Date: **September 23, 2020**
Topic: **Senate Committee on Health, Education, Labor, & Pensions Hearing: "COVID-19: An Update on the Federal Response"**

On September 23, WSW Staff monitored the Senate Committee on Health, Education, Labor, & Pensions hearing entitled "COVID-19: An Update on the Federal Response." The hearing examined the development and distribution of a potential vaccine and methods of controlling the virus before a vaccine is available. A link to the hearing page and live stream is here.

WITNESS LIST, OPENING STATEMENT HIGHLIGHTS

Full Testimony for All Witness

Dr. Anthony Fauci

Director, National Institute of Allergy and Infectious Diseases ("NIAID"), National Institutes of Health ("NIH")

- Some people have symptoms persist past viral infection for weeks or months, called "long-haulers," and others under MRI have shown inflammation of the heart despite being asymptomatic, demonstrating there is still much we do not understand about the virus.
- Remdesivir has been shown to diminish the time to recovery in individuals who are hospitalized, and dexamethasone has been shown to significantly reduce the 28-day mortality, with other treatment options still being tested and optimism for the results.
- Vaccine trials are being harmonized, so information from one could be helpful to another.
- Cautiously optimistic we can have a safe and effective vaccine by the end of this year.

Dr. Robert Redfield

Director, United States Centers for Disease Control and Prevention ("CDC")

- CDC has conducted rapid investigations in disease outbreaks grounded in science and data to identify communities most at risk for increased spread.
- Since July 24th, we've seen nearly a 50% reduction in daily cases and 32% reduction in deaths with a declining mortality rate, though daily case counts are still around 40,000 and deaths around 800.

- Positive case load has shifted to younger Americans who are less likely to suffer severe symptoms or death but can still spread it to others.
- Steps to limit spread: wear a mask, maintain social distance, practice routine hand washing, limit exposure to crowds, stay home when you feel sick, and get the flu vaccine, which has a higher production level this year due to expected increased demand.
- We've developed a diagnostic test that detects Influenza-A, Influenza-B, and COVID from a single testing specimen.

Admiral Brett Giroir, MD

Assistant Secretary for Health, United States Department of Health and Human Services ("HHS")

- Recommended health practices combined with smart testing is the formula to slow the spread, flatten the curve, and save lives.
- The number of people hospitalized is down 54%, and the number in intensive care is down over 60%.
- Federal surge testing sites were deployed in 20 different cities to limit spread in densely populated areas, especially among potentially asymptomatic young adults.
- The federal government signed a contract with Abbott for over 150 million rapid tests, which only cost $5.
- Millions of tests are expected to ship in the coming weeks to schools to protect teachers and students as they return to class.

Dr. Stephen Hahn

Commissioner of Food and Drugs, United States Food and Drug Administration ("FDA")

- We make real-time decisions on a previously unknown virus based on available data, which sometimes need to be reversed as more information is learned.
- When a vaccine sponsor applies based on their trials, the sponsor will make the decision to apply for an Emergency Use Authorization ("EUA") or normal approval.
- We have provided clear guidance as to what is expected and needed if a sponsor intends to apply for an EUA clearance, and there will be a transparent process, including a public comment period.
- Data from at least one, well-designed phase 3 clinical trial that demonstrates the safety and efficacy of the vaccine will be required for EUA, and we will not permit or yield to pressure from anyone to approve a vaccine.

COMMITTEE MEMBER OPENING STATEMENT HIGHLIGHTS

Chairman Lamar Alexander (R-TN)

Full Opening Statement

- The government, in partnership with private industry, is manufacturing vaccines in parallel, meaning tens of millions of doses are being produced while trials are ongoing to ensure distribution is ready at the time of approval.

- The hope is to have 300 million vaccines ready to deploy by mid-2021, though HHS employee has said if all goes well, it's possible 700 million will be ready by April.
- Only FDA scientists, not politicians or political appointees, will be able to determine when a vaccine is ready based on sufficient data, submission of an application for approval by the manufacturer, and ensuing approval.
- New testing methodology production is in process and creating success stories, with many rapid and cheap tests becoming available and even more expected by December.
- The foresight of previous presidential administrations and Congresses has increased our capability to respond. For example, 3 new facilities funded in 2012 are currently working on production of four of the vaccines, which wouldn't be possible without that foresight.

Ranking Member Patty Murray (D-WA)

- The Trump Administration ignored a federal pandemic playbook in the early stages of the crisis and did not make early testing widely available even as we were forced into measures such as closing schools.
- Cases and deaths are alarmingly high, testing and contact tracing are inadequate, minority communities face disproportional impacts from the virus, and the flu season approaches, which will exacerbate issues.
- The American people are counting on the FDA to rely solely on science, though they are losing confidence due to the Trump Administration's pressure on the FDA to allow an EUA for treatments such as convalescent plasma.
- Hundreds of millions of dollars were pulled out of CDC funding for a "feel good ad campaign" run by a political appointee who accused the CDC of being part of the "deep state" conspiracy.
- Over 30 Democrats introduced the Science and Transparency Over Politics Act, which will create a taskforce to investigate political interference in public health agencies.

COMMITTEE QUESTIONS & RESPONSES

Chairman Lamar Alexander (R-TN) – Who makes decisions about safety and efficacy at the FDA?

- Dr. Hahn: Career scientists at the FDA do it. I am briefed on major medical product decisions and overruling a decision is rare.

Once FDA approves a vaccine, will you be willing to take that vaccine for you and your family?

- Dr. Hahn: Absolutely, yes. I have complete faith in the FDA scientists and would encourage my family to take it.

Is the administration cutting corners in safety and efficacy?

- Dr. Fauci: Not at all.

So, we're risking taxpayer money, but not safety or efficacy?

- Dr. Fauci: Correct.

Is the smart thing for colleges to send students home when an outbreak occurs?

- Dr. Fauci: No, they should quarantine at school separate from the rest of the student body, but do not send them home where they can spread the virus in their home community.

Is your position that you want to shut down the entire country to stop the spread of the virus?

- Dr. Fauci: No. We do not need to shut down if we carefully follow the guidelines for opening the country, which I believe we can do safely.

Was it political to ask states to prepare to distribute a vaccine in November?

- Dr. Fauci: It was not political. We want to be ready to distribute a vaccine as soon as one is approved.

How many Americans have been infected by COVID-19?

- Dr. Redfield: CDC is in the process of a study measuring serology across the country. Preliminary results show that more than 90% of the population remains susceptible to the country, though it varies depending on the state.

Based on preliminary indications, as many as 90% of Americans still have not had the virus?

- Dr. Redfield: Correct.

Will the vaccine for COVID likely be more like the polio vaccine or flu vaccine, where with the polio vaccine you'll almost never get polio, but the flu vaccine is sometimes ineffective?

- Dr. Fauci: We don't know that yet, but that is something we will learn. Polio is a highly effective vaccine that gives long-lasting protection, but we don't know this information about the COVID vaccine.

Will the vaccine be free when it is distributed and administered?

- Dr. Fauci: We have been assured the American public will not have to pay for the vaccine.

When discussing vaccines, most of the six are anticipating the need for two shots four weeks apart, then the vaccine will be effective two weeks after that. Is that correct?

- Dr. Fauci: It varies from candidate to candidate. For example, Moderna and Pfizer are two shots, a prime and a boost, with the boost at 28 days or 21 days depending on the vaccine. However, the J&J vaccine is a single shot.

Ranking Member Patty Murray (D-WA) –

Why did the CDC put out guidance that contradicted widespread views of the medical community and was not drafted by CDC scientists? How is it that guidance published on the website was not drafted by CDC scientists?

- Dr. Redfield: The original guidance had full engagement of the CDC but included cooperation with the Coronavirus Task Force and Assistant Secretary. The intention was not to limit testing of asymptomatic individuals. It became apparent that guidelines were not interpreted as intended, which is why we needed to put out a clarification that asymptomatic transmission occurs.

On what scientific basis did members of the Task Force take a different position?

- Admiral Giroir: The original guidance published by the CDC did not recommend against testing asymptomatic individuals and was widely misinterpreted and misrepresented.

If I want the best guidance on the latest science, can I trust CDC's website?

- Dr. Redfield: Yes. The CDC is committed to data, science, and giving the public the best information we have. If the data and science changes, we will update our website to reflect the new information.

Senator Enzi (R-WY) – Some vaccines need to be stored at extremely cold temperatures but some doctor offices don't have the specialized freezers needed to store vaccines. How can we ensure sufficient freezer capacity to store vaccines and distribution isn't just to major cities?

- Dr. Redfield: We are working to ensure distribution in an equitable and fair way across the nation, and each jurisdiction will have to address these issues. This is not something we routinely do, but we will build off our annual routine vaccine administration.
- Dr. Hahn: FDA's role in this is to ensure that the controls around manufacturing and storage are followed. If a vaccine is approved that requires cold storage, we will provide technical assistance and work with the CDC to ensure that happens.

Do you anticipate once the FDA approves a vaccine, CDC will have to work with states to develop new distribution plans, or will the work states be doing in advance suffice?

- Dr. Redfield: This is why the playbook we put out last week is so important. We want to see plans executed by October 16th to ensure best practices can be shared across the states.

Senator Casey (D-PA) – As a way to demonstrate faith and integrity in the approval process, will you commit to receiving the vaccine in public view when one is available?

- Dr. Fauci: Yes, if a vaccine is shown and proven to be safe and effective, I would take it and recommend to my family they do so as well.
- Admiral Giroir: I would have no hesitancy to take the vaccine and recommend the same to my family. However, people should have personal discussions with their physicians and providers.
- Dr. Redfield: Yes, and I would recommend my wife, children, and grandchildren do as well.

How many jurisdictions' immunization information systems meet the standards set forth in the playbook today?

- Dr. Redfield: I'll have to get back to you, but we are building on the systems we regularly use in these jurisdictions for annual vaccine distributions, though there will be new points of service where that technology does not currently exist.

Senator Burr (R-NC) – Have we made up new protocols for the review of a COVID vaccine, or are we following existing protocols that have been a gold standard?

- Dr. Hahn: The FDA does represent the gold standard. The definition of an EUA is different than an approval. Regarding COVID, we look at the primary data, not a paper or press release, and analyze the data and draw our own conclusions, as we did with things like Remdesivir.

Would it be appropriate to say that the phase 3 clinical trials are the most expansive and diverse trials we've seen in recent memory because they are global trials?

- Dr. Hahn: Yes, they are among the most diverse and expansive trials. We were clear in June that we needed to see a floor of 50% efficacy and 30,000 or more participants. These have been very robust trials.

Does the Data Safety Monitoring Board ("DSMB") need to check the data during the approval process?

- Dr. Hahn: Yes. They have set check-ins to examine the data. If there are safety issues, they could stop the trial. They could also do a futility analysis, which stops a trial because it is improbable to succeed.

Are you confident in the process at the FDA that will review the application of clinical data from a platform you helped create at NIAID? How can two people live together and one test positive, but the other does not?

- Dr. Fauci: Although a virus is highly transmissible, some people have a natural resistance, so we see all the time individuals exposed to someone with an infection who do not get it. Yes, I am confident in the FDA's ability.

Senator Baldwin (D-WI) – Why did your office demand that meat-packing plant safety recommendations be watered down?

- Dr. Redfield: I wouldn't characterize it the way you did. Field teams that were on the plant investigation shared a report they did in the field but stressed that the CDC is not a regulatory authority. This was a recommendation and not a regulatory requirement.

Did your office have any contact with the plant, the Department of Agriculture, or the White House concerning this memo before it was edited?

- Dr. Redfield: No, not at that time. There are multi-agency discussions on a variety of issues that intersect, but we wanted to just stress that we are not a regulatory agency and just making recommendations.

Will you change the meat-packing guidance in light of the death toll and harm to remove "if feasible?"

- Dr. Redfield: I appreciate your comments senator.

Senator Paul (R-KY) – Do you have any second thoughts about your mitigation recommendations given the evidence our death rate is worse than places like Sweden?

- Dr. Fauci: Because Sweden is so different from us, we must compare Sweden's death rate to comparable countries, which they do worse than. As new data comes, you make different recommendations, but I do not regret my prior statements and recommendations.

How can we praise Governor Cuomo and New York given they had the worst death rate in the world?

- Dr. Fauci: You misconstrue that, which you've done repeatedly in the past. They were hit badly and made mistakes. But right now, they are looking at the guidelines the task force put together, which has led to a significantly lower positivity rate.

Have they developed herd immunity?

- Dr. Fauci: I challenge that. You are not listening to what the Director of the CDC said. In New York, they are at 22% herd immunity. You are likely alone in believing that is sufficient.

Senator Murphy (D-CT) – What are the long-term effects of someone with myocarditis? Are these effects observable in asymptomatic patients?

- Dr. Fauci: The study in non-athletes were individuals who recovered from COVID-19. By doing MRIs, they found 60-70% had inflammatory disease of the heart but were relatively asymptomatic, so we should monitor their situation, since it could clear up with no issues or result in scarring, which creates later issues.

Where in the August guidance does it tell people they should get a test or proactively see a doctor if asymptomatic but came in close contact with someone with the virus?

- Dr. Redfield: I take the position that more tests will lead to fewer cases. When I issued the clarification on August 27, we were emphasizing symptomatic illness and vulnerable populations. From a public health perspective, we were seeing people coming to get a test then going to work.

Do you tell people in this guidance that they should go see a doctor?

- Dr. Redfield: When we clarified the day after, I clearly put the clarification about the emphasis but mentioned asymptomatic people should get a test when recommended by a medical official. I thought the August 27th clarification statement would carry the ball over the goal line, but it didn't. There was no guidance, though, to decrease testing, but rather linked testing to drive a public health action.

Senator Collins (R-ME) – Could you explain why the changes at HHS are taking place and whether they could affect new medical countermeasures for COVID-19?

- Admiral Giroir: As I understand it and believe it, this was an administrative decision by the Secretary because he wanted to make sure any rules proposed had review and scientific integrity. You have my commitment to provide the best public health advice to the Secretary, but I don't think this change makes a difference.

Are we making any progress in ensuring that the active pharmaceutical ingredients ("APIs") that may be critical in therapeutics for treating people or the ultimate vaccine are manufactured in the U.S. and not in a foreign country?

- Dr. Hahn: We have seen situations where the lack of redundancy in the supply chain and domestic production have caused issues. Ensuring we have this redundancy is important. With respect to medications and PPE, the White House has worked with FEMA and HHS

to ensure we build up our PPE. The FDA's role in this will be to create a pathway to ensure domestic production.

Senator Warren (D-MA) – Yes or no, do you hold direct financial investments in any of the companies developing a vaccine?

- All: No.

If the FDA officials making these decisions had financial conflicts, would that increase or decrease American confidence in a vaccine?

- Dr. Hahn: I'm not aware of anyone with a financial conflict, so it would be difficult to speculate on that. If anyone is aware of a conflict, I would personally like to know.

President Trump's "vaccine czar" owns stock in Glaxo-Smith-Kline and a company working with Moderna. Can you explain why Dr. Slaoui should get to play by a different set of rules?

- Dr. Hahn: I don't have knowledge of this, so I can't comment. However, I can assure you there is a line between the FDA and them, so they will not be able to influence us.

If hypothetically they do exist, should he resign?

- Dr. Hahn: In this hypothetical situation, I can't prejudge because I don't have the facts, though I am concerned how it might affect public perception.

Senator Cassidy (R-LA) – Is there going to be a requirement that these vaccine records are put in the state's immunization registry?

- Dr. Giroir: Yes.

What about federal facilities such as DoD? Will they be required?

- Dr. Giroir: I'm not sure.

Is there going to be compensation for the provider administering the immunization given no patient cost is required?

- Dr. Giroir: We are still working on details but understand providers will experience costs associated with administering the vaccine. The administration is committed to ensuring no patient has out-of-pocket expenses for the vaccine.

For those who are higher risk, will antibody serologies be required after vaccination to ensure efficacy, and do we have enough serology tests to conduct this?

- Dr. Hahn: For the first several trials when they mature, we will likely not have bridging data on the development of antibodies, so I'm not sure whether we will have a requirement there.

Senator Kaine (D-VA) – What about the September 18th website guidance was incorrect that required it to be taken down?

- Dr. Redfield: This was a first-draft document. It's looking at the balance of the component that aerosolized transmission plays compared to droplets.

Is "people who are infected, but do not show symptoms can spread the virus to others" inaccurate?

- Dr. Redfield: No.

Is "there is growing evidence that droplets and airborne particles can remain suspended in the air and breathed in by others and can travel distances beyond 6 feet" accurate?

- Dr. Redfield: There is evidence of that.

Then why was it removed?

- Dr. Redfield: It wasn't removed. The document that went through cleared channels was put up. The document that was posted was not technically reviewed, which is why it was taken down.

Senator Murkowski (R-AK) – Can you further clarify the purposes of the states' plan on guidance with allocation and defining critical populations?

- Dr. Redfield: The answers in terms of process have not been completed. It is important that once completed it is communicated effectively. The Advisory Committee on Immunization Practices ("ACIP") will give the recommendation once they know which vaccine the recommendation is for.

Can you confirm it's the CDC that is responsible for determining the allocation?

- Dr. Redfield: The allocation will be made by Operation Warp Speed ("OWS"). ACIP will make a recommendation on prioritization of who should be vaccinated, though.

What is the administration's plan to ensure states have the support they need for the requirements on reporting for the new vaccine?

- Dr. Redfield: That will be an important part of the plan each state proposes. There is a plan in Operation Warp Speed to augment capabilities where they are lacking. Reporting will be important to monitor for safety purposes and to ensure an equitable distribution.

Senator Hassan (D-NH) – Will the guidance require that the FDA's Vaccines and Related Biological Products Committee hold meetings, review trial data, and release their findings to the public for each vaccine?

- Dr. Hahn: We are committed to having meetings. They will be transparent, and for each vaccine.

Will the findings be public before the FDA offers approval of any of the vaccines?

- Dr. Hahn: The vote, the discussion, and recommendations will be public.

Will CDC's ACIP meet publicly, review data, and issue public recommendations for each vaccine before it enters the market?

- Dr. Redfield: It is important ACIP conducts its meetings in public barring private information concerns, but I anticipate it will be a public process. ACIP will make the recommendations for each product after the FDA makes an EUA or other determination, and ACIP will deliberate in public how it should be used in the U.S.

Do you believe the existing FDA and CDC advisory committees should conduct an independent review of safety and efficacy for each vaccine?

- Dr. Fauci: Yes, I agree with Dr. Hahn that this process does occur independently, and what they do will be public. In addition to a qualified committee, the entire scientific community will analyze the data because it is public.

Senator Romney (R-UT) – When do you believe you'll receive the first application?

- Dr. Hahn: I don't know when, and I cannot speak to confidential commercial information we have. In the case of one, they have exceeded where they expected to be.

Have any applications been received by the DSMB?

- Dr. Hahn: I do not know the answer to that.

If an application were received tomorrow, how long is the process in the FDA between receiving an application and when a determination is made?

- Dr. Hahn: Typically, the process can take weeks, sometimes months depending on the complexity of the data and dataset. We haven't made a commitment to a timeline yet because of this. We do feel the urgency, though, and take our responsibility to protect American lives seriously. We will not delay nor cut corners.

If the FDA were to approve an application November 1st, what proportion of the population would be vaccinated by the end of the year?

- Dr. Fauci: Numbers reported are the totality of all the companies. In November, maybe 50 million doses will be available and 100 million by December. It will not be a large proportion of the population by December. It will be according to the ACIP's recommended priority, likely health care providers and those with underlying conditions.

Senator Smith (D-MN) – Do you still believe masks are the best tool we have to stem the spread of the virus?

- Dr. Redfield: I have total confidence in the importance of vaccines, which will be what get us back to a normal way of life. What I was saying about vaccines is that it's possible half of the people may not develop an immune response, so I wanted to emphasize the importance of masks. We should have 700 million doses by late March or April, and my late 2nd quarter timeline was in reference to the time to actually administer the doses to the entire American public.

Did you get political pushback for saying what you said?

- Dr. Redfield: I stand by presenting the data and science as I see it and will continue to do so and will leave my comment there.

Will we still need COVID-19 testing and contact tracing after a vaccine is available to the public?

- Dr. Fauci: Absolutely, because a vaccine, depending on the degree of efficacy and the number of people who decide to get the vaccine, will still lead to some vulnerable people within the population. A vaccine will control the infection but will not eradicate it.

Senator Braun (R-IN) – Was it your recommendation and that of the Task Force for President Trump to issue the guidelines to shut the country down for 45 days?

- Dr. Fauci: I wouldn't use the term "shut the country down," but yes.

Did you and Dr. Birx explain at a March 31st briefing that initial projections showed that the death toll could exceed 2 million if we did not act?

- Dr. Fauci: Yes, based on a model.

Was the goal of the national mitigation effort to bring the death toll down from over 2 million to the range of 100,000-240,00?

- Dr. Fauci: Yes, with an exception. As I mentioned at a press conference, I said the model would say it would go down, but that we could likely do much better because if we had uniformly accepted the recommendations across the country, we could have had even fewer deaths. Some states were successful, others were not. The model said this range was likely, but I said we should strive to be below it if we followed recommendations.

Do you think the actions of the American people, President Trump, and the Task Force hit the range you were hoping for not withstanding your prior qualification?

- Dr. Fauci: Yes, we did show that the mitigation did save a lot of lives.

Would you agree the Task Force and the President took the outbreak very seriously from the beginning, saving lives?

- Dr. Fauci: Yes, for example shutting down travel from China and Europe, though the latter did affect areas like New York.

If we want to ask the American people to continue to take the virus seriously, do you think the media, politicians, and scientists need to do a better job reminding them of the "blue mountain" (the un-flattened curve) warning and how their actions will continue to save lives?

- Dr. Fauci: Yes, and virtually every time I am given the opportunity to talk about this, I continue to stress the four or five things that if we all did it and consistently, we would prevent the surges we've seen, lower those surges, and reduce case count. We need uniformity across the country.

Senator Jones (D-AL) – Is there a "deep state" in the FDA that is trying to do anything other than quickly get solutions to the American public, as the President says?

- Dr. Hahn: I have 100% confidence in the outstanding employees of the FDA, and I have complete confidence in their decisions and actions to date.

That confidence is based on following the science not political pressure, as expected. Is that reflected in the FDA's process?

- Dr. Hahn: Yes, our career scientists for vaccines will follow the science, data, and our rigorous standards.

What is the public to do when public officials give a different message regarding things such as masks, social distancing, and crowds than those on this panel?

- Dr. Redfield: We must just keep stressing that we want ALL Americans to embrace wearing a mask, be smart about social distancing and crowds, wash their hands, and have

confidence in the flu vaccine. These simple decisions would bring the outbreak under better control if everyone did this, not just 75% of Americans. I have been disappointed and offended when people at HHS have alluded to a "deep state" at CDC.

Senator Rosen (D-NV) – Could you explain the importance of concurrent planning of flu shots and COVID response?

- Dr. Fauci: I'd like to emphasize the importance of getting a flu shot. The logistics of getting a flu shot and COVID vaccine together, though, I can't comment on just yet. In Southern Hemisphere countries, we've seen how taking the preventative measures for COVID we've discussed today will likely have a positive impact on this season's flu outbreak.

I've seen research on the Bradykinin peptide and when it's active that it causes inflammation as a reason that COVID-19 causes a flu-like build-up in the lungs. Are you aware of and discussing this research, and will it or its treatments be helpful?

- Dr. Fauci: There are several interventions that can be used to limit inflammation. There are a variety of trials going on to look at blocking types of inflammation and are being actively pursued. However, there is limited evidence so far other than dexamethasone that by blocking inflammation you can decrease mortality.

Senator Loeffler (R-GA) – What more can we do on the federal level to shine the light on mental health and ensure we aren't turning a blind eye to the issue?

- Dr. Redfield: A recent survey showed 30% of Americans are experiencing anxiety and depression due to COVID. The public is best served by getting students back to in-person learning because schools are a common mental health resource for children. This is a medical condition and needs to be treated as such.

COMMITTEE MEMBER ATTENDANCE

Present	Democrat Members	Present	Republican Members
x	Patty Murray (WA)	x	Lamar Alexander (TN)
x	Tammy Baldwin (WI)	x	Rand Paul (KY)
x	Tim Kaine (VA)		Pat Roberts (KS)
x	Doug Jones (AL)	x	Mitt Romney (UT)
	Bernie Sanders (VT)	x	Michael Enzi (WY)
x	Christopher Murphy (CT)	x	Susan Collins (ME)
x	Maggie Hassan (NH)	x	Lisa Murkowski (AK)
x	Jacky Rosen (NV)	x	Mike Braun (IN)
x	Bob Casey (PA)	x	Richard Burr (NC)
x	Elizabeth Warren (MA)	x	Bill Cassidy (LA)
x	Tina Smith (MN)		Tim Scott (SC)
		x	Kelly Loeffler (GA)