

EXHIBIT 1

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10 IN THE UNITED STATES DISTRICT COURT
11 FOR THE EASTERN DISTRICT OF CALIFORNIA
12 SAN JOSE DIVISION

14 **RITESH TANDON, et al.,**

15 Plaintiffs,

16 v.

18 **GAVIN NEWSOM, et al.,**

19 Defendants.

5:20-cv-07108

**DECLARATION OF DR. MICHAEL A.
STOTO IN SUPPORT OF STATE
DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR
PRELIMINARY INJUNCTION**

Courtroom: 8 – 4th Floor
Judge: The Honorable Lucy H. Koh
Trial Date: None set.
Action Filed: October 13, 2020

1 I, Michael A. Stoto, declare as follows:

2 1. I am over the age of 18 years and a U.S. citizen. I know the following facts of my
3 own personal knowledge, and, if called upon as a witness, I could and would testify competently
4 thereto.

5 **Background and Experience**

6 2. I have been a Professor of Health Systems Administration and Population Health at
7 Georgetown University since 2006, and hold adjunct faculty appointments at the Georgetown
8 University Law Center and School of Medicine. I am also an Adjunct Professor of Biostatistics at
9 the Harvard T.H. Chan School of Public Health, where I am a Senior Preparedness Fellow. My
10 primary training is in statistics, with a PhD from Harvard University and an AB from Princeton
11 University.

12 3. My research includes methodological topics in epidemiology and statistics including
13 systematic reviews/meta-analysis, community health assessment, evaluation methods, and
14 performance measurement. My substantive research interests include public health practice,
15 especially with regard to emergency preparedness; drug and vaccine safety; infectious disease
16 policy; and ethical issues in research and public health practice. I have published 124 peer-
17 reviewed articles, 15 books (primarily as editor), and 140 other publications and reports

18 4. I am an expert in public health systems research, focusing on applying and
19 developing rigorous mixed-methods approaches to studying and evaluating federal, state, and
20 local public health systems. For the last 20 years, most of my research in this area has focused on
21 public health emergency preparedness, including the evaluation of biosurveillance methods, and
22 the development of methods for assessing emergency preparedness capabilities based on
23 exercises and actual events. From 2001 to 2006, I served as the Associate Director for Public
24 Health of the RAND Center for Domestic and International Health Security, where I helped lead
25 the first study of local-level variation in public health preparedness in California.¹

26
27 ¹ Lurie, N., Wasserman, J., Stoto, M.A., Myers, S., Namkung, P., Fielding, J., Burciaga-
28 Valdez, R. Local variation in public health preparedness: Lessons from California. *Health Affairs
Online*, 2004 Jan-Jun; Suppl Web Exclusives: W4-341-53.

1 5. From 2008 – 2014, I was the co-Principal Investigator of the CDC-funded
2 Preparedness and Emergency Response Research Center based at the Harvard T.H. Chan School
3 of Public Health. Some of this research is summarized in the book I co-edited on the public
4 health system response to the 2009 H1N1 pandemic.² One article published during this time on
5 the effectiveness of U.S. public health surveillance systems during the 2009 H1N1 pandemic³
6 won the AcademyHealth Public Health Systems Research Article of the Year Award in 2013.

7 6. Much of my current research is conducted in conjunction with the Emergency
8 Preparedness Research, Evaluation & Practice (EPREP) Program at the Harvard T.H. Chan
9 School of Public Health and the University of Bologna with the support of the European Centre
10 for Disease Prevention and Control (ECDC). We have developed a logic model⁴ and a
11 competency-based training program for public health emergency preparedness in the European
12 Union, and are now beginning a new project to develop a monitoring and evaluation methodology
13 for public health emergency preparedness in the E.U., taking advantage of lessons learned from
14 Member States' experience with COVID-19.

15 7. During the COVID-19 pandemic, my research has focused on interpretation of test
16 results and policy for testing, surveillance systems to guide decision-making, and other aspects of
17 public health practice at the local to global levels. I have published two peer-reviewed papers on
18 test interpretation⁵ and evaluation.⁶ As a member of the National Academy of Sciences,
19 Engineering, and Medicine's Committee on Best Practices for Assessing Mortality and Morbidity
20 Following Large-Scale Disasters, I contributed an analysis of COVID-19 data systems to the

21 _____
22 ² Stoto, M.A., Higdon, M.A., eds. *The Public Health Response to 2009 H1N1: A Systems
23 Perspective*. Oxford University Press, 2015 (<http://bit.ly/1J3YuG9>).

23 ³ Stoto, M. A. The Effectiveness of U.S. Public Health Surveillance Systems for
24 Situational Awareness during the 2009 H1N1 Pandemic: A Retrospective Analysis. *PLoS ONE*
25 2012 7(8): e40984.

24 ⁴ Stoto, M.A., Nelson, C., Savoia, E., *et al.*, Assessing Preparedness for Infectious Disease
25 Threats in the European Region: Development of a Public Health Preparedness Logic Model.
26 *Health Security* 2017, 15(5):473-482,.

26 ⁵ Piltch-Loeb, R.N., Jeong, K.Y., Lin, K., Kraemer, J.D., Stoto, M.A. Interpreting
27 COVID-19 test results in clinical settings: it depends! *Journal of the American Board of Family
28 Medicine*, published online ahead of print on October 9, 2020.

27 ⁶ Reno, C., Lenzi, J, Golinelli, D., *et al.*, SARS-CoV-2/COVID-19 Testing: The Tower of
28 Babel. Forthcoming in *Acta Biomedica*.

1 committee's report.⁷ My colleagues and I have submitted a paper building on this research to the
2 *American Journal of Public Health*.⁸

3 8. I have taught a variety of courses in public health emergency preparedness for over
4 15 years at Georgetown (including at the McCourt School of Public Policy, the School of
5 Medicine, and in the Global Infectious Disease program), Harvard, and the University of
6 Bologna. Since 2013, I have co-taught Global Health Law: An Intensive, Problem-based
7 Exploration, with students from the main campus as well as the Law Center. My education,
8 professional background, and publications are described in additional detail in my curriculum
9 vitae, which is attached hereto as **Exhibit 1**.

10 **Introduction: A Public Health Approach to Pandemic Control**

11 9. In their declarations in *Tandon et al. v. Newsom*, Drs. Bhatia and Bhattacharya make
12 a number of claims regarding the effectiveness of the public health measures adopted by the State
13 of California to deal with the COVID-19 pandemic and an alternative they propose. They also
14 question whether the measures violate professional ethical standards of the field of public health.
15 In order to assess these claims, it is important to understand the public health rationale that
16 motivates the California Blueprint for a Safer Economy.⁹ Only with this as a background can the
17 claims be addressed.

18 10. The basic idea behind the California Blueprint is set forth in a declaration by Dr.
19 James Watt, Chief of the Division of Communicable Disease Control of the Center for Infectious
20 Diseases at the California Department of Public Health, which I have reviewed.¹⁰ It states as

21 _____
22 ⁷ Stoto M.A., Wynia, M.K. Assessing Morbidity and Mortality Associated with the
23 COVID-19 Pandemic: A Case Study Illustrating the Need for the Recommendations in this
24 Report. In National Academies of Sciences, Engineering, and Medicine, *A Framework for
25 Assessing Mortality and Morbidity After Large-Scale Disasters*, 2020.
(<https://www.nap.edu/read/25863/chapter/11>)

24 ⁸ Stoto M.A., Rothwell, R., Lichtveld, M., Wynia, M.K., A national framework to
25 improve mortality, morbidity, and disparities data for COVID-19 and other large-scale disasters.
Submitted to the *American Journal of Public Health*.

26 ⁹ <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID19CountyMonitoringOverview.aspx>

27 ¹⁰ Dr. Watt's declaration was filed in *Samuel A. Fryer Yavneh Academy v. Newsom*, No.
28 2:20-cv-07408-JAK (C.D. Cal 2020), on September 11, 2020 (ECF No. 53-1). I understand that
Dr. Watt's declaration is being supplemented with additional information for the present case,
which I have not reviewed, but that the goals described therein are unchanged.

1 follows: “By reducing community spread, we can decrease death and disability in our community,
2 especially among those vulnerable populations such as the elderly and those with underlying
3 medical conditions at highest risk for poor outcomes, and ensure that critical infrastructure,
4 particularly health care facilities, are not overwhelmed” (Watt 61). This focus on community
5 spread is founded on basic principles of infectious disease epidemiology. In this perspective, the
6 spread of a pathogen through a community is determined by the “reproductive number” R , which
7 essentially describes the expected number of new cases directly generated by one case in a
8 population. The basic reproductive number, R_0 , is the base case, with no interventions and the
9 entire population susceptible. The effective reproductive number, R_t , reflects the relative size of
10 generations at time t , taking into account interventions designed to stop the pathogen’s spread. If
11 R_t is greater than 1.0 the epidemic grows; if R_t is less than 1.0 the number of cases diminishes
12 from one generation to the next. Thus the goal of public health responses is to keep R_t under 1.0
13 because doing so will minimize death and disease in the population. While reducing illness and
14 death is the focus of the approach, underlying the public health approach is the concept that
15 public health measures to reduce R_t are undertaken with the simultaneous goal of minimizing
16 economic and social disruption to the extent possible, as discussed in detail below. This is
17 grounded in the understanding that, if a deadly disease spreads unchecked throughout the
18 community, the economic and social impacts of the preventable deaths and changes in behavior
19 that would occur would be more significant than the mitigating steps taken to reduce
20 transmission.

21 11. R_t in turn depends primarily on three factors: (1) prevalence of COVID-19 in the
22 community (the proportion of individuals infected at time t), (2) the number of interactions
23 between people during which the pathogen can be transmitted, and (3) the average likelihood of
24 transmission per interaction. The goal of non-pharmaceutical interventions (NPIs) is to minimize
25 the second and third factors. Stay at home orders and restaurant closures, for instances, reduce
26 the number of interactions (factor 2). The use of masks, hygiene, and frequent handwashing
27 reduce the likelihood of transmission (factor 3). The key point is that when the prevalence (factor
28 1) is low, factors 2 and 3 can be relaxed while maintaining $R_t < 1.0$.

1 12. It is important to stress the dynamic nature of this public health approach. As long as
2 R_t is less than 1.0, incidence of new cases is reduced from one period to the next. Reduced
3 incidence of new cases correlates with fewer people becoming sick and fewer deaths. This
4 reduction applies to all cases, regardless of severity, as well as the number who die in the coming
5 months, regardless of prior vulnerability. Furthermore, if R_t is kept below 1.0, the prevalence
6 (factor 1) will continue to drop, further reducing R_t . If the daily incidence of new cases is
7 lowered (the “curve is flattened”) the number needing hospitalization at any one time will stay
8 below critical capacity, improving outcomes for those hospitalized. In addition, cases delayed
9 can benefit from better treatments that are developed later. If cases can be delayed until after a
10 vaccine is introduced, some of these cases and associated deaths can effectively be prevented
11 altogether. Finally, the smaller daily number of new cases makes a test, trace, and isolate
12 approach more feasible and effective.

13 13. The most effective approaches to reducing the number of interactions (factor 2) and
14 the likelihood of transmission (factor 3) are context dependent, and may change over time
15 depending on both the epidemic itself and the development of scientific knowledge. In the
16 current pandemic, as in prior epidemics and pandemics, extensive “stay at home” measures were
17 called for in some locations, both in this country and in other countries, and time periods, but over
18 time as scientific knowledge grew public health officials were able to fine-tune control strategies
19 to include specific interventions that better balance efficacy in controlling spread of the virus in
20 the population and economic and social disruption. For example, as evidence has emerged about
21 the importance of “superspreader” events, public health officials have restricted activities in
22 locations where such events have been observed to happen, which minimizes both factor 2 and
23 factor 3. No single intervention is 100% effective, so adopting multiple different interventions in
24 a “layered” approach is critical.

25 14. This public health approach to reducing community spread can, and indeed should, be
26 supplemented by targeted protection of vulnerable populations. This would include, for example,
27 enhanced infection control procedures in hospitals to protect healthcare workers, who are more
28 likely than the general public to be exposed to the virus. Another example is nursing home

1 residents, who are vulnerable because of their exposure risk and the high prevalence of
2 underlying conditions that dispose them to serious consequences of SARS-CoV-2 infection.
3 These measures, however, are in addition to, and not in place of, the broader measures discussed
4 in paragraph 13.

5 15. This public health approach to pandemic control focused on reducing community
6 spread (as summarized by R_t) is supported by a vast and well-established scientific literature, a
7 small fraction of which is cited in a literature review on the subject that I have prepared, attached
8 here as **Exhibit 2**. This includes theoretical and empirical analyses (Fong, Ryu, Xiao, Bueno),
9 historical analyses (Markel, Wilder-Smith, Webster, Morens, Rainey), and modeling (Anderson)
10 going back a century (Stoto). Since the emergence of SARS-CoV-2, scientists have identified
11 COVID-19's epidemiologic characteristics such as the timing of infection, routes of transmission,
12 and so on. This knowledge is synthesized in a series of Rapid Expert Consultations convened by
13 the National Academies of Sciences, Engineering, and Medicine (NASEM, ECDC) and Rapid
14 Risk Assessments prepared by the European Centre for Disease Prevention and Control (ECDC).
15 Numerous rigorous empirical analyses of COVID-19 control interventions in the U.S. (Castillo,
16 Auger, Sen, Courtemanche) and abroad (Cowling, Cowling & Lim, Han, Flaxman, Hao, Liu, Pan,
17 Lai) have demonstrated the validity of this public health approach. Based on these studies, a
18 strong scientific consensus (Alwan, Leung) has emerged in favor of the public health approach.
19 This consensus is reflected in the recommendations issued by a variety of public and private
20 organizations in the United States (White House/CDC Opening up America guidelines, AEI,
21 CAP, NGA, AAMC, Hopkins), and abroad (e.g. the National Academy of Sciences Leopoldina in
22 Germany). Consequently, the public health approach to pandemic control focused on reducing
23 community spread has been adopted in most American States.

24 16. In their declarations, Drs. Bhatia and Bhattacharya argue from a quite different
25 perspective. Dr. Bhatia's preferred strategy of "Targeted Regulatory Strategies Protecting
26 Vulnerable Populations" (Bhatia 73-89) is a somewhat fleshed out version of the approach
27 advocated by the "Great Barrington Declaration," authored by Dr. Bhattacharya and others, and
28

1 co-signed by Dr. Bhatia.¹¹ This proposal has elicited a strong collective official response from
2 the American Public Health Association (APHA) and 16 other public health and related
3 organizations that such a program is (capitalization by authors) “NOT based in science,” “ignores
4 sound public health expertise,” “preys on a frustrated populace,” and promulgates “false hope that
5 will predictably backfire.”¹² The statement contrasts the proposed program with a desired
6 “national, science-based and ethical pandemic disease-control strategy” similar to that described
7 in the previous paragraphs. The statement concludes by stating “What we do not need are wrong-
8 headed proposals masquerading as science.” Almost 7,000 scientists and an additional 21
9 organizations, including the Federation of American Scientists and the Union of Concerned
10 Scientists, have endorsed the “John Snow Memorandum,”¹³ a rebuttal to the Great Barrington
11 Declaration that is distinct from the APHA collective response. It is the product of a grassroots
12 international initiative, named after founder of epidemiology John Snow, which organized to put
13 forth how best to manage the pandemic. While I have not signed the Memorandum, I support and
14 agree with its message. This Memorandum states that the strategy of protecting only vulnerable
15 populations (which Drs. Bhatia and Bhattacharya advocate) incorporates “a dangerous fallacy
16 unsupported by scientific evidence,” “risks significant morbidity and mortality across the whole
17 population,” and would “overwhelm the ability of healthcare systems to provide acute and routine
18 care.” The John Snow Memorandum continues that “special efforts to protect the most vulnerable
19 are essential but must go hand-in-hand with multi-pronged population-level strategies.”

20 **Defining Metrics and Triggers to Adjust the Public Health Approach**

21 17. For both epidemiological and ethical reasons (see below), specific control strategies
22 in the population health approach must be tailored to circumstances, taking into account current
23 scientific knowledge, epidemic status, and local capacities for controlling the pandemic (Watt 62
24 & 63). Epidemic status includes the current value of R_t , the major routes of transmission, and
25 other factors. Capacities include public health services such as (testing and contact tracing) as

26 _____
27 ¹¹ <https://gbdeclaration.org>

¹² <https://apha.org/news-and-media/news-releases/apha-news-releases/2020/public-health-orgs-condemn-sars-covid2-plan>

¹³ <https://www.johnsnowmemo.com/>

1 well as the number of hospital and ICU beds and other health care capacities. All of these factors
2 are likely to change over time and to vary from one county to another.

3 18. For practical reasons, the public health approach to reducing community spread
4 requires metrics and triggers (or “gating criteria”) based on the current epidemiologic situation to
5 gauge when control measures should be adjusted. In particular, these metrics include indicators
6 of the prevalence of COVID-19 in the community (factor 1 defined above). This is critical
7 because, as described in paragraph 10, R_t can be maintained below 1.0 with less restrictive control
8 measures when the prevalence is low. Other metrics typically used include indicators of the
9 effectiveness of interventions (whether R_t is currently less than 1.0), as well as measures of public
10 health and healthcare capacity.

11 19. As a practical matter, the prevalence of COVID-19 infections in a community is
12 difficult to measure, and public health jurisdictions take a variety of approaches to tracking it.
13 The California Blueprint for a Safer Economy¹⁴ uses two metrics: the “case rate” (7-day average
14 of daily COVID-19 cases per 100,000 population) and the “testing positivity rate” (7-day average
15 of all COVID-19 tests performed that are positive). Also, only a fraction of all cases can or will
16 actually be tested, so the case rate will not exactly represent the rate present in the population, but
17 the rate used by the State is sufficiently accurate as a matter of public health science for its
18 principal purpose—which is to identify when cases are increasing, or are rapidly increasing, in a
19 given county so that measure can be adjusted accordingly, on a timely basis, with the goal of
20 reducing R_t below 1.0 so that case counts reduce.¹⁵ This fraction likely varies over time and from
21 one jurisdiction to another based on multiple factors, but especially test availability.^{16,17} The

22 ¹⁴ <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID19CountyMonitoringOverview.aspx>

23 ¹⁵ Stoto M.A., Wynia, M.K. Assessing Morbidity and Mortality Associated with the
24 COVID-19 Pandemic: A Case Study Illustrating the Need for the Recommendations in this
25 Report. In National Academies of Sciences, Engineering, and Medicine, A Framework for
26 Assessing Mortality and Morbidity After Large-Scale Disasters, 2020.
(<https://www.nap.edu/read/25863/chapter/11>)

26 ¹⁶ Piltch-Loeb, R.N., Jeong, K.Y., Lin, K., Kraemer, J.D., Stoto, M.A. Interpreting
27 COVID-19 test results in clinical settings: it depends! *Journal of the American Board of Family
28 Medicine*, published online ahead of print on October 9, 2020.

¹⁷ Reno, C., Lenzi, J, Golinelli, D., *et al.*, SARS-CoV-2/COVID-19 Testing: The Tower of
Babel. Forthcoming in *Acta Biomedica*.

1 testing positivity rate is included to compensate for differences in the number of tests
2 performed.¹⁸ While this measure will not perfectly capture the testing positivity rate that would
3 be found if the entire population could be tested, it is appropriate for the purpose of allowing a
4 given county to adjust its restrictions accordingly.

5 20. Dr. Bhattacharya criticizes this approach because the metrics on which the tier
6 assignment is based “do not distinguish between people who face high mortality risk should they
7 become infected and people who face low mortality risk” (Bhattacharya 32-39). This represents a
8 misunderstanding of the public health approach to pandemic control focused on reducing
9 community spread described above that motivates the California Blueprint. In particular, as
10 described in paragraph 10, the purpose of these metrics is to identify the counties where
11 restrictions can be loosened because the prevalence of COVID-19 is low. Because controlling
12 community spread benefits all residents, the degree of restrictions should not depend on the
13 relative size of the vulnerable population. Furthermore, the Blueprint does not limit efforts
14 targeted to vulnerable populations.¹⁹

15 21. Dr. Bhattacharya also criticizes this approach because the case rate and the testing
16 positivity rate “are not sufficiently accurate regarding infectivity risk to warrant the central role
17 they play” (Bhattacharya 26-31). While these measures can be problematic,²⁰ Dr. Bhattacharya’s
18 criticism fails to recognize the steps that California takes to reduce errors in these metrics. First,
19 methods are standardized across the State with respect to case definitions, reporting processes,
20 types of tests counted in the denominator of the positivity rate, and so on. Second, the State set a

21 ¹⁸ Stoto M.A., Rothwell, R., Lichtveld, M., Wynia, M.K., A national framework to
22 improve mortality, morbidity, and disparities data for COVID-19 and other large-scale disasters.
Submitted to the *American Journal of Public Health*.

23 ¹⁹ It is also notable that not all “vulnerable populations” are readily definable with
24 accuracy in this pandemic. While some populations are, such as the elderly and persons with
25 certain conditions, our experience with this virus is relatively short and we are continuing to learn
about new populations that are particularly vulnerable to infection and/or to severe disease and
death. For example, the CDC includes pregnancy in the likely vulnerable categories, and the
CDC criteria and guidelines are continually evolving.

26 ²⁰ Stoto M.A., Wynia, M.K. Assessing Morbidity and Mortality Associated with the
27 COVID-19 Pandemic: A Case Study Illustrating the Need for the Recommendations in this
28 Report. In National Academies of Sciences, Engineering, and Medicine, A Framework for
Assessing Mortality and Morbidity After Large-Scale Disasters, 2020.
(<https://www.nap.edu/read/25863/chapter/11>)

1 threshold for adequate testing of more than 150 tests per 100,000 population (Watt 74) and
 2 statistically adjusts the case rate for the number of tests performed.²¹ Third, the State provides an
 3 adjudication process.²²

4 22. As noted, neither the case rate nor the testing positivity rate is a perfect estimate of
 5 the prevalence of COVID-19 in the community. The question, however, is whether these two
 6 measures do an adequate job of sorting counties into four risk tiers *based on the current*
 7 *epidemiologic situation and compared to viable, preferable alternatives* (Dr. Bhattacharya
 8 identifies none). The first rows of the following table provide the key metrics for three Tier 1 and
 9 three Tier 4 counties as of November 11, 2020.²³ Clearly, the differences in the metrics between
 10 the Tier 1 and Tier 4 counties are so large that counties are unlikely to be misclassified. The
 11 bottom rows of the table provide the same metrics for November 16, 2020, less than a week later.
 12 Consistent with a state-wide surge in infections, all of the Tier 1 (Widespread) counties in this
 13 analysis exhibited dramatic increases. Two of the three Tier 4 (Minimal) counties moved to Tier
 14 2 (Moderate) based on their adjusted case rate. This suggests that the tier system and metrics are
 15 capable of identifying important epidemiologic changes as well as distinguishing among high and
 16 low risk counties.

Tier	Tier 1 (Widespread)			Tier 4 (Minimal)		
County	Los Angeles	San Bernardino	Imperial	San Francisco	Humboldt	Mariposa
<i>November 11, 2020</i>						
Adjusted case rate (per 100,000)	7.6	16.8	20.3	2.5	2.0	1.6
Testing positivity rate	3.8%	7.7%	12.1%	1.1%	0.7%	0.3%
<i>November 16, 2020</i>						

25 ²¹ <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID19CountyMonitoringOverview.aspx>

26 ²² <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-19-County-Tier-Adjudication-Request.aspx>

27 ²³ Taken from
 28 https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/Blueprint_Data_Chart_111020.xlsx.

Adjusted case rate (per 100,000)	13.7	27.0	37.6	4.7	4.8	1.6
Testing positivity rate	5.3%	10.5%	16.5%	1.8%	2.0%	1.6%
New tier assignment				Tier 2	Tier 2	

23. As an alternative to the case rate and the testing positivity rate, Dr. Bhatia proposes to use hospital admission rates as triggers (Bhatia 47-49). Hospitalization would be a less effective alternative for at least two reasons. First, hospitalizations lag infections in the community by several weeks. In addition, the proportion of cases that are hospitalized changes over time as testing capacity and diagnosis improves, and as treatment patterns change.²⁴ The proportion of cases that are hospitalized also depends on hospital capacity, which can be limited during a surge of infections. This is likely to be a particular problem in rural counties where capacity is very limited. Thus, hospitalization rates are not appropriate indicators of the level of COVID-19 transmission in the community, which is the basis for the public health approach to pandemic control that motivates the California Blueprint. Hospitalization was, in fact, one of the criteria used by California in an earlier part of its response, when its pandemic roadmap/initial county monitoring regime was in place, and the State appears to have stopped using it as a specific criterion in the Blueprint because of the limitations described above.

24. Thus, in my professional judgment, taking into account that there are limits to the accuracy of using case rate and testing positivity rate, as there are limits for any criteria that would be used instead, the steps taken to address these problems, and the alternative Dr. Bhatia proposes, the metrics in the California Blueprint, although imperfect, are reasonable and appropriate for the task.

Ethical Considerations

25. Dr. Bhatia lists several reasons why he believes that the California Blueprint fails to meet public health’s ethical standards (Bhatia 29 and following). The Siracusa Principles

²⁴ National Academies of Sciences, Engineering, and Medicine. 2020. *Evaluating Data Types: A Guide for Decision Makers Using Data to Understand the Extent and Spread of COVID-19*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25826>.

1 are the relevant touchstone. Since we are addressing a global health emergency, I draw on the
2 articulation of these principles by Fidler and Gostin²⁵ with regard to the International Health
3 Regulations (2005). According to Fidler and Gostin’s articulation of the Siracusa Principles, the
4 key public health ethics considerations are that the measures that restrict individual rights must
5 (1) respond to a pressing public or social need; (2) pursue a legitimate aim; (3) be proportionate to
6 the legitimate aim; and (4) be no more restrictive than is required to achieve the purpose sought
7 by restricting the right. The Siracusa Principles recognize that these balancing calculations must
8 be undertaken under a considerable degree of uncertainty, especially early in any pandemic, and
9 that it is appropriate to continually review them. The Siracusa Principles also provide that rights-
10 restricting measures should be implemented in a non-discriminatory manner.

11 ***1. California’s Blueprint responds to a pressing public or social need and pursues a***
12 ***legitimate aim.***

13 26. To assess the California Blueprint from an ethical perspective, one has to first clarify
14 its goals, and specifically whether it responds to a pressing public or social need and pursue a
15 legitimate aim. As described in Dr. Watt’s declaration, the goals of California’s COVID-19
16 policies have evolved from March through August (Watt 64-81) and are stated as follows: “By
17 reducing community spread, we can decrease death and disability in our community, especially
18 among those vulnerable populations such as the elderly and those with underlying medical
19 conditions at highest risk for poor outcomes, and ensure that critical infrastructure, particularly
20 health care facilities, are not overwhelmed” (Watt 61). With over a million reported cases and
21 18,000 deaths in California alone, and the pandemic surging throughout the United States as I
22 write this, it is difficult to say this is not a pressing public or social need.

23 27. Dr. Bhatia argues that the metrics in the Blueprint do not reliably and proportionally
24 relate to a significant public health harm (Bhatia 30-49). This reflects a misunderstanding of the
25 goals of the California Blueprint. Lowering the case rate and the testing positivity rate is not the
26 objective of the Blueprint; rather these rates are merely metrics intended to determine the extent

27 ²⁵ Fidler, D. P., & Gostin, L. O. (2006). The new International Health Regulations: an
28 historic development for international law and public health. *The Journal of law, medicine & ethics*, 34(1), 85–4.

1 of non-pharmaceutical control measures that are necessary and appropriate in a particular county
2 and time period. The goal is to “decrease death and disability in our community, especially
3 among those vulnerable populations such as the elderly and those with underlying medical
4 conditions at highest risk for poor outcomes, and ensure that critical infrastructure, particularly
5 health care facilities, are not overwhelmed” by “reducing community spread” (Watt 61). This is
6 clearly a pressing public or social need and a legitimate public health aim. The fact that
7 California hospitals so far have not exceeded capacity or that the “worst-case” projections did not
8 come to fruition (Bhatia 32) does not diminish the pressing need; rather the relatively good
9 outcomes in California in the Spring of 2020 are generally regarded as a success of the control
10 measures that were undertaken at that time.²⁶

11 28. Dr. Bhatia also argues that hospitalization rates are better indicators of harm than
12 metrics based on testing (Bhatia 36 – 49), but as noted in the previous section, this reflects a
13 misunderstanding of the public health approach underlying the Blueprint and role the metrics play
14 in it. It also overstates the strengths of hospitalization rates as metrics. See discussion above at
15 paragraphs 17-25. Hospitalization rates in fact are not a desirable criterion in these circumstances
16 because they do not permit counties and the State to adapt quickly enough before the harm is
17 done. Thus, it is appropriate that, while California used this criterion in an earlier part of its
18 response, it has now shifted to using the current metrics that it does.

19 29. Dr. Bhattacharya argues that the State provides no scientific justification for its
20 Blueprint for Reopening (Bhattacharya 20). Dr. Bhatia further argues that the State has not
21 established a causal nexus between any of the tier-specific restrictions and disease prevention
22 outcomes (Bhatia 55-65). As noted above, however, this connection is well established by a large
23 body of evidence that is summarized in the attached literature review (Exhibit 2) and is not
24 reasonably disputable. This evidence predates COVID-19 and has been extensively developed
25 since the virus emerged.

26
27 ²⁶ California’s Coronavirus Caseload: 1 Million and Counting, *New York Times*, Nov. 12,
28 2020 <https://www.nytimes.com/2020/11/12/us/california-coronavirus-million-cases.html?referringSource=articleShare>

1 **2. The Blueprint’s Restrictions On Individual Rights Are Proportionate To Its Goals.**

2 30. Establishing whether the measures in the California Blueprint that restrict
3 individual rights are proportionate to its legitimate aim, requires a careful analysis of the detailed
4 plan. Note that the California Blueprint is not a “lockdown,” a term that defies a specific
5 definition in any case. Rather, consistent with the public health approach to pandemic control
6 focused on reducing community spread described at the outset of my statement, the Blueprint
7 describes a nuanced, context-specific approach that tailors the restrictions in each county
8 according to the prevalence of COVID-19 and other local factors. In this way, the Blueprint
9 seeks to balance efficacy in controlling population spread and economic and social disruption. It
10 should also be noted that the Blueprint is not the entirety of California’s COVID-19 control
11 strategy. Alongside the above-discussed Blueprint measures, California’s approach includes
12 providing targeted protection measures for hospitals and long-term care facilities, as an example.
13 This is in keeping with the public health approach set forth above.

14 31. Dr. Bhatia argues that restrictions are disproportionately severe relative to
15 mortality due to other preventable conditions in California (Bhatia 66 - 72). This comparison is
16 not relevant; the Siracusa Principles require that restrictions in individual rights be proportionate
17 to the legitimate aim; they do not address comparisons with other health conditions.

18 32. Dr. Bhatia also argues that because the State’s “current interventions are novel
19 and experimental” their long-term public health harms are likely to outweigh their benefits
20 (Bhatia 93). I disagree with his premise that “public health plans to respond to pandemics much
21 more threatening than COVID-19 never included interventions such as statewide stay-at-home
22 orders or universal closures of ‘non-essential’ businesses” (Bhatia 93). As discussed, extensive
23 evidence establishes the benefits of such interventions for diseases *less* threatening than COVID-
24 19, and for COVID-19 itself. And even if the State’s approach were novel or experimental, that
25 would not necessarily mean that the harms would outweigh the benefits. In the next paragraph,
26 Dr. Bhatia (94) refers to CDC’s Community Mitigation Guidelines to Prevent Pandemic
27 Influenza, which advises that advised that non-pharmaceutical interventions should be (a)
28 implemented early and (b) strategically “targeted, layered, and tailored” to pandemic severity to

1 limit the transmission of infection. California’s state-wide stay at home order in the Spring is an
2 appropriate (and apparently successful) example of early implementation. The pandemic
3 roadmap/county monitoring approach used in the next phase of the State’s reopening, based on
4 the risk level of activities (which was in turn informed by the available science) also was
5 consistent with public health standards; its looseness, however, potentially contributed to the
6 summer surge and reasonably informed the next iteration of the State’s approach. The tiered-
7 approach in the current Blueprint is a good example of CDC’s recommended “targeted, layered,
8 and tailored” to limit the transmission of infection. In other words, the Blueprint’s measures are
9 neither novel nor experimental, and there is no evidentiary basis for Dr. Bhatia’s presumption that
10 they should be regarded *a priori* to be more harmful than beneficial.

11 33. Dr. Bhattacharya argues that the state has provided no indication that it has
12 estimated the economic, social, and health costs of restricting normal activities (Bhattacharya 22),
13 and as an illustration describes the harms associated with school closings (Bhattacharya 23 & 24).
14 Dr. Bhatia suggests that the State’s “ongoing public health restrictions have led and will continue
15 to lead to severe adverse health impacts distinct from infection” (Bhatia 95 & 96). But both
16 declarations ignore the impact of the California Blueprint on saving human lives and preventing
17 serious illness caused by COVID-19. The Siracusa Principles, on the other hand, require that
18 restrictions on individual rights be proportionate to the legitimate aim of the public health
19 measures. Enumerating solely the downside economic and social costs of the pandemic
20 restrictions, even though valid, does not address the balancing criteria of the Siracusa Principles
21 and thus is not evidence that the Blueprint is unethical.

22 34. Because scientific knowledge and epidemiologic facts change rapidly,
23 especially early in the pandemic, the balancing calculations required by the Siracusa Principles
24 must be undertaken under a considerable degree of uncertainty and be continually reviewed.²⁷ As
25 Watt (64-81) notes, the State’s plans did evolve from March through August, 2020, factoring in

26 _____
27 ²⁷ Kathy Kinlaw & Robert Levine, Centers for Disease Control and Prevention Ethical
28 guidelines in Pandemic Influenza – Recommendations of the Ethics Subcommittee of the
Advisory Committee to the Director, CDC,
<https://www.cdc.gov/os/integrity/phethics/ESdocuments.htm#guidelines>

1 changes in scientific knowledge as well as the status of the epidemic. Furthermore, the tiers and
2 triggers in the current Blueprint provide a mechanism for policies to be tailored to each county's
3 circumstances, taking into account local epidemic status and public health and healthcare
4 capacities. Thus, in my opinion, the evolution and current status of California's COVID-19
5 policies seem to meet this ethical standard.

6 ***3. Dr. Bhatia and Dr. Bhattacharya Fail to Propose Meaningful Alternatives.***

7 35. Although they make general claims about the benefits of targeting nursing homes
8 and vulnerable populations, neither Dr. Bhattacharya nor Dr. Bhatia compare the effectiveness of
9 any specific program to the California Blueprint. Dr. Bhattacharya and Dr. Bhatia allude to an
10 approach that eliminates the population-wide measures and employs instead measures to protect
11 vulnerable populations only. But as described in paragraph 16, there are substantial concerns
12 about the efficacy and the ethics of this type of approach. Among many points that could be
13 made, it should be noted that the vulnerable population is far more extensive than those in
14 congregate settings, which is Drs. Bhattacharya and Bhatia's apparent focus. Their approach,
15 therefore, does not appear feasible to achieve. Moreover, even for nursing homes, experience has
16 shown that controlling spread is exceptionally difficult when the prevalence is high, given the
17 reality that for such facilities to operate they must be staffed by individuals who live in the
18 community. In addition, the targeted approach also has harms that have to be factored in, such as
19 the effects of zero restrictions on populations not deemed vulnerable.

20 **Conclusions**

21 36. The public health approach to pandemic control aims to decrease death and
22 disability in the entire population, as well as social and economic disruptions, by reducing
23 community spread of COVID-19. This is accomplished in the California Blueprint by defining
24 tiers based on current estimates of the virus's spread and other metrics and tailoring restrictions to
25 each county's epidemiologic situation and context. This approach is founded on basic principles
26 of infectious disease epidemiology and supported by a vast and well-established scientific
27 literature, including empirical investigations conducted during the COVID-19 pandemic in the
28 U.S. and abroad. Many public and private organizations have recommended, and most states

1 have adopted, versions of this approach. This community-spread focused approach allows
2 California to adopt the least restrictive approach to achieving public health goals.

3 37. The California Blueprint uses a collection of metrics to determine which tier each
4 county belongs in. Although objective, valid, and reliable metrics are difficult to obtain with
5 current data systems, California has taken important steps to improve its metrics, including state-
6 wide standardization of definitions, adjustments for the amount of testing being performed, and
7 providing an adjudication process. Thus, although imperfect, the metrics appear to be reasonable
8 for the task.

9 38. According to the Siracusa principles, the key public health ethics considerations are
10 whether measures that restrict individual rights (1) respond to a pressing public or social need; (2)
11 pursue a legitimate aim; (3) are proportionate to the legitimate aim; and (4) are no more
12 restrictive than is required to achieve the purpose sought by restricting the right. I have not
13 examined how California balanced these factors in developing the Blueprint, but I do not believe
14 that the statements of Drs. Bhattacharya and Bhatia provide evidence that the California Blueprint
15 violates ethical standards.

16 I declare under the penalty of perjury under the laws of the United States that the foregoing is true
17 and correct to my personal knowledge.

18
19
20 Executed on November 18, 2020 in Bethesda, MD.

21 
22

23 MICHAEL A. STOTO
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EXHIBIT 1

Curriculum Vitae
MICHAEL A. STOTO
November 7, 2020

Department of Health Systems Administration
School of Nursing and Health Studies
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EDUCATION

Harvard University: Ph.D. in Statistics, 1979; A.M. in Statistics, 1977.
Princeton University: A.B. in Statistics with High Honors, 1975.

PRIMARY EMPLOYMENT

2006-Present Professor of Health Systems Administration and Population Health, Georgetown University School of Nursing and Health Studies (with tenure as of July 1, 2011)
2012-2013 Senior Scholar in Residence, AcademyHealth
2001-2006 Senior Statistical Scientist and Associate Director for Public Health, RAND Center for Domestic and International Health Security
1998-2001 Professor and Chair, Department of Epidemiology and Biostatistics, School of Public Health and Health Services, George Washington University (with tenure)
1997-1998 Senior Staff Officer, Institute of Medicine, National Academy of Sciences
1993-1996 Director, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy of Sciences
1991-1992 Deputy Director, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy of Sciences
1987-1991 Senior Staff Officer, Institute of Medicine, National Academy of Sciences
1983-1987 Associate Professor of Public Policy, J. F. Kennedy School of Government, Harvard University (on leave, 1983-1984)
1983-1984 Senior Staff Officer, Institute of Medicine, National Academy of Sciences
1979-1983 Assistant Professor of Public Policy, J. F. Kennedy School of Government, Harvard University
1977-1986 Research Scholar, International Institute for Applied Systems Analysis, Laxenburg, Austria (various summers)
1974-1976 Research Assistant, Office of Population Studies, Princeton University, Princeton, New Jersey
1972-1974 Research Assistant, Politics Department, Princeton University

ACADEMIC APPOINTMENTS

2017-Present Senior Preparedness Fellow, Harvard T.H. Chan School of Public Health

- 2006-Present Professor of Health Systems Administration and Population Health, Georgetown University School of Nursing and Health Studies, secondary appointments in
- Center for Global Health Science and Security (2019-)
 - Department of Family Medicine, School of Medicine (2015-)
 - O'Neill Institute for National and Global Health Law, Georgetown University Law Center (2012-)
 - McCourt School of Public Policy (2003-)
 - Lombardi Comprehensive Cancer Center (2006-2011)
- 2002-2006 Professor of Policy Analysis, RAND Graduate School
- 2001-2002 Adjunct Professor of Epidemiology and Biostatistics, George Washington University School of Public Health and Health Services
- 2000-Present Adjunct Professor of Biostatistics, Harvard T.H. Chan School of Public Health, and
- 1998-2001 Professor of Epidemiology and Biostatistics (with tenure), School of Public Health and Health Services, George Washington University
- 1997-2000 Adjunct Lecturer in Biostatistics, Harvard School of Public Health
- 1996-1998 Adjunct Associate Professor of Epidemiology, George Washington University School of Public Health and Health Services
- 1991-1996 Professorial Lecturer, Department of Demography, Georgetown University
- 1990 Senior Research Scholar, Department of Demography, Georgetown University
- 1983-1987 Associate Professor of Public Policy, J. F. Kennedy School of Government, Harvard University
- 1979-1987 Faculty Associate, Center for Population Studies, Harvard University
- 1979-1983 Assistant Professor of Public Policy, J. F. Kennedy School of Government, Harvard University
- 1975-1979 Teaching Fellow, Statistics Department, Harvard University

HONORS AND DISTINCTIONS

Public Health Systems Research Article of the Year Award, AcademyHealth, 2013
Outstanding Achievement in Research Award, Georgetown University Medical Center, 2009
Fellow, American Statistical Association, Elected 2004
American Public Health Association Statistics Section Award, 1999
National Research Council Group Recognition Award, 1994
National Research Council Group Recognition Award, 1992
Institute of Medicine Group Achievement Award, 1991
National Science Foundation Graduate Fellowship, 1975-1978

MAJOR PROFESSIONAL SERVICE**National**

2019-2020 Member, Committee on Best Practices for Assessing Mortality and Morbidity Following Large-Scale Disasters, National Academy of Sciences, Engineering, and Medicine

- 2018-2019 Member, Collaborative Working Group on CHNAs (Community Health Needs Assessments) Principles and Practices, National Academy of Medicine Care Culture & Decision-making Innovation Collaborative, National Academy of Sciences, Engineering, and Medicine
- 2018 Member, Health Services Research and Development (HSR&D) Centers of Innovation (COIN) Review Panel, Department of Veterans Affairs
- 2017-2021 Member, Prevention and Population Health Standing Committee, NQF
- 2017-2020 Member, Scientific Methods Panel, National Quality Forum (NQF)
- 2016 Member, Improving Methods for Patient-Centered Outcomes Research Merit Review Panel, Patient-Centered Outcomes Research Institute (PCORI)
- 2016-2017 Chair, Methods Workgroup, Green Park Collaborative Real-World Evidence project, Center for Medical Technology Policy
- 2016-2017 Member, Technical Expert Panel, Training the Next Generation of Learning Health System Researchers, Agency for Healthcare Research and Quality (AHRQ)
- 2015-2016 Chair, Technical Expert Panel on Population Health Measure Development: Multi-Sector Collaboration, Centers for Medicare and Medicaid Services (CMS)
- 2015-2016 Member, Subcommittee on Sustainability of the U.S. Blood System, Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)
- 2015 Member, Technical Expert Panel on Population Health Measure Development, Centers for Medicare and Medicaid Services (CMS)
- 2014-2017 Member, Health and Well-Being Endorsement Maintenance Project Standing Committee, NQF
- 2013 Chair, Patient-Centered Outcomes Research Methods Research Merit Review Panel, PCORI (two cycles)
- 2012-2014 Member, Consumer Patient Researcher Roundtable, AcademyHealth
- 2012 Member, Special Emphasis Panel to Review Applications for National Research Service Award Institutional Research Training Grants, Agency for Healthcare Research and Quality
- 2012 Member, Regionalized Emergency Medical Care Services Expert Panel, NQF
- 2012-2013 Member, Population Health Steering Committee, AcademyHealth
- 2012-2013 Member, Annual Research Meeting Executive Committee, AcademyHealth
- 2012-2015 Member, Air Force Health Study Data and Specimens Committee, Institute of Medicine
- 2011-2012 Member, Population Health Project Steering Committee, NQF
- 2011-2013 Member (Chair, 2011-2012), AcademyHealth Public Health Systems Research Interest Group Advisory Committee
- 2010-2016 Consultant, Electronic Data Methods Forum (EDM Forum), AcademyHealth
- 2009-2011 Statistics Section Representative, Governing Council, American Public Health Association
- 2009 Member, Algorithms for the Threat Detection review panel, National Science Foundation
- 2009-2010 Member, Public Health Systems Research Methods Advisory Committee, AcademyHealth

- 2008-2009 Member, Advisory Committee for The Health Services Researcher of 2020: A Summit on Data and Methods, AcademyHealth
- 2008 Member, Special Emphasis Panel to Review Applications for National Research Service Award Institutional Research Training Grants, Agency for Healthcare Research and Quality
- 2007-2016 Member, AcademyHealth Methods Council and Chair, Methods Framework Committee
- 2007-2008 Member, Committee to Assess the Current and Future Workforce Needs in Veterinary Medicine, National Academy of Sciences
- 2006 Member, Expert Panel on Statistical Methods for Syndromic Surveillance, American Statistical Association
- 2006-2010 Member, Public Health Practice Committee, International Society of Disease Surveillance
- 2005-2007 Member, Spiegelman Award Selection Committee, Statistics Section, American Public Health Association
- 2005 Member (APHA representative), Program Committee, National Syndromic Surveillance Conference
- 2005-2007 Member, Biosense Public Health Partners Working Group
- 2004-2005 Member, Planning Committee, Workshop on Estimating the Contribution of Lifestyle-Related Factors to Preventable Death, Institute of Medicine
- 2004-2005 Member, Editorial Committee, 2004 Syndromic Surveillance Supplement to the MMWR, Centers for Disease Control and Prevention
- 2004-2007 Chair, Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants, Department of Health and Human Services
- 2004 Member, Program Committee, National Syndromic Surveillance Conference
- 2001-2004 Chair-elect, Chair, and Immediate Past Chair, Statistics Section, American Public Health Association
- 2003 Member, Special Emphasis Panel to Review Applications for Pathways Linking Education to Health, NIH
- 2002-2005 Member, Data Safety Monitoring Board, International Centers for Tropical Disease Research, NIAID/NIH
- 2002-2003 Consultant, Committee on the Ryan White CARE Act: Data for Resource Allocation, Planning, and Evaluation, National Academy of Sciences/Institute of Medicine
- 2002 Member, Special Emphasis Panel to Review Applications for Developmental Centers for Child Health and Development, NICHD/NIH
- 2001-2003 Invited participant, Epidemiology Workshop to Determine the Feasibility and Design of a Study on the Long-Term Effects of Anthrax Vaccine, U.S. Army Medical Research Institute of Infectious Diseases
- 2001 Consultant, Immunization Safety Review Committee, National Academy of Sciences/Institute of Medicine
- 2000-2001 Member, Statistics Section Council, American Public Health Association

- 1999-2004 Member, Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants, Department of Health and Human Services
- 1999-2007 Member, Ethics and Standards of Practice Committee, American College of Epidemiology
- 1999-2000 Consultant, Committee on HIV Prevention Strategies, National Academy of Sciences/Institute of Medicine
- 1999 Member, Special Emphasis Panel to Review Applications for Centers for the Demography of Aging, NIA/NIH
- 1999 Member, Expert Panel on Adherence to HIV Treatment Protocols, American Public Health Association
- 1998-2001 Chair, Biostatistics Council, Association of Schools of Public Health
- 1996-1998 Liaison member and member of methodology working group, Task Force on Community Preventive Services, Department of Health and Human Services
- 1995-1996 Secretary, Statistics Section, American Public Health Association
- 1992-1994 Program Chairman, Epidemiology Section, American Statistical Association
- 1989-1993 Member, Health Services Research and Developmental Grants Review Committee, Agency for Health Care Policy and Research
- 1988-1990 Member, Panel on AIDS Statistics, National Research Council
- 1986-1989 Member, Panel on Decennial Census Methodology, National Research Council
- 1986-1990 Member, U.S. Committee for the International Institute for Applied Systems Analysis
- 1986 Consultant, Committee on a National Strategy for AIDS, National Academy of Sciences/Institute of Medicine
- 1985-1990 Member (Chair in 1989), American Statistical Association Census Advisory Committee
- 1985 Consultant, Panel on Statistics for an Aging Population, National Academy of Sciences
- 1984 Expert witness on census undercount, U.S. Bureau of the Census
- 1982 Expert witness on equal representation, Civil Rights Division, United States Department of Justice
- 1981-1982 Member, American Statistical Association Technical Panel on Census Undercount
- 1980 Consultant, Planning Study for an Ongoing Study of Costs of Environment- Related Health Effects, National Academy of Sciences/Institute of Medicine

Editorial Service

- 2019- Guest Editor, *Globalization and Health*, special issue on “Global health security”
- 2012-2019 Senior Editor, *eGEMs (Generating Evidence & Methods to Improve Patient Outcomes)*, Guest editor for special collection on “New analytical methods for a learning healthcare system”
- 2012-2017 Editorial board member, *Health Services Research (HSR)*
- 2007-2014 Statistical Editor, *Journal of Disaster Medicine and Public Health Preparedness*

2006-2008 Senior Associate Editor, *Advances in Disease Surveillance*
1989-1991 Associate Editor, *Evaluation Review*
1983-1986 Associate Editor, *Journal of the American Statistical Association*

Peer Review Assignments

AcademyHealth Public Health Services Research Interest Group
Agency for Health Care Policy and Research
Centers for Disease Control and Prevention
Food and Health Bureau (FHB) of the Hong Kong SAR Government
Health Research Board, Republic of Ireland
Institute of Medicine
International Society for Disease Surveillance
Medical Research Council, South Africa
Medical Research Council, United Kingdom
National Center for the Study of Preparedness and Catastrophic Event Response
National Institutes of Health (NIA, NICHD)
National Research Council
National Science Foundation
National Security Agency
Oxford University Press
Patient Centered Outcomes Research Institute (PCORI)
RAND Corporation
Robert Wood Johnson Foundation

Journal Reviews

<i>American Journal of Clinical Dermatology</i>	<i>Cancer Causes and Control</i>
<i>American Journal of Preventive Medicine</i>	<i>Circulation</i>
<i>American Journal of Managed Care</i>	<i>Clinical Infectious Diseases</i>
<i>American Journal of Public Health</i>	<i>Demography</i>
<i>Annals of Applied Statistics</i>	<i>Disaster Medicine and Public Health</i>
<i>Applied Health Economics and Health Policy</i>	<i>Preparedness</i>
<i>Archives of Physical Medicine and Rehabilitation</i>	<i>Drugs - Real World Outcomes</i>
<i>Asian Pacific Journal of Tropical Medicine</i>	<i>Drug Safety</i>
<i>BioDrugs</i>	<i>eGEMs (Generating Evidence & Methods to Improve Patient Outcomes)</i>
<i>BioMed Central Global Health</i>	<i>Emerging Infectious Diseases</i>
<i>BioMed Central Health Services Research</i>	<i>Environmental and Ecological Statistics</i>
<i>BioMed Central Infectious Diseases</i>	<i>Epidemiology and Infection</i>
<i>BioMed Central Medical Informatics and Decision Making</i>	<i>European Journal of Public Health</i>
<i>BioMed Central Public Health</i>	<i>Evaluation Review</i>
<i>Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science</i>	<i>Family Planning Perspectives</i>
<i>BMJ Open</i>	<i>Global Challenges</i>
	<i>Globalization and Health</i>
	<i>Health Affairs</i>

<i>Health and Human Rights</i>	<i>Journal of Law, Medicine & Ethics</i>
<i>Health Services and Outcomes Research</i>	<i>Journal of Racial and Ethnic Health</i>
<i>Methodology</i>	<i>Disparities</i>
<i>Health Services Research</i>	<i>Journal of Research Practice</i>
<i>IEEE Transactions on Human-Machine</i>	<i>Journal of the American Medical Association</i>
<i>Systems</i>	<i>Journal of the American Statistical Association</i>
<i>Influenza and Other Respiratory Viruses</i>	<i>Medical Care</i>
<i>International Journal of Infectious Diseases</i>	<i>Medical Decision Making</i>
<i>Journal of Racial and Ethnic Health</i>	<i>Milbank Memorial Fund Quarterly</i>
<i>Disparities</i>	<i>PLOS ONE</i>
<i>Lancet</i>	<i>Population Index</i>
<i>New England Journal of Medicine</i>	<i>Population Research and Policy Review</i>
<i>JAMA Oncology</i>	<i>Progress in Community Health Partnerships</i>
<i>Journal of Comparative Effectiveness Research</i>	<i>Public Health</i>
<i>Journal of Clinical Endocrinology &</i>	<i>Public Health Reports</i>
<i>Metabolism</i>	<i>Research Synthesis Methods</i>
<i>Journal of Disaster Medicine and Public</i>	<i>Science</i>
<i>Health Preparedness</i>	<i>Social Science and Medicine</i>
<i>Journal of General Internal Medicine</i>	<i>Statistical Science</i>
<i>Journal of National Medical Association</i>	<i>Statistics in Medicine</i>
<i>Journal of Official Statistic</i>	<i>Vaccine</i>
<i>Journal of Public Health Management and</i>	<i>Women's Health Issues</i>
<i>Policy</i>	

OTHER PUBLIC SERVICE

2020-	Member, COVID-19 Task Force, Holy Trinity Parish, Washington, DC
2019-	Member, Martha's Vineyard Hospital Community Benefit Advisory Committee
2015-	Member, Survey Advisory Workgroup, Association of State and Territorial Health Officials (ASTHO)
2014-2018	Co-chair, Healthy Montgomery Measurement and Evaluation Committee
2013-2014	Co-chair, Healthy Montgomery Data Project Team
2013-2015	Member, Measures Track of Work Committee, Primary Care and Public Health Collaborative, Association of State and Territorial Health Officials
2012-2014	Member, Consumer-Patient-Researcher (CPR) Roundtable, AcademyHealth
2011	Consultant, Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations, Institute of Medicine
2011	Member, Data Release Guidelines workgroup, National Association of Health Data Organizations (NAHDO)
2009-2010	Member, Steering Committee, Public Health Services Research Track, National Association of County and City Health Officials Annual Meeting
2009-2018	Member, Healthy Montgomery Steering Committee, Montgomery County (MD) Department of Health and Human Services
2009	Member, Grant review panel, National Center for the Study of Preparedness and Catastrophic Event Response

- 2009-2011 Member, Partnerships for a Healthier Arlington Steering Committee, Arlington County (VA) Department of Human Services
- 2008 Member, Working Group on Testing, Exercising, Measuring, and Improving Preparedness, At-risk Populations Project, Association of State and Territorial Health Officials
- 2007-2008 Member, Working Group to Develop a CME Program for Public Health Professionals and Clinicians in Syndromic Surveillance, International Society of Disease Surveillance
- 2007-2008 Member, Working Group on Evaluation of Health Department Web-based Data Query Systems, Robert Wood Johnson Foundation
- 2007-2008 Member, Mobilizing for Action through Planning and Partnerships (MAPP) steering committee, and co-chair, Data Subcommittee, Arlington County Department of Human Services
- 2006-2007 Consultant, Committee on Reviewing Evidence to Identify Highly Effective Clinical Services, National Academy of Sciences/Institute of Medicine
- 2004-2009 Member, Board of Directors, 4th District Community Health Partnership
- 2004-2005 Regional judge, Robert Wood Johnson Foundation Young Epidemiological Scholars program
- 2003 Member, Advisory Committee, 4th District Community Health Partnership
- 2001-2003 Member, Evaluation Committee, DC Area Health Education Center
- 2001 Invited presenter, Consultation on Estimating Incidence of HIV Infection in the United States, Centers for Disease Control and Prevention
- 2000-2004 Member, Bioterrorism Task Force, Metropolitan Washington Council of Governments
- 2000-2001 Member, District of Columbia HIV Surveillance Implementation Advisory Group
- 2000-2005 Member, Institutional Review Board, Aeras Global TB Vaccine Foundation
- 2000-2006 Member, Data Safety Monitoring Board, Aeras Global TB Vaccine Foundation
- 1999-2000 Consultant, Committee on Health Effects Associated with Exposures during the Persian Gulf War, National Academy of Sciences/Institute of Medicine
- 1985-1987 Member, Research Advisory Group of the New England Institute for Healthcare Services Research
- 1981-1982 President, Boston Chapter, American Statistical Association
- 1978-1979 Member, Advisory Committee to Massachusetts Judicial Court, Boston, Massachusetts

PROFESSIONAL SOCIETIES

AcademyHealth
American Public Health Association
American Statistical Association
Interdisciplinary Association for Population Health Science
International Union for the Scientific Study of Population
Population Association of America

MAJOR ADMINISTRATIVE RESPONSIBILITIES

- 2015-2019 Associate Director, Population Health Scholar Track, Georgetown University School of Medicine
- 2008-2014 Co-principal investigator, Linking Assessment and Measurement to Performance in PHEP Systems (LAMPS), Harvard School of Public Health Center for Public Health Preparedness
- 2011-2012 Steering committee member and oversight liaison directors for education, training and professional development, Georgetown/FDA Center of Excellence in Regulatory Science and Innovation (CERSI)
- 2008-2011 Director, Signature initiative on public health emergency preparedness, O'Neill Institute for National and Global Health Law, Georgetown University
- 2007-2010 Director, Evaluation Core, Harvard School of Public Health Center for Public Health Preparedness
- 1999-2001 Director, Metropolitan Washington Public Health Assessment Center
- 1998-2001 Chair, Department of Epidemiology and Biostatistics, School of Public Health and Health Services, George Washington University
- 1993-1996 Director, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy of Sciences
- 1991-1992 Deputy Director, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy of Sciences
- 1985-1987 Associate Director, Institute for the Study of Smoking Behavior and Policy
- 1982-1983 Executive Officer, Health Science Policy Working Group, Division of Health Policy Research and Education, Harvard University

RESEARCH SUPPORT

The development of a monitoring and evaluation methodology for public health emergency preparedness, Emergency Preparedness, European Centre for Disease Prevention and Control (ECDC), €85,000, 1/2021 – 6/2018, Senior expert

Design, development and piloting of a curriculum and training material for Public Health, ECDC, €50,000, 1/2018 – 6/2018, Chair of Preparedness Training Committee

A Community Health Needs Assessment Evaluability Assessment, Robert Wood Johnson Foundation, \$650,000, 8/15/2015 – 12/31/2018; PI (2015-2016), investigator (2017-2018)

Translation, Dissemination, and Implementation of Evidenced-based Public Health Tools and Trainings for Public Health Emergency Preparedness, CDC via the Association of Schools and Programs for Public Health (ASPPH), \$1,080,516, 4/2016 – 8/2017, Director of the Improving the Practice of Critical Incident Analysis sub-project

Development of a Public Health Emergency Preparedness Competency Model for European Union Member States, ECDC, €50,000, 8/16 – 3/17, PI

Development of a Public Health Preparedness Logic Model for Assessing Preparedness for Cross-border Threats in the European Region, ECDC, €20,000, 10/15 – 3/16, PI

Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families, Agency for Healthcare Research and Quality, Contract HHSP233201500022I/HHSP23337002T (to MedStar Health Research Institute), \$156,659 (Georgetown component), 9/25/15 – 9/24/20; Co-investigator

Research support for MedStar Health's 2015 Community Health Needs Assessment process, MedStar Health Community Health Department, \$41,844, 9/1/2014 – 6/30/2015; PI

Electronic Data Methods Forum for Comparative Effectiveness Research (EDM Forum) Phase II AHRQ Cooperative Agreement 1 U18 HS022789-01 (AcademyHealth Subcontract for year 1, \$15,890), 9/30/2013 – 9/29/2016; Key Advisor and Collaborative Methods Project director

Developing a Peer-Assessment Model of Public Health Emergency Preparedness Capabilities Supplement to CDC Program project grant 1 P01 TP000307-01, \$400,000, 9/30/2012-9/29/2014; Supplement PI

Georgetown/FDA Center of Excellence in Regulatory Science and Innovation (CERSI) FDA Cooperative agreement 1 U01 FD 004319-01, \$2,999,328, 09/15/2011-09/14/2012; Steering committee member

Electronic Data Methods Forum for Comparative Effectiveness Research (EDM Forum) AHRQ Cooperative Agreement U13 HS 19564 (AcademyHealth Subcontract, \$70,547), 08/01/2010-07/31/2013; Consultant

Harvard School of Public Health Preparedness and Emergency Response Learning Center CDC Cooperative agreement 5 U90 TP 000147, \$4,464,914, 9/30/2010-9/29/2015; Co-investigator

Linking Assessment and Measurement to Performance in PHEP Systems (LAMPS) CDC Program project grant 1 P01 TP000307-01, 9/30/2008-9/29/14, \$8,743,000 (Georgetown component, \$400,000); co-PI, and PI of the Georgetown component

Harvard School of Public Health Center for Public Health Preparedness CDC Cooperative agreement U90/CCU124242-05, \$6,030,000, Director of evaluation core

Regionalization in Local Public Health Systems
Robert Wood Johnson Foundation grant, \$146,000; PI

DC Department of Health Emergency Room Surveillance System

DC DOH subcontract using CDC evaluation funds, \$72,000; PI

Evaluation of the DC Healthcare Emergency Healthcare Coalition
Washington Hospital Center subcontract using DHHS Office of the Assistant Secretary for Preparedness and Response (ASPR) funds, \$5,000,000, Director of evaluation team (\$150,000), PI

Medical Reserve Corps Evaluation Methods
National Association of County and City Health Officials (NACCHO) subcontract using CDC funds, \$165,000, PI

Massachusetts H1N1 After-Action Report
Massachusetts Department of Health subcontract using CDC funds, \$90,000, PI

Process Evaluation of Project Public Health Ready
NACCHO subcontract using CDC funds, \$200,000, PI

Web-Based Tool for Assessing and Improving Community Health Assessments
NY State DOH subcontract using CDC assessment funds, \$135,000, PI

Setting Priorities for Breast Cancer Prevention and Control in DC
NCI CISNET grant supplement, \$100,000, Supplement project director

Evaluation of AHRQ's Children's Health Activities
AHRQ contract, \$182,000, PI

TEACHING EXPERIENCE

Georgetown University School of Nursing and Health Studies

2016	Quantitative Methods for a Learning Health System (Executive Masters of Health Systems Administration program)
2015-present	Applied Epidemiology and Population Health (Doctor of Nursing Practice program)
2012-present	Health Policy Seminar and Internship, co-director
2010, -13, -14	Epidemiology and Population Health, co-director
2012	Health Care Quality and Performance Measurement (Quality I), co-director
2010-2012	Health Care Quality and Performance Measurement (Quality II), course director
2009-present	Health Services Research for Evidence-based Practice and Policy
2007-2010	Seminar in Population Health, co-director
2007	Crisis Management in College Health, co-director
2007	Research in Health Care, co-director

Georgetown University Medical Center

2021 Interdisciplinary Perspectives in Infectious Disease, COVID-19 module director
2017 Analytic Approaches for Regulatory Science, course co-director

Georgetown Public Policy Institute

2004-2006 Epidemiology for Public Policy, course director
2007-2008 The Epidemiology of Homeland Security: Pandemic Influenza, Bioterrorism, and other Public Health Crises, course director

Georgetown University Law Center

2013-present Global Health Law: An Intensive, Problem-based Exploration, co-director

Georgetown Department of Biostatistics, Bioinformatics and Biomathematics

2009 Research Synthesis and Meta-Analysis for Public Health, course director

Georgetown University, Department of Demography

1990, 1995 Statistics I and II, course director
1998 Research Methods II, lecturer

J.F. Kennedy School of Government and Harvard T.H. Chan School of Public Health

1979-1983 Data Analysis for Public Management, co-course director
1980-1981 Demographic Methods for Public Policy, course developer and director
1985-1987 Empirical Analysis for Public Policy, co-course director
1986-1987 Research Seminar in Demography, co-course director
1986-1987 Health Policy in the United States, co-course director
1986-1987 Research Seminars: Selected Topics in Health Policy, co-course director
1985-1987 Making Public Policies: Values, Democracy, and Public Service, discussion section leader and lecturer
1997-Present Research Synthesis and Meta-Analysis for Public Health, course director

King Abdulaziz University MPH Program

2014-2017 Systematic Reviews and Meta-Analysis for Evidence-based Medicine

Pardee RAND Graduate School

2003-2005 Research Synthesis and Meta-Analysis, course director, course director

Università di Bologna Dipartimento di Medicina e Sanità Pubblica

- 2009 Introduction to Systematic Reviews and Meta-Analysis
 2019 Public Health Emergency Preparedness: Managing responses to health emergencies in a global context

George Washington University School of Public Health and Health Services

- 2001 Advanced Epidemiological Methods, course director
 2001 HIV/AIDS by the Numbers, course developer and director
 2000-2001 Research Synthesis and Meta-Analysis for Public Health and Clinical Medicine, course developer and director
 1998-2001 Introduction to Epidemiology and Preventive Medicine, discussion section leader and lecturer
 1998-1999 Biostatistical Applications for Public Health, course director
 1997-2001 Measurement in Public Health and Health Services Research, course developer & director
 1996-1997 Epidemiological Risk Assessment for Public Health, course developer & director

Professional Education

- 2002-2004 American Public Health Association/American Statistical Association: Statistical Methods for State and Local Public Health
 2003-2004 Prove It! Health Data 101: New Hampshire Public Health Institute
 2004 Harkness Fellows in Health Policy: Case Study Methodology
 2004 U. S. General Accounting Office: Epidemiology Refresher
 2008 Maine Center for Public Health: Essential Tools for Essential Services
 2008 International Chinese Statistical Association: Meta-analysis and Systematic Reviews
 2009 RAND Statistics Group: Meta-analysis and Systematic Reviews
 2009 Introduction to Health Services Research Methods (webinar), AcademyHealth Methods Council
 2009 Methodological Challenges in Public Health Systems Research: Quasi-Experiments, AcademyHealth Public Health Systems Research Interest Group
 2009 Is Your Emergency Department Ready for H1N1?, Institute for Healthcare Improvement (webinar with Joseph T. Crane and Kirk B. Jensen)
 2012 What did we learn from the 2009 H1N1 pandemic about Public Health Emergency Preparedness systems? (webinar), Harvard School of Public Health Preparedness and Emergency Response Learning Center
<http://www.hsph.harvard.edu/policy-translation-leadership/emergency-preparedness-and-response/h-perlc-preparedness-and-emergency-response-learning-center/h-perlc-course-catalog/h-perlc-evaluate-and-improve-practice/>
 2013 Critical Incident Analysis to Enhance Public Health Emergency Preparedness, Public Health Preparedness Summit

- 2013 Overview of Comparative Effectiveness Research, Center for Health Outcomes, Policy and Evaluation Studies, Ohio State University (Module 19)
<http://cph.osu.edu/hopes/online-training-modules>
- 2014 & 2015 Using root cause analysis in a peer assessment format to learn from experiences with public health emergencies, Public Health Preparedness Summit, Atlanta
- 2014 Analytical Methods for Learning Health Systems, AcademyHealth/EDM Forum webinar <http://repository.academyhealth.org/webinars/15/>
- 2015 Introduction to meta-analysis and systematic review methods, Harvard Catalyst Biostatistics seminar series
- 2016 Population Health: What the Primary Care Provider Should Know, Excel Continuing Education for Humana, Coral Gables, Florida
- 2016 Introduction to Big Data in the Health Care Industry and Issues with Data Sharing. Big Data in Health Care: BIG risks, BIG rewards, Pennsylvania Bar Institute, Philadelphia
- 2016 Methods for learning from experience with actual public health emergencies, European Centre for Disease Prevention and Control (ECDC), Stockholm
- 2016 Core competencies for strengthened public health system preparedness. Workshop presented at the European Public Health Association Conference, Vienna
- 2017 Learning from the experience of public health system responses to emergencies. Emergency Preparedness Research, Evaluation, and Practice (EPREP) Program, Harvard T.H. Chan School of Public Health <https://youtu.be/KbNG5NIGmwE>.
- 2018 Public Health Emergency Preparedness Curriculum, European Centre for Disease Prevention and Control (ECDC) in conjunction with the Università di Bologna - Alma Mater Studiorum, Bologna
- 2019 How to Apply Realist Methods to Gain Insights in A Rapidly Changing Environment, Methods workshop, AcademyHealth Annual Research Meeting, Washington

Trainees and Mentoring

G. Elliott Cook, Center for Excellence in Regulatory Science and Innovation (CERSI) Scholar

Tamar Klaiman, Postdoctoral fellow in public health systems research and emergency preparedness, O'Neill Institute for National and Global Health Affairs, Georgetown University

Ying Zhang and Elizabeth Lee, PhD in Global Infectious Diseases, Georgetown University

Served on PhD and DrPH dissertation committees for students at GW SPHHS (2) and Business and Public Management (2); Kennedy School of Government (1), HSPH (3), and University of Texas Medical Branch, Galveston (1).

Faculty advisor, Georgetown Student Chapter, AcademyHealth (2011-present)

Faculty advisor, Georgetown Undergraduate Public Health Bowl team (2014)

PUBLICATIONS

Peer-reviewed journals

1. Barclay, G.W., Coale, A.J., Stoto, M.A., Trussell, T.J. A reassessment of the demography of traditional rural China. *Population Index*, 1975. 42:606-635.
2. Warner, R.M., Kenny, D.A., Stoto, M.A. A new round-robin analysis of variance for social interaction data. *Journal of Personality and Social Psychology*, 1979. 37:1742-1757.
3. Emerson, J.D., Stoto, M.A. Exploratory methods for choosing power transformations. *Journal of the American Statistical Association*, 1982. 77:103-108.
4. Ausubel, J.H., Stoto, M.A. How many will survive the next fifty years? *Journal of Policy Analysis and Management*, 1982. 118-119.
5. Stoto, M.A., DeStefano, P.M., Bacha, P.A. Pathology and probabilities (letter). *New England Journal of Medicine*, 1982. 306:290.
6. Stoto, M.A. The accuracy of population projections. *Journal of the American Statistical Association*, 1983. 78:13-20.
7. Ewbank, D.C., Gomez de Leon, J.C., Stoto, M.A. A reducible four-parameter system of model life tables. *Population Studies*, 1983. 37:105-127.
8. Arthur, W.B., Stoto, M.A. An analysis of indirect mortality estimation. *Population Studies*, 1983. 37:301-314.
9. Emerson, J.D., Stoto, M.A. Rejoinder to Exploratory methods for choosing power transformations. *Journal of the American Statistical Association*, 1984. 79:108-109.
10. Schermerhorn, J.M., Stoto, M.A. Measuring a redistricting plan's deviation from population equality and its effect on minorities: New Mexico's experiment with a 'votes-cast' formula. *University of California Davis Law Review*, 1984. 17:591-610.
11. Stoto, M.A., Ebert, J.D. The organizational structure of the NIH. *New England Journal of Medicine*, 1985. 312:1634-1637.
12. Ebert, J.D., Stoto, M.A. NIH budget growth (letter). *Science*, 1985. 228:1260.
13. Stoto, M.A. Proposed NIH institute of nursing (letter). *New England Journal of Medicine*, 1985. 313:1172.
14. Blumenthal, D., Gluck, M.E., Louis, K.S., Stoto, M.A., Wise, D. University-industry relationships in biotechnology: Implications for the university. *Science*, 1986. 232:1361-1366.
15. Gluck, M.E., Blumenthal, D., Stoto, M.A. University-industry relationships in the life sciences: Implications for students and post-doctoral fellows. *Research Policy*, 1987. 16:327-336.
16. Hatziandreu, E., Graham, J.D., Stoto, M.A. AIDS and biomedical research funding: A comparative analysis. *Reviews of Infectious Diseases*, 1988. 10:159-167.
17. Stoto, M.A. Statistics for an aging population: Dealing with uncertainty. *American Statistician*, 1988. 42:103-110.
18. Stoto, M.A., Blumenthal, D., Durch, J.S., Feldman, P.H. Federal funding for AIDS: Decision process and results in fiscal year 1986. *Reviews of Infectious Diseases*, 1988. 10:406-419.

19. Stoto, M.A. Estimating age-specific transition rates for population subgroups from successive surveys: Changes in adult rates of cigarette smoking. *Population Studies*, 1988. 42:227-239.
20. Louis, K.S., Blumenthal, D., Gluck, M.E., Stoto, M.A. Entrepreneurs in academe: An exploration of behaviors among life scientists. *Administrative Science Quarterly*, 1989. 34:110-131.
21. Stoto, M.A. Screening for HIV infections (letter). *New England Journal of Medicine*, 1989. 320: 461-462.
22. Stoto, M.A. Statistics for the AIDS Epidemic. *Chance*, 1989. 2:52.
23. Siegel, J.E., Graham, J.D., Stoto, M.A. Allocating resources among AIDS research strategies. *Policy Sciences*, 1990. 23:1-23.
24. Weinstein, M., Wood, J.W., Stoto, M.A., Greenfield, D.D. Components of age-specific fecundability. *Population Studies*, 1990. 44:447-468.
25. Stoto, M.A. Assessing the health objectives of the nation (letter). *Health Affairs*, 1990. 9:202-203.
26. Stoto, M.A., Durch, J.S. National health objectives for the year 2000: The demographic impact of health promotion and disease prevention. *American Journal of Public Health*, 1991. 81:1456-1465.
27. Stoto, M.A. Estimation of small area population denominators for public health studies (letter). *American Journal of Public Health*, 1992. 82:1174.
28. Stoto, M.A. Public health assessment for the 1990s. *Annual Review of Public Health*, 1992. 13:59-78.
29. Rigotti, N.A., Stoto, M.A., Bierer, M.F., Rosen, A., Schelling, T.C. Retail stores' compliance with a city no-smoking law. *American Journal of Public Health*, 1993. 83:227-232.
30. Stoto, M.A., Durch, J.S. Forecasting survival, health, and disability: Report of a workshop. *Population and Development Review*, 1993. 19:557-582.
31. Rigotti, N.A., Stoto, M.A., Schelling, T.C. Do businesses comply with a no-smoking law? Assessing the self-enforcement approach. *Preventive Medicine*, 1994. 23:223-229.
32. Stoto, M.A. The term "Years of healthy life" (letter). *American Journal of Public Health*, 1994. 84:866-867.
33. Rosen, P., Stoto, M.A., Harley, J. The use of the Heimlich maneuver in near drowning: Institute of Medicine report. *The Journal of Emergency Medicine*, 1995. 13:397-405.
34. Leveton, L.B., Sox, H.C., Stoto, M.A. HIV and the blood supply: An analysis of crisis decision-making (Executive summary of an IOM report). *Transfusion*, 1996. 36:919-927.
35. Stoto, M.A., ed. Sharing responsibility for the public's health: A new perspective from the Institute of Medicine. *Journal of Public Health Management and Practice*, 1997. 3:22-34.
36. Green, L.W., Stoto, M.A. Linking research and public health practice: A vision for health promotion and disease prevention research. *American Journal of Preventive Medicine*, 1997. 13:S5-8.
37. Stoto, M.A., Evans, G., Bostrom, A. Vaccine risk communication. *American Journal of Preventive Medicine*, 1998. 14:237-239.
38. Stoto, M.A. Healthy People 2010 (letter). *Public Health Reports*, 1998. 113:287-288.

39. Stoto, M.A. Meta-analysis of epidemiological data: The case of calcium intake and blood pressure (invited commentary). *American Journal of Epidemiology*, 1998. 148:229-231.
40. McCormick, M.C., Davidson, E., Stoto, M.A. Preventing perinatal transmission of HIV in the United States. Committee on perinatal transmission of HIV. *Obstetrics and Gynecology*, 1999. 94:795-8.
41. Stoto, M.A. Sharing responsibility for the public's health. *Public Health Reports*, 1999. 114: 231-235.
42. McCormick, M.C., Stoto, M.A. HIV screening (letter). *Pediatrics*, 2000. 105:1375.
43. Stoto, M.A. Saving statistical lives: Contributions of statistics to public health. *American Journal of Preventive Medicine*, 2000. 19:S47-49.
44. Kriebel, D., Tickner, J., Epstein, P., Lemons, J., Levins, R., Loechler, E.L., Quinn, M., Rudel, R., Schettler, T., Stoto, M.A. The precautionary principle in environmental science. *Environmental Health Perspectives*, 2001. 109:871-876.
45. Stoto, M.A. Preventing perinatal transmission of HIV: Target programs, not people. *New Directions in Evaluation*, 2001. 90: 41-53.
46. Stoto, M.A., Hermalin, A., Li, R., Martin, L., Wallace, R., Weed, D. Advocacy in epidemiology and demography. *Annals of the New York Academy of Sciences*, 2001. 954:76-87.
47. Weinstein, M., Hermalin, A., Stoto, M.A., Ewbank, D., Evans, V.J., Haaga, J., Ibrahim, M., Madans, J. Greater collaboration across the disciplines: Challenges and opportunities. *Annals of the New York Academy of Sciences*, 2001. 954:311-321.
48. Stoto, M.A. The precautionary principle and emerging biological risks: Lessons from swine flu and HIV in blood products. *Public Health Reports*, 2002. 117:546-552.
49. Bozzette, S.A., Boer, R., Bhatnagar, V., Brower, J.L., Keeler, E.B., Morton, S.C., Stoto, M.A. A model for a smallpox vaccination policy. *New England Journal of Medicine*, 2003. 348:416-425.
50. McKeown, R.E., Weed, D.L., Kahn, J.P., Stoto, M.A. American College of Epidemiology ethics guidelines: Foundations and dissemination. *Science and Engineering Ethics* 2003. 9:207-214.
51. Stoto, M.A., Schonlau, M., Mariano, L.T. Syndromic surveillance: Is it worth the effort? *Chance*, 2004. 17:19-24.
52. Lurie, N., Wasserman, J., Stoto, M.A., Myers, S., Namkung, P., Fielding, J., Burciaga-Valdez, R. Local variation in public health preparedness: Lessons from California. *Health Affairs Online*, 2004 Jan-Jun; Suppl Web Exclusives:W4-341-53.
53. Blanchard, J.C., Haywood, Y., Stein, B.D., Tanielian, T.L., Stoto, M.A., Lurie, N. In their own words: Lessons learned from those exposed to anthrax. *American Journal of Public Health*, 2005. 95(3):489-495.
54. Asch, S.M., Stoto, M.A., Mendes, M., Burciaga-Valdez, R., Gallagher, M.E., Halverson, P., Lurie, N. A review of instruments assessing public health preparedness. *Public Health Reports*, 2005. 120:532-542.
55. Lemeshow, A., Blum, R.E., Berlin, J.A., Stoto, M.A., Colditz, G.A. Searching one or two databases was insufficient for meta-analysis of observational studies. *Journal of Clinical Epidemiology*, 2005. 58:867-873.

56. Bhatnagar, V., Stoto, M.A., Morton, S.C., Boer, R., Bozzette, S.A. Transmission patterns of smallpox: Systematic review of natural outbreaks in Europe and North America since World War II. *BMC Public Health*, 2006. 6:126-138.
57. Dorn, B.C., Savoia, E., Testa, M.A., Stoto, M.A., Marcus, L.J. Development of a survey instrument to measure connectivity to evaluate national public health preparedness and response performance. *Public Health Reports*, 2007. 122:329-338.
58. Stoto, M.A. Public health surveillance in the 21st century: Achieving population health goals while protecting individuals' privacy and confidentiality. *Georgetown Law Journal*, 2008. 96(2):703-719.
59. Biddinger, P., Cadigan, R.O., Auerbach, B., Burstein, J., Savoia, E., Stoto, M., Koh, H. Using tabletop exercises to identify systems-level changes for improving preparedness. *Public Health Reports*, 2008. 123(1): 96-101.
60. Savoia, E., Stoto, M.A., Biddinger, P.D., Campbell, P., Viswanath, K.V., Koh, H.K. Risk-communication capability for public health emergencies varies by community diversity. *BMC Research Notes*, 2008. 1:6.
61. Koh, H.K., Elqura, L.J., Judge, C.M., Stoto, M.A. Regionalization of local public health systems in the era of preparedness. *Annual Review of Public Health*, 2008. 29:205–218.
62. Stoto, M.A. Regionalization in local public health systems: Variation in rationale, implementation, and impact on public health preparedness. *Public Health Reports*, 2008. 123(4): 461-473.
63. Stoto, M.A., Morse, L. Regionalization in Local Public Health Systems: Public Health Preparedness in the Washington Metropolitan Area. *Public Health Reports*, 2008. 123(4): 441-449.
64. Koh, H.K., Shei, A.C., Judge, C.M., Stoto, M.A., Elqura, L.J., Cox, H., Nick, G.A., Burstein, J.L., Condon, S.K. Emergency preparedness as a catalyst for regionalizing local public health: the Massachusetts case study. *Public Health Reports Online*, 2008. 123(4).
65. Stoto, M.A., Straus, S.G., Bohn, C., Irani, P. A web-based tool for assessing and improving the usefulness of community health assessments. *Journal of Public Health Management and Practice*, 2008. 15(1):10-17.
66. Savoia, E., Testa, M.A., Biddinger, P.D., Koh, H., Cadigan, R.O., Campbell, P., Stoto, M.A. Assessing public health capabilities during emergency preparedness tabletop exercises: Reliability and validity of a measurement tool. *Public Health Reports* 2009. 124:139-148.
67. Esposito, D., Wahl, P., Daniel, G., Stoto, M.A., Erder, M.H., Croghan, T.W. Results of a retrospective claims database analysis of differences in antidepressant treatment persistence associated with Escitalopram and other selective serotonin reuptake inhibitors in the United States. *Clinical Therapeutics*, 2009. 31:644-656.
68. Savoia, E., Biddinger, P.D., Fox, P., Levin, D.E., Stone, L., Stoto, M.A. The impact of tabletop exercises on participants' knowledge of and confidence in legal authorities for infectious disease emergencies. *Disaster Medicine and Public Health Preparedness*, 2009. 3(2): 1-6.
69. Savoia, E., Massin-Short, S., Rodday, A., Sahagian, L., Higdon, M.A., Stoto, M.A. A literature review of public health systems research in emergency preparedness. *American Journal of Preventive Medicine*, 2009. 37(2): 150-156.

70. Savoia, E., Rodday, A., Stoto, M.A. Public health emergency preparedness at the local level: Results of a national survey. *Health Services Research*, 2009. 44(5): 1909-1924.
71. Mandelblatt, J.S., Cronin, K.A., Bailey, S., Berry, D.A., de Koning, H.J., Draisma, G., Huang, H., Lee, S.J., Munsell, M., Plevritis, S. K., Ravdin, P., Schechter, C.B., Sigal, B., Stoto, M.A., Stout, N.K., van Ravesteyn, N.T., Venier, J., Zelen, M., Feuer, E.J. Effects of mammography screening under different screening schedules: Model estimates of potential benefits and harms. *Annals of Internal Medicine*, 2009. 151:738-747.
72. Griffin, B.A. Jain, A.K., Davies-Cole, J., Glymph, C., Lum, G., Kidane, G., Washington, S.C., Stoto, M.A. Early detection of influenza outbreaks using the DC Department of Health's syndromic surveillance system. *BMC Public Health* 2009, 9:483.
73. Stoto, M.A., Dempsey, J.X., Baer, A., Cassa, C., Gibson, P.J., Buehler, J.W. Expert meeting on privacy and confidentiality, and other legal and ethical issues in syndromic surveillance: Report from an International Society for Disease Surveillance consultation. *Advances in Disease Surveillance*, 2009, 7:2.
74. Schultz, D.J., Seid, M., Dougherty, D., Stoto, M.A., McClure, P.J. The Agency for Healthcare Research and Quality's children's health research portfolio. *Maternal and Child Health Journal*, 2010. 14(1):1-8.
75. Savoia, E., Biddinger, P.D., Burstein, J., Stoto, M.A. Inter-agency communication and operations capabilities during a hospital functional exercise: Reliability and validity of a measurement tool. *Prehospital and Disaster Medicine*, 2010, 25:52-58.
76. May, L., Griffin, B.A., Bauers, N.M., Jain, A., Mitchum, M., Sikka, N., Carim, M., Stoto, M.A. Emergency department chief complaint and diagnosis data to detect influenza-like illness with an electronic medical record. *Western Journal of Emergency Medicine*, 2010, 11:1-9.
77. Berry, S.H., Bogart L.M., Pham C., Liu K., Nyberg L., Stoto, M.A., Suttorp, M., Clemens, J.Q. Development, Validation and testing of an epidemiologic case definition for interstitial cystitis/painful bladder syndrome. *The Journal of Urology*, 2010, 183:1842-1852.
78. Croghan, T.W., Esposito, D., Daniel, G., Wahl, P., Stoto, M.A., Erder, M.H. Using medical records to supplement claims-based analysis of comparative effectiveness of antidepressants. *Pharmacoepidemiology and Drug Safety*, 2010 (published on-line July 1).
79. Savoia, E., Massin-Short, S., Higdon, M.A., Tallon, L., Matechi, E., Stoto, M.A. A toolkit to assess Medical Reserve Corps Units' performance. *Disaster Medicine and Public Health Preparedness*, 2010, 4: 213-219.
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81. van Ravesteyn, N.T., Schechter, C.B., Near, A.M., Heijnsdijk, E.A.M., Stoto, M.A., Draisma, G., de Koning, H.J., Mandelblatt, J.S. Race-specific impact of mammography screening and adjuvant treatment on breast cancer mortality rates. *Cancer Epidemiology, Biomarkers & Prevention* 2011, 20:112-122.
82. Klaiman, T., Kraemer, J.D., Stoto, M.A. Variability in school closure decisions in response to 2009 H1N1. *BMC Public Health* 2011, 11:73.

83. Zhang Y., May L., Stoto, M. A. Evaluating Syndromic Surveillance Systems at Institutions of Higher Education (IHEs) During the 2009 H1N1 Influenza Pandemic. *BMC Public Health* 2011, 11:591.
84. Berry, S.H., Elliott, M., Suttorp, M., Bogart L.M., Stoto, M.A., Eggers, P., Nyberg L., Clemens, J.Q. Prevalence of symptoms of interstitial cystitis/painful bladder syndrome among adult females in the U.S. *Journal of Urology*, 2011 186:540-544.
85. Esposito, D., Wahl, P., Daniel, G., Stoto, M.A., Croghan, T.W. Health care costs associated with Escitalopram and alternative SSRIs. *American Journal of Pharmacy Benefits*, 2011, 3:e93-e101.
86. Near, A.M., Mandelblatt, J.S., Schechter, C.B., Stoto, M.A., Reducing Breast Cancer Mortality in Black Women in the District of Columbia. *Epidemiology Research International* 2012, Article ID 241340, doi:10.1155/2012/241340
87. Stoto, M. A. The Effectiveness of U.S. Public Health Surveillance Systems for Situational Awareness during the 2009 H1N1 Pandemic: A Retrospective Analysis. *PLoS ONE* 2012 7(8): e40984. doi:10.1371/journal.pone.0040984
88. Stoto, M. A., Cox, H, Higdon, M.A., Dunnell, K, Goldmann, D. Using Learning Collaboratives to Improve Public Health Emergency Preparedness Systems. *Frontiers in Public Health Systems and Services Research*, 2013, Vol. 2: No. 2, Article 3.
89. Zhang Y, Lopez-Gatell H, Alpuche-Aranda CM, Stoto MA. Did Advances in Global Surveillance and Notification Systems Make a Difference in the 2009 H1N1 Pandemic?—A Retrospective Analysis. *PLoS ONE* 2013 8(4): e59893. doi:10.1371/journal.pone.0059893.
90. Klaiman, T., O'Connell, K., Stoto, M.A., Local Health Department Public Vaccination Clinic Successes During 2009 pH1N1. *Journal of Public Health Management and Practice*. 2013, 19(4), E20–E26.
91. Stoto, M. A., Nelson, C., Higdon, M. A., Kraemer, J. D. Singleton, C.M. Learning About After Action Reporting from the 2009 H1N1 Pandemic: A Workshop Summary. *Journal of Public Health Management and Practice*, 2013;19(5), 420-427.
92. Stoto, M. A., Nelson, C., Higdon, M. A., Kraemer, J. D. Singleton, C.M. Lessons about the State and Local Public Health System Response to the 2009 H1N1 Pandemic: A Workshop Summary. *Journal of Public Health Management and Practice*, 2013; 19(5), 428-435.
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 - Repeated at Public Health Systems Research Interest Group meeting, June, 2014.
60. Piltch-Loeb, R. N., Nelson C., Savoia E., Kraemer, J.D., Stoto M.A., Using root cause analysis in public health emergency preparedness to improve lessons learned, Public Health Systems Research Interest Group meeting, AcademyHealth, San Diego, June, 2014.
61. Stoto M.A., Piltch-Loeb, R. N., Kraemer, J.D., Nelson C., Savoia E., Using peer assessment to assess and improve health system emergency response, Third Global Symposium on Health Systems Research, Cape Town, South Africa, October, 2014.
62. Cook, G.E., Fernandez, S.J., Wilhelm, E.E., Stoto M.A., The Impact of FDA Drug Safety Communications on Zolpidem Prescribing in a Large Health System, Concordium 2016, Crystal City, Virginia, September, 2016.
63. Moloney, R., Messner, D., Stoto, M.A., Tunis, S., A Decision Maker's Framework for Assessing Real World Evidence, International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Boston, May, 2017.
 - Repeated at AcademyHealth, New Orleans, June, 2017.

64. Stoto, M.A., Savoia E., Nelson C., Piltch-Loeb, R. N., Guicciardi, S., Takacs, C., Varela Santos, C. Ciotti, M., Development of a Public Health Preparedness Competency Model for European Union Member States, European Public Health Conference, Stockholm, November, 2017.
65. Stoto, M.A., Measuring population health and using data to improve the population's health, International Conference on Health Policy Statistics, Charleston, S.C., January, 2018.
66. Stoto M.A., Davis, M.V., Atkins, A., Best Practices in Population Health Measurement for Community Health Improvement, AcademyHealth, Seattle, June, 2018.
67. Davis, M.V., Mikolowsky, K., Guptill, M., Atkins, A., Stoto M.A., Characteristics of Innovative Community Health Improvement Processes, American Public Health Association annual meeting, San Diego, November, 2018.
68. Patel, S., Powell, S., Patel, M., Ahmad, A., Stoto, M.A., Wang, H., Tornatore, C. In Light of Social Determinants of Health: Early Validation of Multiple Sclerosis Measures in an African American Patient Population, Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRMS) Forum, Dallas, February, 2019.
69. Darling, N., Gasior, J., Harmsen, M., LeBlanc, N., Stoto, M.A., Zipfel, C.M. A century of influenza: is the world prepared for the next pandemic? Undergraduate Conference in Public Health, Johns Hopkins University, April, 2019.
70. Darling, N., Gasior, J., Harmsen, M., LeBlanc, N., Stoto, M.A., Zipfel, C.M. A century of influenza: is the world prepared for the next pandemic? Undergraduate Research Conference, Georgetown University, April, 2019.
71. Guicciardi, S., Fantini, M.P., Savoia, E., Stoto, M.A., Nelson, C., Piltch-Loeb, R., Riley, P., Ciotti, M., Takacs, J., Wurz, A., Pommier, J., The Bologna Curriculum Toolkit: development of a European Public Health Emergency Preparedness Curriculum. Pitch presentation, European Public Health Conference, Marseille, France, November 2019.
72. Huffstetler, A.N., Fraiman, J., Brownlee, S., Stoto, M.A., Lin, K.L. An Estimate of Harms Associated with Overuse of Screening Colonoscopy in the United States, American Public Health Association Annual Meeting, Philadelphia, November, 2019.
73. Huffstetler, A.N., Fraiman, J., Brownlee, S., Stoto, M.A., Lin, K.L. An Estimate of Harms Associated with Overuse of Screening Colonoscopy in the United States, Family Medicine Education Consortium Annual Meeting, Lancaster, PA, November, 2019.
74. Stoto M.A., Piltch-Loeb, R. N., Wolfe, R., Albrandt, R., Melnick, A., After Action Review of the 2019 Measles outbreak in Clark County, Washington. 16th World Congress on Public Health, Rome (virtual), October, 2020.

National Academies of Sciences, Engineering, and Medicine reports (with contributions from M. A. Stoto, other than those listed above)

1. *Confronting AIDS: Directions for Public Health, Health Care, and Research* (1986).
2. *AIDS: Sexual Behavior and Intravenous Drug Use* (1989).
3. *Scientific Review of the CDC Selected Cancers Study* (1990).
4. *Adverse Effects of Pertussis and Rubella Vaccines* (1991).
5. *Disability in America: Toward a National Agenda for Prevention* (1991).

6. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* (1993).
7. *Clinical Applications of Mifepristone (RU486) and Other Antiprogestins: Assessing the Science and Recommending a Research Agenda* (1993).
8. *The Social Impact of AIDS in the United States* (1993).
9. *Overcoming Barriers to Immunization: A Workshop Summary* (1994).
10. *Protecting and Improving Quality of Care for Children Under Health Care Reform: Workshop Highlights* (1994).
11. *Benefits and Systems of Care for Maternal and Child Health Under Health Care Reform: Workshop Highlights* (1994).
12. *Fetal Research and Applications: A Conference Summary* (1994).
13. *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (1994).
14. *Research Strategies for Assessing Adverse Events Associated with Vaccines* (1994).
15. *Government and Industry Collaboration in AIDS Drug Development: Summary of a Workshop* (1994).
16. *Environmental Medicine and the Medical School Curriculum* (1994).
17. *Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research* (1994).
18. *AIDS and Behavior: An Integrated Approach* (1994).
19. *The Best Intentions: Unintended Pregnancy and the Well-being of Children and Families* (1995).
20. *The Children's Vaccine Initiative: Continuing Activities. A Summary of Two Workshops* (1995).
21. *Changing Demographics of the HIV Epidemic: Implications for Clinical Research* (1995).
22. *Preventing HIV Transmission: The Role of Sterile Needles and Bleach* (1995).
23. *Environmental Medicine: Integrating a Missing Element into Medical Education* (1995).
24. *Assessing the Social and Behavioral Science Base for HIV/AIDS Prevention and Intervention* (1995).
25. *Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention, and Treatment* (1996).
26. *Evaluation of the Department of Defense Persian Gulf Comprehensive Clinical Evaluation Program* (1996).
27. *Medical Research in Cold War Alaska: Radioactive Iodine-131 Studies of Thyroid Function and Cold Adaptation in Alaska Natives and Military Personnel* (1996).
28. *Paying Attention to Children in a Changing Health Care System* (1996).
29. *Characterizing Exposure of Veterans to Agent Orange and Other Herbicides Used in Vietnam: Scientific Considerations Regarding A Request for Proposals* (1997).
30. *Detecting and Responding to Adverse Events Following Vaccination: Summary of a Workshop* (1997).
31. *Research To Identify Risks For Adverse Events Following Vaccination: Biological Mechanisms and Possible Means of Prevention: Summary of a Workshop* (1997).
32. *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule* (1999).
33. *Gulf War and Health (Volume 1): Depleted Uranium, Pyridostigmine Bromide, Sarin, Vaccines* (2000).

34. *Beyond Six Billion: Forecasting the World's Population* (2000).
35. *Health and Behavior: The Interplay of Biological, Behavioral, and Societal Influences* (2001).
36. *Vaccines for the 21st Century: A Tool for Decision-making* (2001).
37. *Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism* (2001).
38. *Improving Birth Outcomes: Meeting the Challenge in the Developing World* (2003).
39. *Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act* (2003).
40. *The Year 2000 Census: Counting Under Adversity* (2004).
41. *Estimating the Contributions of Lifestyle-Related Factors to Preventable Death: A Workshop Summary* (2005).
42. *Valuing Health for Regulatory Cost Effectiveness Analysis* (2006).
43. *Improving the Presumptive Disability Decision-Making Process for Veterans* (2007).
44. *Knowing What Works in Health Care: A Roadmap for the Nation* (2008).
45. *Assessment of the Role of Intermittent Preventive Treatment for Malaria in Infants* (2008).
46. *Contaminated Water Supplies at Camp Lejeune: Assessing Potential Health Effects* (2009).
47. *Strengthening Benefit-Cost Analysis for Early Childhood Interventions* (2009).
48. *Vital Statistics: Summary of a Workshop* (2009).
49. *Explaining Divergent Levels of Longevity in High-Income Countries* (2011).
50. *Accounting for Health and Health Care* (2011).
51. *Measuring the Risks and Causes of Premature Death* (2015)
52. *The Air Force Health Study Assets Research Program* (2015)
53. *A Framework for Assessing Mortality and Morbidity After Large-Scale Disasters* (2020)

RAND reports (with contributions from M. A. Stoto, other than those listed above)

1. Davis, L.M., Blanchard, J.C. Are local health responders ready for biological and chemical terrorism? IP-221-OSD, 2002.
2. Homeland security: Physical protection of critical infrastructure. PM-1373-OSD, 2002.
3. Brower, J., Chalk, P. The global threat of new and reemerging infectious diseases: Reconciling U.S. national security and public health policy. MR-1602-RC, 2003.
4. Eiseman, E., Fossum, D. The challenges of creating a global health resource tracking system. MG-317-BMG, 2005.
5. Shugarman, L.R., et al. Assessing the adequacy of extant exercises for addressing local and state readiness for public health emergencies. TR-249-DHHS, 2005.
6. Jones, S.G., Treverton, G.F. Early warning watchlist. PM-1906, October 2005.
7. Davis, L.M., et al. Combating terrorism: How prepared are state and local response organizations? MG-309-OSD, 2006.
8. Cecchine, G., Moore, M. Infectious disease and national security: Strategic information needs. DRR-3870-OSD, 2006.

Teaching cases

1. Kennedy, D., Stoto, M.A. Social Security and the Fertility Rate. Case 724.0, John F. Kennedy School of Government, 1987.
2. Brunetta, L., Stoto, M.A. AIDS and the Insurance Industry. Case 730.0, John F. Kennedy School of Government, 1987.
3. Stoto, M.A. Case study: 2011 E. coli outbreak. Prepared for the European Centre for Disease Prevention and Control (ECDC), 2018.

Selected presentations

1. Stoto, M.A. What makes a good performance measure? Maternal and Child Health Information Resource Center Dataspeak, 1999.
2. Stoto, M.A. Performance and outcome measurement I: Epidemiological and statistical concepts. Association of Maternal and Child Health Programs, Washington, 1999.
3. Stoto, M.A. Evaluation for Maryland tobacco settlement fund activities. Maryland Public Health Officials Association, July 2000.
4. Stoto, M.A. Risk assessment and management under uncertainty: Lessons from swine flu and HIV in blood products. Invited presentation to the IOM Immunization Safety Review Committee, Washington, January 2001.
5. Stoto, M.A. Overview of epidemiological studies examining MMR, IBD, and autism. Invited presentation to the IOM Immunization Safety Review Committee, Washington, 2001.
6. Stoto, M.A. The IOM's recommendation regarding HIV surveillance. CDC Consultation on Estimating Incidence of HIV Infection in the United States, Atlanta, 2001.
7. Petitti, D., Stoto, M.A. Meta-analysis for policy decisions. Invited Presentation at the Workshop and Symposium on Challenges for Meta-Analysis of Medical and Health Policy Data, Mathematical Sciences Research Institute, Berkeley, May 2002.
8. Stoto, M.A. Statistical issues in interactive web-based public health data dissemination systems. CDC Assessment Initiative/NAPHSIS Leadership Institute Conference, Atlanta GA, February, 2003. Also presented at:
 - Annual meeting of the National Association for Public Health Statistics and Information Systems, New York, June 2003
 - As a webcast by the National Association of Health Data Organizations, September 2003
9. Stoto, M.A. A model for a smallpox vaccination policy, invited presentation at the Gordon Research Conference on Chemical and Biological Terrorism Defense, Santa Barbara, California, March 2003.
10. Stoto, M.A., Schonlau, M., Mariano, L.T. Syndromic surveillance: Is it worth the effort? Invited presentation at the Conference on Statistical Issues in Counterterrorism, Washington Statistical Society/American Statistical Association, Washington, May 2003. Also presented at:
 - American Association for the Advancement of Science Annual Meeting, Seattle, February 2004
 - Eastern North American Region/International Biometric Society Annual Meeting, Pittsburgh, March 2004

- Western North American Region/International Biometric Society, Albuquerque, June 2004
 - National Association of County and City Health Officials, St. Paul MN, July 2004
11. Stoto, M.A. The Ranch Hand (Air Force Health) Study. Invited presentation at the U.S. Medicine Institute forum on The Value of Long-Term Studies, Washington, March 2004.
 12. Stoto, M.A., Myers, S.S., Straus, S. Developing and implementing a web-based tool to determine and enhance the usefulness of community health assessments in New York State. Community Health Assessment: Current Issues and Future Directions Conference, Atlanta, September 2004.
 - Also presented as a Webcast by CDC Assessment Initiative, November 2004
 13. Stoto, M.A., Jain, A., Diamond, A., Davies-Cole, J.O., Adade, A., Washington, S.C., Kidane, G., Glymph, C. Time series analysis of the District of Columbia's syndromic surveillance data. National Syndromic Surveillance Conference, Boston, November 2004.
 14. Stoto, M.A. Statistical Methods for State and Local Public Health Data, APHA/ASA Continuing Education Institute, November 6, 2004.
 - I. Community health assessment
 - II. Biosurveillance, privacy and confidentiality
 15. Stoto, M.A., Jain, A., Fricker, R.A., Davies-Cole, J.O., Washington, S.C., Kidane, G., Glymph, C., Lum, G., Adade, A. Multivariate methods for aberration detection: A simulation study using the District of Columbia's syndromic surveillance data. National Syndromic Surveillance Conference, Boston, November 2004. Also presented at:
 - American Public Health Association Annual Meeting, Washington, November 2004
 - CDC Statistical Methods Symposium Annual Meeting, Bethesda, MD, March 2005
 - Academy Health Public Health Systems Annual Research Meeting, June 2005
 16. Stoto, M.A. Discussion: What have we learned; where do we go from here? Invited presentation to the IOM Workshop on Estimating the Contribution of Lifestyle-Related Factors to Preventable Death, Washington, December 2004.
 17. Stoto, M.A., Aledort, J.E. Points for policy and decision makers. Workshop on Mathematical Modeling for 21st Century Public Health Practice, Palm Springs, March 2005.
 18. Stoto, M.A. The Air Force Health Study. Invited presentation to the IOM Committee on the Disposition of the Air Force Health Study, Washington, April 2005.
 19. Stoto, M.A. Syndromic surveillance: Is it worth the effort, and if so, for what? Public Health Surveillance Working Group, Harvard Department of Biostatistics, Boston, March 2005.
 - Also presented at DC Department of Health Bureau of Epidemiology and Health Risk Assessment Grand Rounds, August 2005
 20. Stoto, M.A. Achieving Healthy People 2010 objectives: The importance of data. Healthy DC Residents: A Status Report on Healthy People 2010 Goals. DC Department of Health, Washington, April 2005.
 21. Stoto, M.A. The "precautionary principle" and blood products. Interdisciplinary Forum on Emerging Pathogens, Baxter BioScience, Chicago, May 2005.

22. Stoto, M.A. The role of systematic reviews (possibly) including meta-analysis in drug, vaccine, and food safety monitoring. Harvard/Schering-Plough Workshop, Boston, June 2005.
23. Stoto, M.A., et al. Learning from experience: The public health response to West Nile Virus, SARS, Monkeypox, and hepatitis A outbreaks in the United States. Public Health Systems Research Meeting, AcademyHealth, Boston, June 2005.
24. Stoto, M.A., Normand, S.L., Colditz, G., Flaig, R., Howe, E., Wolf, R. Bayesian meta-analysis of the dose-response relationship of alcohol consumption and health outcomes. International Conference on Health Policy Research, Boston, October 2005.
25. Stoto, M.A. Statistical analysis of the identifiability of pharmaceutical data under HIPAA. Human Research Protection Programs Conference, Boston, December 2005.
26. Stoto, M.A. Evaluation of syndromic surveillance systems. American Statistical Association Section on Statistics in Defense and National Security, Santa Monica, February 2006. Also presented at:
 - National Center for Health Statistics, Hyattsville MD, May 2006
 - 2006 Congress of Epidemiology, Seattle, June 2006
 - Centre for Epidemiology and Research, New South Wales Department of Health, Sydney, Australia, June 2006
 - Centre for MEGA Epidemiology, University of Melbourne, Melbourne, Australia, July 2006
27. Stoto, M.A. Standards of evidence. Board on Health Care Services, Institute of Medicine, Washington, April 2006.
28. Stoto, M.A. Assessing the usefulness of community health assessments. The Impact of Community Assessments in New York State conference, Syracuse, September 2006.
29. Stoto, M.A. Syndromic surveillance in public health practice. Institute of Medicine Forum on Microbial Threats, Washington, December 2006.
30. Stoto, M.A. The identifiability of pharmaceutical data: A test of the statistical alternative to HIPAA's safe harbor. Privacy in Statistical Databases 2006. Italian Statistical Institute, Rome, December 2006.
31. Stoto, M.A., Griffin, B.A., Jain, A., et al. Evaluation of DC Department of Health's syndromic surveillance system: Fine-tuning statistical detection algorithms. International Biometrics Society, Eastern North America Region (ENAR) meeting, Atlanta, March 2007.
32. Stoto, M.A. The evidence base for regionalization. AcademyHealth Public Health Services Research Cyber Seminar, May 2007.
33. Stoto, M.A., Straus, S.G., Bohn, C., Irani, P. A web-based tool for assessing and improving the usefulness of community health assessments. Public Health Assessment Initiative Conference, Atlanta, August 2007.
34. Stoto, M.A. Regionalization in local public health systems. California Health Policy Forum, Sacramento, September 2007.
35. Stoto, M.A. Syndromic Surveillance in Public Health Practice. U.S. Medicine Institute, Washington, October 2007.
36. Stoto, M.A. Meta-Analysis for Drug Safety Assessment. International Conference on Health Policy Statistics, Philadelphia, January 2008.

37. Stoto, M.A., Biddinger, P.D., Savoia, E., Cadigan, R., Koh, H. Using exercises to evaluate public health emergency preparedness. Public Health Preparedness Summit, Atlanta, February 2008.
38. Stoto, M.A. Legal and ethical issues in syndromic surveillance: Implications for the DOD longitudinal health record. National Forum on the Future of the Defense Health Information System, Washington, March 2008.
39. Stoto, M.A. Infectious disease surveillance & national/health security. Committee on National Statistics Workshop Vital Data for National Needs, Washington, April 2008.
40. Stoto M.A. Meta-analysis for drug safety. Schering-Plough Research Institute, Kenilworth NJ, January 2009.
41. Stoto M.A. Regionalization: rationale, implementation, and impact on public health preparedness. Harvard School of Public Health Center for Public Health Preparedness, Boston, February 2009.
42. Savoia, E., Rodday, A., Stoto, M.A. Public Health Emergency Preparedness at the Local Level: Results of a National Survey. AcademyHealth Annual Research Meeting, Chicago, June 2009.
43. Higdon, M.A., Short, S., Tallon, L., Savoia, E., Rodday, A.M., Stoto, M.A. Assessing Attitudes and Barriers Experienced by Medical Reserve Corps (MRC) Volunteers Assisting Local Public Health Departments. AcademyHealth Annual Research Meeting, Chicago, June 2009.
44. Savoia, E., Massin-Short, S.B., Rodday, A.M., Aaron, L.A., Higdon, M.A., Stoto, M.A. Public Health Systems Research in Emergency Preparedness. A Review of the Literature. AcademyHealth Annual Research Meeting, Chicago, June 2009.
45. Higdon, M.A., Klaiman, T., Shin, P., Stoto, M.A. Evaluation of the DC Emergency Healthcare Coalition (DCEHC). Presented at National Healthcare Preparedness, Evaluation, and Improvement Conference, Crystal City VA, July 2009.
46. Stoto M.A. Did military service cause my illness? New approaches to assessing causality for veterans' compensation policy. American College of Epidemiology, Silver Spring, MD, September 2009.
47. Stoto M.A. State and local health rankings. Public Health Services Research Interest Group Policy Breakfast, AcademyHealth National Health Policy Conference, Washington, February 2010.
48. Stoto M.A. Learning from 2009 H1N1 about Public Health Surveillance. Public Health Preparedness Summit, Atlanta, February 2010. Repeated at:
 - National Emergency Management Summit, Washington, March 2010.
49. Klaiman, T., Kraemer, J., Stoto M.A., School Closures in Response to A/H1N1: Issues for Decision-Makers. Public Health Preparedness Summit, Atlanta, February 2010.
 - Repeated at National Emergency Management Summit, Washington, March 2010.
50. Stoto M.A. A Learning Collaborative to Improve the Effectiveness of MRC Flu Clinic Deployments. Public Health Preparedness Summit, Atlanta, February 2010.
51. Savoia, E., Higdon, M.A., Short, S., Tallon, L., Stoto, M.A. A Toolkit to Assess the Effectiveness of MRC Volunteers Assisting Local Public Health Departments. Public Health Preparedness Summit, Atlanta, February 2010.

52. Stoto M.A. "Real-Time" After Action Report for the Massachusetts Public Health System Response to 2009 H1N1. Keeneland Conference, Lexington, KY, April 2010.
53. Stoto M.A. What Has 2009 H1N1 Taught Us About the Performance of Public Health Disease Surveillance Systems?, Harvard School of Public Health Center for Public Health Preparedness, Boston, June 2010.
 - Also presented at CDC, January, 2011
54. Stoto M.A. Learning from H1N1 about Public Health Systems. Methods workshop, AcademyHealth Annual Research Meeting, Boston, June 2010.
55. Stoto M.A. Conducting PHSSR Research in Public Health Agency Settings, Practice-based Research Workshop, National Association of County and City Health Officials Annual Meeting, Memphis, July 2010.
56. Viswanath K, Stoto M.A. Opportunities and Challenges in Developing Public Health Emergency Preparedness (PHEP) Measures and Metrics: Exemplars from the Harvard PERRC, CDC, January 2011
57. Higdon, MA, Stoto M.A. Using Learning Collaboratives to Improve Public Health Emergency Preparedness. Public Health Preparedness Summit, Atlanta, February 2011.
58. Stoto M.A. What have we learned from 2009 H1N1 about public health emergency response capabilities? Public Health Preparedness Summit, Atlanta, February 2011.
59. Stoto M.A., Zhang, Y., Did Advances in Global Surveillance and Notification Systems Make a Difference in the 2009 H1N1 Pandemic? Building the Evidence Base for Public Health Emergency Preparedness, VHA Comprehensive Emergency Management Program Evaluation and Research Conference, Alexandria VA, May 2011.
60. Stoto M.A. A Decade after 9/11, Are we Better Prepared for Public Health Emergencies? A Population Health Perspective, Jefferson School of Population Health Policy Forum, Philadelphia, September 2011. <http://jdc.jefferson.edu/hpforum/55/>
61. Stoto M.A. Disposition of the Air Force Health Study, Air Force Health Study Data and Specimens Committee, Institute of Medicine, March 2012.
62. Stoto M.A. Study Designs for the Safety Evaluation of Childhood Immunization Schedules, Committee on Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule, Institute of Medicine, May 2012.
63. Stoto M.A. A Public Health Emergency Preparedness Critical Incident Registry, AcademyHealth Public Health Systems Research Interest Group methods panel, Orlando, June 2012.
64. Stoto M.A. Model Design of the National Health Security Preparedness Index, State Public Health Preparedness Directors Conference, Philadelphia, September, 2012.
65. Stoto M.A. Research Contributions to the National Health Security Preparedness Index, Dynamics of Preparedness Conference, Pittsburgh, October, 2012.
66. Stoto M.A. Early Warning and Characterization of Infectious Disease Outbreaks (panel discussion), AAAS Center for Science, Technology, and Security Policy, Washington, November, 2012.
67. Stoto M.A. Measuring and Assessing Public Health Preparedness, Emergency Public Health and Disasters Conference, Torrance, CA, May, 2013.
68. Stoto M.A. A New Paradigm for Population Health and the Use of Population-Based Health and Health Care Measures, AHRQ Learning Network for Chartered Value Exchanges Webinar, September, 2013.

69. Stoto M.A. Learning from singular events in public health emergency preparedness: The role of peer assessment and a Critical Incidents Registry, CDC, Atlanta, September 2013.
70. Stoto M.A. Their First Real Test: Did Advanced Biosurveillance Systems Help Detect and Provide Situational Awareness for the 2009 H1N1 Pandemic? Medicine 2.0, London, September, 2013.
71. Stoto M.A. History Doesn't Have to Repeat Itself: Using Lessons Learned From Disasters (panel discussion). Public Health Preparedness Summit, Atlanta, February 2014.
72. Stoto M.A. New Avian Influenzas in East Asia: Global Health Security and Policy (panel discussion). Georgetown University, Washington, April, 2014.
73. Stoto M.A. Population Health and System Integration (panel discussion). Moving beyond Compliance Current Practices and Future Considerations for Health Systems Georgetown University, Washington, April, 2014.
74. Stoto M.A. Population Health: What It Is, What It Is Not, and Where It Is Heading (panel discussion). Creating an Integrated Child Health System Using a Population Health Perspective. Grantmakers In Health, Washington, April, 2014.
75. Stoto M.A. & Piltch-Loeb, R.N. Using Root Cause Analysis and Peer Assessment to Learn from Experiences with Public Health Emergencies. ASPPH/PERLC Webinar, August, 2014. <http://www.aspph.org/event/preparedness-and-emergency-response-learning-center-webinar-using-peer-assessment-and-root-cause-analysis-to-assess-and-improve-health-system-emergency-response/>
76. Stoto M.A. Assessing and measuring public health emergency preparedness (keynote address), European Centre for Disease Prevention and Control, Stockholm, Sweden, October, 2014.
77. Stoto M.A. Population Health in the Affordable Care Act Era: Implications Healthcare Providers, Big Data & Healthcare Analytics Forum, Boston, November, 2014.
78. Stoto, M.A. A tale of two cities: Ebola in Dallas & New York, and the lessons for public health emergency preparedness. AcademyHealth National Health Policy Conference, Washington, February, 2015.
79. Stoto, M.A. Learning from Critical Incidents. In West Virginia Water Crisis—A Look Back: Moving Forward to Building an Evidence-Based Water Security Program for Public Health (workshop). Public Health Preparedness Summit, Atlanta, April, 2015.
80. Stoto, M.A. Population Health Measurement: Applying Performance Measurement Concepts in Population Health Settings. AcademyHealth Population Health Community of Practice (POPCOP) webinar, April, 2015.
81. Stoto, M.A. Discussant: Best of Annual Research Meeting session. AcademyHealth Annual Research Meeting, Minneapolis, June, 2015.
82. Stoto, M.A. Options and Issues for Sustainable Expansion of Scope and Content of the National Library of Medicine's Public Health Information Access Project. AcademyHealth Annual Research Meeting, Minneapolis, June, 2015.
83. Stoto, M.A. A Logic Model for Public Health Emergency Preparedness, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden, December, 2015.

84. Stoto, M.A. Organizational learning from actual public health emergencies: Development and analysis of a Critical Incident Registry, Addressing Knowledge Gaps in Infectious Disease Emergency Preparedness in Europe meeting, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden, February, 2016.
85. Stoto, M.A. North American Lessons from Critical Incident Reviews, Effective Use of Critical Incident Reviews to Support Emergency Preparedness meeting, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden, February, 2016.
86. Stoto, M.A. Can we really learn from our mistakes (and successes) to improve public health preparedness? Staff seminar, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden, February, 2016.
87. Stoto, M.A. Using a logic model and standard capabilities to assess Member States' preparedness and design competency-based training programs to fill the gaps, Public Health Capacity and Communication unit staff meeting, European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden, February, 2016.
88. Stoto, M.A. The Road Less Traveled: Applying Performance Measurement Concepts in Population Health. Population Health Forum, Boston, May, 2016.
89. Stoto, M.A. Core competencies for strengthened public health system preparedness. European Public Health Association Conference, Vienna, Austria, November, 2016.
90. Stoto, M.A. From SARS to H1N1 to Ebola and beyond: learning from experience with institutional responses to public health emergencies. European Public Health Association Conference, Vienna, Austria, November, 2016. *European Journal of Public Health*, Volume 26, Issue suppl_1, 1 November 2016.
91. Stoto, M.A. Learning from the experience of public health system responses to emergencies. Sichuan Center for Disease Control, Chengdu, China, December, 2016.
92. Stoto, M.A. Why do we need small area estimates? Innovations in Monitoring Population Health, AcademyHealth, Washington, January, 2017.
93. Stoto, M.A. International Perspectives on review of public health emergency events, Expert Meeting on Good Practice in the Review of Public Health Emergency Events, European Centre for Disease Prevention and Control (ECDC), Berlin, Germany, March, 2017.
94. Stoto, M.A., Klaiman, T., Davis, M.V., Community Health Needs Assessments: An environment scan of the context, expectations, current practices, and opportunities for improvement. Public Health Systems Research Interest Group meeting, AcademyHealth, New Orleans, June, 2017.
95. Stoto, M.A., Meta-analysis for Drug Safety Assessment: Promises and Pitfalls, Biostatistics, Bioinformatics, and Biomathematics seminar, Georgetown University, October, 2017.
96. Stoto, M.A., Learning from the experience of public health system responses to emergencies. Global Consultation on After Action Reviews and Simulation Exercise under the IHR Monitoring and Evaluation Framework, WHO, Geneva, February 2018.
97. Stoto, M.A., Davis, M.V., Atkins, A., Measurement for Community Health Improvement Processes. Association for Community Health Improvement, Atlanta, March, 2018.

98. Stoto, M.A., International perspectives on assessing public health system emergency preparedness. Think Tank on Local Jurisdiction Measures, National Health Security Preparedness Index, Washington, March, 2018.
99. Stoto, M.A., The Great Influenza Pandemic of 1918: Will we be ready for the next pandemic? Last Chance Lecture, Georgetown University, May, 2018.
100. Stoto, M.A., Presentation to the Committee on Evidence-Based Practices for Public Health Emergency Preparedness and Response, National Academies of Science, Engineering, and Medicine, Washington, April, 2018.
101. Jarris, Y.S., Lin, K., Cammack, A., Stoto, M.A., Integrated Training for Population Health & Prevention in Medical Education. Society of Teachers of Family Medicine Spring Conference, Washington, May, 2018.
102. Stoto, M.A., Bouey, J., Song, T., Luo, H., Boyce, M., Katz, R. At the Frontier of the Global Battle Against Emerging Infections: Managing Avian Influenza in Guangdong, China. U.S.-China Research Group on Global Health and Migration, Georgetown University, Washington, May, 2018.
103. Stoto, M.A., The Great Influenza Pandemic of 1918: When will it recur, and will the world be ready? Last chance lecture, Georgetown University, Washington, May, 2018.
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EXHIBIT 2

Literature supporting the public health approach to pandemic control focused on reducing community spread:

The public health approach to pandemic control focused on reducing community spread is supported by a vast literature, only a very small fraction of which is cited here.

Specific areas of emphasis include:

- Theory (Trump), empirical analyses (Fong, Ryu, Xiao, Bueno), historical analyses (Markel, Wilder-Smith, Webster, Morens, Rainey), and modeling (Anderson) going back a century (Stoto)
- Analyses of COVID-19
 - Epidemiologic characteristics, e.g. timing of infection, routes of transmission, etc. (NASEM, ECDC)
 - Empirical analyses of COVID-19 control interventions in the U.S. (Castillo, Auger, Sen, Courtemanche) and abroad (Cowling, Cowling & Lim, Han, Flaxman, Hao, Liu, Pan, Lai)
- Scientific consensus (Fineberg, Alwan, Leung, Christakis)
- Broadly consistent with recommendations by a variety of organizations
 - White House/CDC Opening up America guidelines
 - AEI, CAP, NGA, AAMC, Hopkins, Leopoldina

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CERTIFICATE OF SERVICE

Case Name: **Tandon, Ritesh, et al. v. Gavin
Newsom, et al.**

Case No. **5:20-cv-07108**

I hereby certify that on November 18, 2020, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

**DECLARATION OF DR. MICHAEL A. STOTO IN SUPPORT OF STATE
DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY
INJUNCTION**

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct and that this declaration was executed on November 18, 2020, at Los Angeles, California.

Beth L. Gratz
Declarant

Signature