2020 PUBLIC HEALTH LAW VIRTUAL SUMMIT

COVID-19 Response and Recovery

September 16-17

Fast-Tracking Development of Medical Products and Vaccines

2020 Public Health Law Virtual Summit

Expanding Access to Patents for COVID-19

Jorge L. Contreras
September 17, 2020

University of Utah
S.J. Quinney College of Law and School of Medicine

IPR and Covid-19

Updated: OEM Threatens to Sue Startup that Saved Lives by 3D Printing Medical Valves

by: Norbert Sparrow in Medical, COVID-19, 3D Printing on March 19, 2020

MOTHERBOARD
TECH BY VICE

Hospitals Need to Repair Ventilators. Manufacturers Are Making That Impossible

We are seeing how the monopolistic repair and lobbying practices of medical device companies are making our response to the coronavirus pandemic harder.

By Jason Koebler

Mar 18 2020, 8:15am Share Tweet Snap

$3,000 for Prior Art on Former Panasonic Patent being asserted against ventilator companies by IP Edge, an NPE

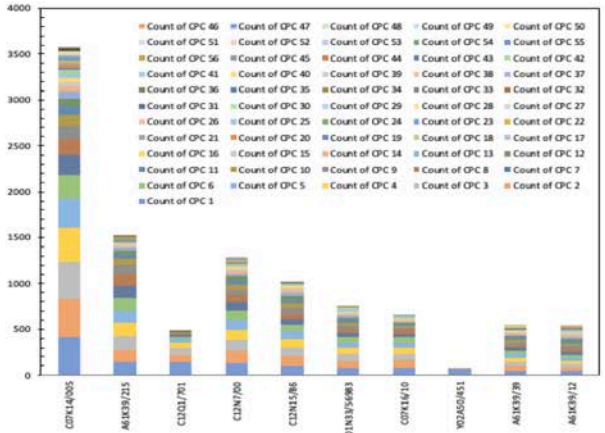
future tense

How Patent Abuse Could Hurt the Fight Against the Pandemic

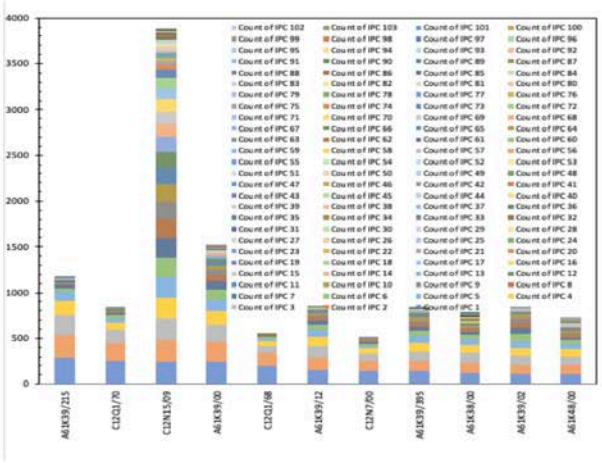
Scientific research that is funded by the public should be available to the public.

By ELLIOT HARMON APRIL 27, 2020 • 1:29 PM

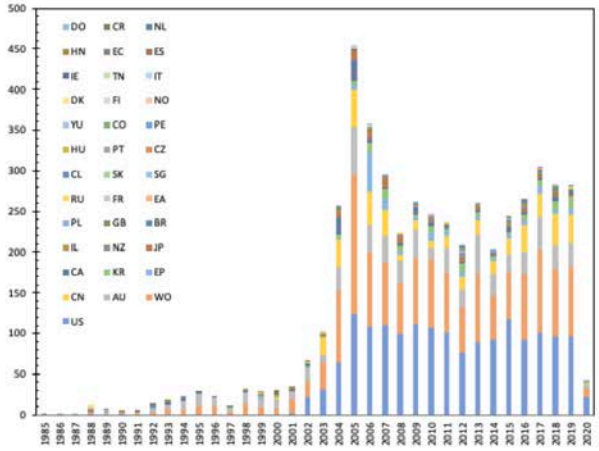
Covid-19 Patent Landscape



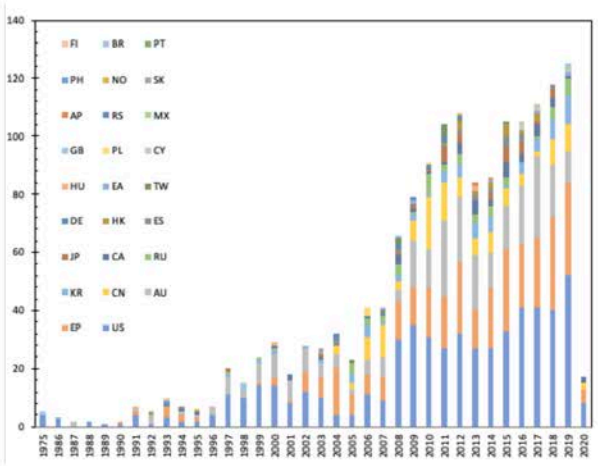
(a) Top 10 CPC Classification Distribution
(sorted by descending order of primary CPC main group)



(b) Top 10 IPC Classification Distribution
(sorted by descending order of primary IPC main group)



(c) Patent Applications Distribution vs. Publication Year
(filter by jurisdiction)



(d) Granted Patents Distribution vs. Publication Year
filter by jurisdiction

F. Tietze, P. Vimalnath, L. Aristodemou, J. Molloy, *Crisis-Critical Intellectual Property: Findings from the COVID-19 Pandemic*, IEEE Transactions on Engineering Management (Jun. 2020)

The Exclusionary Nature of IP

- Like most "property", IP is exclusionary by design
  - Art. I, Sec. 8, Cl. 8
- Ability to exclude competitors creates financial incentives to innovate
- But exclusion also prevents broad access to:
  - Products (by consumer)
  - Production (by competitors)
  - Research materials, methods (by researchers)

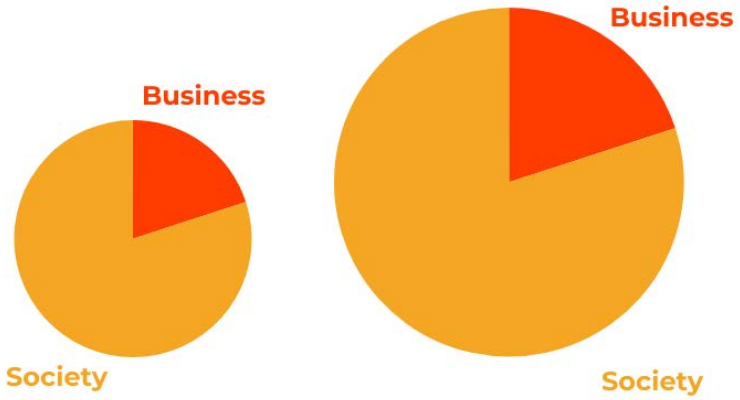
The "Incentive - Access Tradeoff"

- Stronger IP (patent) protection
  → greater incentives to create
  →but less access to the results
  - Scherer, 1993; Rai, 2001; Grabowski, 2002; Landes & Posner, 2003; Outterson, 2013; Hemel & Ouellette, 2019

- Alternate framing: static (access) v. dynamic (innovation) factors:
  - **Static** → availability/allocation of resources given existing IP entitlements
  - **Dynamic** → generation/creation of <u>new</u> resources

Dynamic/Innovation Levers

- IP strength
  - Duration, eligibility, enforcement, remedies, etc.
- Supplier subsidy
  - grants, prizes, tax incentives
  - *Ex ante* or *ex post* rewards
- Making "bigger pies" [?]



Static/Access/Allocative Levers

- Market/Price - default
- State interventions
  - Demand side subsidy (e.g., CMS)
  - Supply side (reduce IP strength)
    - Compulsory lic.
    - March-in/Govt use
    - Exceptions and limitations

Quantifying the Static/Dynamic Tradeoffs

- Easterbrook (1992)
  - "An antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the cost of production would be a calamity. In the long run, a continuous rate of change, compounded, swamps static losses."

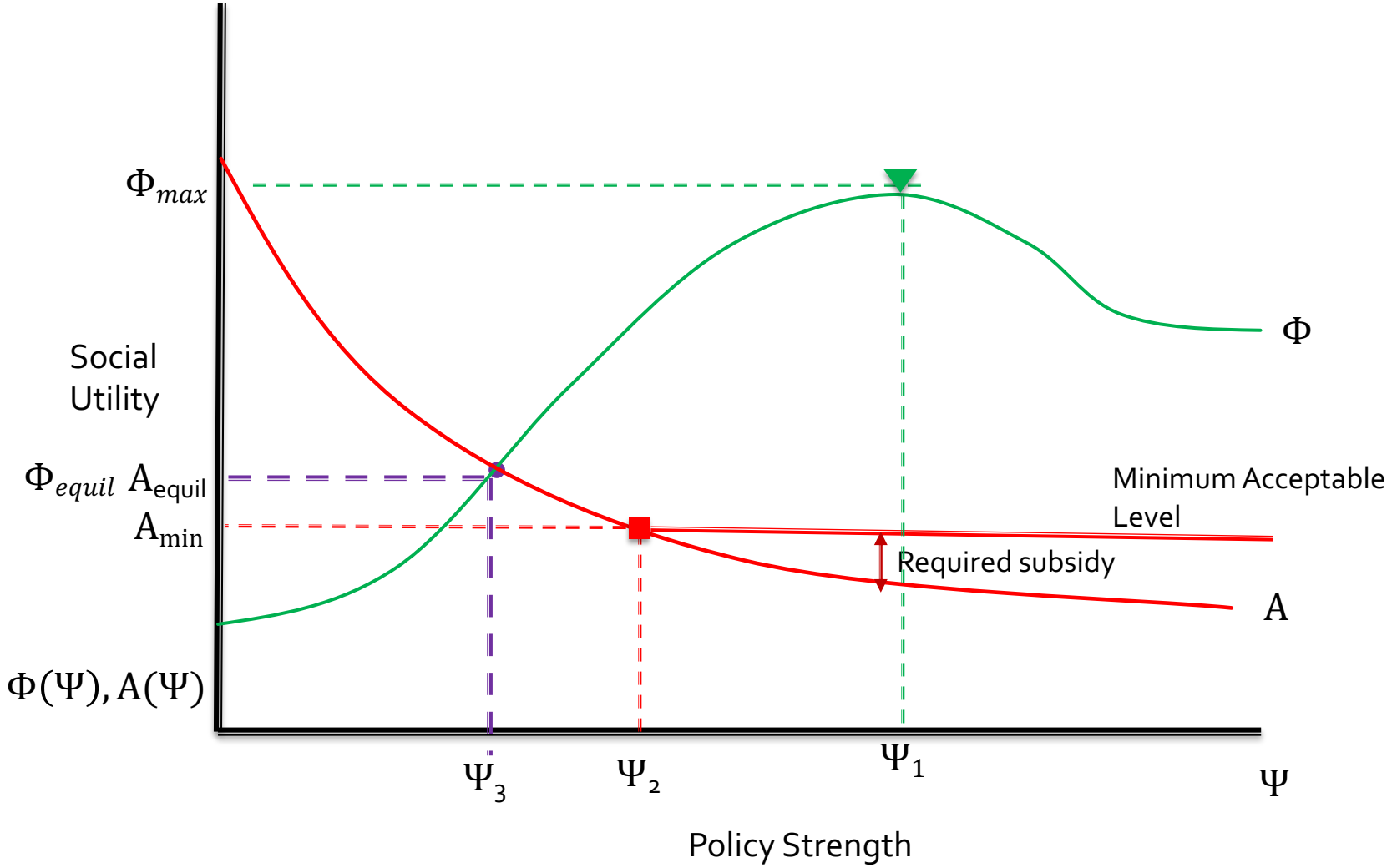
- Hughes et al (2002) -- model eliminates all pharma patents
  - Every $1 in consumer benefit from greater access to current stock → $3 loss from future innovation

$$PV = \frac{C_1}{(1+r)^n}$$

Access v. Innovation Tradeoff

- Increasing IP policy strength
  - Increases innovation incentives (to a point)
  - Decreases access
- Ensuring minimum access levels can be achieved by adding subsidies

Access + Innovation vs. Incentive Policy



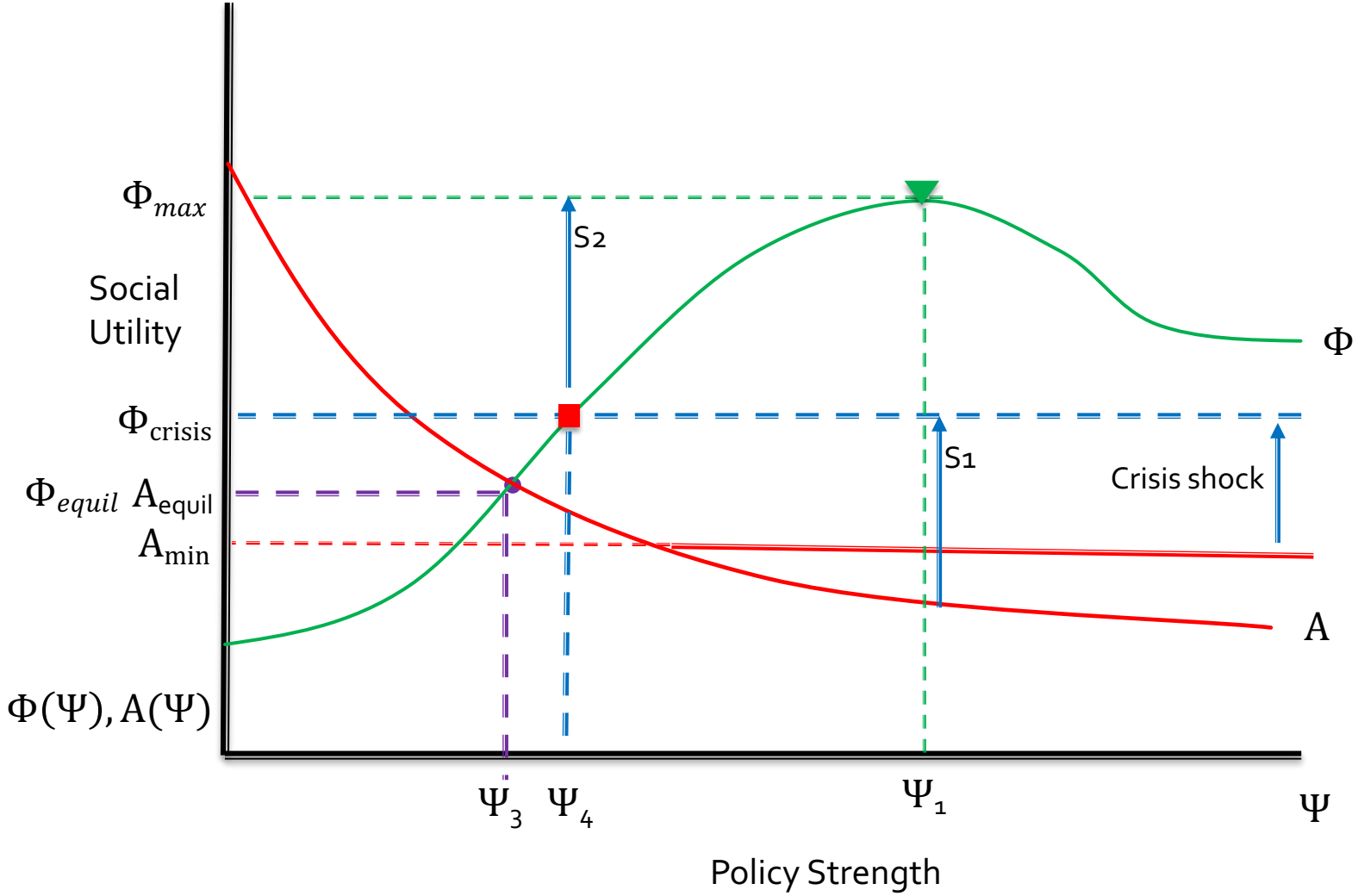
Impact of a Crisis

- Crisis (pandemic, war, natural disaster, etc.) introduces shock to system
- Minimum socially acceptable access increases
  - Greater need for vaccine, drug, equipment, etc.

Crisis tradeoff

- When minimum access requirement is increased:
  - Reduce IP strength or
  - Pay Access subsidy
  - Restore Innovation to prior level by paying greater subsidy
- In both cases, more is required than under ordinary circumstances

Access + Innovation in Crisis



Practical Implications - Equipment

- **Access**
  - Compulsory license for manufacture of replacement parts
- **Innovation**
  - Reasonable royalty (infringer)
  - Reasonable royalty (state)
  - Tax benefit (state)

Practical Implications - Therapy

- **Access**
  - Compulsory license for manufacturing of approved therapy
  - Procurement subsidy
- **Innovation**
  - Conditional Prize/Grant (state)
  - Buyout (state)
  - Reasonable royalty (infringer)
  - Reasonable royalty (state - 1498)
  - Tax benefit (state)

Implications for Private Ordering

- Shadow of state intervention can motivate private ordering
- Voluntary commitment of crisis-critical IP

Conclusion

- IP strength and subsidies should be considered part of the same policy toolkit

- In a crisis, to address increased Access requirements:
  - Reduce IP strength (and make-up thru subsidy) or
  - Increase user subsidy and retain high IP strength
  - measures can be temporary, reducing long-term impact on innovation

Thank you!

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MORITZ COLLEGE OF LAW

COVID-19 Drug and Vaccine Access and Development

Patricia J. Zettler, JD

Micah L. Berman, JD

Efthimios Parasidis, JD, MBE

U.S. FOOD & DRUG ADMINISTRATION

About FDA Product Approval

The Food and Drug Administration's regulatory approaches to marketing approval of the products it regulates are as varied as the products themselves. These differences are dictated by the laws FDA enforces and the relative risks that the products pose to consumers.

Some products — such as new drugs and complex medical devices — must be proven safe and effective before companies can put them on the market. The agency also must approve new food additives before they can be used in foods. Other products — such as x-ray machines and microwave ovens -- must measure up to performance standards. And some products — such as cosmetics and dietary supplements — can generally be marketed with no prior approval.

At the heart of all FDA's medical product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great — especially for products used to treat serious, life-threatening conditions.

People
June 27, 1977 • Vol. 7 • No. 25

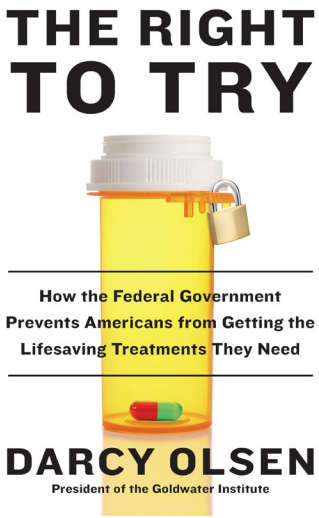
A Once-stricken Seed Salesman Whips Up a Storm in Kansas Over the Cancer Drug Laetrile

By Frank W. Martin

WSJ.com

The FDA's Deadly Track Record

By RONALD L. TROWBRIDGE and STEVEN WALKER
August 14, 2007; Page A17



The Boston Globe

Sick kids, desperate parents, and the battle for experimental drugs

The complex world of compassionate use drugs and who gets access to them.

Emergency Use Authorizations (EUAs)

- U.S. Secretary of the Department of Health and Human Services determines that there is a public health emergency or threat
- **"It is reasonable to believe" "the product may be effective"**
- FDA may impose restrictions on products issued EUAs (e.g., on what groups of patients may be administered the products or to require info collection)
- EUAs are time-limited
- FDA may revoke or revise

21 U.S.C. § 360bbb-3

BuzzFeed News Internal FDA Documents Show How Little Evidence The Agency Had Be

SCIENCE / CORONAVIRUS

Internal FDA Documents Show How Little Evidence The Agency Had Before Allowing Malaria Drugs To Be Used To Treat COVID-19

A May whistleblower complaint alleged that the FDA's emergency authorization of chloroquine and hydroxychloroquine came about as a result of political pressure from the White House.

Zahra Hirji
BuzzFeed News Reporter

Dan Vergano
BuzzFeed News Reporter

Jason Leopold
BuzzFeed News Reporter

Last updated on June 1, 2020, at 7:31 p.m. ET
Posted on June 1, 2020, at 3:55 p.m. ET

Emergency Use Authorization (EUA) for chloroquine phosphate, an unapproved product and hydroxychloroquine sulfate, an unapproved use of an approved product
Center for Drug Evaluation and Research (CDER) Review

Identifying Information

Application Type (EUA or Pre-EUA) If EUA, designate whether pre-event or intra-event EUA request.	EUA
EUA Application Number(s)[1]	EUA-039
Sponsor (entity requesting EUA or pre-EUA consideration)	Biomedical Advanced Research Authority (BARDA)
Manufacturer, if different from Sponsor	Bayer Pharmaceuticals Sandoz/Novartis
Submission Date(s)	March 26, 2020
Receipt Date(s)	March 26,2020
OND Division / Office	DAV
Reviewer Name(s)/Discipline(s)	Aimee Hodowanec, MD/Clinical Reviewer, Divison of Antivirals Mary Singer, MD, PhD/Medical Team Leader, Division of Antivirals Debra Birnkrant, MD/Director, Division of Antivirals John Farley, MD, MPH/Director (Acting), Office of Infectious Diseases Don Ashley, Director, Office of Compliance Linda Buhse, Office Director, Office of Surveillance, Office of Pharmaceutical Quality
Integrated Review Completion Date	March 28.2020
Proprietary Name)	
Established Name/Other names used during development	
Dosage Forms/Strengths	

F.D.A. 'Grossly Misrepresented' Blood Plasma Data, Scientists Say

Many experts — including a scientist who worked on the Mayo Clinic study — were bewildered about where a key statistic came from.

Dr. Stephen M. Hahn, the F.D.A. commissioner, erroneously said on Sunday that convalescent plasma would have saved 35 percent of coronavirus patients this year.
Oliver Contreras for The New York Times

By Katie Thomas and Sheri Fink

KATZ, MARSHALL & BANKS, LLP

ADDENDUM TO
THE COMPLAINT OF PROHIBITED PERSONNEL PRACTICE
AND OTHER PROHIBITED ACTIVITY
BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBMITTED BY DR. RICK BRIGHT

I. Introduction

Dr. Rick Bright is an internationally recognized expert in the fields of immunology, therapeutic intervention, vaccine, and diagnostic development. He is also one of the nation's leading experts in pandemic preparedness and response and in the design of diagnostic tools required to track pandemics, such as COVID-19, a virus that at this writing has infected more than a million people in the United States and has already killed 70,000 people in our country alone.

Dr. Bright earned his PhD in Immunology and Molecular Pathogenesis (Virology) from Emory University, and has 25 years of experience working in government, industry, and nonprofit settings to research and develop drugs and vaccines responsive to emerging infectious diseases and to expand vaccine production capacity in the United States and around the world. He began his career researching viruses, immunology, vaccine development, and antiviral drugs at the

FDA U.S. FOOD & DRUG ADMINISTRATION

August 23, 2020

Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Kadlec:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19 (the virus was later named SARS-CoV-2).[1] On March 27, 2020, on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use

Special Considerations for Vaccines

Recommendations include . . .

- Clear, accurate communication
- Proactive transparency
- FDA independence

- For EUAs:
  - Issue EUAs judiciously
  - Consider routine patient registries
  - Active review of issued EUAs
  - Decline to issue EUAs for vaccines (and if issued, limited to high-risk populations)

Contact Information:
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Twitter: @pzettler

https://www.publichealthlawwatch.org/covid19-policy-playbook