD; David E. Newby, MD

A Reporting Guideline for Mediation Analyses

Kabir Yadav, MDCM, MS, MSHS; Roger J. Lewis, MD, PhD

JAMA Clinical Guidelines Synopsis

Recommendations for Prevention and Management of Chemotherapy-Induced Peripheral Neuropathy

Benjamin A. Derman, MD; Andrew M. Davis, MD, MPH

From The Medical Letter on Drugs and Therapeutics

Pitolisant (Wakix) for Narcolepsy

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Reporting Findings from Mediation Analyses

Phil B. Fontanarosa, MD, MBA

Medical News & Perspectives

Twenty Years After 9/11, Responders Are Still Healing

News From the Food and Drug Administration

New Treatment Approved for Adults and Children with Pompe Disease

Lupus Drug Is Approved Despite Previous Clinical Trial Setback

“Collaborative Communities” Tackle Device Development Challenges

Global Health

Increase in Myopia Reported Among Children During COVID-19 Lockdown

India Takes Aim at Eliminating Visceral Leishmaniasis

US Health System Ranks Last Among High-Income Countries

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Penned

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JAMA Revisited

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MD-Granting Medical Schools in the United States, 2020-2021

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Graduate Medical Education, 2020-2021
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JAMA Patient Page
Pulmonary Hypertension
Kristin Walter, MD, MS

Comment & Response
Therapeutic Drug Monitoring vs Standard Therapy
During Infliximab Induction in Patients with
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Original Investigation
Effect of Thrombectomy with Combined Contact
Aspiration and Stent Retriever vs Stent Retriever
Alone on Revascularization in Patients with Acute
Ischemic Stroke and Large Vessel Occlusion: The
ASTER2 Randomized Clinical Trial
Bertrand Lapergue, MD, PhD; Raphaël Blanc, MD;
Vincent Costalat, MD, PhD; et al.

Association of Labor Epidural Analgesia with Autism
Spectrum Disorder in Children
Anders Pretzmann Mikkelsen, MD; Iben Katinka
Greiber, MD; Nikolai Madrid Scheller, MD; et al.

Association of Epidural Analgesia During Labor and
Delivery with Autism Spectrum Disorder in
Offspring
Gillian E. Hanley, PhD; Celeste Bickford, BSc; Angie
Ip, MD; et al.

Research Letter
Myocarditis Pericarditis After Vaccination for
COVID-19
George A. Diaz, MD; Guilford T. Parsons, MD, MS;
Sara K. Gering, BS, BSN; et al.

A Piece of My Mind
Shots in Arms
Shara L. Kronmal, MD, PhD

US Preventive Services Task Force
Aspirin Use to Prevent Preeclampsia and Related
Morbidity and Mortality: US Preventive Services
Task Force Recommendation Statement
US Preventive Services Task Force

Antimicrobial Therapy and Respiratory
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Correction
Incorrect Group Sizes in Figure
Addition of Nonauthor Collaborator Names of the
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Aspirin Use to Prevent Preeclampsia and Related
Morbidity and Mortality: Updated Evidence Report
and Systematic Review for the US Preventive Services
Task Force
Jillian T. Henderson, PhD, MPH; Kimberly K.
Vesco, MD, MPH; Caitlyn A. Senger, MPH; et al.

Viewpoint
COVID-19 in Canada: Experience and Response to
Waves 2 and 3
Allan S. Detsky, MD, PhD; Isaac I. Bogoch, MD,
MS

World Trade Center Health Program, 2012-2020:
Implications for Clinicians and Health Care Systems
Alejandro Azofeifa, DDS, MSc, MPH; Gayatri R.
Martin, MD, MPH; John Howard, MD, JD

Governing Human Germline Editing Through
Patent Law
Jacob S. Sherkow, JD, MA; Eli Y. Adashi, MD, MS;
I. Glenn Cohen, JD

Editorial
Low-Dose Aspirin for the Prevention of Preeclampsia
Jimmy Espinoza, MD, MSc

Labor Epidural Analgesia and Autism Spectrum
Disorder: Is There an Association?
Cynthia A. Wong, MD; Hanna Stevens, MD, PhD

JAMA Performance Improvement
Safety Culture as a Patient Safety Practice for Alarm
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Bradford D. Winters, MD, PhD; Jennifer M. Slota,
BA; Karl Y. Bilimoria, MD, MS

Medical News & Perspectives
Why Farmworkers Need More Than New Laws for Protection from Heat-Related Illness

News From the Centers for Disease Control and Prevention
Shifting Trends in West Nile and Other Arboviral Diseases
Salmonella Outbreak Is Linked to Restaurant Rather Than Food

Clinical Trials Update
Early Rehabilitation Leads to Better Function in Heart Failure
Pain Management Video Reduces Opioid Use After Cesarean Delivery
Remote Monitoring Reduced Symptoms Among Patients with Cancer
Closed-Loop Insulin Delivery for Outpatients with Type 2 Diabetes

Health Agencies Update
COVID-19 Vaccine Nasal Spray

KENNEDY INSTITUTE OF ETHICS JOURNAL

September 2021

Truthfulness and Deceit in Dementia Care: An argument for truthful regard as a morally significant human bond
Philippa Byers

Must Consent Be Informed? Patient rights, state authority, and the moral basis of the physician's duties of disclosure
D. Robert MacDougall

Can Treatment for Substance Use Disorder Prescribe the same Substance as that Used? The Case of Injectable Opioid Agonist Treatment
Daniel Steel, Şerife Tekin

L'OSSERVATORE ROMANO

September 3, 2021

A grave planetary crisis threatens our common home
Pope after operation: "It never crossed my mind to resign" – Interview by COPE
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New Grants for Suicide Prevention
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Time of Death

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A Comparison of Greek and Modern Scientific Methods

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Use of Aspirin During Pregnancy to Prevent Preeclampsia

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Comment & Response

Association of Coronary Artery Bypass Grafting vs Percutaneous Coronary Intervention with Memory Decline in Older Adults

Semaglutide vs Placebo as an Adjunct to Intensive Behavioral Therapy and Body Weight in Adults with Overweight or Obesity

Free to Decide: The Positive Moral Right to Reproductive Choice

Tess Johnson

The Moral Requirement for Digital Connectivity

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The Tragedy of Heterosexuality by Jane Ward (review)

Catharine Saint-Croix

Animals as Legal Beings: Contesting Anthropocentric

Legal Orders by Maneesha Deckha (review)

Angela Fernandez

Exploiting Hope: How the Promise of New Medical Interventions Sustains Us—and Makes Us Vulnerable
by Jeremy Snyder (review)

Children, walls and airplanes

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The gratuitousness of Christ's salvation gives us new dignity: The Holy Father on the Letter to the Galatians

Prayer and fasting for Afghanistan: Closeness to flood victims in Venezuela

Accepting differences while respecting human dignity: Holy Father's prepared discourse

The richness of being small: Pope's extemporaneous words

Politics at the service of the common good not for personal advantages

September 10, 2021

The dignity denied to millions of "new slaves": The Pontiff at the General Audience

Pope's Apostolic Visit to Budapest and Slovakia

September 11: What remains twenty years on Alessandro Gisotti

Welcome and protect Afghans: The Holy Father's appeal

Urgent response to the environmental crisis: Joint appeal of Pope Francis, Patriarch Bartholomew and Archbishop Welby to Cop26 leaders

Prayer and action: Season of Creation

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The Bread broken for a fraternal and welcoming world: Pope Francis arrives in Budapest, the first leg of his Apostolic Journey

To transform Agri-Food Systems Together: FAO ready to follow up on the UN Food System Summit Qu Dongyu

Francis in the heart of Hungarian people
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The Holy Father on his way to Budapest

Overcoming the fear of diversity to cultivate the dream of a fraternal society: Meeting with Bishops at the Museum of Fine Arts

The small flock: With Monsignor Veres

Liturgy at the centre of Christian faith: Message of the Holy Father signed by Cardinal Secretary of State on the 71st National Liturgical Week

'I love Ethiopia': Society of Saint Vincent de Paul humanitarian project
Rossana Ruggiero

Listening to the faithful: The basic text for the consultation
Salvatore Cernuzio

The style of journeying together: Press conference to present the Preparator Document

Justice and reconciliation to build peace: Video message of Cardinal Pietro Parolin to Korea Global Forum for Peace

The Day for Humanity: Reflections on the Beginning of the New Jewish Year

Exchanging experiences together: Towards the Warsaw Conference
Hanna Suchocka

No to divisive words that stroke hatred and anti-Semitism: With the Ecumenical Council of Churches and some Jewish Communities

Reciprocity is possible: The words of Calvinist Bishop and of the Rabbi

Jesus the Living Bread opens our hearts: Mass in Heroes' Square

The Cross, a bridge between the past and the future: Angelus Message

Europe will not rediscover its roots without the unity of all Christians: To the Ecumenical Council of the Churches, Bratislava

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