

Public Health Emergency Medical Countermeasures Enterprise Review - Press Conference – August 19, 2010 - Raw Transcript

>> GED MORNING, EVERYBODY GOOD MORNING, EVERYBODY AND THANK YOU FOR BEING HERE TODAY.

I WANT TO INTRODUCE MY COLLEAGUES ON THE STAGE AT THE OUTSET.

DR. NICKY LURIE WHO IS THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

DR. TONY FAUCI THE DIRECTOR OF THE NATIONAL INSTITUTE OF ALLERGIC AND INFECTIOUS DISEASES AT NIH.

DR. PEGGY HAMBURG, FDA COMMISSIONER.

DR. ROBIN ROBINSON, THE DIRECTOR OF BARDA, AND DR. FRIEDEN, DIRECTOR FOR THE CDC AND PREVENTION.

AND JOINING US BY PHONE IS DR. ERIC LANDER AND HAROLD VARMUS AND THEY ARE WITH PCAST AND YOU WILL HEAR FROM THEM DURING THE COURSE OF THIS PRESENTATION.

OUR GREATEST RESPONSIBILITY IN GOVERNMENT IS KEEPING THE AMERICAN PEOPLE SAFE AND TO UPHOLD THAT RESPONSIBILITY WE'VE ALWAYS HAD A POWERFUL MILITARY THAT CAN GUARD AGAINST CONVENTIONAL THREATS BUT INCREASINGLY THE RANGE OF DANGERS WE FACE IS WIDENING TO INCLUDE BIOLOGICAL, CHEMICAL, NUCLEAR AND RADIOLOGICAL HAZARDS.

TODAY WE REALLY DON'T KNOW WHERE OUR NEXT PUBLIC HEALTH CRISIS CAN COME FROM, IT CAN BE A DIRTY BOMB SET OFF IN A SUBWAY CAR.

IT COULD BE A NATURALLY OCCURRING SUPER BUG THAT'S RESISTANT TO ALL TREATMENTS.

IT COULD BE A BIOLOGICAL WEAPON WE'VE NEVER SEEN BEFORE ASSEMBLED FROM THE BUILDING BLOCKS OF LIFE BY A TERRORIST IN THE LAB AND IT WAS WITH THIS INCREASINGLY CROWDED LANDSCAPE OF NATURAL AND MANMADE THREATS IN MIND THAT WE RELEASED OUR COUNTRY'S FIRST EVER NATIONAL HEALTH SECURITY STRATEGY LAST DECEMBER.

THE PRINCIPLE AT THE HEART OF THE STRATEGY IS THAT OUR PUBLIC HEALTH RESPONSE IS ONLY AS STRONG AS ITS WEAKEST LINK.

SO USING IT AS A GUIDE, WE WORK TO UPGRADE OUR ENTIRE END TO END RESPONSE FROM HOW WE ASSESS AND IDENTIFY THREATS TO HOW WE DISTRIBUTE AND ADMINISTER PRODUCTS TO COUNTER THOSE THREATS AND CITIES AND TOWNS ACROSS THIS COUNTRY.

BUT AS WE STUDY THE LANDSCAPE, IT BECAME CLEAR THAT ONE AREA IS WHERE WE NEEDED TO PUT A SPECIAL FOCUS ON MEDICAL COUNTERMEASURES.

MEDICAL COUNTERMEASURES ARE THE VACCINES ANTIVIRALS, ANTIBIOTICS, DIAGNOSTICS AND MEDICAL EQUIPMENT. IN A PUBLIC HEALTH CRISIS, THERE ARE MOST DIRECT AND OFTEN OUR MOST EFFECTIVE DEFENSE.

TO REACH OUR NATIONAL STOCK PILES MOST COUNTERMEASURES TRAVEL ALONG THE EXACT SAME PATH.

THEY BEGIN WITH DISCOVERY IN A LAB.

THEN THE DISCOVERY GETS TRANSLATED INTO A USEFUL PRODUCT AND THEN THAT PRODUCT GETS TESTED FOR SAFETY AND EFFECTIVENESS AND THEN SOMEONE MANUFACTURES IT AND IF THE PROCESS WORKS WELL, THERE'S A STEADY OUTPUT OF NEW COUNTERMEASURES TARGETED AT OUR BIGGEST

POTENTIAL THREATS.

BUT THE CLOSER WE LOOKED AT THE COUNTER MEASURE PIPELINE, THE MORE LEAKS, CHOKE POINTS AND DEAD ENDS WE SAW.

SO IN THIS AGE OF NEW THREATS, WE AREN'T GENERATING ENOUGH PRODUCTS.

IN A BUSINESS WHERE DELAY COSTS LIVES, WE COULDN'T MANUFACTURE AND DEVELOP COUNTERMEASURES FAST ENOUGH.

AND AT A MOMENT WHEN THE GREATEST DANGER WE FACE MAY BE A VIRUS WE'VE NEVER SEEN BEFORE LIKE ONE THAT CARS S. A. R. S., WE DON'T HAVE ENOUGH FLEXIBILITY TO ADAPT TO UNFORESEEN THREATS.

SO WE BASICALLY HAD THREE CHOICES, CROSS OUR FINGERS AND HOPE THE WORST NEVER HAPPENED. PUMP MORE MONEY INTO WHAT WE KNOW IS A LEAKING PIPELINE, OR ROLL UP OUR SLEEVES AND TAKE A HARD LOOK AT WHAT WAS GOING LONG AND START BUILDING THE 21st CENTURY COUNTER MEASURE ENTERPRISE WE NEED TO KEEP AMERICA SAFE FROM 21st CENTURY THREATS.

SO FOR US THE CHOICE WAS PRETTY CLEAR AND THAT'S WHY LAST DECEMBER WITH THE ENCOURAGEMENT AND STRONG SUPPORT OF PRESIDENT OBAMA I CALLED FOR AN UNPRECEDENTED REVIEW OF OUR ENTIRE MEDICAL COUNTER MEASURE ENTERPRISE.

THE REVIEW WAS LED BY OUR DEPARTMENTS ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DR. NICKY LURIE AND THAT REVIEW DREW ON DOZENS OF CONVERSATIONS WITH OUR OWN HHS EXPERTS.

WE STAY INDEED LOCAL HEALTH DEPARTMENTS, WITH INDUSTRY GROUPS, VENTURE CAPITAL EXPERTS, ACADEMIC SCIENTISTS AND BIOTECH DEVELOPERS AROUND THE COUNTRY.

AS WE CONDUCTED THESE CONVERSATIONS, COMMON THEMES EMERGED.

WE NEEDED TO FOCUS MORE ON CHILDREN'S UNIQUE NEEDS.

WE NEEDED TO WORK MORE CLOSELY WITH OUR PARTNERS ACROSS GOVERNMENT, INCLUDING DEPARTMENT OF DEFENSE.

BUT MOST OF ALL, WE NEEDED TO MOVE TOWARD THE REPORTS VISION OF THE NATION WITH AND I QUOTE, THE NIMBLE FLEXIBLE CAPACITY TO PRODUCE MEDICAL COUNTERMEASURES QUICKLY IN THE FACE OF ANY ATTACKS KNOWN OR UNKNOWN INCLUDING A NOVEL PREVIOUSLY UNRECOGNIZED NATURALLY OCCURRING AND EMERGING INFECTIOUS DISEASE.

PRETTY LOFTY BUT PRETTY CRITICAL GOAL.

TODAY WE'RE RELEASING THE REPORT THAT SUMS UP THOSE FINDINGS AND YOU CAN READ IT ON OUR WEB SITE AT HHS.GOV.

BUT WE'RE NOT HERE JUST TO TALK ABOUT HOW WE CAN DO BETTER, WE'RE MOVING FORWARD WITH A PLAN THAT WILL STRENGTHEN OUR COUNTERMEASURES PIPELINE AND SEVERAL KEY POINTS.

SO THERE ARE FIVE KEY AREAS WE ARE INTENDING TO FOCUS ON: GUIDED BY THE REVIEW, THE FIVE AREAS WHERE WE BELIEVE WE NEED TO ACT NOW TO MAKE BIG IMPROVEMENTS IN OUR PUBLIC HEALTH DEFENSES ARE THE FIRST LEVEL OF PRIORITIES.

FIRST, STRENGTHEN THE REGULATORY SCIENCE AT THE FDA.

ONE OF THE HARDEST PARTS ABOUT GETTING A PRODUCT FROM TEST TUBE TO OUR NATIONAL STOCK PILE IS MAKING SURE IT'S SAFE AND EFFECTIVE AND MEETS MANUFACTURING STANDARDS.

AND IT'S EVEN HARDER FOR DRUGS THAT TARGET A RARE OR EMERGING DISEASE THAT'S OFTEN POORLY UNDERSTOOD.

FOR TOO LONG WE'VE UNDERINVEST INDEED THE TOOLS ISSUES MODELS, METHODS AND KNOWLEDGE NEEDED FOR MAKING THESE ASSESSMENTS.

WHAT'S COLLECTIVELY KNOWN AS REGULATORY SCIENCE.

BECAUSE OF THIS UNDERINVESTMENT WE'RE OFTEN TESTING AND PRODUCING CUTTING EDGE PRODUCTS USING SCIENCE THAT'S DECADES OLD.

SO WE'RE GOING TO GIVE OUR WORLD CLASS SCIENTIST AT THE FDA, THE RESOURCES THEY NEED TO CREATE CLEAR REGULATORY PATHWAYS.

ANALYZE PROMISING NEW DISCOVERIES FASTER, AND HELP IDENTIFY AND SOLVE SCIENTIFIC PROBLEMS AS THEY OCCUR.

AND WE'RE ALSO GOING TO REACH OUT TO PROJECT DEVELOPERS, PRODUCT DEVELOPERS, EXCUSE ME, EARLY IN THE PROCESS SO THEY KNOW WHAT TO EXPECT.

NOW THE BENEFITS ARE CLEAR FOR OUR MEDICAL COUNTER MEASURE ENTERPRISE BUT ALSO HAVE GREAT BENEFITS FOR OTHER DRUG PRODUCTION TO CURE DISEASES.

THE SECOND AREA WE'LL FOCUS ON IS DEVELOPING FLEXIBLE MANUFACTURING.

RIGHT NOW, TOO MANY OF OUR COUNTER MEASURE FACILITIES ARE FILLED WITH BIG EQUIPMENT THAT'S DESIGNED TO PRODUCE JUST ONE PRODUCT OVER AND OVER AGAIN, NOW THAT WORKS WELL FOR SEASONAL FLU VACCINE BUT LEAVES US VULNERABLE WHEN THE COUNTER MEASURE WE NEED MAY ALSO BE ONE WE DON'T USE REGULARLY.

OR HAVEN'T EVEN INVENTED YET.

SO THAT'S WHY, SOON WE'LL, KNOWNS A SOLICITATION FOR THE NEW CENTERS FOR INNOVATION FOR ADVANCE DEVELOPMENT AND MANUFACTURING.

FACILITIES THAT WILL WORK TO GIVE NEW FLEXIBLE MANUFACTURING PLATFORM WHILE GIVING US A DEPENDABILITY DOMESTIC SOURCE OF SURGE CAPACITY FOR FLU VACCINE SO WE DON'T HAVE TO RELY ON FOREIGN PRODUCERS AS WE DID DURING THE H1N1 CRISIS.

AND THESE CENTERS WILL ALSO SERVE AS A RESOURCE WHERE SMALL BIOTECH COMPANIES WITH BIG IDEAS CAN GET THE REGULATORY AND MANUFACTURING KNOWLEDGE THEY NEED TO BRING THEIR PRODUCTS TO MARKET.

THE THIRD AREA WE WANT TO MOVE ON IS NURTURING DISCOVERIES AT THEIR EARLIEST STAGES.

NOW TODAY IT'S COMMON TO FOR SCIENTIST TO MAKE A DISCOVERY WITHOUT REALIZING IT; WITHOUT REALIZE TING CAN BE TURN INTOED A USEFUL COUNTER MEASURE, OR THEY MAY SEE THE POTENTIAL BUT NOT KNOW EXACTLY WHAT THE NEXT STEPS ARE AND THAT'S WHY WE'RE GOING TO USE A WIDE ARRAY OF NIH RESOURCES TO IDENTIFY AND NURTURE THESE PROMISING DISCOVERIES. INCLUDING CREATING NEW SHERP A TINES TO GUIDE THEM THROUGH THE PROCESS.

AS WE CONDUCTED THIS VIEW, WE LOOK AT THE FULL RANGE OF HEALTH THREATS, BUT AFTER DEALING WITH H1N1 AND H5N1, THE AVIAN FLU LOOMING ON THE HORIZON, WE NATURALLY PUT A SPECIAL FOCUS ON OUR FLU RESPONSE AND THAT'S WHY THE FOURTH PRIORITY IS UPGRADING THE WAY WE MANUFACTURE FLU ZACH SEEN FOR MODERNIZING POTENT STERILITY AND TESTING TO SPEEDING UP THE PRODUCTION OF VACCINE STRAINS.

THESE ARE THE SAME STEPS RECOMMENDED IN THE NEW REPORT FROM PCAST THAT YOU'LL HEAR ABOUT IN A FEW MINUTES AND THEY'LL INSURE WE'RE BETTER PREPARED FOR FLU SEASONS TO COME.

AND FINALLY THE FIFTH AREA WEE EXPLORE IS A STRATEGIC INVESTMENT FUND FOR NEW COUNTER MEASURE TECHNOLOGIES, RIGHT NOW THERE'S LITTLE INCENTIVE FOR PRIVATE COMPANIES TO

PRODUCE MEDICAL COUNTERMEASURES FOR RARE CONDITIONS LIKE EBOLA VIRUS OR EXPOSE
TOWER NONMEDICAL RADIATION AND YET IN THE EVENT OF AN EBOLA EBOLA OUTBREAK, THESE
COUNTERMEASURES WOULD BE CRITICAL.

A STRATEGIC INVESTOR COULD SUPPORT THE COMPANY WITH LITTLE HOPE OF MAKING PROFITS BUT
BIG POTENTIAL FOR IMPROVING PUBLIC HEALTH PREPAREDNESS.

TAKEN TOGETHER THESE FINE INITIATIVES WILL ADD MORE LIFE SAVING PRODUCTS TO THE PIPELINE.
ENABLING CRITICAL PROGRAMS LIKE BIOSHIELD TO WORK THE WAY THEY ARE SUPPOSED TO.
NOW AS THIS REVIEW WENT ON.

WE ALSO LOOKED BEYOND OUR LABS AND FACTORIES AT WHAT WE COULD DO DIFFERENTLY, RIGHT
HERE IN D. C.

WE FOUND THAT OUR CONTRACTS PROCESSES WERE TOO RIGID FOR EXAMPLE.

WE REALIZED WE NEEDED TO DO A BETTER JOB, TALK TO THE PRIVATE SECTOR THROUGHOUT THE
PRODUCT DEVELOPMENT PROCESS, RATHER THAN JUST ONE WE WANT TO LICENSE A PRODUCT.
AND WE SAW WE NEEDED BETTER COORDINATION NOT JUST WITHIN OUR DEPARTMENT BUT ACROSS
GOVERNMENT, WE INCORPORATED SOME OF THESE LESSONS INTO OUR RESPONSE IN THE H1N1
PANDEMIC LAST WE'RE AND WE WILL KEEP WORKING TO MAKE SURE WE'RE DOING OUR PART TO
STRENGTHEN OUR CAPACITY TO RESPOND.

NOW THERE'S AN OLD SAY NOTHING SPORTS THAT VICTORIES ARE WON ON THE PRACTICE FIELD WHEN
NO ONE IS WATCHING.

IN THE SAME WAY, HOW SUCCESSFULLY WE RESPOND TO TOMORROW'S PUBLIC HEALTH CRISIS WHICH
THE SPOT LIGHT IS ON, IS DETERMINED BY HOW HARD WE WORK BEHIND THE SCENES TODAY TO BUILD
A 21st CENTURY COUNTER MEASURE ENTERPRISE THAT COULD RESPOND QUICKLY AND EFFECTIVELY TO
ANY THREAT.

AND THAT'S WHY IN THE COMING YEARS WE'LL INVEST NEARLY TWO BILLION DOLLARS IN
PREPAREDNESS FUNDS TO THESE FIVE KEY AREAS AND ALTHOUGH OUR OFFICIAL COUNTER MEASURE
REVIEW CONCLUDES TODAY, OUR WORK TO STRENGTHEN OUR PUBLIC HEALTH PREPAREDNESS WILL
NEVER END.

WE KNOW THAT OUR ENEMIES ARE CONSTANTLY PROBING FOR WEAKNESS.

EVERY YEAR, NEW THREATS EMERGE AND THE OLD ONES EVOLVE TO BECOME RESISTANT TO OUR
KNOWN MEDICINES AND THAT'S WHY WE'LL CONTINUE TO LOOK FOR WAYS TO BUILD, NOT JUST
STRONGER COUNTER MEASURE, ENTERPRISES WITH THE SOLID BASE OF DISCOVERY, A CLEAR
REGULATORY PATHWAY AND AGILE MANUFACTURING BUT ALSO A STRONGER PUBLIC HEALTH
RESPONSE ALL THE WAY FROM DISEASE SURVEILLANCE TO ADMINISTERING COUNTERMEASURES TO
PEOPLE IN OUR CITIES AND TOWNS.

TODAY WE'RE TAKING A BIG STEP TOWARD A SAFER AMERICA, TOMORROW THE NEXT STEP BEGINS.

AND NOW, TO TALK ABOUT THE NEW REPORT FROM THE PRESIDENT'S COUNCIL FOR ADVISERS, OF
ADVISERS ON SCIENCE AND TECHNOLOGY, I'D LIKE TO INTRODUCE ONE OF OUR FINEST SCIENTISTS, DR.
HAROLD VARMUS.

NOW TODAY DR. VARMUS RUNS THE NATIONAL CANCER INSTITUTE BUT HE'S SPEAKING TODAY AS ONE
OF THE COUNCILS CO CHAIR WHEN IS THEY WROTE THE REPORT.

DR. VARMUS.

>> THANK YOU MADAM SECRETARY.

I'M SORRY I DIDN'T BE THERE WITH YOU.

TODAY PCAST WHICH IS THE SECRETARY MENTIONED IS THE COUNCIL OF INDEPENDENT ADVISERS TO THE PRESIDENT'S ON SCIENCE AND TECHNOLOGY, IS RELEASING ITS REPORT ON INFLUENZA VACCINES THAT, REPORT IS AVAILABLE TO ALL AT OFTP.GOV.

THE REPORT ANALYZES THE EFFORTS WE MADE TO PROTECT THE U.S. POPULATION DURING THE 2009 H1N1 PANDEMIC AND THE REPORT IDENTIFIED SEVERAL ASPECTS OF THE TRADITIONAL EGG BASED PRODUCTION PROCESS THAT COULD BE IMPROVED IN THE NEXT YEAR OR TWO TO INCREASE THE LIKELIHOOD THAT WE WILL HAVE ADEQUATE AMOUNTS OF VACCINES AVAILABLE DURING THE NEXT INFLUENZA PANDEMIC.

THE REPORT ALSO SUPPORTS MORE FUNDAMENTAL WILL CHANGES IN PRODUCTION OF INFLUENZA VACCINES IN THE LONGER TERM USING UP TO DATE METHODS.

MANY OF THE RECOMMENDED SHORT AND LONG TERM CHANGES ARE APPLICABLE TO THE DEFENSE AGAINST OTHER INFECTIOUS AGENTS AND HENCE THEIR RELEVANT TO THE HHS REPORT ON MEDICAL COUNTERMEASURES THAT IS YOU HEARD IS ALSO BEING RELEASED TODAY.

WHY WAS THIS STUDY DONE?

AS YOU'LL RECALL, DURING THE H1N1 INFLUENZA PANDEMIC OF 2009, PRODUCTION OF A NEW INFLUENZA VACCINE OUR MOST POTENT DEFENSE AGAINST A PANDEMIC WAS NOT FAST ENOUGH TO AFFORD OPTIMAL PROTECTION.

THE FIRST DOSES ARRIVED AFTER THE SECOND WAVE OF INFECTION BEGAN IN THE FALL OF 2009. AND SUFFICIENT VACCINE TO PROTECT THE MAJORITY OF THE POPULATION WAS NOT AVAILABLE UNTIL WELL AFTER THE SECOND WAVE HAD PEAKED IN THE MIDDLE OF THE FALL.

THESE DELAYS REFLECTED THE INHERENT UNCERTAINTY OF OUR CURRENT PROCESSES FOR MAKING INFLUENZA VACCINE, NO ONE WAS AT FAULT.

FORTUNATELY THE VIRULENCE OF THE PANDEMIC INFLUENZA STRAIN REMAIN RELATIVELY MILD. STILL, THE CDC ESTIMATES THAT APPROXIMATELY 13,000 U.S. RESIDENTS DIED AND MANY OTHERS WERE SEVERELY ILL.

THOSE NUMBERS COULD HAVE BEEN SIGNIFICANTLY REDUCED BY MORE TIMELY PRODUCTION OF VACCINES AND OF COURSE, THE DIFFERENT VIRUS, THE DELAYS IN VACCINE PRODUCTION COULD HAVE HAD MUCH MORE SEVERE CONSEQUENCES.

HOW DOES THIS STUDY GET DONE?

LATE IN 2009, EVEN BEFORE THE PANDEMIC HAD SUBSIDED, PCAST WAS ASKED BY THE PRESIDENT HIMSELF AND BY MEMBERS OF HIS SENIOR STAFF TO EVALUATE THE CURRENT AND ALTERNATIVE POSSIBLE METHODS TO THE PRODUCTION OF VACCINES AGAINST PANDEMIC INFLUENZA, SO THEY WERE LESS LIKELY TO FACE THE PREDICAMENT OF 2009 IN THE FUTURE.

PCAST ASSEMBLED A GROUP OF EXPERTS WHO SYSTEMATICALLY EXAMINED THE SEVERAL STEPS THAT MUST OCCUR BETWEEN THE DECLARATION OF A PANDEMIC BY THE WHO, THE WORLD HEALTH ORGANIZATION AND THE RELEASE OF THE FIRST DOSES OF A NEW VACCINE.

THOSE STEPS ARE OUTLINED IN THE REPORT GRAPHICALLY.

WE CAN'T PROTECT THOSE EFFECTIVELY.

THOSE IN THE ROOM HAVE COPIES OF SOME OF THE FIGURES THAT SHOW THESE STEPS.

THE GROUP ALSO GATHERED EVIDENCE THAT OTHER ASPECTS OF THE VACCINE PROCESS, ABOUT THE ECONOMICS OF THE VACCINE INDUSTRY AND ABOUT OTHER MEANS OF PRODUCING INFLUENZA

VACCINES OTHER THAN THE TRADITIONAL METHOD THAT USES FERTILIZED EGGS.

IN ITS FINDING, PCAST IDENTIFIED FIVE STEPS IN THE PROCESS THAT COULD BE IMPROVED OVER THE SHORT TERM, THE NEXT ONE TO THREE YEARS TO HASTEN DELIVERY OF A PANDEMIC VACCINE USING THE STRATEGIES THAT ARE ALREADY IMPROVED FROM MAKING INFLUENZA VACCINES, THESE ARE SUMMARIZED IN THE REPORT AND IN YOUR HANDOUT.

THEY WERE CLUED: INCREASED SURVEILLANCE FOR PATHOGENIC AGENTS TO IDENTIFY PANDEMICS EARLIER AND GIVE US AN EARLIER START SIGNAL FOR MAKING VACCINES.

A NUMBER OF STEPS IN THE VACCINE PROCESS, SOME THE SECRETARY'S MENTIONED INCLUDING MAKING SEED VIRUSES OR PRODUCTION IN A MORE EFFICIENT WAY USING FASTER NOVEL METHODS TO VERIFY THE STERILITY OF VACCINES AND BETTER WAY TO TEST VACCINES FOR POTENCY AND IN ADDITION THE MANUFACTURING PROCESS THAT IS ESSENTIAL TO THE FINAL STAGES OF PRODUCTION, FILLING AND FINISHING THE VACCINE VIAL CAN BE STREAM LINED AND EXPANDED, OVERALL THESE IMPROVEMENTS COULD PRODUCE THE TIME REQUIRED TO DELIVER THE VACCINES AND THE LAST DOSES FROM A FEW WEEKS TO A FEW MONTHS.

FOR EACH STEP IN THE PROCESS, PCAST RECOMMENDED ASSIGNMENTS TO FEDERAL AGENCIES WHICH WILL HELP THE INDUSTRY.

PCAST RECOMMENDED MORE FUNDAMENTAL LONG TERM CHANGES IN THE PRODUCTION OF INFLUENZA VACCINES.

A SHIFT TO CELL CULTURE AWAY FROM FERTILIZED EGGS AS A WAY OF EFFICIENT AND MORE MEANS OF PRODUCTION AND THE GREATER USE OF LIVE ATTENUATE VACCINES BECAUSE OF THEIR GREATER POTENCY.

WE ALSO ARGUED FURTHER DEVELOPMENT OF IMMUNE LOGICAL STIMULANTS, SO CALLED ADJUVANTS, COMPONENTS OF THE EFFECT OF VACCINES TO DECREASE THE AMOUNT OF VIRAL MATERIAL IN VACCINES.

WE URGED THAT INDUSTRY, AND THAT THE GOVERNMENT ACCELERATE THE USE OF RECOMBINANT DNA METHODS TO PRODUCE VACCINES TO ELIMINATE THE NEED OF LARGE SCALE GROWTH FOR VIRUS AND THEREBY HASTEN THE PRODUCTION OF THE VACCINE.

AND WE ALSO RECOMMEND CONTINUED STUDY OF THE POTENTIAL TO DEVELOP THE SO CALLED UNIVERSAL VACCINE THAT WOULD PROTECT AGAINST MOST RAW STRAINS OF INFLUENZA VIRUS, NOW LIMP IMPLEMENTATION OF THESE METHODS OF PRODUCTION COULD FURTHER SHORTEN THE TIME AND COST FOR PRIOR PRODUCE VACCINES.

WOULD REDUCE THE AMOUNT REQUIRED FOR PROTECTION, WOULD IMPROVE THE MANUFACTURING OF VACCINE USED ANNUALLY AGAINST SEASONAL FLU AND WOULD ALLOW PRODUCTION OF ENOUGH VACCINE TO PROTECT OTHER VULNERABLE POPULATIONS OUTSIDE THE U.S. WHEN WORLD WIDE PANDEMICS STRIKE.

TO ACHIEVE THIS COMPLEX SET OF BOTH LONG AND SHORT TERM GOALS, PCAST RECOMMENDS THE NOVEL MANAGEMENT PRACTICES OUTLINED IN THE REPORT FOR USE BY THE U.S. GOVERNMENT AND ALSO RECOMMENDS A NUMBER OF WAYS IN WHICH FEDERAL AGENCIES CAN COLLABORATE CLOSELY WITH INDUSTRY.

PCAST WAS UNABLE TO AND NOT ABLE TO PREPARE A DETAILED COST ACCOUNTING OF COST AT THIS STAGE.

BUT IT EXPECT THAT A BILLION DOLLARS OF SUPPORT BY GOVERNMENT WOULD BE REQUIRED FOR

YEARS ALONG WITH INDUSTRY TO REACH THE GOALS OUTLINED.

THESE ARE VIEWED AS MODEST IN SAVING LIVES DURING THE NEXT INFLUENZA PANDEMIC.

WHEN THE PANDEMIC IS OVER, WE TEND TO FORGET WHAT HAS HAPPENED DURING THE PANDEMIC.

IN A PANDEMIC THERE'S A LIFE AND DEATH RACE BETWEEN THE DEFENSE THAT IS THOSE OF US WHO WERE SADDLED WITH THE RESPONSIBILITY ALONG WITH INDUSTRY FOR GETTING VIRUS TO THE PUBLIC, AND THE I HAVEULOUS ITSELF WHICH IS ALWAYS ABOUT TO RETURN TO THE POPULATION AND THREATEN SEVERE ILLNESS AND DEATH.

ACCEL BRATTING DELIVERY OF VACCINE BY EVEN A FEW WEEKS COULD MEAN SAVING 10S OF THOUSANDS OF LIVES.

IN ADDITION MOST OF THE INVESTMENTS THAT WE'RE DISCUSSING WOULD CONTRIBUTE TO THE NATION'S DEFENSES AGAINST OTHER KINDS OF BIOLOGICAL THREATS THAT DESCRIBED BY THE SECRETARY IN THE HHS REPORT ON MEDICAL COUNTERMEASURES.

THANKS VERY MUCH FOREVER YOUR ATTENTION AND HAPPY TO TAKE QUESTION WHEN IS THE OPPORTUNITY ARISES.

>> THANK YOU HAROLD AND DR. VARMUS AND I WOULD BE PLEASED TO ANSWER A FEW QUESTIONS BEFORE I TURNOVER THE CONFERENCE TO DR. NICKY LURIE BUT I WANT TO END MY PART OF THE PRESENTATION BY JUST RECOGNIZING THAT THIS REVIEW WAS AN INCREDIBLY COLLABRATIVE EFFORT AND NOT ONLY DID IT INVOLVE OUR WORLD CLASS SCIENTISTS SCREWS HHS AND BUDGET TEAMS AND POLICY TEAMS AND OTHERS, BUT WE HAD GREAT PARTNERS AT THE NATIONAL SECURITY COUNCIL AND THE DEPARTMENT OF DEFENSE AND OTHER GOVERNMENT AGENCIES AS WELL AS THE PRIVATE SECTOR WHO PARTICIPATED AND I WANT TO RECOGNIZE THAT THIS REVIEW IS NOT ONLY CRITICALLY IMPORTANT, BUT A GREAT EXAMPLE OF ALL GOVERNMENT APPROACH WHICH THE PRESIDENT CALLED ON US TO DO TO MAKE SURE THAT THE SAFETY AND SECURITY OF THE AMERICAN PEOPLE IS OUR TOP PRIORITY.

SO WITH THAT I WOULD BE PREESED TO TAKE A FEW QUESTIONS PLEASED TO TAKE A FEW QUESTIONS. YES MA'AM?

>> THANK YOU.

I HAD A QUESTION ABOUT THE TWO BILLION DOLLARS.

WHERE WILL THAT COME FROM?

HOW MUCH OF THAT WILL BE DIRECTED TOWARD INDUSTRY ITSELF?

LIKE TO THE BIOTECH COMPANIES, WILL ANY OF THOSE FUNDS ACTUALLY GO TOWARDS THE BIOTECH COMPANIES AND THEN FOR YOUR THE NEW CENTER OF INNOVATION, WHERE WILL THAT BE LOCATED AND HOW WILL YOU FUND THAT AS WELL.

WILL THAT BE FUNDED BY THE TWO BILLION DOLLARS?

>> THAT'S SORT OF THREE QUESTIONS, BUT [LAUGHTER]

LET ME SEE IF I CAN TAKE THEM IN ORDER.

THE TWO BILLION DOLLARS, THE BULK OF THE TWO BILLION DOLLARS IS MONEY THAT IS ALREADY ALLOCATED AND DIRECTED TO HHS FOR PREPAREDNESS, MUCH OF IT COMES FROM THE 2009 SUPPLEMENTAL FUNDING FOR THE PANDEMIC RESPONSE AND SO WE ARE REPURPOSING REDIRECTING THESE FUNDS TO THESE FIVE INITIATIVES, THE CENTERS FOR INNOVATION AND ADVANCE MANUFACTURING WILL REALLY BE COMPETED FOR IN RFPs THAT WILL BE RELEASED HOPEFULLY IN THE NEAR FUTURE, THEY'RE BEING DEVELOPED RIGHT NOW BUT THERE ARE A NUMBER OF

INTERESTED ENTITIES AROUND THE COUNTRY, A NUMBER OF CREATIVE IDEAS FOR FLEXIBLE, MUCH MORE FLEXIBLE MANUFACTURING THAT COULD BE USED FOR MULTIPURPOSE WHICH REALLY, WE LACK RIGHT NOW IN ADDITION TO ADDITIONAL MANUFACTURING CAPACITY.

SO THOSE ARE THE TWO GOALS AND IN TERMS OF THE MONEY DIRECTLY TO THE INDUSTRY, I WOULD SAY, THE FUNDING FOR THE STRAY STIGIC INVESTOR THAT WE ARE ANTICIPATING AND WE WILL GO TO CONGRESS TO ASK FOR THIS AUTHORITY REALLY IS THE KIND OF NONPROFIT VENTURE CAPITAL ABILITY. WHAT WE KNOW IS THAT SOME OF THESE GREAT IDEAS ARE GOING TO COME FROM VERY SMALL COMPANIES WHO DON'T HAVE THE CAPITAL AND THE WHERE WITH ALL TO GET A PRODUCT FROM MICROSCOPE TO MARKET.

SO THE INVESTMENT EARLY IN THAT PIPELINE CAN NOT ONLY INSURE THAT THE GREAT IDEA BECOMES A PRODUCT BUT WILL HELP SPUR THAT DEVELOPMENT.

BIOSHIELD WILL REMAIN AS THE ENTITY FOR PURCHASING A DEVELOPED PRODUCT BUT WHAT WE KNOW IS THAT A LOT OF PRODUCTS NEVER GET TO THE POINT WHERE THEY CAN BE PURCHASED BECAUSE THE PROCESS STOPS AT SOME POINT ALONG THE WAY.

SO PART OF THIS EFFORT IS TO MAKE SURE THAT PIPELINE CONTINUES TO FLOW.

>> YES MA'AM?

>> HI, MEGAN WITH NPR NEWS.

I WAS WONDERING ABOUT, YOU TALK A LOT ABOUT THE MANUFACTURING PROCESS, BUT WHEN YOU GET A LOT OF VACCINES TOGETHER, DO YOU THINK THE CURRENT DISTRIBUTION SYSTEM IS GOING TO BE ALL RIGHT FOR IN THE CASE OF A PANDEMIC?

>> WELL, WHAT WE FOUND IN THE H1N1 VACCINE SITUATION WAS THAT WE WERE ABLE TO WITH GREAT PARTNERS AT THE STATE AND LOCAL LEVEL TO DEVELOP A SIGNIFICANTLY ENHANCED AND ROBUST DISTRIBUTION SYSTEM VERY QUICKLY.

IDENTIFY THE PCAST SCIENTISTS ON THE PRESIDENT'S ADVISORY COUNCIL, IDENTIFY THE TARGET POPULATION, OUR STATE AND LOCAL PARTNERS THEN IDENTIFIED THE SPECIFIC SITES THAT WERE BEST TO REACH THAT POPULATION AND WE SIGNIFICANTLY ENHANCED WHAT HAD BEEN IN PLACE AS THE CHILDREN'S VACCINE DISTRIBUTION METHODOLOGY AND MADE THAT CONSIDERABLY MORE ROBUST AND ALSO USED SCHOOL BASED CLINIC IN A VARIETY OF STRATEGIES KNOWING THAT THAT WAS A TARGET POPULATION THAT ISN'T TYPICAL IN THE FLU.

I THINK THAT'S A STEP FORWARD.

WHAT I SINGLE A CONSIDERABLE CONCERN AND WE'RE GOING TO CONTINUE TO WORK ON EVERYTHING FROM SURVEILLANCE TO DISTRIBUTION.

I MEAN THIS PARTICULAR REPORT FOCUSES TODAY ON THE DEVELOPMENT PRODUCTION AND STOCK PILING OF MEDICAL COUNTERMEASURES BUT WHAT WE KNOW IS THAT, WE NEED FASTER MORE NIMBLE, BETTER WAYS TO DO SURVEILLANCE SO WE FIND WHAT'S GOING ON AS EARLY AS POSSIBLE, WHETHER IT'S HERE IN THE COUNTRY OR AROUND THE WORLD AND WE NEED AT THE OTHER END TO MAKE SURE IF WE GET A PRODUCT AND WE HAVE AN IDENTIFIED TARGET POPULATION, WE NEED A BETTER AND MORE ROBUST DISTRIBUTION SYSTEM SO WE'LL CONTINUE TO WORK ON THAT.

I WOULD SAY OF GREAT CONCERN, IS THE REALLY DECIMATION OF THE PUBLIC HEALTH INFRASTRUCTURE AROUND THE COUNTRY DUE TO THE ECONOMIC DOWN TURN.

A LOT OF STATES HAVE SEVERELY CUT PUBLIC HEALTH OFFICIALS, EMERGENCY PREPAREDNESS OFFICIALS, THE KIND OF INFRASTRUCTURE THAT'S NEEDED IN THIS COUNTRY WHICH IS THE BACKBONE

OF THE FIRST RESPONDERS.

SO, THE PREPAREDNESS FUNDS THAT ARE SENT BY THE FEDERAL GOVERNMENT TO STATE THE KIND OF PARTNERSHIP THAT WAS DEVELOPED DURING H1N1 BY DR. FRIEDEN AND OTHER COLLEAGUES TO WORK VERY CLOSELY WITH STATE AND LOCAL PARTNERS.

I THINK WE WILL NEED TO CONTINUE TO MAKE SURE THAT'S A ROBUST INFRASTRUCTURE BECAUSE THAT'S REALLY THE HEART OF OUR DISTRIBUTION SYSTEM.

WITH THAT I THINK I WILL TURN OVER THE PROGRAM TO DR. NICKY LURIE WHO LED THIS RESPONSE. DR. LURIE?

[APPLAUSE]

>> WELL, THANK YOU MADAM SECRETARY AND THANKS DR. VARMUS.

I'D LIKE TO EXTEND A SPECIAL THANKS TO PCAST FOR LENDING THEIR EXPERTISE HERE.

WE WERE CONDUCTING OUR REVIEWS CONCURRENTLY AND WE HAD A HUGE AMOUNT OF BACK AND FORTH AND EXCHANGE AND I CONTINUING WAS VERY PRODUCTIVE.

TO GET TO THE REALLY ROOT CAUSE ISSUES THAT WERE AT THE SORT OF HEART OF THIS MEDICAL COUNTER MEASURE ENTERPRISE AND THE LEAKY PIPELINE IN THE ROAD BLOCKS THAT YOU HEARD ABOUT AND TO TO COME TO REALLY NOVEL CREATIVE AND REALISTIC SOLUTIONS, AS I THINK YOU HEARD FROM THE SECRETARY, WE TALK TO ALL KINDS OF PEOPLE.

AROUND THE COUNTRY AND FRANKLY AROUND THE WORLD, SCIENTIFIC LEADERS, FEDERAL AGENCIES, THAT DEVELOP AND PLAY A PART IN THIS ENTERPRISE INCLUDING COLLEAGUES AT THE DEPARTMENT OF HOMELAND SECURITY, VARIOUS COMPONENTS OF D.O.D. AND AS YOU HEARD THE COMPONENTS OF HHS WHOSE LEADERS ARE REPRESENTED HERE TODAY.

AS WELL, WE SPENT A LOT OF TIME TO THE PREVIOUS QUESTION, TALKING TO PEOPLE AT STATE AND LOCAL HEALTH DEPARTMENTS.

WE CONSULTED WITH COLLEAGUES INIA ACADEMIA AND INDUSTRY.

WE WERE CONDUCTING THIS REVIEW AND SOME OF THE HEART OF OUR REVIEW ACTUALLY WAS GOING ON WHEN WE HAD THOSE LOVELY BLIZZARDS WE HAD IN WASHINGTON AND WE HAD TO CANCEL AND RESCHEDULE ADVISORY COMMITTEES AND WORKSHOPS A COUPLE OF TIMES AND I PARTICULARLY WANT TO THANK COLLEAGUES AT THE INSTITUTE OF MEDICINE WHO HOSTED A WORKSHOP FOR US THAT HAD TO BE RESCHEDULED AND COLLEAGUES FROM THE NATIONAL ADVISORY BIOSCIENCE BOARD WHO REALLY DID THE SAME AND WE TALK WIDE INDUSTRY LEADERS AS YOU HEARD FROM THE SECRETARY, PEOPLE FROM THE VENTURE CAPITAL WORLD AND PEOPLE IN INVESTMENT BANKING WORLD ALL OF WHOM ARE INVOLVED IN ONE PLACE OR ANOTHER IN THIS COMPLICATED PIPELINE THAT GETS US MEDICAL COUNTERMEASURES AT THE END.

I WANT TO TAKE A MOMENT AND JUST SAY, A HUGE THANKS TO PEOPLE INSIDE AND OUTSIDE OF GOVERNMENT REALLY ALL OVER THE PLACE WHO STEPPED UP, PROVIDED THEIR TIME AND INSIGHT, ALL OF THEIR FEEDBACK WAS JUST A TREMENDOUS, TREMENDOUS VALUE IN HELPING SHAPE OUR REVIEW AND THE PATH FORWARD.

AND WHILE WE'RE SEEING AGENCY LEADERS HERE ON THE STAGE, MANY OF MY COLLEAGUES HERE IN THE AUDIENCE, MANY UNSPOKEN AND UNSUNG HEROES IN PUTTING THIS TOGETHER, THERE ARE A LOT OF PEOPLE WHO ARE INSTRUMENTAL IN PUTTING THIS TOGETHER.

I WANT TO PARTICULARLY THANK DR. GEORGE KORCH, WHO WAS SITTING HERE WHO WAS REALLY MY RIGHT HAND PERSON IN LEADING THIS EFFORT.

AND AS WELL A STAFF FROM THE NATIONAL SECURITY STAFF WHO WORKED IN A REALLY INTREPID WAY COLLABORATIVELY WITH US THROUGHOUT THIS AND THEY WERE LED BY HEIDI AVRIS SITTING HERE. AND SIMILARLY OTHER COLLEAGUES WHO ARE NOT ON THE STAGE WHO WERE INVOLVED IN WHICH INCLUDE ANDIE WEBER FROM THE DEPARTMENT OF DEFENSE WHO IS ALSO HERE, IT WAS A TERRIFIC COLLABORATION AND LOTS OF VERY THOUGHTFUL AND DYNAMIC EXCHANGES, WE WORK THIS THROUGH.

SO LET ME JUST, I THINK REVIEW FOR A MOMENT WHAT THE SECRETARY SAID ABOUT WHY THIS MATTERS.

YOU KNOW IN INFECTIOUS DISEASE DOESN'T REALLY CARE ABOUT ECONOMIC CONDITIONS, DOESN'T REALLY CARE ABOUT RICH OR POOR COUNTRIES, DOESN'T CARE ABOUT HOW IT GOT HERE AND AS WE KNOW THAT WE CAN'T PREDICT WHEN THE NEXT PANDEMIC WILL OCCUR.

WE CAN'T PREDICT WHEN WE WILL SEE ANOTHER ACT OF BIOTERRORISM.

WHEN PEOPLE SAY TO ME, WHAT'S THE MOST SURPRISING THING TO YOU SINCE TAKE THANKSGIVING JOB?

MY FIRST ANSWER IS HOW MANY EARTHQUAKES THERE ARE IN THE WORLD AND THE SECOND QUESTION IS HOW MANY REPORTS I GET ABOUT NEW AND CONCERNING DISEASES INCLUDING CONTINUES CASES OF HONE NFIVE AVIAN FLEW THAT COME ON MY BLACK BERRY ON A DAY TO DAY BASIS.

AND IT REMINDS US WHY WE NEED TO BE PREPARED AND THE THREATS ARE VERY, VERY REAL.

AS YOU HEARD, WE HAVE A STRONG VISION HERE WHICH IS TO HAVE THE NATIONAL CAPABILITY THAT IS ADVANCED ENOUGH AND FLEXIBLE NOTIFY TO MAKE COUNTERMEASURES QUICKLY IN THE FACE OF A PUBLIC HEALTH THREAT WE'VE NEVER SEEN BEFORE.

WHETHER IT'S A NATURALLY OCCURRING ONE OR WHETHER IT'S MANMADE.

SO MANY OF THE ACTIONS WE'RE TAKING ARE REALLY AIMED TO ADDRESS THAT, BUT WON OF THE THINGS I WANT TO POINT OUT IS THAT WE EXPECT THAT MANY OF THEM AND I THINK YOU CAN PROBABLY TELL FROM LISTENING TO THIS, OUGHT TO HAVE APPLICATIONS BE ON THE MEDICAL COUNTER MEASURE ARENA TO HELP US DEAL WITH OTHER EMERGING THREATS AND OTHER NEGLECTED DISEASES, BOTH THROUGH NEW SCIENTIFIC BREAK THROUGHS BOTH THROUGH THE REGULATORY INNOVATION YOU'VE HEARD, THROUGH HELPING COMPANIES GET OTHER KINDS OF PRODUCTS TO MARKET AND WE'RE REALLY QUITE EXCITED ABOUT IT, YOU KNOW HAVING COME THROUGH H1N1 AND SEEING THESE RECENT REPORTS OF A SCARY NEW SUPERBUGS, WE HAVE A TREMENDOUS SENSE OF URIGENCE TOW GET THIS DONE AND AWFUL US HERE CARRY WITH US A TREMENDOUS SENSE OF RESPONSIBILITY TO DO THIS, THIS IS REALLY OUR JOB IN GOVERNMENT. AND SO, THE APPROACH THAT WE HAVE ANNOUNCED TODAY WITH ALL OF ITS INITIATIVES AND ENHANCEMENTS REFLECT THAT SENSE OF URGENCY DESIGNED TO BUILD A BETTER SYSTEM.

THE OTHER POINT I WANT TO MAKE REALLY QUICKLY, IS WE HAVEN'T WAITED FOR THIS ANNOUNCEMENT TO GET GOING.

ALREADY, IN FACT, EVEN AS THIS REVIEW WAS GOING ON, WE STARTED WORKING ACROSS FEDERAL AGENCIES TO PUT A LOT OF CHANGES IN PLACE.

WE'VE NOW CONDUCTED THE FIRST OF REVIEWS AT MAJOR PRODUCT PORTFOLIOS FOR THINGS LIKE SMALLPOX, ANTHRAX, RADIOLOGIC AND NUCLEAR PRODUCTS AND SOON TO GET ANOTHER LOOK AT OUR FLU ENTERPRISE AND THE NEXT FEW WEEKS AS YOU HEARD, WE'LL BE RELEASING THE STRESSED

SOLICITATION FOR THE ADVANCE AND MANUFACTURING CENTER FOR EXCELLENCE.

WE'RE ESTABLISHING AN HHS REGULATION FOR THE USE OF OTHER TRANSACTION AUTHORITY SO THE SECRETARY HAS THE FULL USE SHE NEEDS, A NEW CONTRACTING METHODS AND WE'RE INSTITUTING A FIVE YEAR BUDGET PLANNING PROCESS SO THAT WE CAN REALLY SYSTEMICALLY THINK ABOUT THIS FROM END TO END BECAUSE AS YOU KNOW, SOME OF IT BEGINS AND ENDS WITH THE SCIENCE AND IT ALL BEGINS AND ENDS WITH THE MONEY.

AND INSIDE WE'VE IMPLEMENTED ALREADY A NUMBER OF WAYS TO DO OUR OWN WORK BETTER AND SMARTER INCLUDING THINGS LIKE SHORTENING THE TIME OF A CONTRACTING PROCESS, ET CETERA.

I THINK ALL OF US ARE REALLY PLEASED AND EXCITED TO BE HERE TODAY.

I THINK FOR ALL OF US, IT'S BEEN A LONG ROAD GETTING HERE.

IT'S BEEN AN EXCITING PROCESS, BUT NOW WE ARE ACTUALLY AT A NEW POINT BEGINNING A LOT OF REALLY EXSEATING WORK, A LOT OF HARD WORK IS GOING TO CONTINUE TO TAKE OUR FOCUS AND DETERMINATION TO TAKE THIS REPORT WHICH LOOKS LOVELY AND GLOSSY AND IMPLEMENT THESE INITIATIVES AND PLAN TO GET TO JOB DONE FOR THE AMERICAN PEOPLE AND I THINK WE'RE ALL EXCITED ABOUT TAKING ON THAT CHALLENGE.

I'D LIKE TO INTRODUCE TO YOU MY COLLEAGUES AND AND PEOPLE WHO HELP MAKE THIS REPORT POSSIBLE AND I THINK EACH WILL SPEAK FOR A FEW MINUTES BEGINNING WITH DR. TONY FAUCI KNOWN TO ALL OF YOU AS THE DIRECTOR OF THE NATIONAL INSTITUTES OF ALLERGY AND INFECTIOUS DISEASE.

AND DR. ROBIN ROBINSON FROM BARTA, AND DR. PEGGY HAMBURG FROM THE FDA AND THEN ALSO DR. LANDER FROM THE FDA.

>> THANK YOU, YOU HEARD THEM OUTLINE THE MEDICAL INTENSIVE COUNTER MEASURE, AND AND IMPACT TO A GREATER OR LESSER DEGREE ON VIRTUALLY ALL OF THE SISTER AGENCIES THAT ARE INVOLVED IN THIS PROCESS INCLUDING OUR COLLABORATIONS WITH THE DEPARTMENT OF DEFENSE. WHAT I'D LIKE TO DO OVER THE NEXT TWO OR THREE MINUTES IS JUST TO VERY BRIEFLY OUTLINE FOR YOU TWO OF THESE INITIATIVES WHICH HAVE A PARTICULAR IMPORTANCE FOR THE NIH EFFORTS BUT ALSO IN GREAT COLLABORATION WITH A VARIETY OF OTHERS THAT YOU'LL HEAR FROM TODAY.

THE FIRST IS WHAT SECRETARY MENTIONED, WHAT WE'RE REFERRING TO AS A CONCEPT ACCELERATION PROGRAM AND WHAT THAT REALLY IS IS FUNDAMENTALLY A NURTURING PROGRAM FOR SCIENTISTS WHO COME UP WITH CONCEPTS SO THAT THEY REALLY DO NOT HAVE EITHER THE EXPERTISE OR EVEN THE REALIZATION OF THE POTENTIAL IMPACT OF A SCIENTIFIC DISCOVERY OR A CONCEPT, HOW IT MIGHT BE TRANSLATED INTO SOMETHING THAT'S A DEFINABLE PRODUCT AS A MEDICAL COUNTER MEASURE BE IT FOR A DELIVERED THREAT OR FOR MANY, MANY OF THE NATURALLY EMERGING CHALLENGES THAT WE OFTEN FACE.

THE UNDERLYING PRINCIPLE OF THIS PROGRAM IS TO NOT LEAVE ANY PROMISING CONCEPTS ON THE VINE.

I'LL GIVE YOU AN EXAMPLE OF WHAT HAPPENS VIRTUALLY EVERY DAY IN SCIENCE.

MANY SCIENTISTS ARE FUNDAMENTALLY FOCUSED ON DEVELOPING A CONCEPT OR A BASIC SCIENCE DISCOVERY.

AND WE LIKE THAT.

THAT'S THE FUNDAMENTAL CREATIVITY THAT GIVES US THE SEEDS FOR DEVELOPING THE IMPORTANT PRODUCTS THAT WE NEED.

HOWEVER, MORE OFTEN THAN NOT, ONCE THEY PUBLISHED THEIR PAPER IN SCIENCE OR NATURE, OR WHAT HAVE YOU, IT COULD ESSENTIALLY STAY THERE AS THEY GO ON TO THE NEXT CONCEPT, AS OPPOSE TO REALIZING WHAT IMPLICATIONS THAT DISCOVERY MIGHT HAVE.

WHAT WE HAVE BEEN DOING, BUT WE'RE GOING TO DO NOW WITH MUCH GREATER INTENSITY WITH THIS NEW PROGRAM IS TO SERVE AS A GUIDE OR A SHIRP A FOR THESE INDIVIDUALS NOT ONLY IN GETTING THEM THE EXPERIENCE THAT THEY HAVE, HOW YOU DEAL WITH REGULATORY AGENCIES OR DEAL WITH THE NIH TO GET THROUGH THE MONEY FOR GRANTS BUT ALSO TO SUPPLY FOR THEM ACCESS TO OUR REAGENT REPOSITORIES OR ANIMAL MODELS, CLINICAL TRIALS, NETWORK, AND ABOVE ALL, THE EXPERTISE THAT WE HAVE, WE HAVE A NUMBER OF EXAMPLES OF THESE WHICH WE HAVE BEEN DOING EVEN PRIOR TO THE OFFICIAL LAUNCHING OF THIS OF INDIVIDUAL PROGRAM.

THE KEY ISSUE IN THIS IS REALLY STAFF TIME AND THE EXPERTISE THAT WE HAVE.

WE'VE BEEN DOING THIS AS IT WERE ON OUR SPARE TIME, IF YOU CAN SAY THAT THERE'S SUCH A THING AS SPARE TIME IN THIS BUSINESS, BUT NOW WE'RE GOING TO LAUNCH THIS IN A MUCH MORE ORGANIZED AND MUCH MORE INTENSIVE WAY.

THE SECOND ISSUE THAT RELATES VERY CLOSELY TO WHAT THE NIH DOES IS WHAT THE SECRETARY MENTIONED, AS A STRATEGIC INVESTMENT FUND.

THIS REALLY IS A 501 C THREE NONPROFIT ORGANIZATION WITH AN INDEPENDENT BOARD OF DIRECTORS AND AS THE SECRETARY MENTIONED, WE WILL REQUIRE AUTHORIZATION FOR THIS, BUT THE FUNDAMENTAL PRINCIPLE OF THIS IS THAT INDIVIDUAL COMPANIES BE IT BIOTECH OR WHAT HAVE YOU THAT, INVOLVE INDEED HEALTH NA PRECARIOUS SITUATION, THEY'RE AN ENDANGERED SPECIES BECAUSE THERE'S NOT A LOST INCENTIVE TO DEVELOP ISSUES THAT HAVE TO DO WITH PUBLIC HEALTH, PARTICULARLY THREATS THAT ARE POTENTIAL THAT HAVE NOT YET EVEN OCCURRED.

SO WHAT WE'RE GOING TO DO IS WE'RE GOING TO BE SERVING AS A SIMILAR TO A VENTURE CAPITOL BUT WITH INVESTMENTS IN THE COMPANIES THEMSELVES OR IN ANY PARTICULAR PRODUCT BUT TO INSURE THE VIABILITY OF COMPANIES TO MAKE AND SO IMPORTANT FOR THE PROTECTION, SO WITH THAT I'LL CLOSE, AND ANSWER QUESTIONS WITH OTHERS AFTER THEY ARE FINISHED.

THANK YOU.

>> THANK YOU, I'M HAROLD VARMUS WITH BARTA, WE WORK WITH D. O. J. AGENCIES TO CROSS ALL OF THESE INITIATIVES AND FROM THE MEDICAL COUNTER MEASURE REVIEW AND ALL PCAST REPORT AND WE'LL LEAVE THREE SPECIFIC AREA AND I GUESS WANT TO OUTLINE THOSE.

AS MENTIONED BY THE SECRETARY AND DR. LURIE THAT FIRST IS FLEXIBLE MANUFACTURING AND ADVANCE DEVELOPMENT CORE SERVICE PARTNERSHIPS.

AS HHS IS COMMITTED TO DEVELOPING NEW NIMBLE AND ROBUST WAYS TO MANUFACTURE MEDICAL COUNTERMEASURES THAT, IS FLEXIBLE AND MULTIPURPOSE MANUFACTURING, BARTA WILL LEAD THE HHS EFFORT WITH D.O.D. TO SUPPORT THE ESTABLISHMENT OF U.S. BASED CENTERS OF INNOVATIONS FOR ADVANCED DEVELOPMENT AND MANUFACTURING AS PUBLIC PARTNERSHIPS.

BETWEEN THE U.S. GOVERNMENT AND EXPERIENCE PHARMACEUTICAL COMPANIES AND ACADEMIA, THIS INITIATIVE PRIMARILY WILL SUPPORT THE CONSTRUCTION AND OPERATION OF NEW FACILITIES, AND/OR THE RENOVATION OF EXISTING FACILITIES IN THE UNITED STATES TO PROVIDE ON A RUE TINE BASIS CORE ADVANCEMENT AND SERVICES TO MEDICAL COUNTER MEASURE CANDIDATES INNOVATIVE COMPANIES UNDER CONTRACT WITH THE U.S. GOVERNMENT USING FLEXIBLE MANUFACTURING AND PLATFORM TECHNOLOGIES.

THESE CORE SOCIAL CAPITAL SERVICES FROM THE CORE SERVICES FROM THE CORE SERVICES THAT ARE PROVIDED BY THE NIH FOR ANIMAL TESTING AND CLINICAL TESTING.

, AND ADDITIONALLY THESE FACILITIES WILL SERVE AS A COMMERCIAL SCALE MANUFACTURING SITES FOR PANDEMIC INFLUENZA AND FOR EMERGING INFECTIOUS DISEASES AS THE INFECTIOUS DISEASES AS THE NEED ARISES.

THIS INCLUDES HHS ABILITY OF CELL BASED MANUFACTURING FACILITY IN NORTH CAROLINA. AND IN RETROFITTED MANUFACTURING FACILITIES IN PENNSYLVANIA AND CALIFORNIA THAT PROVIDED VACCINE DURING THE H1N1 PANDEMIC AND SO THAT'S THE FIRST, SECONDLY WHAT THE PCAST RECOMMENDATIONS AND MEDICAL COUNTER MEASURE REVIEW WITH INFLUENZA WILL BE IMPROVING THE INFLUENZA MANUFACTURING AND THIS WILL BE AN EFFORT THAT WILL BE FDA, NIH AND BARTA TO BRING ABOUT THE FIRST AND LAST DOSES OF PANDEMIC VACCINE SOONER. THEREFORE WE LOOK AT WE'LL LOOK AT EVERY STEP OF THE MANUFACTURING PROCESS TO BUILD EFFICIENCIES INTO THE SYSTEMS AND SHARPEN OUR SCIENTIFIC UNDERSTANDING FOR BOTH CURRENT AND NEW VACCINE TECHNOLOGIES.

THESE AGENCIES WILL WORK WITH THE VACCINE MANUFACTURERS AND AND WE WILL SHORTEN THE INFLUENZA MANUFACTURING CYCLE BY WEEKS AND MAKE THE FIRST AND LAST DOSE OF PANDEMIC VACCINE AVAILABLE SOONER AND IN LARGER AMOUNTS.

THREE AREAS THAT WILL RECEIVE THE MOST ATTENTION WILL BE OPTIMIZATION OF VIRUS C, POTENCY ASSAYS, AND STERILITY ASSAYS.

THE THIRD AND LAST AREA THAT BARTA WILL BE LEADING WHICH IS ADVANCED DEVELOPMENT OF NEW TECHNOLOGIES.

WE WILL CONTINUE TO HELP DIAGNOSTICS AND INFLUENZA AND CANDIDATES USING TECHNOLOGIES THAT ARE NOT VULNERABLE TO SLOW GROWING VIRUSES WITH THE H1N1 PANDEMIC.

SECONDLY ANTIVIRALS TARGETED AGAINST NOVEL TARGETS SUCH AS HOST AND VIRAL SEEDS. AND SECONDLY THIS WILL STEM THE EMERGENCE OF DRUG RESISTANCE WE'VE SEEN WITH ANTIVIRALS, THIRD WITH CDC, WE WILL WORK WITH MORE AND SENSITIVE RAZER POINT OF CARE AND HIGH THROUGH PUT DIAGNOSTICS AND OTHER PATHOGENS.

IN CLOSING BARTA SEES THIS AS A NEW ERA TO IMPROVE THE MISSION OF PROVIDING MEDICAL COUNTERMEASURES TO THE PUBLIC WHEN IT NEEDS IT.

OKAY?

>> THANK YOU VERY MUCH.

IT'S A PLEASURE TO BE HERE THIS MORNING.

I HAVE BEEN WORKING ON MEASURES OF BIOSECURITY AND PUBLIC PREPAREDNESS FOR MANY, MANY YEARS NOW AND IT'S EXCITING TO SEE THIS DEGREE OF COMMITMENT, OF COLLABORATION AND REAL PROGRESS IN A FIELD THAT'S SO IMPORTANT TO THE HEALTH OF A NATION.

TOGETHER WE CAN AND WE WILL BUILD A SAFER AMERICA.

WE'RE ALL HERE TODAY BECAUSE WE'RE COMMITMENTED TO DOING MORE AND WE MUST.

WE LIVE IN A RAPIDLY TRANSFORMING WORLD AND BIOLOGICAL, CHEMICAL, RADIO LOGICAL AND NUCLEAR THREATS POSE A UNIQUE AND GROWING CHALLENGE.

DEVELOPING AND EVALUATING MEDICAL PRODUCTS TO PROTECT AGAINST THESE THREATS IS A COMPLEX TIME URGENT REQUIREMENT AND THAT'S WHY THE FDA PARTICIPATED CLOSELY AND ACTIVELY IN THIS DEPARTMENT LED REVIEW AND BECAUSE FDA EVALUATION OF PRODUCT SAFETY AND

EFFICACY SO SIGNIFICANTLY IMPACTS THE COURSE OF PRODUCT DEVELOPMENT.

AS THE SECRETARY INDICATED, THE REVIEW IDENTIFIED OUR AGENCY AS FUNDAMENTAL TO THE SUCCESS OF THE OVERALL ENTERPRISE.

ALREADY THE FDA CONDUCTS ACTIVITIES TO INCREASE ACCESS TO AND AVAILABILITY OF SAFE EFFECTIVE MEDICAL COUNTERMEASURES.

THIS INITIATIVE, WILL ENABLE US TO TAKE OUR ACTIONS TO THE NEXT LEVEL.

WE DEVELOPED AN FDA ACTION PLAN THAT ONCE IMPLEMENTED WILL ALLOW OUR AGENCY TO DO ITS PART IN HELPING TO STRENGTHEN AND TO TRANSFORM THE MEDICAL COUNTER MEASURE ENTERPRISE.

AND THIS WILL HAVE VERY BROAD IMPLICATIONS FOR HEALTH AND FOR SAFETY.

SPECIFICALLY, THE PLAN HAS BEEN DESIGNED TO ADDRESS IN THREE MAJOR WAYS SOME OF THE KEY CHALLENGES WE FACE AS AN AGENCY AND AS A NATION IN THE DEVELOPMENT AND AVAILABILITY OF MEDICAL COUNTERMEASURES.

FIRST, FDA WILL SUPPORT ENHANCED REVIEW OF NEW PRODUCTS AND NOVEL MANUFACTURING APPROACHES FOR THE HIGHEST PRIORITY MEDICAL COUNTERMEASURES.

WE'LL WORK WITH DEVELOPERS AND GOVERNMENT PARTNERS FROM VERY EARLY IN THE DEVELOPMENT PROCESS AND IN A HIGHLY INTERACTIVE MANNER TO DEFINE VIABLE REGULATORY PATHWAYS, SPEEDING PROGRESS TOWARDS PRODUCT APPROVAL BY HELPING TO ANTICIPATE AND REVOLVE BOTTLE NECK AND TO IDENTIFY AND ADDRESS SCIENTIFIC ISSUES AS THEY EMERGE.

SECOND, FDA WILL ADVANCE REGULATORY SCIENCE AND IMPROVE COUNTER MEASURE DEVELOPMENT AND EVALUATION PATHWAYS BY STRENGTHENING OUR OWN SCIENTIFIC CAPACITY AND BUILDING SCIENTIFIC RESEARCH COLLABORATIONS WITH GOVERNMENT ACADEMIA AND INDUSTRY.

THIS EMERGING SCIENCE WILL SUPPORT THE DEVELOPMENT OF NEEDED INNOVATIVE TOOLS AND STANDARDS TO BETTER ASSESS THE SAFETY, EFFICACY AND QUALITY OF NEW MEDICAL PRODUCTS.

THIS INITIATIVE WILL ALLOW FDA TO IDENTIFY AND HELP SOLVE THE SCIENTIFIC CHALLENGES THAT HINDER COUNTER MEASURE DEVELOPMENTS AND WITHOUT SOLUTIONS RESULT IN UNACCEPTABLE LONG DELAYS IN GETTING THE PRODUCTS YOU NEED.

THIRD, AND FINALLY, WE'LL WORK WITH HHS, AND OTHER GOVERNMENT PARTNERS TO CONDUCT AN EXAMINATION OF THE LEGAL FRAMEWORK AS WELL AS REGULATORY AND POLICY APPROACHES TOWARD MEDICAL COUNTER MEASURE DEVELOPMENT AND AVAILABILITY TO ASSESS ADEQUACY OR IMPROVEMENTS NEEDED TO PROPERLY SUPPORT PREPAREDNESS AND RESPONSE.

ULTIMATELY, OUR MISSION AT FDA IS TO DO EVERYTHING THAT WE CAN TODAY TO INSURE THE SAFETY, EFFECTIVENESS AND AVAILABILITY OF MEDICAL COUNTERMEASURES TOMORROW.

WE CANNOT AFFORD TO WAIT UNTIL AN EMERGE TO DISCOVER THAT A PRODUCT IS TOO RISKY OR THAT IT DOESN'T WORK AND WE MUST DO OUR PART TO EXPEDITE THE DEVELOPMENT OF PROMISING PRODUCTS AND IDENTIFY THOSE THAT WON'T MAKE THE CUT AS EARLY AS POSSIBLE IN THIS PROCESS AS WELL.

SO WE ARE VERY EXCITED ABOUT THIS NEW INITIATIVE AND THE OPPORTUNITIES THAT IT REPRESENTS TO IMPROVE HEALTH, SAFETY AND SECURITY FOR OUR NATION AND FRANKLY, FOR THE WORLD.

SO I'D LIKE TO CLOSE BY THANKING EVERYONE AT THE FDA THROUGHOUT THIS REVIEW TO MAXIMIZE OUR AGENCY'S CONTRIBUTION TO THE EFFORT.

OUR FRIENDS AND PARTNERS AT OTHER AGENCIES AND OUTSIDE, WITH WHOM WE'VE COLLABORATED

AND FINALLY DR. SEBELIUS AND LURIE TO THEIR DEDICATION OF ISSUE OF SUCH CRITICAL IMPORTANCE TO OUR COUNTRY.

SO I WISH ALL OF US GOOD LUCK IN THE TASKS AHEAD.

THANK YOU.

>> THANKS VERY MUCH.

I ALSO WANT TO THANK THE SECRETARY AND DR. LURIE FOR THEIR LEADERSHIP IN THIS PROCESS FOR PCAST FOR A VERY THOUGHTFUL AND HELPFUL INSIGHTFUL REVIEW AND OUR MANY PARTNERS AT THE DEPARTMENT OF DEFENSE, STATE, USID, THE U.S. GOVERNMENT, AND ALSO GLOBALLY AS I'LL DISCUSS BRIEFLY IN A MINUTE.

INVOTEMENTS ANNOUNCED TODAY WILL HELP US HAVE VACCINE SOONER FOR A FUTURE PANDEMIC. CDC IS INVOLVED IN SEVERAL WAYS AS HAVE BEEN MENTIONED, NOT JUST OUTLINED IN VERY BRIEFLY. FIRST WE WILL TWEAK THE VACCINE PRODUCTION METHODS.

WE ALL HOPE FOR GAME CHANGERS, GAME CHANGERS WILL BE I UNIVERSAL LONG LASTING VACCINE OR A RECOMBINANT VACCINE THAT COULD BE PRODUCE INDEED LARGE QUANTITYS AND QUICKLY. AND THE GOVERNMENT IS INVESTING NOR IN THAT, ANNOUNCED TODAY BUT IN ADDITION, WE CAN USE EXISTING TOOLS TO CUT, DAYS, WEEKS OR O OR EVEN A MONTH OR TWO OUT OF OUR CURRENT VACCINE PRODUCTION METHODS WITHOUT ANY CONCERNS ABOUT NEW PRODUCTS OR THE DIFFICULTIES OF GETTING THOSE TO MARKET.

THAT'S POSSIBLE BY FIRST OPT MIDSING THE WAY WE MAKE SEED STRAINS.

SO FINDING SEED STRAINS THAT WILL GROW QUICKLY, ONE OF THE FUNDAMENTAL PROBLEMS WITH HOW THE RESPONSE TO THE 2009 H1N1 PANDEMIC VACCINATION PRODUCTION PROGRESSED IS THAT THE SEEDS GREW TOO SLOWLY.

THERE ARE WAYS IN THE LABORATORY FOR OPTIMIZING THAT AND WITH ADDITIONAL INVESTMENTS FROM BARTA WE THINK THAT IS ACHIEVABLE IN THE NEXT FEW YEARS.

SECOND, AND ACHIEVABLE WE THINK EVEN SOONER IN COLLABORATION WITH THE FDA, AND WITH SUPPORT FROM BARTA ARE ENHANCEMENTS IN POTENCY TESTING, CURRENTLY TO SEE WHETHER THERE'S ENOUGH VACCINE IN A VILE TAKESSA AN EXTRAORDINARILY CUMBERSOME AND INACCURATE POTENTIALLY TECHNIQUE.

STUDIES DONE IN CDC ABULATORYS OUTLINE A PATHWAY TO DO THAT MUCH MORE QUICKLY AND ACCURATELY AND WE HOPE TO HAVE THAT IN PLACE WHICH IS AN IMPORTANT THING I SHOULD SAY RELATIVELY SOON.

WE ALSO AS DR. ROBINSON MENTIONED WILL PROMOTE MODERNIZED DIAGNOSTIC TESTS SO THAT ULTIMATELY, WE HOPE THAD IN THE DOCTOR'S OFFICE, DIAGNOSIS NOT ONLY OF FLU, BUT THE SPECIFIC TYPE OF FLU OR OTHER LUNG INFECTIONS CAN BE MADE.

THESE ARE ALL CRITICALLY IMPORTANT AND CAN MAKE AN ENORMOUS DIFFERENCE.

AS THE SECRETARY HIGHLIGHTED, WE ARE FOCUSING TODAY ON THAT MIDDLE SECTION.

OF DEVELOPING, PRODUCING VACCINES, BIOLOGICALS, TREATMENTS, NEW DRUGS.

THERE'S ALSO A NEED TO IMPROVE BOTH ENDS OF THAT PROCESS, THE DETECTION OF NEW PATHOGENS OR NEW PATHOGENS IN NEW AREAS AROUND THE WORLD AND IN THE U.S.

AND THE CDC IS INVESTING HEAVILY IN THIS WITH PEOPLE, WITH CAPACITY BUILDING, WITH LABORATORY DEVELOPMENT, AFTER ALL IF WE HAD KNOWN TWO MONTHS SOONER THAT THE H1N1 VIRUS HAD BEEN SPREADING IN MEXICO, WE VALID BEEN ABLE TO START VACCINE PRODUCTION TWO

MONTHS SOONER AND HAVE IT AVAILABLE TWO MONTHS SOONER AND SECOND AT THE OTHER END OF THE PROCESS, WE ARE DEALING WITH THE CHALLENGES THAT SECRETARY SEBELIUS OUTLINED CLEARLY AND STATE AND LOCAL GOVERNMENTS ARE FACING UNPRES DEBTED FISCAL CRISIS WHICH ARE PUTTING GREAT STRAINS ON THE ABILITY OF THE PUBLIC HEALTH SYSTEM TO DETECT AND RESPOND.

IN THAT CONTEXT WE'RE DOING WHAT WE CAN TO STRENGTHEN THE ABILITY OF GOVERNMENTS TO RESPOND TO OPTIMIZE SYSTEMS TO ENHANCE COLLABORATIONS BETWEEN THE HEALTHCARE AND PUBLIC HEALTH SYSTEMS.

TO USE THE ELECTRONIC HEALTH RECORD INITIATIVE TO MAKE IT EASIER TO REACH OUT TO AND VACINATE OR TREAT PATIENTS AS NEEDED.

AND FINALLY AS DR. LURIE SAID, WE'RE ALREADY WORKING ON IMPLEMENTING THIS PLAN.

THE PLAN IS CAREFULLY INSTRUCTED AND HAS TAKEN TIME TO GET RIGHT BUT IT HAS NOT RESULTED IN THE DELAY OF RESEARCH AND INITIATIVES SUCH AS THE POTENCY TESTING AND OTHER PROJECTS THAT ARE ALREADY WELL UNDERWAY.

FUNDMENTALLY WITH THIS RESPONSE, WE AS A SOCIETY NEED TO DETERMINE WHAT'S NEEDED AND WHEN.

WE NEED TO DECIDE WHAT TO MAKE AND HOW MUCH OF IT.

AND WE NEED TO MAKE SURE THAT IT GETS TO PEOPLE USING SYSTEMS THAT THEY'RE FAMILIAR WITH FROM THEIR EVERYDAY LIFE AND TODAY'S ANNOUNCEMENT AND INITIATIVES WILL MAKE THAT A REALITY MUCH SOONER AND MUCH MORE SECURELY FOR AMERICANS.

THANK YOU.

>> THANK YOU AS WE'RE TALKING ABOUT NEW TECHNOLOGY TO MAKE THESE COUNTERMEASURES, I GATHER SWREE MODERATE NOW TECHNOLOGY THAT BRINGS DR. ERIC LANDER THE OTHER CO CHAIR OF PCAST TO US FROM I BELIEVE TURKEY.

>> [LAUGHTER]

>> WELL, SO MUCH FOR ADVANCED TECHNOLOGY BUT IT IS A CELL PHONE BUT I HOPE IT'LL WORK.

[LAUGHTER]

>> I THINK MUCH HAS BEEN SAID, I WOULD LIKE TO EXPRESS MY THANKS BOTH TO THE SECRETARY AND DR. LURE SCHE TO EVERYBODY THROUGHOUT HHS.

IT HAS BEEN A TREMENDOUS PLEASURE FOR PCAST TO WORK TOGETHER WITH HHS AND I HAVE GOT TO SAY, AND I AM, I THINK PCAST AS A WHOLE IS TREMENDOUSLY EXCITED ABOUT ABOUT THE COORDINATION EXPRESSED IN THIS REPORT ON MEDICAL COUNTERMEASURES.

THERE IS NO MAGIC BULLET WITH RESPECT TO MEDICAL COUNTERMEASURES, IT'S A SYSTEMS PROBLEM.

AND THAT'S WHY THE KIND OF COORDINATION EXPRESSED TODAY, THE KIND OF THINKING THAT RANGES ALL THE WAY FROM SMALL SPEAKS ASK OPTIMIZATIONS AND IMPROVEMENTS, TO LOOKING AHEAD TO DISCOVERY OCCASIONALLY SWINGS FOR THE FENCES IS VERY IMPORTANT TO HAVE THAT WHOLE PORTFOLIO COVERED.

PCAST WAS GIVEN A PARTICULAR ASSIGNMENT IN LOOKING AT INFLUENZA, IT'S JUST ONE SPECIFIC THREAT, BUT IT'S OFTEN VERY VALUABLE TO LOOK AT A SPECIFIC CASE BECAUSE IT IS A CASE IN WHICH WE ACTUALLY DO HAVE A COUNTER MEASURE AND IT DOES WORK.

WE DO KNOW HOW TO MAKE A VACCINE.

WE HAVE AN INDUSTRY THAT ALREADY CREATES VACCINES.

THE ONLY PROBLEM IS, IT TAKES A BIT TOO LONG, A COUPLE OF MONTHS SOMETIMES TOO LONG. AND THE TRUTH IS THAT'S JUST FINE, THE AMOUNT IT TAKES TO PRODUCE A SEASONAL INFLUENZA VACCINE, IT'S PREDICTABLE, WE CAN PRODUCE IT, THE ONLY PROBLEM IS IN A PANDEMIC.

SO INFLUENZA IS IN A SENSE, THE PERFECT TEST CASE.

IT DOESN'T REQUIRE A TREMENDOUS AMOUNT OF NEW INVENTION, OF VACCINES THAT WE DON'T KNOW CAN EXIST, IT REQUIRES A SYSTEMS OPTIMIZATION AND HAS BEEN EXPRESSED ALREADY BY ALL THE SPEAKERS, THAT SYSTEM OPTIMIZATION IS ALREADY WELL UNDERWAY FROM IMPROVING THE EFFICIENCIES OF SURVEILLANCE, IMPROVING EFFICIENCIES OF PRODUCTION WITH NEW PRODUCTION METHODOLOGIES AND POTENCY TESTING AND STERILITY TESTING, TO AS IS DISCUSSED IN THE PCAST REPORT, RECENT AND EXCITING SCIENTIFIC DATA THAT SUGGESTS THAT IT MAY IMMEDIATE BE POSSIBLE TO PRODUCE UNIVERSAL FLU VACCINES THAT WOULDN'T REQUIRE ANNUAL IMMUNIZATION, OR A NEW SEASONAL AND PANDEMIC FLU ARISE.

SO IN ALL OF THESE WAYS, FLU IS A TEST CASE.

I THINK THE WAYS OF WORKING WITH INDUSTRY, THE WAYS OF STREAM LINING REGULATORY APPROVALS AND REALLY ADVANCING REGULATORY SCIENCES THAT THE FDA FOCUSED ON IT NOW WILL BE WONDERFUL MODELS FOR PERHAPS THE MORE DIFFICULT CASES IN MEDICAL COUNTERMEASURES.

SO I SIMPLY WANT TO EXPRESS MY TREMENDOUS ENTHUSIASM FOR BOTH THE SPECIFIC FIVE MEASURES THAT WERE LAID OUT AND MORE GENERALLY FOR THE BOLD AND COORDINATED SPIRIT THAT EVERYONE AT HHS HAS ENGAGED THE PROBLEM WITH AND STAY THAT PCAST STANDS READY TO HELP IN ANY WAY AS THE WORK MOVES FROM CREATING A PLAN AND A PLAN FRONT ACTUALLY IMPLEMENTATION, SO THANK YOU VERY MUCH.

>> SO TRIED AND TRUE TECHNOLOGY BRINGS HIM HERE.

>> IT WORKED, I HOPE IT WORKED.

>> IT'S GREAT.

YOU KNOW THE OLD ADAGE THE SYSTEM IS PERFECTLY DESIGNED TO GET THE RESULT THAT IT DOES, I THINK APPLIES HERE AND AS YOU'VE HEARD, WE REALLY TOOK A STEP BACK, SYSTEMS APPROACH TO LOOKING AT THE WHOLE MEDICAL COUNTER MEASURE ENTERPRISE AND PROBLEM I THINK CAME UP WITH SYSTEMS SOLUTIONS I WANT TO STRESS THAT EACH OF THE INITIATIVES AND ENHANCEMENTS WE TALK ABOUT TODAY ARE INTENDED TO WORK TOGETHER AND AS YOU HEARD FROM THE SECRETARY, ALSO INTENDED TO WORK WITH PROJECT BIOSHIELD AND THE SPECIAL RESERVE FUND. THIS IS NOT THAT WE'VE PUT A BUNCH OF THINGS ON THE TABLE THAT CAN YOU BE A KID IN A CANDY STORE AND PICK THE CANDY YOU LIKE THE BEST AND JUST DO IT AND EXPECT TO GET THE RESULT. WE BELIEVE THAT WE NEED TO DO ALL THESE THINGS AND TO DO ALL OF THESE THINGS REALLY IN CONCERT AND IN A COORDINATED WAY TO GET TO THE END RESULT, THAT'S THE REAL SYSTEM REDESIGN PART.

WE CAN'T BE IN THIS SITUATION THAT WE'VE BEEN IN OF HAVING A SYSTEM THAT GETS THE RESULTS THAT IT DOES AND THAT'S WHY REALLY WE'VE TAKEN THIS NEW APPROACH.

SO WITH THAT I WANT TO THANK EVERYBODY AGAIN FOR THEIR INCREDIBLE HARD WORK AND PARTICIPATION, ENERGY AND DEDICATION AND THROW THIS OPEN TO QUESTIONS.

>> THANK YOU.

THANK YOU FOR THE PRESENTATION.

MY QUESTION IS FOR COMMISSIONER HAMBURG AND WITH REGARD TO THE INITIATIVES FOR REGULATORY SCIENCE INITIATIVE, IMPROVING THE LEGAL AND REGULATORY FRAMEWORK. MY QUESTION SIMPLY IS TO WHAT EXTENT THE INITIATIVE FOCUSES ON HARMONIZATION OF BOTH THE PROCESS, THE REGULATORY PROCESS AND THE STANDARDS OF REVIEW AMONG THE UNITED STATES AND OUR PRINCIPLE ALLYS.

THERE'S A SUBSTANTIAL BODY OF OPINION THAT SAYS THAT THE THREATS THAT YOU ALLUDED TO, WELL, EVERYBODY ALLUDED TO THE PANEL CAN BE MANIFEST NOT SIMPLY TO AMERICANS BUT WILL HAVE DREADFUL IMPACTS ON NATIONAL SECURITY EVEN IF THEY IMPACTED OUR ALLYS.

THERE'S CLEAR INDICATION THAT AMONG OUR ALLYS, THERE ARE INCONSISTENT PROCEDURES AND INCONSISTENT STANDARDS WITH REGARD TO LICENSING A MEDICAL COUNTERMEASURES AND IN ADDITION TO THE SECURITY IMPLICATIONS FROM AN ENTREPRENEURIAL PERSPECTIVE OPENING UP THE OTHER MARKET SYSTEM A WAY TO INCENTIVIZE ENGAGEMENT, THE UNITED STATES IS NOT THE ONLY MARKET, IT IS BIG BUT IT IS LIMITED SO MY QUESTION IS TO WHAT EXTENT THE NEW INITIATIVE ADDRESSES TRANSNATIONAL HARMONIZATION OF BOTH PROCEDURES AND STANDARDS.

>> WELL YOUR QUESTION IS AN IMPORTANT ONE AND IT ADDRESSES CRITICAL PRIORITIES WITHIN THE FDA.

>> IN ADDITION TO THE ARENA OF GREAT IMPORTANCE TO THE SUCCESS OF THIS EFFORT.

FDA CAN NO LONGER OPERATE AS A DOMESTIC AGENCY EXCLUSIVELY AND IT'S IMPORTANT AS WE OPERATE AS PART OF A GLOBAL COMMUNITY OF REGULATORS AND WE ADDRESS THIS THAT IN TERMS OF HARMONIZATIONS AND APPROACHES TO THE GREATEST DEGREE POSSIBLE AND ALSO IN TERMS OF SCIENCE IS A GLOBAL ENTERPRISE AND THE RESEARCH UNDERLIES OUR DECISION MAKING AS WELL AS IT UNDERLIES THE PRODUCTS THAT COME BEFORE US FOR REVIEW AND IS PRODUCED AS A RESULT OF INTERNATIONAL SCIENTIFIC EFFORTS.

SO, YES WE ARE VERY MUCH CONCERNED ABOUT WORKING IN COLLABORATION ON AN INTERNATIONAL BASIS.

WE HAVE ALREADY SEEN THE VALUE OF THAT IN OTHER ARENAS, INCLUDING IN ADDRESSING H1N1 THIS PAST YEAR WHERE AS I'M SURE, YOU KNOW, DIFFERENT APPROACHES WERE IN FACT TAKEN BY DIFFERENT RAG LATTERYS AND NATIONS IN TERMS OF THE SPECIFICS OF THE VACCINES THAT WERE DEVELOPED AND WE'RE WORKING IN CLOSE COORDINATION AND SHARING INFORMATION AND WE WERE ALSO IN IMPORTANT WAYS SHARING OPPORTUNITIES SO THAT IF IT HAD BEEN NEEDED, WE WERE GOING TO BE ABLE TO ADJUST APPROACHES USING INFORMATION THAT WAS EMERGING FROM THE EXPERIENCES OF OTHER NATIONS FOR EXAMPLE.

HAD WE, WE WERE PREPARE FEDERAL WE NEEDED TO ON EMERGENCY USE AUTHORIZATION BASES TO THE USE OF ADJUVANT AND THE EXPERIENCE OF OTHER REGULATORS AND OTHER PARTS OF THE WORLD WITH ADJUVANTS WAS VERY INFORMATIVE TO OUR THINKING THEN, AND CERTAINLY GOING FORWARD TO OUR THINKING.

SO, YES, A STRATEGY OF WORKING AS A GLOBAL PARTNER IS VERY FUNDAMENTAL TO OUR OVERALL APPROACH TODAY IN THE FDA, AND TO THE NEEDS OF ADDRESSING MEDICAL COUNTERMEASURES.

>> [INDISCERNIBLE].

>> GREAT, GO AHEAD.

ON THE PHONE?

>> FIRST QUESTION COMES FROM MAGGIE FOX WITH ROYDERS, YOUR LINE IS OPEN.

>> THANKS VERY MUCH.

I WANT TO CLARIFY A BIT MORE ABOUT THE MONEY, EXACTLY HOW MUCH MONEY IS GOING TO BE NEEDED OVER THE FIRST YEAR AND OVER THE COMING FIVE YEARS AND WHERE PRECISELY IT WILL COME FROM?

THANKS SO MUCH.

>> SURE, WELL AS YOU HEARD FROM THE SECRETARY ABOUT 1.9 BILLION DOLLARS AS NOW BEEN ALLOCATED AND IDENTIFIED TO GET ALL OF THESE ACTIVITIES OFF THE GROUND.

I THINK YOU ALSO HEARD THAT ONE OF THE THINGS THAT WE'VE UNDERTAKEN IS REALLY A FIVE YEAR BUDGET PLANNING PROCESS.

SO THAT WE CAN ANTICIPATE, IDENTIFY AND ANTICIPATE BUDGET NEEDS DOWN THE ROAD IN A MUCH MORE HOLISTIC AND COMPREHENSIVE WAY SO THAT WE'RE NOT CONTINUALLY LOOKING AT DOING THINGS A YEAR AT A TIME.

SO AS YOU HEARD, THE CURRENT FUNDING AS BEEN IDENTIFIED FROM CURRENT ALLOCATIONS TO HHS IN LARGE PART FROM ALLOCATED AND REPURPOSING FLU FUNDS AND WILL BE CONTINUING TO WORK WITH THOSE FUNDS AS WE MOVE FORWARD.

>> GOOD MORNING I'M CHRIS REVERE WITH THE NATIONAL CHILDREN ON DISASTERS AND THE COMMISSIONER APPRECIATES THE EFFORT IN PUTTING TOGETHER THIS REPORT AND WE WANT TO THANK YOU.

CHILDREN REPRESENT 25% OF OUR POPULATION, THERE'S 74 MILLION CHILDREN UNDER THE AGE OF 18 IN OUR COUNTRY, YET THERE ARE FEW MEDICAL COUNTERMEASURES THAT HAVE BEEN APPROVED FOR USE IN CHILDREN, THERE ARE FEW MEDICAL COUNTERMEASURES AVAILABLE IN STOCK PILES ACROSS THIS COUNTRY, AND THERE ARE LITTLE IF ANY VIABLE INCENTIVES FOR MANUFACTURES TO CREATE THIS, CREATE THESE IMPORTANT MEDICATIONS FOR CHILDREN.

SO THE QUESTION IS, WITH THIS REPORT CHRKS IS VERY TIMELY AND IMPORTANT TO THE COMMISSIONS WORK, HOW DO YOU BELIEVE THE RECOMMENDATIONS AND THE MECHANISMS AND INVESTMENTS GOING FORWARD, CAN BE APPLIED TO THE CRITICAL NEEDS OF CHILDREN IN THE COUNTRY.

GREAT, THANKS SO MUCH FOR THAT QUESTION.

I DON'T FINISH OTHERS WANT TO JUMP IN HERE AS WELL.

BUT I'LL START.

AND I THINK YOU CAME IN AFTER, THE SECRETARY HAD JUST FINISHED SAYING THAT ONE OF LET IMPORTANT THINGS WE HEARD THROUGHOUT OUR REVIEW WAS THE SET OF ISSUES ABOUT THE NEED FOR COUNTERMEASURES IN CHILDREN.

AND I THINK AS YOU KNOW WE HAVE REALLY BEGUN TO LOOK AT THE PROCESSES AND WE NEED TO WHICH WE NEED PRODUCTS IN GENERAL AND IN LARGE PART, THAT'S WHAT THAT'S ABOUT AND IN THE PROCESS OF WHAT WE CALL REQUIREMENTS FIRST OF ALL VETTING THE COUNTERMEASURES AND WHAT COUNTERMEASURES THEY NEED IN THE POPULATIONS AND WHAT FORM IS A CRITICALLY IMPORTANT THING.

YOUNG CHILDREN DON'T SWALLOW PILLS, SO YOU NEED LIQUID JUST AS A STARTING POINT.

YOUNG CHILDREN ARE NOT JUST SMALL ADULTS AND YOU CAN'T JUST CUT THE DOSE IN HALF, AND MAKE IT EFFECTIVE,.

WHAT IS IT ABOUT THIS PRODUCT, AND THESE COMMISSIONS THAT DON'T ACT, YOU KNOW LIKE THE

AVERAGE AMERICAN AS IF THERE EVER WERE SUCH A THING ANYMORE AS AN AVERAGE AMERICAN, BUT THE NEEDINGS OF CHILDREN ARE VERY CLEARLY UP THERE, NIH, RIGHT NOW IS INVEST NOTHING A WHOLE SERIES OF STUDIES TO LOOK AT SOME OF THE EXISTING COUNTER MEASURES AND THEIR DOSING IN CHILDREN, BARTA RIGHT NOW IS SUPPORTING A WHOLE SUPPORTING STUDIES AS WE SPEAK TO LOOK AT THE PALLET ABILITY OF DIFFERENT COUNTERMEASURES BECAUSE CHILDREN DON'T SWALLOW PILLS AND WE GOT A LOT OF PILLS IN THE STOCK PILE WE HAVE TO GET TO ANOTHER FORMULATION AND YOU KNOW THAT'S A GREAT EXAMPLE OF SOMETHING THAT'S NOT ONLY GOING TO HELP IN THE COUNTER MEASURE DOMAIN BUT I THINK ACROSS MANY OTHER DOMAINS AND ACTUALLY IF YOU CAN MAKE THE STUFF TASTE BETTER SO KIDS WON'T SPIT IT OUT, TELL BE EASIER TO GET ALL KINDS OF OTHER MEDICINES IN CHILDREN JUST AS AN EXAMPLE. AND FDA IS LOOKING HARD AT THE SET OF ISSUES ABOUT HOW TO MOVE FORWARD WITH THE KIND OF EVIDENCE THAT'S REQUIRED TO DETERMINE YOU KNOW WHEN SOME OF THESE COUNTERMEASURES ARE GOING TO BE LIKELY TO BE SAFE AND EFFECTIVE.

I THINK THAT'S PART WHAT HAVE COMMISSIONER HAMBURG WAS TALKING ABOUT WHEN WE TALKED ABOUT LOOKING AT ALL OF THE COMPONENTS OF REGULATION, THE SCIENCE, THE LEGAL AND REGULATORY FRAMEWORKS ET CETERA.

SO I SEE THAT THE ISSUES OF CHILDREN ARE SORT OF BAKED IN AT EVERY STEP OF THE WAY.

I DON'T KNOW IF ANYBODY WANTS TO JUMP IN MORE WITH THAT.

>> ANOTHER PERSON ON THE PHONE.

>> THE QUESTION COMES FROM MAGGIE FOX OF ROYDERS.

>> I'M INTERESTED IN THE GOVERNMENT INVOLVING IN MANUFACTURING AND DEVELOPMENT.

CAN YOU BROADEN THE DETAILS OF THAT PLAN, PLEASE?

>> SO I THINK THE U.S. GOVERNMENT HAS FOR A LONG TIME NOW AND IN PARTICULARLY IN THE AREA OF PANDEMIC SUPPORTED VACCINE MANUFACTURING AS YOU KNOW AS PART OF OUR PANDEMIC PLAN TO GET READY FOR YOU KNOW H5N1, AND THEN IN THE USE OF H1N1.

WE SUPPORTED COMMERCIAL VACCINE MANUFACTURES TO EXPAND OR RETROFIT THEIR EXISTING FACILITIES.

WE PARTNERED WITH A FACILITY IN NORTH CAROLINA TO BE ABLE TO CREATE SEARCH CAPACITY AS NECESSARY TO MANUFACTURE VACCINES IN THE CASE OF A PANDEMIC OR OTHER EMERGENCY AND THESE I'LL TURN THIS OVER TO ROBIN IN A MINUTE BUT THESE CENTERS FOR ADVANCED DEVELOPMENT AND MANUFACTURING ARE INTENDED BOTH TO HELP THE DEVELOPERS OF THESE VACCINES OR OTHER PRODUCTS GET THEM TO MARKET.

AND AS WELL TO CREATE ADDITIONAL RESEARCH VACCINE MANUFACTURING CAPACITY FOR THE UNITED STATES.

BUT THE INTENT IS LARGELY FOR THESE TO GET MADE, IN PART OF A PUBLIC PRIVATE PARTNERSHIP BUT IN THE PUBLIC SECTOR.

>> AS SHE SAID, THIS IS TRUE PUBLIC PARTNERSHIP FOR WHICH WE ESTABLISHED EXAMPLES ALREADY AND HAVE BEEN CITED.

WE WILL NOT BE PRODUCING THE VACCINES.

THE PEOPLE THAT NOW HAVE THE BEST KNOW HOW, THE PHARMACEUTICAL COMPANIES AND THE ACADEMIC CONSULTANTS WILL BE PROVIDING THESE VACCINES AND THESE SERVICES WILL BE IN A CALL SHARING PARTNERSHIP WITH THEM, THE MORE CORE SERVICES THEY PROVIDE, THE MORE THE

GOVERNMENT WILL PROVIDE FUNDING, BUT WE WILL BE THERE TO HELP MANAGE THE PRODUCTS AS THEY GO THROUGH BUT THEY WILL MAKE NATURAL PRODUCTS IN THE FACILITY WILL ACTUALLY BE THEIRS.

WAS THERE ANOTHER QUESTION ON THE PHONE OR GOING OVER HERE?

>> WE HAVE THREE MORE QUESTIONS.

>> I HAVE A QUESTION THIS MIGHT BE A BIT MORE DIFFICULT, THOUGH.

I KNOW IN THE PREPORT YOU TALK A LOT ABOUT HOW YOU WANT TO COMMUNICATE MORE WITH INDUSTRY, BUT, LIKE WHEN BARTA CANCELED ITS CONTRACT THIS YEAR FOR THE ANTHRAX VACCINE AND THEN ALSO WHEN HUMAN GENOME SCIENCES, WHEN BEFORE LIKE THE FDA COMMITTEE ON THE RECOMMENDATIONS, THESE WERE LAST MINUTE ISSUES THAT CAME UP, IN BOTH OF THESE SITUATIONS, INDUSTRY SEEMED TO BE CAUGHT OFFGUARD KIND OF BLIND SIDED BY BOTH OF THOSE SITUATIONS WHERE THE THE GENOME SCIENCES CAME TO THE COMMITTEE, THEY COULDN'T ACTUALLY VOTE ON WHETHER TO APPROVE THAT PRODUCT BECAUSE THERE WERE LAST MINUTE ISSUES THAT CAME UP RIGHT BEFORE THE MEETING SO WHAT ARE YOU ALL GOING TO DO TO KIND OF COMMUNE KACCTICATE BET TORE INDUSTRY SO THAT THEIRS NOT WALKING AWAY IN INSTANCES LIKE THAT, WHERE THEY FEEL LIKE, WHAT'S THE INCENTIVE FOR US NOW WE GET IN SITUATIONS WHERE WE'VE GOT TO, YOU KNOW SO FAR IN DEVELOPMENT AND THEN EITHER THE CONTRACT GETS CANCELED AND THAT ONE WITH THE BARTA ONE SAID THEY DIDN'T THINK THEY COULD MEET THE EIGHT YEAR BIOSHIELD BUT WHAT CAN THEY DO MAYBE TO COMMUNICATE MORE EARLY ON OR SOMETHING LIKE THAT SO THE INDUSTRY DOESN'T LOSE THAT INSENTIVE THEY HAVE TO DEVELOP THE PRODUCT NECESSARY.

>> I THINK YOU'RE ASKING A REALLY GREAT QUESTION.

AS PART OF THIS REVIEW, AND LOOK AT THIS EXPERIENCE, EVERY SINGLE PRODUCT AND WHAT WORK WELL AND DO MORE WELL AND LOOK AT THOSE THINGS THAT DIDN'T WORK VERY WELL AND FIGURE OUT WHAT WENT WRONG AND WHERE WE HAD SUCCESSES AND REALLY LOOK AT SMALLPOX VACCINE IS A GREAT EXAMPLE AND WHAT WE FOUND IS THAT WE HAD CDC, NIH, FDA SCIENTISTS WORKING TOGETHER WITH THE DEVELOPERS FROM THE BEGINNING AND MEETING ON A REGULAR BASIS SO THAT YOU COULD SAY, WHERE IS THE SCIENCE TAKING US?

WHAT NEW SCIENCE IS NEEDED AND BRING SCIENTIFIC EXPERTISE TO BEAR.

WHERE ARE WE GOING TO MOVE FORWARD ON REGULATION, WHETHER THE REGULATORY PATHWAYS ANTICIPATE SOME OF THESE PROBLEMS BEFORE THEY ARRIVE ARISE AND HAVE EARLY FREQUENT COMMUNICATION.

YOU KNOW WHERE THINGS HAVE NOT GONE SO WELL, THERE HASN'T BEEN A PROCESS OF EARLY DISCIPLINE, FREQUENT COMMUNICATION AND WHAT YOU HAVE AT THE BACK END AND NOT ONLY COMMUNICATION BUT REALLY ACTIVE PROBLEM SOLVING.

NOW SOMETIMES THE SCIENCE JUST ISN'T GOING TO BE THERE AND WE HAVE TO FACE THAT AND AS COMMISSIONER HAMBURG AND EVERYBODY IN DRUG DEVELOPMENT SAYS, ANOTHER TASK IS TO FIGURE OUT THINGS THAT AREN'T GOING TO MAKE THE CUT, HOW TO IDENTIFY THOSE EARLY ON IN THE PROCESS SO THAT PEOPLE DON'T SPEND TIME AND ENERGY AND MONEY AND PUT THOSE THINGS TO RESOURCES THAT ARE MORE LIKELY TO SUCCESS.

SUCCEED.

BI WE HAVE RECOGNIZED AND DEDICATED OURSELVES TO A VERY DIFFERENT WAY OF WORKING

TOGETHER GOING FORWARD.

I DON'T KNOW IF ANYONE WANTS TO ADD TO THAT?

>> I WANT TO EXPAND ON WHAT DR. LURIE SAID, THE APPROACH GOING FORWARD FROM LESSONS LEARN SIDE A CASE MANAGEMENT APPROACH THAT INCLUDES ALL THE AGENCIES REPRESENTED HERE, TO ASSIST THESE DEVELOPERS AS THEY GO FORWARD IN A FREQUENT AND ROBUST CONVERSATION AS TRUE PARTNERS SO I THINK WE CAN AVOID SOME OF THE ISSUES WE'VE COME IN BEFORE.

>> AND I GUESS, YOU KNOW PARTLY IT'S JUST A REITERATION WITH ALL OF THESE SAID, I THINK THAT THE APPROACH OUTLINED IN THE NEW INITIATIVE SPEAKS TO THE QUESTION YOU ASK IN THE SENSE OF THE IMPORTANT NEED, TO REALLY ADD CLARITY AND RELIABILITY TO THE REGULATORY PATHWAY AND THAT INVOLVES BOTH STRENGTHENING THE UNDERLYING SCIENCE AND REALLY HARNESSING ALL THE BEST AVAILABLE SCIENCE AND TECHNOLOGY TO MAKE TAKEN THEY REGULATORY PATHWAY AS DEFINED AS POSSIBLE AND AS EFFECTIVE AND EFFICIENT AS POSSIBLE AND ALSO THIS EARLY ENGAGEMENT AND MORE INTERACTIVE ENGAGEMENT FROM THE VERY BEGINNING TO ENABLE THE ISSUES TO BE SURFACED EARLY AND ADDRESSED IN A CLEAR AND WELL UNDERSTOOD WAY MOVING FORWARD.

>> I HAVE THREE QUESTIONS.

ONE IS, I'M WONDERING WHAT THE DIFFERENCE IS BETWEEN THE STRATEGIC INVESTOR THAT YOU'VE DESCRIBED AND WHAT CONGRESS INTENDED BARTA TO BE WHEN IT CREATED THE AGENCY A FEW YEARS AGO?

ALSO, THE I'M WONDER IF YOU CAN PROVIDE MORE DETAIL ON FUNDING FOR EACH OF THE FIVE POINTS THAT YOU'VE MENTIONED.

AND I'M ALSO WONDERING THEN, IF YOU THINK THAT THE TWO BILLION DOLLARS, ROUGHLY TWO BILLION THAT YOU'RE GOING TO APPLY TO THE PROGRAM WILL BE ENOUGH TO INCENTIVIZE BIG PHARMA TO GET INVOLVED WITH THE PROGRAM?

>> GREAT, YOU WANT TO START, TIM?

>> YEAH, THE FIRST QUESTION, GOOD QUESTION ABOUT WHAT THE DIFFERENCE BETWEEN WHAT BARTA DOES AND THE PROPOSED STRATEGIC INVESTMENT PROGRAM WOULD DO.

BARTA IS INVOLVE WIDE A SPECIFIC PRODUCT, NOT NECESSARILY WITH THE VIABILITY OF THE COMPANY AND THE ABILITY OF THE COMPANY TO SUSTAIN ITSELF TO GET THROUGH THE PROCESS. IT IS INVOLVED ONLY WITH GETTING A PARTICULAR PRODUCT THROUGH THE DEVELOPMENTAL STAGE INTO THE POINT OF HAVING A PRODUCT THAT WE CAN ULTIMATELY PUT INTO THE STRATEGIC STOCK PILE OF PURCHASE THROUGH BIOSHIELD.

WHAT THE STRATEGIC INVESTMENT IS MORE ENHANCING AND ASSURING THE VIABILITY OF THE COMPANY BECAUSE THE COMPANY MAY HAVE A PRODUCT AND THE INVESTMENT IN THE PRODUCT IS MAKING THE PRODUCT GO BUT THE COMPANY ITSELF IS GOING TO FAIL BECAUSE THEY DON'T HAVE THE RESOURCES, THE INVESTMENTS TO DO THAT SO IT REALLY IS MORE VIABILITY OF COMPANY VERSES A VERY SPECIFIC PRODUCT THAT WE'RE TRYING TO MAKE.

>> GOOD, SO I THINK THE OTHER TWO QUESTION HIS TO DO ABOUT WITH THE BREAK DOWN OF THE FUNDS AND WAS TWO BILLION ENOUGH?

SO RIEHL GET TO I'LL GET TO THE BREAK DOWN OF THE FUNDS BUT FIRST LET ME COMMENT ON IS TWO BILLION ENOUGH?

BECAUSE IT'S NOT SIMPLY A CASH INFUSION TO INDUSTRIES THAT'S GOING TO BRING PEOPLE TO THE

TABLE AND GET THIS DONE, BUT AGAIN, IT SORT OF REALLY ELIMINATING OTHER BARRIERS AND RISKS THEY FACE ALONG THE WAY AND SO, FOR EXAMPLE, THE ISSUES THAT YOU'VE JUST HEARD ABOUT ABOUT THE REGULATORY PATHWAY, I THINK WERE THE MOST COMMON THINGS THAT WE REALLY HEARD IN TERMS OF WHY IS INDUSTRY OFTEN SO RELUCTANT TO COME TO THE TABLE BECAUSE THEY PERCEIVED IT AS TOO RISKY, THE PATHWAY ISN'T CLEAR, ET CETERA.

SO A HUGE PART OF THE EFFORT HERE IS AIMED AT SORT OF "DE RISKING" PART OF THAT PROCESS OR REDUCING THE OPPORTUNITY COSTS THAT COMPANIES FACE TO GET INTO THIS OR STAY IN THIS BUSINESS, ET CETERA.

AND THEN, REALLY THIS PARTNERSHIP BETWEEN FEDERAL GOVERNMENT AND INDUSTRY ALONG THE WAY.

WE CERTAINLY SAW IT VERY DRAMATICALLY IN A LOTE OF OUR FLU EFFORTS.

AND I'M ACTUALLY VERY ENCOURAGED FROM ALL OF OUR CONVERSATIONS WITH INDUSTRY THAT WERE VERY MUCH ON THE RIGHT TRACK HERE.

NO, I DON'T HAVE A CRYSTAL BALL AND WE DON'T KNOW AND IT MAY BE THAT SOME OF THIS HAS TO BE ANITYRATIVE PROCESS AS WE MOVE FORWARD BUT WE WORKED VERY HARD TO LISTEN TO WHAT PEOPLE HAD TO SAY TO REALLY CRITICALLY ANALYZE THE SITUATION AND TO LOOK AT THE WAYS IN WHICH WE REDUCE ROAD BLOCKS ALONG THE WAY.

AND IF DOWN THE ROAD FINE TUNING IS NECESSARY THEN WE'LL DO FINE TUNING.

I DON'T SEE ANY OF THIS AS COMPLETELY CAST IN STONE FROM THIS PERSPECTIVE.

NOW IN TERMS OF THE SOME OF THE FUNDS AND BREAK DOWN OF FUNDS RIGHT NOW, YOU KNOW AS THINGS STAND NOW, WE WOULD ANTICIPATE ABOUT A 170 MILLION TO THE REGULATORY SCIENCE INITIATIVES AT FDA, 678 MILLION RIGHT NOW FOR THE ADVANCED DEVELOPMENT OF FLEXIBLE MANUFACTURING CORE SERVICES FACILITIES.

THE ACCELERATION PROCESS AT NIAID, 33 MILLION DOLLARS, A WHOLE SET OF ISSUES RELATED TO FLU AND ADDRESSING THE ADVANCED DEVELOPMENT NEEDS AND FLU IN A VARIETY OF AREAS, 822 MILLION AND THE STRATEGIC INVESTMENT IDEAS ABOUT 200 MILLION SO I HOPE THAT HELPS.

LAST QUESTIONS IN THE PHONE OR IN HERE?

IF THERE'S NOT A LAST QUESTION?

ALL RIGHT.

WELL, GOOD.

WELL, THANKS OH?

>> HI, JILL WAXLER PHARMACEUTICAL EXECUTIVE MAGAZINE.

AT THE END OF THIS LAST PANDEMIC SEASON, WITH THE DISEASE NOT BEING AS SEVERE AS ANTICIPATED IN THE TIME LAG, THERE WAS AN EXCESS VACCINE HELD BY MANY MANUFACTURES AND I'M WONDERING IF THAT EXPERIENCE MIGHT INFLUENCE THE INTEREST OF INDUSTRY AND FURTHER PARTICIPATE NOTHING ALL THESE INITIATIVES?

>> YOU KNOW I THINK THAT THAT'S A QUESTION THAT WE WOULD NEED TO POSE TO INDUSTRY, BUT I ALSO THINK AS YOU HEARD DR. FRIEDEN SAY AND OTHERS, I THINK IT'S WHY REALLY BEING SERIOUS ABOUT THE EARLY DETECTION AND SURVEILLANCE GETTING, A JUMP START ON THIS SO THAT YOU KNOW YOU CAN START MAKING VACCINE FASTER AND GETTING IT TO PEOPLE MUCH MORE QUICKLY AND N A PANDEMIC, AND THEN HAVING FASTER METHODS OF YOU KNOW MANUFACTURING AND GETTING THE VACCINE OUT TO PEOPLE ARE ALL THE REALLY IMPORTANT THINGS.

YOU KNOW IF YOU IF YOU GET THAT RIGHT, YOU'RE NOT GOING TO BE LEFT WITH THE KIND OF
CHANGE IN PUBLIC ATTITUDE, I THINK THAT SORT OF TRANSPIRED WITH THE PANDEMIC.
SO I THINK AGAIN, ALL OF THESE INITIATIVES AND ENHANCEMENTS WILL HELP US DO THE JOB BETTER
AND FASTER, I HOPE FOR EVERYBODY.
>> THANKS, EVERYONE FOR COMING AND THANKS FOR ALL OF YOUR SUPPORT.
LOOK FORWARD TO MORE OF IT.
[APPLAUSE]