Live closed captioning content for FDA’s “Modernizing FDA’s Data Strategy” public meeting, held virtually on June 30, 2020.

Please note that due to the nature of live captioning, this may not be 100% accurate.

My name is Allison Hoffman and ON BEHALF OF FDA'S OFFICE OF COMMISSIONER WELCOME TO
TODAY'S PUBLIC MEETING MODERNIZING FDA'S STRATEGY. THE RESCHEDULING AND CONVERSION TO A
VIRTUAL ONLY FORMAT HOWEVER I'M SURE YOU'LL AGREE IT'S WORTH THE WAIT. OPEN THROUGH JULY
30TH. INSTRUCTIONS ON COMMENTS ARE AVAILABLE TO THE FEDERAL REGISTER NOTICE. WE'LL START
WITH AN ORIENTATION FOR THE MEETING OF AMY ABERNETHY FDA'S PRINCIPAL DEPUTY COMMISSIONER
AND ACTING CIO WE'LL HAVE THREE SESSIONS EACH FOCUSED ON DIFFERENT ASPECT OF DATA
STRATEGY. EACH SESSION WILL START WITH A SHORT DISCUSSION PRESENTATION. FOLLOWED BY
RESPONSE AND PANEL DISCUSSION. LAST SESSION WILL BE A PRECISION FDA DATA CHALLENGE
PRESENTATION THAT WILL INCLUDE RESULTS OF THE OPEN DATA COMPETITION FOCUSED ON EXAMINING
ADVERSE EVENT DATA. IT'S MY PLEASURE TO INTRODUCE AMY ABERNETHY AND VID DESAI AND
RAM IYER
>>GOOD MORNING, WELCOME. I'M AMY ABERNETHY, PRINCIPAL DEPUTY COMMISSIONER AND ACTING
COHESIVE INFORMATION OFFICER AT THE FOOD AND DRUG ADMINISTRATION. I WELCOME YOU
HERE TODAY TO OUR MEETING ON MODERNIZING FDA'S DATA STRATEGY. I'M GOING TO SAY A HUGE
THANK YOU TO ALLISON HOFFMAN AND FDA INNOVATION LAB, OUR TECHNICAL GROUP, A WHOLE FDA AND
TO YOU FOR BEING PART OF THIS CONVERSATION. ALSO I WANT TO THANK OUR PANELISTS AND
THIS IS AN IMPORTANT CONVERSATION TODAY AND WE'RE -- FOLLOWING OUR TECHNOLOGY
MODERNIZATION ACTION PLAN THAT WE ANNOUNCED IN SEPTEMBER. PRECISION MEDICINE, DIGITAL
HEALTH, BETTER MANAGEMENT OF FOOD BORN ILLNESS, ATTACKING PANDEMICS, ALL OF THESE CAN BE
HELPED TO BE SOLVED THROUGH INNOVATION. AND THAT CARRIES US ON THE PATH FORWARD. BUT
IN ORDER TO DO SO, INDUSTRY, THE AMERICAN PEOPLE, YOU, NEED US, THE FDA, TO BE AS
EFFICIENT AS MODERN AND POSSIBLE. WE CAN EITHER BE AN ENABLER OR BOTTLENECK.
DID YOU KNOW THE FDA REGULATES 20 TO 25% OF THE WORLD'S ECONOMY? SO WHAT WE TALK ABOUT
TODAY ALSO HAS GLOBAL IMPACT. BETTER TELLING CAPABILITIES CAN HELP US TO IMPROVE
EFFICIENCY. SO WE'RE TALKING ABOUT DIGITAL TRANSFORMATION. USE OF CLOUD TECHNOLOGY. USE
OF SHARED DATA, DIGITIZED INFORMATION. WE'RE NOT JUST TALKING ABOUT DIGITAL

PAPER BUT
RATHER STRUCTURED INFORMATION THAT PREPARES US FOR LONGITUDINAL AND
ARTIFICIAL INTELLIGENCE FOR PREDICTION AND BLOCK CHAIN FOR TRACK AND TRACE OF
DRUGS AND
FOOD. IN SEPTEMBER, WE ANNOUNCED THE TECHNOLOGY MODERNIZATION ACTION PLAN.
IT WAS IN
THREE PARTS. FIRST, MODERNIZING OURING TECHNICAL APPROACH, SECOND,
DEVELOPING A PRODUCT
DEVELOPMENT MIND SET SO WE LEARN HOW TO PUT OUR DATA AND TECHNOLOGY TO WORK
AT FDA THROUGH
PROTOTYPE AND IS PROOF POINTS AND OPENING UP COMMUNICATION CHANNELS WITH THE
MODERN TECH
AND DATA INDUSTRY TO PREPARE FOR THE FUTURE. YOU'RE GOING TO HEAR MORE FROM
THEM. TODAY
WE NEED TO THINK ABOUT DATA AND ANALYTICS. THIS IS HOW WE MAKE DATA USEFUL.
PUTTING
IT TO WORK. YOU'RE GOING TO HEAR MORE FROM RAM. WHAT THIS MEETING IS AND
WHAT IT ISN'T.
THIS MEETING IS ABOUT HOW WE AT THE FDA THINK ABOUT AND USE DATA TO CONDUCT
OUR REGULATORY
WORK. IT'S NOT ABOUT THE GENERATION AND USE OF DATA TO MEET SPECIFIC
REGULATORY
REQUIREMENTS, FOR EXAMPLE, THE MEETING DOESN'T ADDRESS THE USE OF DATA TO
SUPPORT APPROVAL
OF A MEDICAL PRODUCT LAKE DRUG. IT'S ALSO NOT ABOUT FDA SPECIFICALLY
REGULATES
ARTIFICIAL INTELLIGENCE, DIGITAL HEALTH, DEVICES, OR THE OTHER. BUT THAT
BEING SAID,
DATA IS A CRITICAL COMPONENT OF FDA'S SCIENCE-BASED APPROACH TO REGULATIONS
AND FDA'S
DIGITAL TRANSFORMATION THEREFORE HAS VERY IMPORTANT IMPLICATIONS FOR ALL OF
THE INDUSTRIES
THAT WE REGULATE AND ULTIMATELY FOR PATIENTS AND CONSUMERS WHO DEPEND ON FDA.
THESE ARE
CENTRAL POINT WE WANT TO EMPHASIZE TODAY. WE NEED TO YOU UNDERSTAND WHAT
WE'RE
CONTEMPLATING AND PROVIDE INPUT. THIS IS ABOUT TRANSPARENCY AND PUBLIC
COMMENT. AND ALSO
ENSURING THAT WE'RE CUTTING EDGE AND PRAGMATIC. TO BE AS SMART AS POSSIBLE.
>>AMY INTRODUCED THE KEY ELEMENTS OF THE TEAM APP. MY FOCUS IS GOING TO BE
TO TALK
A LITTLE BIT ABOUT THE FIRST TWO, THE MODERNIZING OF IT INFRASTRUCTURE AND
ALSO SHIFTING
TO A MIND SET THROUGH THE USE OF NEAR TERM AND ASPIRATIONAL USE CASES. THE
TEAM APP
CAPTURES THE SCIENCE AND TECHNOLOGY AND THROUGH THE COVID PANDEMIC WE'VE ALSO
LEARNED THAT
WE NEED TO VERY QUICKLY ACCESS, ANALYZE AND USE DATA INFORMATION AVAILABLE
FROM THE MANY
DIFFERENT SOURCES TO MAKE INFORMED DECISIONS. SPEED AND JUST A MINUTE IS
KEY. IN
TECHNOLOGY WE OFTEN HEAR THE TERM INTERNET SPEED AND IN HEALTHCARE WE NEED TO
ADOPT TO A
NEW TERM, MOVING AT PANDEMIC SPEED. THE FDA LEGACY ARCHITECTURE SO FAR IS
DESIGNED AROUND
INTERNAL DATA CENTERS AND HARD PERIMETER TO KEEP OUTSIDE THREATS OUT. THIS
IS VERY

TRADITIONAL SIMILAR TO WHAT MANY ORGANIZATIONS DESIGN THEIR INFRASTRUCTURES AROUND. THE
NEW EMERGING HEALTHCARE ENVIRONMENT CHALLENGES US. THE CLOUD CHALLENGES THIS. FROM A
TECHNOLOGY PERSPECTIVE. TODAY WE SEE AND HEAR EVERY DAY PEOPLE DOING THINGS IN HOURS AND
DAYS WHAT USED TO TAKE WEEKS AND MONTHS. NOT ONLY DOES THE CLOUD IMPROVE JUST A MINUTE
BUT IT IS ALSO VERY COST EFFECTIVE IN THAT YOU ONLY PAY FOR WHAT YOU USE AND WHEN YOU USE
IT. RAM WILL TALK ABOUT THE DATA SIDE. THIS PANDEMIC HAS CLEARLY HIGHLIGHTED THERE IS A
LOT OF REALLY USEFUL DIVERSE DATA AVAILABLE ALL OVER THE PLACE. SOURCES CAN BE GLOBAL,
NATIONAL, STATE, LOCAL, IT'S VERY DISTRIBUTED. ON THE DATA SOURCE PERSPECTIVE THE FDA'S
INTERESTS SPAN PATIENTS, PROVIDERS, POLICYMAKERS TO EXPANDED ENTIRE HEALTHCARE SYSTEM
ECOSYSTEM GLOBALLY. WE CAN NO LONGER ASSUME THAT DATA WILL BE SUBMITTED TO AND RESIDE
INSIDE FDA. WE LIVE IN A HIGH DISTRIBUTED WORLD WHERE DATA, SKILLS, PEOPLE WE NEED TO
COLLABORATE WITH ARE NOT ALWAYS GOING TO BE WITHIN THE CONFINES OF FDA PERIMETER. SO THE
NEW TECHNOLOGY ENVIRONMENTARY BUILDING HAS TO ASSUME A VERY DISTRIBUTED AND COLLABORATIVE
BUT SECURE INTERNAL AND EXTERNAL ENVIRONMENT. THE NEW ENVIRONMENT HAS TO BE AGILE WITH
WORKLOADS THAT CAN BE EASILY MOVED FROM ON PREM TO THE VARIOUS CLOUD ENVIRONMENTS AND ALSO
TO SGRAIT ARE INTEGRATE AND COLLABORATE WITH DATA AND PEOPLE ANYWHERE IN THE SECURE AND
TRUSTED MANNER. SECURITY AND TRUST REMAIN KEY PRIORITIES AND CRAIG TAYLOR IS ON
ONE OF THE PANELS TO DISCUSS WHY THIS IS IMPORTANT TO THE AGENCY. GOING TO BE BUILD ABOUT
0 TRUST SECURITY CONCEPTS AND THIS RECOGNIZES THAT MUCH OF THE DATA AND PEOPLE WE WANT TO
COLLABORATE WITH ARE NOW INCREASINGLY ON THE OUTSIDE OF THE FDA. BUT AGAIN, WE WANT TO
ENSURE WE DO THIS IN A VERY SECURE MANNER. THE NEW ENVIRONMENT WILL DO DEAL IN SOFTWARE
AND BY POLICIES THINGS THAT PREVIOUSLY DID BY MOVING HARDWARE OUT AND COVID-19 HAS
FUNDAMENTALLY CHANGED THE WORK ENVIRONMENT FOR ALL OF US. TELEWORKING WILL BE IMPORTANT
EVEN AFTER THE PANDEMIC IS OVER. THE ENVIRONMENT WE'RE NOW CONTEMPLATING WAS DISTRIBUTED
ENOUGH WHEN WE HAD OUR PEOPLE IN BUILDINGS AND FACILITIES BUT NOW PEOPLE ARE EMPLOYEES
WILL BE SPREAD ALL OVER THEIR HOMES, AROUND THEIR HOMES AND WHEREVER ANYWHERE PREFERRED
WORK LOCATIONS ARE. THIS IS GOING TO BE HAPPENING NOT JUST TO US BUT TO EXTERNAL PARTNERS
AS WELL. FROM AN IT PERSPECTIVE WE'RE GOING TO HAVE TO RETHINK OUR TECHNOLOGY AND
PROCESSES TO ENABLE AND ENGAGE THIS PRETTY DISTRIBUTED WORKFORCE INTERNALLY

AS WELL AS
EXTERNALLY. MODERNIZATION EFFORTS AT THE FDA ARE NOT JUST ABOUT TECHNOLOGY. WE ALSO NEED
TO MODERNIZE OUR INTERNAL PROCESSES MAKE THEM MORE EFFICIENT AND EFFECTIVE AND EQUALLY
IMPORTANT IS THE NEED TO INVEST IN OUR PEOPLE AND CULTURE IF WE WANT THIS MODERNIZATION
TO BE SUSTAINABLE AND HAVE TO MODERNIZE TECHNOLOGY PROCESS AND PEOPLE IN A CONTINUOUS
MANNER OTHERWISE MODERNIZATION IS JUST GOING TO BE A PROJECT AND IS IT SHOULDN'T BE A
PROJECT. THANK YOU FOR YOUR ENGAGEMENT TODAY. I HOPE MY COMMENTS GAVE YOU AN IDEA WHAT
WE'RE WORKING TOWARDS AND I'M EXCITED NOW TO HAND THE MICROPHONE TO MY COLLEAGUE RAM WHO
WILL BE TALKING ABOUT THE CORE THEME OF TODAY'S MEETING ON HOW WE USE THIS FOUNDATIONAL
TECHNOLOGY INFRASTRUCTURE AND PUT DATA TO USE. RAM?
>>THANK YOU, VID. AMY AND VID TALKED ABOUT THE TECHNOLOGY MODERNIZATION ACTION PLAN AND
GETTING VALUE OUT OF DATA AS A CRITICAL PART OF THE STRATEGY. I WOULD LIKE TO THINK THE
CREATION OF THE FIRST EVER CHIEF DATA OFFICER ROLE FOR THE AGENCY IN ITSELF IS IS A
MANIFESTATION AND IMPLEMENTATION OF THAT STRATEGY AND NOW WE'RE EMBARKING ON MODERNIZING
OUR DATA STRATEGY. MY COMMENTS WILL BE BRIEF BECAUSE AT THIS POINT, JUST TWO MONTHS IN
THE AGENCY, I HAVE MORE QUESTIONS AND HYPOTHESIS THAN ANSWERS. AND THE PURPOSE OF THIS
MEETING IS NOT TO LISTEN FOR ME BUT REALLY TO LISTEN TO YOU ALL. SO WE CAN DEVELOP
AN INFORMED AND STAKEHOLDER-BASED DATA STRATEGY. MANY OF THE USE CASES THAT AMY
MENTIONING SUCH AS MANAGEMENT OF FOOD BORN ILLNESSES OR PANDEMIC RESPONSIVENESS ARE VERY
COMPLEX, DYNAMIC INTERDEPENDENT PROBLEMS. SO THE INNOVATION THAT IS SILOED MAY NOT BE
ABLE TO SOLVE THESE PROBLEMS AND WE'VE SEEN SOME EXAMPLES IN THE PPE SHORTAGES. IN THESE
EXAMPLES IT'S NOT THE DATA AVAILABILITY THAT IS A PROBLEM. THE PROBLEM WAS OUR
AVAILABILITY TO INGEST, INTEGRATE AND INTERPRET THEM. WHAT WE NEED TO LOOK AT IS EMERGING
DATA MANAGEMENT AND EMERGING OPERATING MODELS SO WE CAN REMOVE THAT FRICTION IN OUR
SYSTEM. AMY MENTIONED FDA HAS AN IMPACT IN ABOUT 20 TO 25% OF THE GLOBAL ECONOMY.
THAT WAS FINE WHEN WE ARE IN AN ENVIRONMENT WHERE WE WERE DOING LOTS OF EPISODIC APPROVES
AND STRATEGIES THAT COULD BE HAVING A LONG RUNWAY BUT NOW OUR ABLE TO RESPOND IS CRITICAL
AND THE AMOUNT, COMPLEXITY AND VARIETY OF DATA THAT WE NEED TO GATHER FOR SUCH A LARGE
NETWORK OF PRODUCTS AND SERVICES IS GOING TO BE GROWING EXPONENTIALLY. SO WHAT WE NEED
TO DO IS CREATE INNOVATIVE AND EMERGING PARTNERSHIPS TO ACHIEVE THIS GOAL.

AT THE SAME TIME, WE'RE WITNESSING A TREMENDOUS GROWTH AND MATURITY OF AI, BLOCK CHAIN,
IOT, AR, VR, TO NAME A FEW, AND THEY ADD AN ADDITIONAL LAYER OF DATA SKILLS ASK DATA
MANAGEMENT WE TYPICALLY HAVE NOT INVESTED IN. WE TALK ABOUT ALL OF THESE THINGS AND WHEN
WE'RE LOOKING AT THE OVERALL PUBLIC HEALTH ECOSYSTEM, ONE MIGHT THINK WE HAVE A VERY GOOD
HANDLE ON THE SHARING OF DATA WITHIN OUR AGENCY. AND THAT IS NOT ALWAYS THE CASE. WHAT
I'M WITNESSING AS PART OF THE FEDERAL CDO COUNCIL IS PHENOMENAL PARTNERSHIP ACROSS ALL THE
FEDERAL AGENCIES AND SHARING OUR DATA, SHARING OUR EXPERTISE AND KNOWLEDGE BUT I'M
NOT SURE IF THIS IS A RESPONSE TO AN EMERGENCY OR THIS IS A SYSTEMIC BEHAVIOR. I THINK
IT'S IMPORTANT FOR US TO MAKE THIS SYSTEMIC BEHAVIOR AND THEN WE WILL LEARN FROM YOUR
EXPERIENCES ALSO ON HOW TO MAKE THAT AN INSTITUTIONAL COLLABORATION. THERE ARE TWO
IMPORTANT PARTS OF OUR STRATEGY. WE'RE LOOKING AT THE EMERGING OPERATING MODELS, EMERGING
PARTNERSHIPS AND EMERGING TECHNOLOGY, IT'S ALSO IMPORTANT THAT WE REMOVE THE FRICTION THAT
MIGHT COME FROM SPECIALIZING IN THIS AREA BY REDUCING THE FRICTION BETWEEN MACHINE TO
MACHINE AND MACHINE TO HUMAN. AND THAT WILL BE AN IMPORTANT PART OF OUR STRATEGY. THE
SECOND PART WILL BE HIGHLY BIASED TOWARDS ACTION. WE'RE INTERESTED IN ALL KINDS OF
INTERESTING EMERGING TECHNOLOGIES BUT WE WILL BE VERY CAREFUL IN APPLYING THEM FOR THE
RIGHT PROBLEM AT THE RIGHT TIME. WE WANTED TO BE FAST FOLLOWERS AND IT SHOULD BE USE CASE
DRIVEN. THIS MEETING IS A BEGINNING OF A SERIES OF CONVERSATIONS THAT WE HOPE WE WILL
START TO SOME BROAD TOPICS BUT WE EXPECT TO GO INTO MUCH DEEPER PERHAPS SMALLER MEETINGS
THAT LOOK INTO SPECIFIC AREAS SUCH AS DATA MANAGEMENT OR AI OR OPERATIONAL AI, ET CETERA.
SO THOSE ARE THE THINGS THAT WILL HAPPEN COMING OUT OF THIS MEETING. IN THIS COMPLEX
ENVIRONMENT, NO SINGLE ENTITY HAS ALL THE ANSWERS. WE KNOW THAT. BUT A CONCERTED EFFORT
THROUGH A COLLECTIVE PARTNERSHIP WILL GIVE US AN ABILITY THAT'S REQUIRED IN THIS
ENVIRONMENT AND BEYOND. SO WITH THAT I WILL HAND IT OVER TO AMY WHO HAS SOME DETAILS
ON THE CONTENT AND FURTHER STRUCTURE OF THIS MEETING. THANK YOU. AMY?
>>TERRIFIC. THANK YOU SO MUCH. IT'S A DELIGHT TO WORK WITH YOU AND I'M VERY EXCITED
TO SEE WHAT'S GOING TO COME OUT OF TODAY. AS RAM HIGHLIGHTED, IN ORDER TO GET YOU
THINKING AND TO MAKE IT TANGIBLE, THIS MEETING IS ORGANIC AROUND THREE-CASE EXAMPLES. HOW
WE'RE CURRENTLY MODERNIZING OUR APPROACH TO DATA AND ANALYTICS AND THEN START TO POINT THE

WAY TO WHERE WE'RE GOING IN THE FUTURE. THERE WILL BE THREE PANELS, EACH OF WHICH STARTS
WITH A CASE EXAMPLE, FOLLOWED BY A RAPID FIRE DISCUSSANT TO UNEARTH CRITICAL ISSUES THAT A
PANEL DISCUSSION TO FURTHER EXPLORE A AND HIGHLIGHT THE ISSUES WE ANTICIPATE NEED TO BE
ADDRESSED AND ALSO CONTEMPLATED AS WE MODERNIZE OUR DATA STRATEGY. THE PACKAGES ARE
GOING TO BE MODERATED BY THE THE TERRIFIC CLIFF GOODMAN AND AT THE END OF THE DAY WE WILL
HAVE AN EXAMPLE FROM OUR OWN PRECISION FDA INITIATIVE WHERE RECENT COMPETITION SHOWS HOW
FDA HANDSHAKES WITH INDUSTRY AND THE WHOLE COMMUNITY, YOU, IN PUTTING DATA TO WORK. THE
SECTIONS ARE ORGANIZED AROUND THREE THEMES. FIRST THEME IS UNITING DATA. AN EXAMPLE OF
DATA SHARING AND AGGREGATION USING A DATA LAKE STRATEGY. THE SECOND PANEL IS ABOUT
IMPROVING DATA. AN EXAMPLE OF TRANSITIONING FROM AN UNRULY UNSTRUCTURED DATA ENVIRONMENT
TO DIGITIZE RAPIDLY ANALYZABLE DATA AND THE THIRD PANEL IS ABOUT USING DATA. AN EXAMPLE
OF USING AI AND PREDICTIVE ANALYTICS TO IMPROVE FOOD INSPECTIONS. WHAT ARE OUR
ANTICIPATED NEXT STEPS? WE'RE GOING TO LIBRARY MORE AT THE END OF THE MEETING. THE GOAL
IS TO SET THE STAGE FOR WHAT WE NEED TO DO AS AGENCY AND AS A WHOLE PUBLIC HEALTH
COMMUNITY TO LEVERAGE THE MOST MODERN ASPECTS OF WHAT DATA AND COMPUTER TECHNOLOGY HAVE TO
OFFER ASK I SUBMIT THIS IS ONLY JUST THE BEGINNING. SO NOW LET'S GET ON WITH. OVER
TO YOU, CLIFF.
>>CLIFF, PLEASE UNMUTE YOUR MICROPHONE.
>>THANK YOU VERY MUCH AS WE SAID, AMY AND RAM AND VID. WE'RE VERY EXCITED TO PRESENT THE
SET OF THREE PANELS FOR YOU. THE FIRST IS GOING TO BE ON DATA SHARING, FOLLOWED BY DATA
EXCHANGE, AND PUTTING DATA TO USE. EACH ONE OF THESE PANELS IS GOING TO BE SET UP WITH
AS YOU HEARD, STIMULUS PRESENTATION FOLLOWED BY RAPID FIRE RESPONSE AND THEN A PANEL
DISCUSSION OF FIVE OR SIX PANELISTS WILL GET INTO THESE ISSUES. THE VERY FIRST PANEL ON
DATA SHARING YOU'RE GOING TO HEAR ABOUT THE FOLLOWING KINDS OF CONCEPTS, DATA LAKES, DATA
WAREHOUSES IN THE CLOUD, GOING TO DIVE INTO THE RISKS OF DATA SHARING, AND GET
A LITTLE BIT INTO PRIVACY AND CONFIDENTIALITY, OF COURSE, AND THEN TRY TO UNDERSTAND SOME
OF THE SOME OF THE TOOLS THAT CAN BE BROUGHT TO BEAR TO ACHIEVE DATA SHARING AND
THEN WE'LL LOOK AT THE BIG PICTURE DEPARTMENT-WIDE, WHAT IS DATA SHARING MEAN ACROSS THE
WHOLE DEPARTMENT. . AND SO TO GET THIS STARTED I'M GOING TO ASK MARY ANN SLACK TO
INTRODUCE HERSELF AND HER TOPIC AND WHEN SHE'S FINISHED WE'LL GO TO OR RAPID

FIRE RESPONSE
AND THEN OUR PANEL. MARY ANN, YOU'RE ON.
>>THANK YOU, CLIFF. AND WELCOME, EVERYBODY, THANKS FOR JOINING, THANKS FOR LISTENING
TO US. . I WILL BET THAT THIS IS NOT THE PICTURE THAT YOU WERE EXPECTING ME TO START OUT
WITH. BUT I ASK YOU, ACTUALLY TO THINK ABOUT A SAILING SHIP AND WHAT IT TAKES TO MAKE
SOMETHING SO COMPLEX AND BEAUTIFUL AND FUNCTIONAL. CLEARLY IT TOOK A LOT TO BUILD WHAT
YOU SEE HERE. IT TOOK THE MATERIALS, THE CRAFTSMEN AND ARCHITECTURAL DESIGN, THE RIGHT
TOOLS AND TESTING FOR SEA WORDINESS AND A CAPTAIN AND CREW TO MAKE ANY USE OF IT. SO SHIP
BUILDING IS NOT MY EXPERTISE BUT I SEE A LOT OF ANALOGY TO FDA'S WORK AND PROMOTING PUBLIC
HEALTH. MY NAME IS MARY ANN SLACK. I'M THE DIRECTOR OF CDER'S OFFICE OF STRATEGIC
PROGRAMS AND WE'RE CHARGED WITH HELPING CDER ADVANCE THE PUBLIC HEALTH MISSION THROUGH
ANALYSIS, INFORMATICS AND PRACTICING MATICS SOLUTIONS TO I'M HERE TO TALK TO YOU ABOUT OUR
EFFORTS TO MAKE BEST USE OF DATA AND NOT JUST OUR DATA. NEXT SLIDE, PLEASE. . REMEMBER
THE OPIOID EPIDEMIC? IT MAY NOT BE THE DAILY HEADLINE THESE DAYS, ACTUALLY DID
UNFORTUNATELY READ SOMETHING ABOUT DRUG ABUSE, DEATHS ON THE RISE, WHICH IS REALLY
UNFORTUNATE. AND CLEARLY IT'S STILL WITH US. . THIS IS A COMPLICATED, MULTIFACTED
PROBLEM REQUIRING MULTI PRONGED APPROACH. AND IT'S THE IMPETUS FOR OUR CASE STUDY FOR
TODAY. NEXT SLIDE. WE'RE FOCUSED ON SEVERAL PRIORITIES IN THIS SPACE, INCREASING ACCESS
TO THE OPIOID ANTAGONIST NALOXONE, EXPANDING ACCESS TO OPIOID USE DISORDER TREATMENTS, AND
IMPROVING PAIN TREATMENT, PAIN MANAGEMENT, AND PRESCRIBING PRACTICES. . NEXT SLIDE. .
THERE ARE MULTIPLE POTENTIAL ACTIONS IN ALL OF THESE AREAS. FOR OUR PURPOSES TODAY I'M
GOING TO 0 IN ON JUST ONE OF THE PRIORITIES AND THAT'S INCREASING ACCESS TO NALOXONE.
EACH YEAR TENS OF THOUSANDS OF PEOPLE DIE FROM OVERDOSE AND THE SAD TRUTH IS THE WITH
NALOXONE ADMINISTERED IN TIME, POTENTIALLY ALL OF THESE OPIOID OVERDOSE DEATHS ARE
PREVENTABLE. NEXT SLIDE, PLEASE. WE'VE CONSIDERED SEVERAL ACTIONS THAT COULD PROMOTE AND
INCREASE THE NALOXONE ACCESS. BUT WE HAVE TO ASK OURSELVES, WHAT IMPACT WILL THEY HAVE?
WILL IT BE ENOUGH? WHAT SIDE EFFECTS MIGHT THEY HAVE? ARE THEY GOING TO TO CAUSE
UNEXPECTED ISSUES ELSEWHERE. IS JUST ONE ANSWER GOING TO DO IT HAD OR WE HAVE MULTIPLE
STEPS WE HAVEN'T THOUGHT ABOUT YET? HAD FOR INSTANCE, PRESCRIBING NALOXONE WITH OPIOID
PRESCRIPTION SEEMS LIKE A LOGICAL AND SIMPLE APPROACH. EXCEPT THAT WHEN OUR

EXPERTS
CONNECT AND ANALYZE THE DATA FOR MULTIPLE SOURCES SOME THAT WE HAVE INSIDE, SOME THAT ARE
EXTERNAL TO US LIKE PRESCRIPTION DATA AND DEATH AND INJURY DATA, THEY FOUND THAT THIS WILL
BE OVERWHELMINGLY COSTLY TO THE HEALTH SYSTEM. AND IT WOULDN'T HAVE THE DESIRED EFFECT
BECAUSE THE MAJORITY OF OVERDOSE DEATHS ARE ACTUALLY CAUSED BY NON-PRESCRIBED SYNTHETIC
NARCOTICS, MAINLY FENTANYL. IT'S A SIMPLE GOAL BUT IT'S NOT A SIMPLE RESPONSE. NEXT
SLIDE. WHAT DO WE NEED TO RESPOND? REMEMBER WHAT I WAS SAYING ABOUT BUILDING THE SAILING
SHIP? SIMILAR NEEDS ACTUALLY EXIST HERE. WE NEED THE DATA. WE NEED MULTIPLE INTERNAL
AND EXTERNAL DATA SOURCES. WE NEED LIKELY, CERTAINLY, DATA THAT MAY NOT EVEN EXIST YET
BUT IN PARTNERSHIP COULD BE FOUND, COULD BE PULLED TOGETHER. WE NEED ANALYTICS TOOLS, WE
NEED TO MAKE SURE THAT WE'RE PRACTICING DATA HYGIENE AND UNDERSTAND WHAT WE HAVE. WE NEED
DATA MANAGEMENT AND THE ANALYSIS TOOLS TO DO SOMETHING WITH IT AND WE NEED TO
TO BE ABLE TO DO THAT ANALYSIS AND MODELLING, WE NEED EXPERTS WHO KNOW HOW TO DO ANALYSIS.
WE NEED THE DATA OWNERS WHO REALLY UNDERSTAND THE DATA AND THE CONTEXT IN WHICH IT'S BEING
CAPTURED AND KEPT. WE NEED DATA SCIENTISTS WHO CAN ACTUALLY APPLY THESE MODELLING, THESE
ADVANCED MODELLING TECHNOLOGIES, TECHNIQUES, EXCUSE ME, AND WE NEED THE SUBJECT MATTER
EXPERTS, OBVIOUSLY. BECAUSE THE SUBJECT MATTER EXPERTS WITH THE DOMAIN KNOWLEDGE ARE THE
ONES WHO CAN ACTUALLY INTERPRET THE FINDINGS AND COME TO A GOOD DECISION. AS YOU CAN SEE,
ANY ONE OF THESE BY ITSELF IS JUST NOT ENOUGH. WE NEED THE FULL ECOSYSTEM. WE NEED AN
ENVIRONMENT THAT SUPPORTS DATA INTAKE, AGGREGATION, LINKING, ANALYTICS, DATA GOVERNANCE
AND MANAGEMENT, SUPPORTS DATA QUALITY AND SECURITY. NEXT SLIDE. . SO TODAY OUR OPIOID
DATA WAREHOUSE INITIATIVE IS A HYBRID COMBINATION OF DATA LAKE AND DATA WAREHOUSE WITH A
SET OF FOCUSED ANALYTICS THAT ARE BEING STOOD UP TO SUPPORT DECISION MAKING RELEVANT TO
OPIOIDS. . IT HOSTS 40-PLUS DATA SOURCES SOME INTERNAL, SOME EXTERNAL, SOME AS I WAS
SAYING, ARE QUITE NEW TO US, AND BEING GENERATED FROM SOCIAL MEDIA, FOR INSTANCE. THE
ABILITY TO INGEST AND SECURE THIS DATA AND ABIDE BY THE DATA USE AGREEMENTS THAT WE'RE
PUTTING IN PLACE BOTH WITH INTERNAL AND EXTERNAL PARTNERS TO BE ABLE TO LINK THIS DATA AND
APPLY ANALYTICS IS REALLY SIGNIFICANT. OUR CHALLENGE IS THAT THIS BE ISN'T THE ONLY SUCH
ANALYTIC NEED OR ENVIRONMENT WE HAVE. WE NEED TO EXTEND THIS MODEL TO SUPPORT MULTIPLE
SUCH NEEDS WHILE STILL ENSURING GOOD DATA GOVERNANCE AND MANAGEMENT AND MOST

OF ALL
SECURITY. NEXT SLIDE, PLEASE. WHERE ARE WE HEADED? WELL, RIGHT NOW WE'RE WORKING ON A
BROADER ARCHITECTURE THAT CONNECTS AND SUPPORTS THESE MULTIPLE DATA ENVIRONMENTS AND WILL
ULTIMATELY INCLUDE SUPPORT FOR OUR TRANSACTIONAL SYSTEMS TOO. WE ENVISION THIS
CLOUD-BASED ECOSYSTEM TO INCLUDE EXTENSIVE METADATA ANNOTATION, SECURE DATA INGESTION,
RULES BASED DATA MANAGEMENT AND HYGIENE AND GOVERNANCE TO ENSURE THE DATA IS PROTECTED AND
IT'S ACCESSIBLE FOR THE AGREED PURPOSES. THAT QUALITY IS MAINTAINED, AND STRUCTURE IS
UNDERSTOOD TO SUPPORT AGGREGATION AND LINKING FOR ANALYSIS. THIS ENVIRONMENT WE EXPECT
TO BE CAPABLE OF HOSTING BOTH RAW DATA AND DATA WAREHOUSES AND DATABASES. WE WANT TO
ENABLE OUR EXPERTS TO UTILIZE ANALYTIC ENVIRONMENTS LEVERAGING THIS ARCHITECTURE TO
PERFORM RELATIVELY SIMPLE TO HIGHLY COMPLEX ANALYTICS, TO BE ABLE TO APPLY
ARTIFICIAL INTELLIGENCE METHODS AND MODELLING. AND WHEN THEY'RE GENERATING ADDITIONAL
DATA WHICH THEY DO, TO BE ABLE TO APPLY APPROPRIATE TAGGING AND ACCESS CONTROLS AND
INGEST IT BACK INTO THE SECURE DATA LAKE TO ENRICH THE EXISTING INFORMATION. THE
ENVIRONMENT SHOULD BE ACCESSIBLE THROUGH APIS TO PROMOTE A MORE CONSISTENT AND DISCIPLINED
DEVELOPMENT APPROACH, AND WE DON'T WANT TO LOSE THE ALREADY-EXISTING AND EMERGING
CAPABILITIES SUCH AS THE OPIOID DATA WAREHOUSES BUT MAKE IT FASTER, MORE CONSISTENT AND
LESS COMPLEX TO EXPAND OR ABILITY TO LEVERAGE DATA FOR KNOWLEDGE.,
PLEASE. IN SUMMARY, FDA AS EVERYBODY KNOWS, I THINK THAT'S ON THIS CALL, SENIOR THE DATA-DRIVEN
ORGANIZATION AND OUR FUTURE IS EVEN MORE DATA RICH. IN ORDER TO DO THAT, WE NEED TO AND
WE ARE INVESTING IN ALL OF THE COMPONENTS THAT I'VE SPOKEN ABOUT TO LEVERAGE IT BEST AND I
THANK YOU FOR YOUR TIME. BACK TO YOU, CLIFF.
>>THANK YOU, MARY ANN, YOU PUT A LOST GREAT CONCEPTS ON THE TABLE AND IT REALLY SEEMS THAT
AT THE AGENCIES IT LOOKING TOWARD A LONGER TERM STRATEGY, A DATA STRATEGY, ACROSS THE
ENTERPRISE AND HAVE TO INTEGRATE ALL THE PLATFORMS TO WHICH YOU REFERRED. I WANT TO
WELCOME THE RAPID FIRE RESPONSE. DEVEN, CAN YOU TELL US HOW YOU FIND YOURSELF ON A PANEL
LIKE THIS AND BEING OUR FIRST RESPONDENT?
>>THANKS A LOT CLIFF. I'M CURRENTLY THE CHIEF EXECUTIVE OFFICER -- CHIEF REGULATORY
OFFICER OF A TECHNOLOGY START UP CALLED CITIZEN. I'M PRETTY SURE I'M
ON THIS PANEL BECAUSE MORE THAN A DECADE OF EXPERTISE ON PRIVACY AND DATA GOVERNANCE.
I WAS PREVIOUSLY AT THE HHS OFFICE FOR CIVIL RIGHTS ENFORCING AND DOING POLICY ON HIPAA
AND PRIOR THAT THAT DIRECTOR OF THE HEALTH PRIVACY ACT. SO THIS SORT OF

DICHOTOMY OF
HOW DID WE MAKE DATA MORE AVAILABLE AND LEVERAGE IT BETTER WHILE ALSO PROTECTING IT IS
A VERY COMMON ONE. AND IS OUR ENDURING CHALLENGE IN THIS ARENA WHERE WE'RE TRYING TO MAKE
MORE OUT OF DATA. AND I HAVE TO SAY, I'LL BOTH CONGRATULATE THE FDA AND SAY, WOW, FOR
PICKING THIS AS SORT OF THE INITIAL USE CASE. IT REALLY ACTUALLY ILLUSTRATES THE DO I
COULD THE MY WELL BECAUSE YOU HAVE OPIOID DATA WHICH IS EXTRAORDINARILY SENSITIVE BOTH
WITH RESPECT TO INDIVIDUALS AND ALSO PROPRIETARY DATA OFTENTIMES ACTUALLY THIS.DATA IS
PROTECTED EVEN BY STRONGER PRIVACY LAWS THAN OTHER TYPES OF PHYSICAL AND EVEN MENTAL
HEALTHCARE DATA AND AGAIN OUR NEEDS FOR BEING ABLE TO LEVERAGE THIS DATA ARE
EXTRAORDINARY. WE'RE IN A CRISIS THAT MAY NOT BE ON THE FRONT PAGE OF NEWS ANYMORE GIVEN
THE PANDEMIC THAT WE'RE DEALING WITH, BUT IT IS STILL SOMETHING THAT'S EXTRAORDINARILY
CHALLENGING AND WE LOSE FAR TOO MANY LIVES. THE NEED TO BE ABLE TO LEVERAGE THIS DATA FOR
THE AGENCY IS VERY GREAT. AND YOU REALLY CAN'T ERROR TOO FAR ON EITHER SIDE. WHAT MAKES
DATA GOVERNANCE SUCH A CHALLENGE. IF YOU FAIL TO PROTECT IT, YOU WILL LOSE THE TRUST
OF THE PUBLIC AND YOU WILL NOT BE ABLE TO ACCOMPLISH WHAT YOU NEED TO ACCOMPLISH
IN TERMS OF LEVERAGING THE DATA. THE OTHER HAND IF YOU LEAN TOO FAR INTO DATA SECURITY
AND IT'S ALMOST IMPOSSIBLE FOR PEOPLE TO ACTUALLY LEVERAGE THE DATA AND BE ABLE TO USE IT
AND ANALYZE IT IN THE WAYS THEY NEED TO IN ORDER TO DO THEIR JOB, THEN YOU REALLY ERROR TO
FAR ON THE OTHER SIDE. WE CALL THAT SECURITY BY OBSCURITY. MEANING WE CAN'T GET TO THE
DATA SO IT SURE IT SECURE BUT ORTHOPEDIC YOU'RE NOT BEING ABLE TO LEVERAGE IT VERY WELL.
SO THAT'S BALANCE BETWEEN THE TWO POINTS IN TERMS OF PROTECTION AND EFFECTIVE UTILIZATION
IS ONE THAT IS IS ONGOING CHALLENGE IN THE DATA GOVERNANCE SPACE. REALLY REQUIRES YOU
TO BE NIMBLE. CAN'T JUST BE OKAY WE'VE GOT OUR POLICIES, WE CAN SET IT AND FORGET IT.
YOU NEED TO BE CONSTANTLY LOOKING AT WHETHER YOU'RE ABLE TO MEET BOTH GOALS. IT'S THE
DATA PROTECTED, IS THE DATA ACCESSIBLE. NOT EITHER OR, IT'S BOTH. AND BEING ABLE TO
AGAIN TO SORT OF BE BETWEEN THOSE TWO POINTS. THE OTHER THING I'LL SAY IS WITH RESPECT
TO THE FEDERAL GOVERNMENT I THINK OFTENTIMES WE AND I SAY WE BECAUSE I USED TO BE IN THE
FEDERAL GOVERNMENT HAVE A TENDENCY TO ERROR MORE ON THE SIDE OF PROTECTION THAN ON THE
SIDE OF ACCESS. WE'VE GOT A LOST RULES IN PLACE THAT GOVERN HOW GOVERN HOW WE CAN ACCESS
AND USE DATA AND OUR INTERPRETATIONS OF THOSE RULES SOMETIMES MEAN WE CAN'T,

WE HAVE
DIFFICULTY ACCESSING IT. AND THIS IS ALWAYS PART OF THE CHALLENGE WHETHER THE RULES WE
NEED TO FOLLOW AND WHAT ARE WHAT'S THE MYTHS OF THE RULES THAT HAVE SORT OF BEEN
PERCOLATING OUT THERE AND MAKE US THINK THERE ARE THINGS WE CAN'T DO WHETHER IN FACT
SOMETIMES IT JUST TAKES GETTING THAT RULE BOOK OUT AGAIN AND SAYING WAIT A MINUTE, THIS
DOESN'T SAY THAT WE CAN'T DO XY AND Z IT JUST SAYS WE NEED TO DO IT IN A WAY THAT IS
RESPONSIBLE AND SECURE. REALLY MODERN DATA ENTERPRISES REALLY DO BOTH THAT ACCESSIBILITY
AND PROTECTION REALLY WELL. IT'S NOT SOMETHING THAT IS SECOND NATURE. IT'S SOMETHING
THAT TAKES WORK, IT TAKES A LOT OF DILIGENCE, AGAINS, BEING ABLE TO LINK DATA ACROSS DATA
SETS AND MAKE IT AVAILABLE TO A BROADER GROUP OF PEOPLE BRINGS ADDITIONAL CHALLENGES.
YOU HAVE TO FIGURE OUT HOW TO MEET THOSE CHALLENGES. I'LL SAY AGAIN THE GOVERNMENT TENDS
TO ERROR ON THE SIDE OF PROTECTION VERSUS ACCESSIBILITY AND THERE'S ALMOST A NEED TO
KIND OF REORIENT TOWARDS MAKING SURE THAT YOU'RE PAYING ATTENTION TO BOTH OF THOSE
ASPECTS. ON THE OTHER HAND, WHAT I'VE SEEN TOO OFTEN WITH THE
PANDEMIC AND THIS IS PROBABLY TRUE MORE OF THE PRIORITY SECTOR THAN GOVERNMENT IS OH,
THIS IS AN EMERGENCY, WE REALLY NEED THIS DATA AND JUST NEED TO THROW ALL THE RULES OUT
THE WINDOW. AND THAT'S NOT A HELPFUL MIND SET EITHER. EVERYTHING IS ON FIRE THESE DAYS.
WE HAVE SOME ENORMOUS CHALLENGES THAT WE NEED TO HANDLE AND DATA IS THE WAY IT'S GOING TO
GET US THROUGH THESE CHALLENGES BUT WE HAVE TO MAKE SURE WE'RE DOING IT RESPONSIBLY. I'LL
ADD A COUPLE THINGS AND THEN STOP BECAUSE THIS IS RAPID FIRE. BUT TRANSPARENCY TO THE
PUBLIC ABOUT THE DATA THAT'S BEING COLLECTED AND HOW IT'S ACCESSED AND ALSO HOW WELL THE
AGENCY IS USING IT IS GOING TO BE CRITICAL TO EARNING THE PUBLIC'S TRUST. AND SO KEEPING
THAT IN MIND, THIS IS NOT JUST A PAPERWORK REDUCTION ACT EXERCISE, SYSTEM RECORDS
NOTIFICATION EXERCISE, BUT MORE OF ONE WHERE HOW CAN WE THINK CREATIVELY ABOUT WAYS TO
CONTINUALLY ENGAGE THE PUBLIC IN WHAT WE'RE DOING AND THEN HAVE WE DONE INTERNALLY TO
MAKE SURE THERE ARE ACCESS AND USE OF OF DATA IS ETHICAL AND ACTUALLY WORKS TO REDUCE
DISPARITIES AND NOT EXPAND THEM OR INCREASE THEM. AND SO WITH THAT, I'LL STOP AND I LOOK
FORWARD TO PARTICIPATING ON THE PANEL. THANK YOU.
>>THANKS VERY MUCH, DEVEN. THIS POINT YOU MAKE ABOUT DATA PROTECTION VERSUS DATA ACCESS,
I'M THINKING OF A VERY, VERY LARGE FEDERAL AGENCY THAT HAS, HAS BEEN REGULATING 25% OF THE

WORLD'S ECONOMY, HOW IT MAINTAINS A VERY -- THAT VERY DELICATE BALANCE BETWEEN PROTECTION
AND ACCESS IN THESE TIMES AS AN EXTRAORDINARY SORT OF GOAL TO TRY TO ATTAIN. AND I THINK
WE'RE GOING TO GET INTO KIND OF THE UPS AND DOWNS AND RISKS AND AGAIN BENEFITS OF DOING
THAT BUT THIS IS REALLY A KEY ELEMENT THE DISCUSSION FOR TODAY. REALLY WANT TO FOLLOW UP
ON THAT. WITH REGARD TO OUR PANEL, I'M GOING TO ASK EACH OF OUR PANELISTS TO INTRODUCE
HIMSELF OR HERSELF AS WE GO DOWN HERE, AGAIN, NAME, AFFILIATION AND HOW IT IS YOU FIND
YOURSELF ON A PANEL ON DATA SHARING. START FIRST WITH CRAIG TAYLOR.
>>THANK YOU, CLIFF. I'M CRAIG TAYLOR CHIEF INFORMATION SECURITY OFFICE AT THE
FOOD AND DRUG ADMINISTRATION. I FIND MYSELF HERE TODAY BECAUSE I'M PRETTY MUCH
RESPONSIBLE FOR THE CONFIDENTIALITY, INTEGRITY AND AVAILABILITY OF INFORMATION. I WORK
VERY CLOSELY WITH DR. ABERNETHY, CTO AND NEWLY MINUTED CTO. WE'LL BE WORKING CLOSELY
TOGETHER AS A TEAM WORKING WITH FAT OFFICES AND CENTERS TO MAKE CERTAIN DATA IS SECURE AND
PROTECTED AS WE MOVE THROUGH THE MODERNIZATION OF OUR PLAN
>>THANK YOU, CRAIG, GAVE A LIST THERE OF RESPONSIBILITIES FOR YOU. YOU'LL HAVE PLENTY
TO DO WHEN WE GET OFF THIS CALL, GOOD GOSH. THANKS, CRAIG.
>>THANK YOU.
>>TIM WILLIAMS.
>>I'M HERE REPRESENTING THE ORGANIZATION THAT BRINGS TOGETHER INDUSTRY REGULATORY AND
STANDARDS ORGANIZATIONS IN THE PRECOMPETITIVE SPACE TO DEVELOP TOOLS STANDARDS AND
TECHNOLOGIES WE NEED FOR THE FUTURE. PHUSE I'M A PRODUCT LEAD WHERE I'VE LED NUMEROUS
PROJECTS INVESTIGATING HOW TO FUTURE PROOF DATA MODELS AND STANDARDS, USING SEMANTIC WEB
AND LINKED DATA APPROACHES. HAPPY TO BE HERE TODAY
>>THANKS, TIM, YOU'LL BE A GREAT FIT FOR A COUPLE OF SUBJECTS COMING YOU HAVE.
I DON'T SEE MIKE FLECKENSTEIN ON IF I'M MISS, WE'VE MET MARY ANN, LET'S GO TO JOSE. JOSE,
ARE YOU OUT THERE?
>>MY NAME IS JOSE ARRIETA THE HHS CIO, INTIMIDATE CHIEF DATA OFFICER. RESPONSIBILITIES
ARE INVESTMENT DECISIONS ACROSS HHS AND CYBERSECURITY POSTURE AS WELL AS SECURING DATA AT
REST FOR THE DEPARTMENT. SOME HAPPY TO BE HERE AND I'VE ALWAYS WANT TO DO A PRESENTATION
IN A T-SHIRT AND I GOT TO DO IT EARLIER IN THE WEEK AND NOW I'M GETTING TO DO IT AGAIN. I
ACTUALLY TOOK A PICTURE OF MYSELF SO I CAN USE IT AS MY NEW LINK IN PAGE
>>GOT A LOT TO EMBRACE HERE AND APPRECIATE THE T-SHIRT. MIKE, YOU'RE UP. TELL US WITH
WHOM YOU ARE AND HOW IT IS YOU FIND YOU YOURSELF IN IN PANEL
>>: GOOD MORNING, I'M MIKE FLECKENSTEIN A PART OF THE DATA MANAGEMENT TEAM AT MITRE AND

MITRE, OF COURSE, IS A FEDERALLY FUNDED RESEARCH AND DEVELOPMENT ORGANIZATION WORKING IN
CLOSE CONJUNCTION WITH THE GOVERNMENT IN THE PUBLIC GOOD. MY BACKGROUND IS ALL ASPECTS OF
DATA MANAGEMENT INCLUDING STRATEGY, DATA ARCHITECTURE, DATA GOVERNANCE, RECORDS MANAGEMENT
PRIOR TO THAT I'VE BEEN INVOLVED IN VARIOUS ASPECTS BUILDING ENTERPRISE DATA WAREHOUSES
FOR LARGE INSURANCE ORGANIZATIONS, AND EVEN RUNNING A SMALL DATA MANAGEMENT COMPANY. SO
THAT'S WHY I'M HERE.
>>GOOD TO HAVE YOU ON. THANK YOU VERY MUCH. I WANT TO START OUT WITH SOME BASIC
CONCEPTUAL AND DISTINCTIONS HERE AND START WITH MARY ANN AND FOLLOW UP WITH MIKE.
MARY ANN, YOU TALKED ABOUT A BROADER ARCHITECTURE. THERE'S SOME VERY IMPORTANT COMPONENTS
MOVING PARTS TO THIS. CAN YOU CLARIFY FOR US THE DISTINCTIONS AMONG DATA LAKES,
DATA WAREHOUSES, THEIR RELATION TO THE CLOUD, AND WHY THAT'S IMPORTANT TO THE AGENCY.
>>SURE. LET ME JUST MAKE SURE I'M UNMUTED. OKAY. YES, SURE. SO A DATA LAKE AND A
DATA WAREHOUSE ARE REALLY, THEY'RE CONSIDER THEM REPOSITORIES, THE THING ABOUT A DATA LAKE
IS IT'S DESIGNED TO STORE EVERYTHING. ALL YOUR STRUCTURED AND UNSTRUCTURED DATA.
THEY CAN SORT ANY TYPE OF DATA USING ITS NATIVE FORMAT. I THINK THEY WERE ORIGINALLY
DEVELOPED TO HANDLE VOLUMES OF BIG DATA. YOU WOULD TYPICALLY BRING THAT DATA IN THERE
AND THEN YOU DO EXTENSIVE TAGGING OF EVERYTHING. THE ELEMENTS. IN ORDER TO BE ABLE TO
UTILIZE IT. DATA WAREHOUSES, ON THE OTHER HAND, ARE -- THEY'RE LARGE CAPACITY
REPOSITORIES THAT STORE MEDIUM TO LARGE AMOUNTS OF STRUCTURED DATA AND THEY'RE INTENDED
FOR FREQUENT OR REPEATABLE ANALYSES. THE COMBINATION OF THE TWO IS ACTUALLY QUITE
POWERFUL BECAUSE YOU CAN CAPTURE YOUR STRUCTURED DATA THE STUFF YOU'RE GOING TO USE A LOT
BY STILL HAVE ACCESS TO THAT UNSTRUCTURED DATA OR TO THOSE THINGS YOU MAY NOT ORDINARILY
REACH OUT TO IT TAKES A LITTLE BIT LONGER, BUT THEY'RE THERE. IT'S AVAILABLE TO YOU. AND
HOW DOES IT RELATE TO THE CLOUD? BOTH OF THESE COULD ACTUALLY -- THEY COULD RESIDE ON
PREMISE. IN FACT, THEY DO RESIDE ON PREMISE IN SOME CASES IN FACT EVEN HERE WE'VE GOT
BOTH ON PREMISE HE IS AND WE'RE WORKING WITH THE CLOUD. THE THING ABOUT THE CLOUD IS THAT
IT ADDS -- IT ADDS VALUE ALL OVER THE PLACE. IT AT AGILITY YOU CAN PROVISION AND
DEPROVISION THINGS. PRICING AND PERFORMANCE ARE MORE PREDICTABLE BECAUSE YOU'RE PAYING
FOR WHAT YOU NEED AND YOU CAN EXPAND RAPIDLY, YOU PAY FOR THAT. IF YOU DON'T NEED IT

YOU CAN REDUCE IT IF YOU NEED ADDITIONAL PERFORMANCE POWER YOU CAN GET IT FASTER THAN
YOU CAN PROVISION SOMETHING ON PREMISE. ACCESS CONTROL IS SUPPORTED. THERE ARE LOTS OF
POWERFUL CLOUD-BASED NATIVE SERVICES AND HOSTED THIRD PARTY SERVICES THAT CAN BE
TAKEN ADVANTAGE OF IN THE CLOUD. AND INFORMATION SHARING AND COLLABORATION, REMOVING THE
PHYSICAL CONSTRAINTS, STILL MAINTAINED BEING THE ACCESS CONTROLS, OBVIOUSLY, AND
DRAMATICALLY IMPROVES THE ABILITY TO SHARE INFORMATION AND TO COLLABORATE
>>THANKS, MARY ANN. SOUNDS LIKE AN AGENCY ALONG THE MAGNITUDE OF THE FDA NEEDS SOMETHING
LIKE A DATA LAKE BECAUSE IT'S HE SO MANY SOURCES OF STRUCTURED AND UNSTRUCTURED DATA.
THEN YOU'VE GOT A DATA WAREHOUSE WHICH SOUNDS A LOT MORE ORGANIZED AND PRIMARILY FOCUSING
ON STRUCTURED DATA AND CLOUD IS A GRAND ENABLER OF ALL OF THIS, STILL A LOT FOR THE AGENCY
TO MANAGE AS PART OF AN OVERALL STRATEGY. MIKE, I'M WONDERING IF YOU COULD CHIME IN AND
IN PARTICULAR, MIKE, I KNOW YOU'RE A DATA LAKE GUY. BUT CAN YOU TALK ABOUT HOW YOU MAKE A
PUBLIC HEALTH AND AN ECONOMIC CASE FOR TAKING THIS ROUTE WITH A DATA LAKE. WHAT'S THE
PUBLIC HEALTH CASE FOR DOING THIS, WHAT'S THE ECONOMIC CASE THAT HAS TO BE MADE SWELL,
MIKE?
>>SURE. THANKS, CLIFF. I CAN JUST ADD TO WHAT MARY ANN SAID. I AGREE WITH EVERYTHING
THAT SHE SAID AND JUST WANTED TO ADD A COUPLE THINGS. ONE OF THE LIMITATIONS WITH A
DATA WAREHOUSE IS THE LATENCY BECAUSE IT'S HIGH CURATED TAKES A LONG TO GET THAT DATA IN
THERE. OF COURSE, THE BENEFITS OF OF A DATA LAKE IS ACCESS TO DATA MUCH QUICKER MAYBE
EVEN STREAMING ACCESS. SO THERE ARE PROS AND CONS AND YOU TO
TAKE A LOOK AS A DATA HIGHWAY. IF YOU LOOK AT THE DIFFERENT LANES, THE LEFT
LANE IS MAYBE THE FASTEST IN TERMS OF ACCESS AND MIGHT BE GOOD FOR THINGS LIKE FRAUD ANALYTICS OR
TO SEE WHETHER THERE'S A CYBER INCIDENT. BUT THE DATA IS FAIRLY RAW IN ITS FORMAT. THE
QUALITY IS LESS REFINED. ON THE RIGHT-HAND SIDE OF THE HIGHWAY THERE'S GREAT LATENCY, BUT
THE DATA IS MUCH MORE CURE RATED AND THAT MIGHT BE GOOD FOR THINGS LIKE FINANCIAL DATA,
YOU DON'T WANT IT TO BE LOOSY GOOSY. I JUST WANTED TO ADD A COUPLE OF COMMENTS.
IN TERMS OF THE ECONOMIC BENEFIT, I THINK THE BIGGEST ECONOMIC BENEFIT IS THE SIGNIFICANT
AGGREGATION OF DATA IN A DATA LAKE. AS MARY ANN ALREADY SAID, THERE ARE LIMITATIONS TO
DATA WAREHOUSES IN TERMS OF SIZE, BUT A DATA LAKE CAN SCALE TO WHATEVER SIZE YOU WANT. IT
CAN INCLUDE STRUCTURED AS MARY ANN SAID, STRUCTURED AND UNSTRUCTURED DATA VERSUS AT LEAST
UNTIL RECENTLY THE RELATIONAL DATA WAREHOUSES. SO NOW YOU HAVE THE ABILITY

TO -- WITH A
HUGE AMOUNT OF DATA AGGREGATION, YOU CAN -- THAT EFFECTS MACHINE LEARNING, YOU HAVE A
LARGER DATA SET FOR MACHINES TO LEARN, AND ARTIFICIAL INTELLIGENCE, AND AS AN OUTCOME,
THEN YOU HAVE BETTER, FOR EXAMPLE, PRECISION CARE OR EVEN THE ABILITY TO DRIVE POLICY FOR
THE PUBLIC GOOD. ANOTHER BENEFIT OF A DATA LAKE IS THE SHARING ACROSS THE HEALTHCARE
ECOSYSTEM AS VID SAID EARLIER. SO THE ABILITY FOR RESEARCHERS TO UPLOAD THEIR DATA AND
COMBINE IT WITH DATA THAT'S ALREADY THERE. MUCH EASIER TO DO BECAUSE IN A DATA LAKE
YOU HAVE A FLEXIBLE DATA MODEL AND YOU CAN CRAFT THAT MODEL TO YOUR NEEDS VERSUS A
DATA WAREHOUSE, IT'S VERY REGIMENTED IN TERMS OF THAT THE TAUGHT MODEL IS VERY WELL
DEFINED. YOU HAVE SANDBOXES IN DATA LAKES FOR RESEARCHERS TO FIND NEW PATTERNS, VERY
IMPORTANT. AS WITNESSED, FOR EXAMPLE, WITH COVID,, THE ABILITY TOP FIND SOLUTIONS TO
UNKNOWN PROBLEMS. IT IS LESS EXPENSIVE THAN A DATA WAREHOUSE BECAUSE IT CAN SCALE AS
MARY ANN ALREADY SAID, AT WILL, AND, OF COURSE, DESCALE. YOU REMOVE THE MAINTENANCE COST,
BECAUSE IT'S A PLATFORM INFRASTRUCTURE AS A SERVICE.
>>MIKE, SOUNDS LOOK SOME OF THE KEY CONCEPTS ARE UNDERSTANDING THE RESPECTIVE ROLES,
UTILITY AND BASICALLY USER FRIENDLINESS FOR A DATA WAREHOUSE VERSUS A LAKE. MATTERS OF
SCALE, TIMELINESS, AND UTILITY. ALL FITTING INTO THE BROAD ARCHITECTURE. YOU SET OF FOOD
POINTS ABOUT THE COMPLICATION BENEFITS. I'M WONDERING AND CRAIG, JOSE AND/OR TIM MIGHT
WANT TO COMMENT ON SORT OF PUBLIC HEALTH IMPACT AND MORE FROM THE STANDPOINT OF THE AGENCY
IN PARTICULAR. CRAIG, DO YOU HAVE A THOUGHT OR TWO ON THAT?
>>ON THE RISK SIDE OR JUST IN GENERAL FROM A CYBERSECURITY RISK? I'LL TAKE THAT AREA,
CLIFF, BECAUSE I THINK IT'S A VERY IMPORTANT QUESTION HOW WE BALANCE THOSE PARTICULAR
RISKS. WITHOUT A DOUBT CYBERSECURITY THREATS OF NATION STATES AND OTHER ACTORS IS OUR
GREATEST RISK WHEN WE THINK ABOUT SHARING IN THIS ENVIRONMENT. TRADE SECRET AND OTHER
INTELLECTUAL PROPERTY PERSONAL HEALTH INFORMATION AND OTHER SENSITIVE DATA IS ON THE
RISE. DURING COVID-19, FOR EXAMPLE, WE HAVE SEEN A SIGNIFICANT INCREASE IN PHISHING,
SOCIAL ENGINEERING, ACTIVITIES FROM CRIMINAL ORGANIZATIONS THAT HAVE TARGETED INDIVIDUALS
AND PRIVATE INDUSTRY AND GOVERNMENT ENTITIES. THERE'S SOME GOOD NEWS HERE, TOO, THOUGH,
CLIFF. WE DID SEE A REPORT LAST YEAR FROM THE INTELLECTUAL PROPERTY COMMISSION REPORT
THAT OUTLINED ABOUT $600 BILLION IN LOSSES IN THE UNITED STATES DUE TO THEFT OF DATA.

THE GOOD NEWS FOR FDA, WE SEE STEWARDS OF INDUSTRY AND INDUSTRY INFORMATION AND PUBLIC
HEALTH AND WE WILL CONTINUE TO ENSURE THE SAFETY AND SECURITY MEASURES ARE IN PLACE TO
MAINTAIN THAT THE PUBLIC TRUST THAT YOU HEARD ABOUT TODAY AND OUR REPUTATION AS A WORLD
LEADER WHEN IT COMES TO HEALTH AS WE MOVE MORE TOWARDS SHARED ENVIRONMENTS AND ALSO AS WE
MODERNIZE OUR ENVIRONMENT. WE DO SEE CYBERSECURITY AND OR OTHER RISKS AS AN ENABLER
STRATEGIC ENABLER HOW WE MODERNIZE IN THIS ENVIRONMENT
>>I'M WONDERING, JOSE, FROM A DEPARTMENT STANDPOINT, WE CONSIDER THE WAY THAT WE HEARD THE
ROLES OF A DATA LAKE, OF A DATA WAREHOUSE AND THE EXPANSIVENESS OF THE CLOUD, WHAT
DO YOU SEE AS THE PUBLIC HEALTH IMPACT OF THESE CAPABILITIES?
>>I THINK WE'VE SEEN THAT SINCE APRIL 10TH AT HHS. ON APRIL 5TH WE STARTED TO BUILD
SOMETHING WE CALLED HHS PROTECT AND LAUNCHED ON APRIL 10TH. SINCE APRIL 10TH WE'VE
COLLECTED 4 BILLION DATA ELEMENTS FROM ALL 50 STATES AND TERRITORIES. THE IMPACT FOR
FOLKS ON THE CALL IT'S IMPORTANT TO HIGHLIGHT THREE SPECIFIC LESSONS LEARNED FROM ACTUALLY
ESTABLISHING THAT CAPABILITY. IF YOU LOOK ACROSS THE DEPARTMENT AND ANY FEDERAL AGENCY
THERE'S MULTIPLE IDENTITY ACCESS MANAGEMENT AUTHENTICATION CAPABILITIES, HIGH FIXED
COSTS. ONE OF THE THINGS WE LEARNED IN THE FIVE DAYS WHERE WE WERE SETTING UP HHS PROTECT
IS THAT WE NEED A MODERN IDENTITY ACCESS MANAGEMENT AUTHENTICATION ABILITY THAT CAN
FLEXIBLY INTERACT WITH THE -- HHS PROTECT WE'RE SHARING AND COLLECTING DATA AS I SAID,
FROM ALL 50 STATES AND SIX U.S. TERRITORIES BUT WE'RE ALSO YOU A THEN THE INDICATING AND
DOING IDENTITY AND ACCESS MANAGEMENT FOR FEDERAL, STATE AND LOCAL PARTNERS AS WELL AS
COMMERCIAL ENTITIES SO THAT'S EXTREMELY IMPORTANT. I THINK THE SECOND THING THAT WE
LEARNED IS THAT YOU HAVE TO HAVE A SEPARATE SECURE FILE TRANSFER CAPABILITY TO RECEIVE
DATA THAT EMPOWERS ANYBODY THAT'S PROVIDING DATA TO YOU WITH CONTROLS SO THAT THEY CAN
ACTUALLY HAVE VISIBILITY INTO WHO SEES THE DATA ITSELF. AND ENSURE ACCESS FOR ANYBODY
THAT REQUESTS ACCESS. WHEN YOU HAVE SOMETHING LIKE 4 BILLION DATA ELEMENTS IN HHS
PROTECT, BEING ABLE TO PROVIDE THAT VISIBILITY BACK TO A COMPANY THAT'S PROVIDING DATA
TO YOU IN OUR INSTANCE FOR THE COVID RESPONSE IS EXTREMELY IMPORTANT AND EXTREMELY
COMFORTING. SO WE'VE 2,000 USERS ON THE PLATFORM KNEW AND WE HAVE A TEECHL FOLKS THAT
HAVE LITERALLY VIRTUALLY FACE TO FACE MET WITH EVERY SINGLE PERSON THAT'S BEEN
AUTHENTICATED AND EVERY PEN THAT'S BEEN AUTHENTICATED THAT'S SHARING DATA HAS

THE CONTROL
AT THE ELEMENT LEVEL OR THE DATA SET LEVEL TO CONTROL WHO ACTUALLY SEES THE DATA THAT
THEY HAVE PROVIDED. AND I THINK THAT'S EXTREMELY IMPORTANT FROM A COMFORT PERSPECTIVE.
I THINK THE THIRD THING WE LEARNED IS THAT THE, I'LL TALK ABOUT THE IMPACT IS THAT CORRECT
THE PLATFORM ITSELF OR THE DATA IS ANALYZED, WE'RE NOT REPLATFORMING EVERYTHING AND
WE'RE NOT MOVING EVERYTHING TO A SINGLE PLATFORM. WE'RE INTERCONNECTING OVER 200
DIFFERENT DATA SETS ACROSS THE UNITED STATES. SO WE HAVE DATA FROM 6200 HOSPITALS, WE'VE
CREATED A FLEXIBLE MECHANISM TO COLLECT THAT INFORMATION. WE HAVE DATA FROM YOU HAVE A
MERGES LABS, ALL GOVERNMENT LABS, 80% OF THE HOSPITAL LABS, 85% OF THE LABS FROM THE
TRIBAL REGIONS OF THE UNITED STATES AS AN EXAMPLE. WHAT WE'VE LEARNED IS THAT WE WILL LET
THE SINGLE SOURCES OF TRUTH THAT EXIST ACROSS THE UNITED STATES EXIST AND WHAT WE WANT
TO DO IS ACTUALLY BRING THAT DATA TOGETHER SO WE CAN CREATE THE ABILITY TO DO MULTILEVEL
ANALYSIS AND WE DON'T THINK OUR SCIENTIFIC COMMUNITY SHOULD HAVE TO LOG INTO 200 DIFFERENT
SYSTEMS AND PULL OUT INFORMATION TO DO ANALYSIS. WE JUST CREATED ONE LOCATION WHERE
THEY CAN LOG INTO, HAVE ACCESS TO THE DATA, SO THEY CAN DO DIFFERENT TYPE OF MODELLING AND
ANALYSIS WORK. THE LAST THING THAT WE LEARNED THROUGHOUT THE PROCESS AND WE'VE JUST BUILT
THIS AND WE'RE TESTING IT AND BY THE WAY, THERE'S EIGHT DIFFERENT COMMERCIAL TECHNOLOGIES
THAT WE INTEGRATED AND PUT TOGETHER TO ACTUALLY CREATE THIS. THIS ISN'T JUST ONE
PLATFORM. THERE'S TWO DIFFERENT CLOUD CAPABILITIES THAT ARE ACTUALLY POWERING THIS BEHIND
THE SCENES. I THINK THE LAST THING WE LEARNED IS WHETHER YOU DO DATA SHARING, YOU NEED TO
ENSURE INTEGRITY, CRAIG TALKED ABOUT THAT, SO I THINK I'VE HIT AVAILABILITY, I THINK I'VE
HIT CONFIDENTIALITY BUT YOU NEED TO ENSURE INTEGRITY IN UNDERLYING DATA SETS. WE DO
BELIEVE THERE'S A FUTURE FOR DISTRIBUTED ECOSYSTEM, BUT HAVING DONE SOME BLOCK CHAIN WORK
AT HHS BEFORE I THINK THAT'S ENTIRELY POSSIBLE AND WE HAVE A CAPABILITY TO DO THAT WE'VE
ESTABLISHED A HATCH ASSOCIATED WITH THE DATA SET BUTT PUT A QR CODE ON TOP SO WHEN WE
SHARE DATA WE CAN ENSURE INTEGRITY. WHAT HAS BEEN THE IMPACT. ABOUT APRIL 28TH OF THIS
YEAR, LIKE I SAID, WE STARTED BUILDING ON APRIL 5TH, LAUNCHED APRIL 10TH. ABOUT APRIL --
WE'RE WE STARTED INFORMING INSIGHTS AS TO WHAT'S HAPPENING ACROSS THE UNITED STATES. SO
ONE OF THE THINGS THAT WE'VE BEEN DOING OVER LAST THREE WEEKS WITH A DIFFERENT COMMERCIAL

PARTNER IS WE'VE BEEN RUNNING A SUPERVISED MACHINE LEARNING CAPABILITY OFF THE THE DATA
SETS AND CAN RUN AN ENSEMBLE OF 25 DIFFERENT SIMULATIONS IN REALTIME. LEVERAGING
ALGORITHMS LIKE RANDOM FOREST, SCENARIO ANALYSIS BASICALLY ANY ML CAPABILITY THAT HAS BEEN
CREATED AND/OR IS PUBLIC. AND WE CAN RUN IT IN A MATTER OF MINUTES. WE STARTED TO
ACTUALLY LOOK AT AND START TO UNDERSTAND WHERE OUTBREAKS MAY OCCUR AS IT RELATES TO
COVID-19 BASED ON UNDERLYING ACTIVITY IN THE MARKETPLACE. REMEMBER, WE HAVE WHEN WE
TALK ABOUT 200 DIFFERENT DATA SETS ABOUT A HUNDRED ARE OPEN SOURCE DATA SETS WE'RE PULLING
TOGETHER, ABOUT 50 GOVERNMENT DATA SETS WE PARTNERED WITH AGENCIES, WE RETROSPECTIVE THE
ND HE WILL POWER THEM TO ACTUALLY CONTROL ACCESS. AND THEN SOME ARE THERE'S A COUPLE WE
COLLECTED ON OUR OWN TO CREATE INSIGHTS. . SO NOW WE CAN TAKE THIS SUPERVISED
MACHINE LEARNING CAPABILITY AND BE PREDICTIVE ABOUT HOT SPOT IDENTIFICATION ACROSS THE
UNITED STATES AND HELPS CLINICAL TRIALS. WE'VE BEEN WORKING TO PROVIDE THAT INSIGHT IN
PARTICULAR AND THE OTHER THING WE'VE BEEN DOING AND THIS WAS KIND OF OVER A TWO-DAY PERIOD
THIS WEEKEND IS ACTUALLY LOOKING AT AND GETTING AN UNDERSTANDING OF MULTIPLE SIMULATIONS
OF HOW DISTRIBUTING LAB SUPERVISING TESTING MAY HAVE AN IMPACT ON LOCAL PLACES WHERE,
LOCAL MAYBE CITIES OR GEOS WHERE AN OUTBREAK MAY CAN I. IT'S NOT PERFECT BUT I THINK
THOSE ARE THE THREE LESSONS LEARNED AND THOSE ARE SOME OF THE IMPACTS THAT WE'RE ABLE TO
DRIVE VERY RAPIDLY WITH SHARING DATA. AND THEN PUTTING MODELLING CAPABILITIES ON TOP OF
IT
>>THANKS, JOSE. WE MAY COME BACK TO THE SORT OF BROADER DEPARTMENTAL-WIDE IMPLICATIONS
THIS HAS. THOSE ARE VERY IMPORTANT. JUST WANT TO BOUNCE BACK TO MARY ANN FOR A MOMENT,
MARY ANN. SO HAVING HEARD SOME FEEDBACK FROM MIKE AND CRAIG AND JOSE AND COME TO TIM IN A
MINUTE, CAN YOU SORT OF WRAP YOUR ARMS AROUND THE PUBLIC HEALTH IMPACT NOW. YOU LED US
OFF WITH A BROAD ARCHITECTURE AND DISTINGUISHED AMONG THE LAKE, THE WAREHOUSE, ENABLING
CAPABILITY OF THE CLOUD, AND JOSE KIND OF JUMPED AHEAD AND TALKED ABOUT SOME CLINICAL
TRIALS AND SOME OTHER GREAT APPLICATIONS WITH THE PANDEMIC AND SO FORTH R WHAT THE HIGH
LEVEL -- WHERE DOES THIS TAKE THE AGENCY TO ENABLE PUBLIC HEALTH IMPACT ACROSS THE
NATION? WHERE ARE WE NOW AND WE'RE ON THE VERGE OF SOMETHING WE COULDN'T DO BEFORE
>>SOME OF THE THINGS THAT JOSE WAS JUST TALKING ABOUT ARE -- THEY'RE VERY RELEVANT TO WHAT

WE'RE DOING TOO. WE'RE CAPTURING, WE'RE UTILIZING THE DATA THAT WE HAVE AND THE DATA THAT
WE HAVE ACQUIRED FROM PARTNERS, EXTERNALLY, AND WE'RE GENERATING ADDITIONAL DATA, FOR
INSTANCE, CRITICAL DRUG UTILIZATION FROM HOSPITALS IN ORDER TO PULL THIS INFORMATION AND
DO ENOUGH ANALYSIS TO DETERMINE WHERE WE MAY HAVE PENDING DRUG SHORTAGES, FOR INSTANCE,
IN THE CURRENT SITUATION. . AND BE ABLE TO RESPOND TO THAT, RESPOND AS RAPIDLY AS
POSSIBLE, INCREDIBLY RAPIDLY AS A MATTER OF FACT, IN TERMS OF ANTICIPATING THAT A CRITICAL
DRUG SHORTAGE OR DRUGS -- A PARTICULAR DRUG IS BEING UTILIZED MUCH MORE QUICKLY IN
HOSPITALS THAN WOULD ORDINARILY BE USED AND DETERMINING WHERE AND HOW AND ACTING ON
CHANGES, PROMOTING CHANGES TO SUPPLY CHAINS SO SO THE SUPPLY CAN KEEP UP WITH THE
ANTICIPATED DEMAND. SO I THINK THAT'S JUST ONE EXAMPLE OF WHAT WE'RE DOING NOW AND
IT'S, OF COURSE, OBVIOUSLY RELEVANT GENERALLY, BUT VERY SPECIFICALLY RELEVANT TO OUR
CURRENT SITUATION.
>>THANKS VERY MUCH. I WANT TO BOUNCE BACK TO DEVEN NOW. DEVEN, I'M GETTING SORT OF THE
COMPLEXITY AND HOW -- WHAT THE MAGNITUDE OF THIS IS. YOU TALKED ABOUT THAT IMPORTANT
BALANCE BETWEEN DATA PROTECTION AND DATA ACCESS. WHERE ARE WE GOING TO BE LANDING NOW ON
PRIVACY AND CONFIDENTIALITY? THINK ABOUT ENTERPRISE-WIDE DATA STRATEGY, SO MUCH TO GRASP
HERE. WHAT'S THE KNEW WORLD NOW OF PRIVACY AND CONFIDENTIALITY TODAY?
>>WELL, I MEAN, THESE ISSUES ARE ALWAYS A LITTLE BIT IN FLUX. I SORT OF FEEL LIKE I
DECIDED TO SPECIALIZE IN THE PRIVACY AND DATA GOVERNANCE FIELD ABOUT TEN OR 12 YEARS AGO
AND YOU ALWAYS THINK, WELL, IT'S A HOT BUTTON ISSUE NOW BUT WE'LL GET IT ALL SETTLED AND
DIMENSION STYLES DIE DOWN AND IT NEVER DOES. IT NEVER DOES, BECAUSE THERE ARE ALWAYS NEW
CHALLENGES IN TERMS OF THE NEEDS FOR DATA AND TYPES OF DATA AND NEW CHALLENGES ASSOCIATED
WITH CYBERSECURITY RISKS. AND YOU'RE SORT OF -- AND NEW CHALLENGES IN TERMS OF
WHETHER -- HOW ARE WE GETTING THE DATA WE NEED? ONE THING THAT OCCURRED TO ME WHEN
MARY ANN WAS TALKING ABOUT GETTING DATA FROM HOSPITALS TO DETERMINE WHERE THE DRUG
SHORTAGES ARE, WELL, THE ANALYSIS OF THAT IS OWN GOING TO BE AS GOOD ATS DATA COME IN THE
FDA CAN DO A FANTASTIC JOB OF BRING IN THE DATA THEY'RE GETTING, ANALYZING IT, OF
PROTECTING IT, AND YET IF ONLY 50% OF HOSPITALS ARE REPORTING DATA, YOU'RE GOING TO HAVE
AN ANSWER THAT'S MISSING. AND THAT'S ALSO A CHALLENGE. AND NOT ONE NECESSARILY THAT
GOVERNMENT FACES BUT MAYBE THEY DO, WHICH IS THIS IDEA THAT ENTITIES HAVE TO

BE
COMFORTABLE AND HAVE TO SORT OF KNOW THAT FROM A LIABILITY STANDPOINT, THEY'RE PROTECTED
IN TERMS OF WHEN THEY SHARE DATA WITH YOU AND THAT THEIR OWN COMPETITIVE NEEDS ARE
PROTECTED IN TERMS OF SHARING DATA THAT'S PROPRIETARY TO THEM. AND THAT'S A HUGE
CHALLENGE. WE'RE SEEING IT IN THE PRIVATE SECTOR WITH RESPECT TO DATA SHARING RELATED TO
THE COVID-19 PANDEMIC, AND EVEN PROBABLY INTERNALLY WITHIN GOVERNMENT I CERTAINLY SAW IT
WHEN I WAS THERE, THAT EVEN SOMETIMES AGENCIES ARE NOT HAPPY ABOUT SHARING DATA WITH ONE
ANOTHER FOR A WHOLE HOST OF REASONS WHERE PRIVACY AND SECURITY IS OFTEN WHAT IS THEIR
RATIONALE BUT THERE'S USUALLY A COMPLEX SET OF REASONS WHY PEOPLE HAVE SOME RELUCTANCE
IN THAT REGARD. IT'S AN EVER GREEN ISSUE. IT'S ONE THAT NEVER GETS FULLY SOLVED BECAUSE
IT ALWAYS IS VERY SITUATIONALLY DEPENDENT IN TERMS OF WHAT IS OFTEN THE BEST WAY TO
SOLVE IT AND HAS MANY PIECES TO IT
>>DEVEN, GIVEN THESE BROADER CAPACITIES, HAVE THE GROUND RULES CHANGED? ARE THE
GUARDRAILS MOVING FOR PRIVACY AND CONFIDENTIALITY?
>>YOU KNOW, THE GROUND RULES, THE RULES HAVEN'T NECESSARILY CHANGED. BUT PEOPLE'S
INTERPRETATIONS OF THEM ARE SHIFTING. AND SOMETIMES THAT'S FOR THE GOOD, BECAUSE AGAIN,
SOMETIMES PEOPLE OVER INTERPRET, THERE'S A LOT OF PRIVACY OVERFIT THAT HAPPENS IN THE
WORLD TODAY WHICH KEEPS YOU FROM BEING ABLE TO UTILIZE DATA WHICH ALSO PRIVACY UNDERFIT OR
SECURITY UNDER FIT WHERE PEOPLE ARE NOT DOING WHAT THEY'RE SUPPOSED TO BE DOES FOR THOSE
JOBS. THE RULES HAVEN'T NECESSARILY CHANGED ALTHOUGH CERTAINLY WE'RE SEEING THE EUROPEAN
RULES ARE MUCH STRICTER THAN THEY USED TO BE. SOME OF OF THE STATES ARE ENACTING LAWS
THAT ARE MUCH STRICTER. THAT DOESN'T NECESSARILY IMPACT WHAT THE FDA IS DOING INTERNALLY
WITH ITS DATA BUT DOES HAVE AN IMPACT ON HOW THE PRIORITY SECTOR DEALS WITH DATA
>>JOSE?
>>YEAH. SO I AGREE WITH DEVEN. I WANT TO SHARE, AND I'M LEARNING THIS KIND OF AS I GO --
AND I ALSO WASN'T AWARE THAT I WAS GOING TO BE DOING THIS ON APRIL 4TH SO THIS IS -- JUST
A COUPLE OF POINTS THAT I THINK ARE EXTREMELY IMPORTANT. I THINK DATA SHARING WAS ALWAYS
A VERY INTENSE TOPIC. YOU WOULD SEE IT REGULARLY IN THE NEWS, SOME FOLKS DIDN'T WANT TO
AND THE CONVERSATIONS THAT I'VE HAD WITH SOME OF THE CEOS WE'VE PARTNERED WITH TO SHARE
DATA, THE CONVERSATION REALLY CENTERED AROUND I KNOW YOU BUILT A BUSINESS AND YOU HAVE
CONTRACTS WITH YOUR CUSTOMERS AND YOU BUILT A BUSINESS ON NOT SHARING CERTAIN

TYPES OF
DATA. SO ALL I'M ASKING YOU IS JUST LIKE WHEN YOU FOUNDED YOUR COMPANY I'M ASKING YOU TO
TAKE A STEP FORWARD, SHARE SOME DATA WITH ME THAT MAY HELP US FIGHT THIS PANDEMIC AND THIS
INVISIBLE ENEMY, AND LET'S SEE IF WE'RE COMFORTABLE WITH THAT AND I'LL GIVE YOU COMPLETE
CONTROL OVER WHERE THAT DATA GOES AND VISIBILITY INTO HOW YOU SHARE IT. PART OF WHAT THE
PANDEMIC HAS DONE IS CREATED A LITTLE BIT BROADER APERTURE FOR A DISCUSSION. I THINK THE
SECOND PIECE THAT I'VE LEARNED AND I'M NOT A SCIENTIST AND I SAID THIS TO A SCIENTIST THE
OTHER DAY AND I PROBABLY SHOULD HAVE TALKED TO CRAIG FIRST TO SEE IF THIS WAS SOMETHING
THAT I SHOULD HAVE SAID OR NOT OR MAYBE AMY. I SAID, SHE SAID WELL YOU HAVE SOME MISSING
DATA FIELDS AND SO WE DON'T -- THAT'S NOT VALID. AND I SAID YOU KNOW, IF THERE WAS A GUN
MAN WALKING AROUND THE FDA CAMPUS BUT YOU DIDN'T FLOW IF THE PEPPER WAS MALE OR FEMALE
WOULD YOU NOT REPORT IT? BECAUSE THERE'S SOME MISSING DATA FIELDS? . AND I THINK SO
KIND OF A DISCUSSION, THERE NEEDS TO BE A DISCUSSION OF THERE IS DATA -- DATA QUALITY IS
EXTREMELY IMPORTANT. BUT WHEN YOU LOOK AT MISSING DATA FIELDS, I DON'T KNOW THAT THAT'S A
QUALITY ISSUE AND THAT'S -- AND IT MAY BE FOR RESEARCH PURPOSES BUT WHEN YOU'RE RESPONDING
TO SOMETHING MORE INFORMATION IS BETTER, AND BEING ABLE TO VISIBLY DISPLAY GAPS OR
DIFFERENTIATIONS IN DATA SETS HELPS YOU UNDERSTAND THE UNDERLYING CHALLENGES THAT MAYBE
STRUCTURALLY OR POLICY WIDE EXIST WITHIN THE INDUSTRY. JUST
A LAST POINT. AT THE BEGINNING OF THIS PANDEMIC, I'VE BEEN WORKING LIKE SEVEN DAYS A WEEK
SO I WAS WALKING UP TO SAY GOOD NIGHT TO THE KIDS, AND I HAPPENED TO COME, THE TV WAS ON
AND I HAPPENED TO WALK BY AND STOPPED AND THERE WAS A CONVERSATION WITH A HUSBAND AND HIS
TWO-YEAR-OLD DAUGHTER. AND HE WAS LITERALLY TALKING ABOUT -- I JUST BROKE UP -- LITERALLY
TALKING ABOUT LIKE HIS DAUGHTER HAVING TO SAY GOODBYE TO HER MOM VIA ZOOM. . SO WHEN IT
COMES TO DATA SHARE, WHEN IT COMES TO HOW IT COULD POSSIBLY HAVE AN IMPACT WE TRY TO THINK
ABOUT THAT AND SAY, SHOULDN'T HAVE TO DO THAT. SO LET'S FIND A WAY TECHNOLOGICALLY TO
ENSURE PRIVACY AND ENSURE SECURITY BECAUSE I NEVER WANT MY KIDS TO HAVE TO SAY GOODBYE TO
MY WIFE VIA ZOOM CONVERSATION. SO I THINK THOSE ARE JUST THREE THINGS THAT I LEARNED
ALONG THE WAY
>>THANK YOU VERY MUCH. CHARACTERIZATION BRIEFLY, AND THEN TIM.
>>THERE'S A LOST TALK ABOUT A BILLION BETWEEN THE SHARING AND SECURITY. AND I CAN JUST
SAY THIS, BEING ABLE TO INTEGRATE THESE ENVIRONMENTS AND SHARING, WE HAVE TO

BALANCE THOSE
THINGS, AND I KNOW HERE WITH THE TEAM THAT WE HAVE AND THE FDA CENTERS WITHIN OUR IT
TEAMS, WITH OUR HHS TEAMS, WE'RE GOING TO WORK DILIGENTLY TO MAKE SURE THAT WORKS.
OBVIOUSLY WE GET MORE OF AN ADVANTAGE WHEN WE ARE SHARING AND GIVES AS YOU COMPETITIVE
ADVANTAGE, AND THAT'S THE WAY WE'RE HEAD IN OUR T MAP. WITH RESPECT TO THAT WE'RE NOT
GOING TO ALLOW SECURITY AND THE BALANCE OF THAT TO BE AN IMPEDIMENT TO THAT. BUT MORE
IMPORTANTLY WE'RE GOING TO MAKE SURE WE'RE WE'RE AN ENABLER AND THAT'S SOMETHING WE WANT
TODAY TAKE AWAY FROM
>>THANKS VERY MUCH, CRAIG. TIM THANKS FOR YOUR PATIENCE. I WANTED TO ASK YOU --
WANTED TO SAVE THIS DISCUSSION. I KNOW YOU'RE QUITE INVOLVED IN SORT OF BRINGING TOGETHER
INTERDISCIPLINARY TEAMS AND THEIR DISCIPLINARY THINKING ALONG THESE LINES. AND YOU'RE
KIND OF A REAL EXPERT ON DATA VISUALIZATION SO I WANT TO ASK YOU HOW WE TAKE ALL THOSE
OR ISES ABOUT WHICH YOU'VE HEARD AND THE CONCERNS THAT HAVE BEEN VOICED ABOUT PRIVACY AND
CONFIDENTIALITY AND SO FORTH AND WHERE ARE THE GUARDRAILS AND WHATNOT AND DATA QUALITY.
HOW DO YOU BRING INTERDISCIPLINARY THINKING INTO THE AGENCY SPHERE AND HOW YOU USE
VISUALIZATION TO TAKE THIS DATA AND CONVEY IT IN A MUCH HIGHER RICHER LEVEL.
>>THANK YOU VERY MUCH. I THINK THERE'S A LOT AT PLAY AND WE'VE BEEN TALKING ABOUT
DATA WAREHOUSES WHICH I THINK ARE AN EXCELLENT FIRST STEPS. BEYOND THAT, IT DOES SOLVE
THE PROBLEM OF DATA CO LOCATION. BUT THERE ARE A LOT OF OTHER ISSUES IT CAN SERVE AS
A FOUNDATION FOR WHICH IS BUILDING IN MORE HUMAN UNDERSTANDABLE CONCEPTS AND RELATIONSHIPS
WITHIN THAT DATA. NOT JUST MACHINE READABLE WHICH WE HAVE IN MANY FORMS NOW BUT ALSO
MACHINE AND HUMAN INTERPRETABLE AND GET DOWN -- WE CAN GET DOWN TO A GRANULAR LEVEL IN
TERMS OF ASSIGNING WHAT DATA CAN BE SHARED, WHAT DATA SHOULD BE USED FOR A PARTICULAR
ANALYSIS OR SHOULD NOT, BECAUSE WE NEED TO UNDERSTANDING OF WHAT THE ACTUAL DATA IS. AND
TO MAKE THAT HAPPEN, THAT'S WHERE WE REALLY NEED THESE INTERDISCIPLINARY TEAMS. WE NEED
ON OUR TEAMS PHYSICIANS, RESEARCHERS, BIOSTAT TECHNICIANS, REGULATORS AND PATIENTS TO
COME UP WITH THESE MODELS OF THE REAL WORLD STUDY CONDUCT, THE CLINICAL TRIAL ENTITIES IN
THE RELATIONSHIPS BETWEEN THESE THINGS AND THEN MAP THE DATA TO THE MODEL. THAT'S WHERE
-- GETTING THAT DATA AND THAT CO LOCATED DATA WAREHOUSE OR DATA LAKE IS A GOOD FIRST
STEP. SO MUCH OF OUR TIME AS DATA ANALYSTS IS SPENT TRYING TO KEN TEXTUALIZE THAT DATA.

THAT'S NOT TIME WELL SPENT AS RESEARCHERS OR EVEN PATIENTS TRYING TO FIND WHERE IS THE
CLOSEST TRIAL FOR MY PARTICULAR CONDITION. WE CAN EXPOSE RELEVANT DATA THROUGH VARIOUS
APIS BE THEY RESEARCHERS OR PATIENTS ONE WE KNOW WHAT THAT DATA IS AND I THINK THAT'S
WHERE WE REALLY NEED TO MOVE. SO WE'VE HAD SEVERAL INITIATIVES WITHIN PHUSE LOOKING AT
DATA DEIDENTIFICATION. WE'RE TRYING TO ADOPT COMMON STANDARDS LIKE THE FAST HEALTHCARE
INTEROPERABILITY RESOURCES AND ALSO LOOKING AT HOW DO WE APPLY KNOWLEDGE GRAPH
REPRESENTATIONS FOR BOTH CLINICAL AND NON-CLINICAL DATA. THERE'S GOOD OPPORTUNITIES.
IT'S A BIT OF A HARD ROAD FOR SURE BUT THE PAY OFFICE ARE IMMENSE. IN TERMS OF THE
VISUALIZATION ASPECTS, WE'RE LOOKING AT APPLYING TECHNIQUES LIKE GRAPH ANALYTICS, THESE
ARE VERY MATT MATTED CAL THINGS. WE NEED TO SURFACE IN A DATA TO OUR VARIOUS CONSUMERS
AND THAT'S WHERE VISUALIZATION HELPS WHERE MATHEMATICIANS LIKE MYSELF WHEN YOU CAN
PHYSICALLY SEE VISUALIZE CLUSTERED DATA THAT COMES FROM THESE WAREHOUSES. WHEN WE'RE
DEALING WITH LARGE VOLUMES, VISUALIZATION BECOMES EVEN MORE IMPORTANT AND ESPECIALLY
INTERACTIVE VISUALIZATIONS FROM VARIOUS FORMS LIKE WE'RE SEEING NEW YORK TIMES REGULARLY
PUTS OUT THE COVID GRAPHS AND JOHNS HOPKINS AND OTHERS. . SO WE HAVE VARIOUS INITIATIVES
WITHIN OUR INDUSTRY LIKE AN INTERACTIVE SAFETY DATA EXPLORER THAT IS COLLABORATIVE BETWEEN
FDA AND INDUSTRY BUILDING INTERACTIVE APPS FOR THAT AND I'LL POST A COUPLE OF THESE LINKS
IN THE CHAT LATER SO PEOPLE CAN INVESTIGATE THESE. WE HAVE A DATA VISUALIZATION GROUP
WITHIN PHUSE THAT'S --
>>YOU BROUGHT UP PATIENTS -- AND ALSO THE CONTEXT OF VISUALIZATION. SO FDA'S LET'S SAY
CONSUMER ORIENTED AUDIENCE OR TARGET AUDIENCE IS PATIENTS, CONSUMERS AND SO FORTH. HOW
DOES THIS INTERDISCIPLINARY APPROACH EMBRACE, INCORPORATE, ENGAGE PATIENTS? IS THERE A
SPECIAL ROLE FOR VISUALIZATION FOR PATIENTS AND CONSUMERS MORE BROADLY?
>>I THINK WE'RE SEEING A REAL DEPENDENCE ON AND ACCEPTS OF THESE INTERACTIVE
VISUALIZATIONS AND WE HAVE TO MAKE A VERY CONCERTED EFFORT TO ENGAGE WITH THE PATIENT
COMMUNITY MORE THAN EVER BECAUSE OUR PATIENTS ARE MORE TECHNOLOGY AWARE AND LEVERAGING
MORE TECHNOLOGY, SOCIAL MEDIA, VARIOUS INFORMATION STREAMS THAT ON THE BACK END,
RESEARCHERS HAVE TO THINK ABOUT HOW DO WE BUILD DATA MODELS AND A FLEXIBLE WAY THAT CAN
ACCOMMODATE THESE NEW SOURCES OF DATA AND THEN HOW DO IDENTIFY WHAT WE NEED TO EXPOSE
TO THE PATIENT COMMUNITY TO MAKE IT MORE VALUABLE. HOW CAN THESE PATIENTS LOOK FOR

PARTICULAR DRUG INTERACTIONS AND SO ON. SO I THINK ONCE WE HAVE MEANINGFUL SEMANTIC DATA
ON THE BACK END THAT MAKES IT EASIER TO EXPOSE THE RIGHT DATA TO THE RIGHT PEOPLE, IT WILL
BE A GREAT STEP FORWARD. WE'RE FINDING, JUST THE BASICS WE HAVE TO GET RIGHT. WE'VE SEEN
WITH COVID, FOR EXAMPLE, YOU THINK ONE OF THE FUNDAMENTAL RESOURCES FOR SHARING
INFORMATION WOULD BE AN ONLINE REGISTRY OF CLINICAL TRIALS DATA AND YES, WE HAVE
REGISTRIES, MULTIPLE, WHICH IS PART OF THE PROBLEM. EVEN THE CONSOLIDATED WHO, ICTRP
REPOSITORIES WON'T DOWN DURING THE EARLY PART OF THE PANDEMIC. AND IT WAS POINTED OUT
RECENTLY IT WAS DIFFICULT TO QUICKLY ANSWER BASICALLY QUESTIONS LIKE WHAT TRIALS ARE
CURRENTLY ACTIVE FOR HYDROXY CHLOR QUINN. IT'S HIGHLIGHTED HOW OUR REGISTRIES ARE OFTEN
INCOMPLETE, OUT OF DATE, INCONSISTENT ASK REQUIRE A TEAM TO MERGE THE DATA TO ANSWER NOVEL
QUESTIONS. AND THAT'S NOT TIME WELL SPENT WHEN TIME IS OF THE ESSENCE TRYING TO FIGHT A
GLOBAL PANDEMIC.
>>THAT'S A GREAT POINT. ACTUALLY THE A LITTLE SCARY AT TIMES WHEN YOU THINK ABOUT THE
PROBLEMS THAT WE'RE FACING AND OUR ABILITY TO KIND OF MANAGE THE DATA. SO MANNERS, I'M
WONDERING, TIM BROUGHT THIS UP ABOUT PATIENT DATA AND THINKING ABOUT PATIENT SOURCED DATA
OR PATIENT STREAMED DATA. DOES THAT DIRECTLY OR INDIRECTLY FIND ITS WAY INTO THE
DATA LAKE OR DOES IT FIND ITS WAY INTO CLINICAL TRIALS OR OTHER PRODUCTS THAT ARE
REGULATED BY THE AGENCY? HOW DO YOU THINK ABOUT ACCOMMODATING NEW DATA STREAMS?
>>WELL, THAT'S A GOOD QUESTION. IT CERTAINLY DOES FIND ITS WAY TO CLINICAL TRIAL DATA.
FINDS ITS WAY OBVIOUSLY INTO ADVERSE EVENT REPORTS. . WE BELIEVE IN PATIENT FOCUSED DRUG
DEVELOPMENT SO THAT KIND OF INPUT COMES FROM THERE. IT ALL WOULD CERTAINLY GO INTO THE
DATA LAKE. WE REALLY ARE ANTICIPATING THAT WE'RE GOING TO CAPTURE AS MUCH OF EVERYTHING
AS WE CAN IN THIS DATA LAKE, INFORMATION THAT'S VALUABLE OR HOLDS SOME VALUE TO IT. AND
I CAN'T ACTUALLY SAY HOW WE WILL BE USING IT RIGHT NOW, BUT I ABSOLUTELY KNOW THAT IT'S --
IN CONTEXT OF THE DATA LAKE, BUT I ABSOLUTELY KNOW THAT IT'S IMPORTANT TO US AND UTILIZED
IN THE CONTEXT OF OUR REGULATORY PROCESS RIGHT NOW
>>SO THIS IS -- THIS IS THE KIND OF THING YOU COULD PUT ON THE DOCKET, MIKE JUST A SECOND,
THE SORT OF THING YOU PUT ON THE DOCKET OR INBOX AS IT WERE FOR CONSIDERATION IN THE
ENTERPRISE-WIDE DATA STRATEGY IS ALL THESE NEW DATA SOURCES INCLUDING PATIENT SOURCE DATA,
HOW WHAT'S THE INTAKE FOR THAT AND HOW TO WE UNDERSTANDING APPROPRIATELY,

MIKE, COMMENT
ON THAT.
>>THANKS, CLIFF. AND THANKS, MARY ANN. I WAS JUST GOING TO -- WE TALKED EARLIER ABOUT
THE DIFFERENCES BETWEEN DATA LAKE AND DATA WAREHOUSE. AND SO OF COURSE HAS THIS ABILITY
TO HOUSE LOTS OF DIFFERENT DATA SOURCES OFTEN IN RAW FORMAT. . WE WANT TO REMEMBER THAT
THE DATA LAKE ISN'T A PANACEA. MARY ANN OR SOMEBODY SAID EARLIER THAT IT'S IMPORTANT TO
UNDERSTAND THAT THESE TWO LIVE SIDE BY SIDE. BECAUSE IT'S OFTEN THE CASE AND I THINK
COMPANIES AND AGENCIES ARE BEGINNING TO REALIZE THIS NOW, THAT THE DATA LAKE WAS
CONSIDERED A REPOSITORY FOR ALL SORTS OF RAW DATA AND BECOMES SORT OF A DUMPING
GROUND. WHAT'S IMPORTANT, BUT WHAT I THINK FOLKS ARE REALIZING, IN A DATA LAKE, WE OUGHT
TO KEEP A DATA CATALOG AND KEEP SOME METADATA ABOUT HOW THAT DATA IS BEING USED SO THAT
WE CAN PROMOTE, WE CAN PRIORITIZE AND PROMOTE THE DATA THAT'S BEING USED FREQUENTLY AND SO
THERE'S A DATA GOVERNANCE COMPONENT TO DATA AND DATA LAKE BECAUSE WITH THINGS LIKE SELF
SERVICE APPLICATIONS IF WE PROVIDE THAT TO THE USER AND IS THE USERS GO AT IT, YOUR
ANALYSIS LIKE I THINK DEVEN WAS SAYING, IS ONLY GOING TO BE AS GOOD AS THE DATA YOU'RE
ANALYZING. JUST WANTED TO MAKE THAT POINT
>>SO, DEVEN, NOW CONSIDERING ALL THESE MULTIPLE DATA SOURCES A THAT ARE GOING INTO A
DATA LAKE AND WE KNOW THAT DATA LAKES CAN BE SUBSETS OF DATA LAKES CAN BE FORMED
DATA WAREHOUSES AND CONSIDERING ALL THE VARIOUS APPLICATIONS AND REGULATED INDUSTRIES
ON THE PART OF THE FDA, ARE YOU FEELING MORE AT EASE OR LESS AT EASE WITH PRIVACY AND
CONFIDENTIALITY? I MEAN, CERTAINLY THE POINT YOU MADE EARLIER ABOUT PROTECTION VERSUS
ACCESS, THIS SOUNDS LIKE A WONDERFUL OPPORTUNITY FOR ACCESS. AND INPUT, OF COURSE. BUT
DOT PROTECTIONS START LOOKING A LITTLE SKETCHY AT THIS POINT? WHAT DO YOU THINK?
>>I MEAN, I'M NOT IN A POSITION TO SAY PROTECTIONS LOOK SKETCHY BUT FOR SURE THE
CHALLENGES GET STEEPER THE MORE DATA YOU'VE GOT AND THE MORE OPPORTUNITIES YOU WANT TO
PROVIDE FOR ACCESS. LIKE MANAGING THAT ACCESS, WHETHER IT'S PARTICULARLY IN A WAY THAT
YOU'RE MAKING SURE THAT ANY PARTICULAR CREDENTIALED USER ONLY HAS ACCESS TO THE DATA THAT
THEY NEED OR THAT ARE WITHIN THE PURVIEW OF THEIR JOB IN ORDER TO GET SOMETHING DONE.
THAT'S -- IT'S NOT AN UNMANAGEABLE CHALLENGE, BUT IT CAN BE A CHALLENGE. IT'S ONE BY ANY
MODERN DATA ENTERPRISE. IF YOU THINK ABOUT A HEALTHCARE FACILITY, FOR EXAMPLE, THEY'VE

GOT A LOT OF DATA, DOES THE REGISTRATION CLERK NEED ACCESS TO THE SAME AMOUNT OF DATA AS A
DOCTOR DOES? PROBABLY NOT. BUT EVEN WITHIN THE CLINICAL TEAM, YOU KNOW, HOW DO YOU TIER
ACCESS BETWEEN NURSES, BETWEEN DOCTORS, BETWEEN RESPIRATORY THERAPISTS, BETWEEN -- THAT'S
JUST I THINK IT'S PROBABLY SIMPLER EXAMPLE THAN WHAT THE FDA MIGHT FACE WITH RESPECT TO
ACCESS CREDENTIALS AND HOW DO YOU TEACHER IT AND HOW DO YOU MAKE SURE THAT THE DATABASE IS
IN THE DATA THAT SOMEONE CAN ACCESS ON ARE TURNED ON FOR THEM VERSUS OTHERS, HOW DO YOU
DEAL WITH EXCEPTIONS. BECAUSE PEOPLE MAY NEED LIMITED ACCESS TO CERTAIN DATA BUT NOT
CONTINUOUS ACCESS TO CERTAIN DATA. IT UPS THE CHALLENGES BUT I DON'T THINK PEOPLE SHOULD
THINK THAT JUST BECAUSE THE DATA IS GETTING BIGGER AND WE'RE GETTING MORE OF IT FROM
SOURCES THAT THAT SUDDENLY MEANS THAT, YOU KNOW, WE HAVE TO SHUT THINGS DOWN FROM A
PRIVACY STANDPOINT. I KNOW IT MAKES SOME PRIVACY ADVOCATES NERVOUS AND IT SHOULD. BUT
WHAT THAT SHOULD MEAN IS JUST ARE WE PAYING ATTENTION TO ALL THE STUFF, ARE WE STAYING ON
TOP OF THE PRIVACY AND SECURITY NEEDS AS WE'RE ADDING MORE DATA, AS WE'RE GETTING MORE
COMPLEX IN TERMS OF THE LAYERS OF OUR VARIOUS DATA LAKES, DATA WAREHOUSES, AND I'LL ALSO
TELL YOU, THE PUBLIC DOES NOT UNDERSTAND THE DIFFERENCE BETWEEN A LAKE AND A WAREHOUSE.
THIS IS REALLY NEXT SLIDE INFORMATICS BASEBALL. YOU HAVE TO BE ABLE TO BREAK THOSE DOWN
AND MAKE SURE PEOPLE UNDERSTAND AT SOME BASIC LEVEL WHAT THAT MEANS IN TERMS OF TYPES
OF DATA AND WHAT KINDS OF ACCESS PEOPLE ARE GETTING.
>>GREAT POINT. THANKS SO MUCH, DEVEN. JOSE, YOU HAVE GOT TO HAVE A VIEW ON THIS I'M
THINKING.
>>YEAH. I THINK DEVEN IS ABSOLUTELY RIGHT AND I THINK SOME OF THE FEEDBACK SHE'S GIVING
ACTUALLY MAKES IT EASIER TO GET TO THE OBJECTIVE THAT WE WANT TO GET TO IN TERMS OF ACCESS
TO DATA. IF INDIVIDUAL, THE INDIVIDUALS THAT MANAGE LIKE IN OUR CASE, THE DATA SOURCES WE
CONNECT WITH, THERE'S OVER 200, THEY'RE MANAGED AT A LOCAL LEVEL. WE'RE NOT ASKING THEM
TO CHANGE THEIR IDENTITY ACCESS MANAGEMENT AUTHENTICATION CAPABILITIES. WE'RE NOT ASKING
THEM TO MOVE THE DATA AND THEN SET UP A SERIES OF RULES OF HOW THAT DATA IS MANAGED. ALL
WE'RE DOING IS CREATING AN INTEGRATION POINT WHERE WE ENSURE THAT EVERYONE HAD A THAT IS
ACCESS TO OUR ENVIRONMENT IS AUTHENTICED AND WE HAVE IDENTITY ACCESS MANAGEMENT
DONE ON THEM AND THEN WE SHARE IT WITH AND LET'S SAY A THE FDA DATA LAKE SO THE FDA
OFFICIALS CAN ACTUALLY AUTHENTIC THAT USER SHOULD THEY WANT ACCESS TO FDA

DATA.
AND I THINK -- IF YOU WANT TO -- & IN THIS INSTANCE IT'S NOT GOOD TO DISRUPT AN ECOSYSTEM,
IT'S GOOD TO FIT INTO AN ECOSYSTEM AND CREATE CONNECTIVITY AMONGST THAT ECOSYSTEM AND
LEAVE THE POWER AT THE LEGACY ASPECTS OF THAT ECOSYSTEM THAT EXIST. IT'S INTERESTING,
MOST -- I DON'T KNOW HOW PEOPLE WOULD RESPOND TO THIS, BUT YOU WOULD THINK THAT SOME OF
THE PRIVACY FEEDBACK THAT DEVEN IS GIVING IS AN INHIBITER. I THINK IT REALLY ACTUALLY
IF YOU LISTEN TO IT AND TAKE IT TO HEART MAKES IT EASIER TO SHAPE A MODERNIZATION EFFORT.
BECAUSE IT SAYS WE'RE GOING TO CREATE CONNECTIVITY, WE'RE GOING TO ALLOW YOU TO MAINTAIN
YOUR EXISTING AUTHENTICATION BUT WE'LL SHARE SHARE IDENTITY ACCESS MANAGEMENT WITH YOU SO
YOU CAN APPROVE ANYONE WHO HAS ACCESS TO YOUR DATA. CREATE THAT THREAD BETWEEN ANY DATA
SET YOU SHARE AND HOW IT'S CURATED PARSED AND SHARED IN OUR ENVIRONMENT. BY THE WAY,
YOU'LL HAVE APPROVAL OVER WHO IT'S SHARED WITH. AND I THINK THAT'S A REALLY IMPORTANT
POINT. WE'RE NOT REPLATFORM THE DATA OR MOVING THE BUSINESS RULES. WE'RE JUST SITTING
WITHIN AN ECOSYSTEM AND CONNECTING WITH THE ENVIRONMENT OF THE WAY THAT IT IS. THAT
ACTUALLY ALLOWS MODERNIZATION TO OCCUR. THAT CREATES A LEVEL OF COMFORT. I'LL GIVE
AN EXAMPLE. MIGHT HAVE WIFE IS FROM --
>>BRIEF EXAMPLE, JOSE
>>BRIEF. MY WIFE IS FROM LATIN AMERICA, AND I MET HER, I WENT AND MET HER UNCLE ONCE AND
I'M, HE LEANED IN TO KISS ME ON THE CHEEK AND WE DON'T TOUCH IN THE UNITED STATES AND SHE
WHISPERED IN ENGLISH HE'S GOING TO KISS YOU ON THE CHEEK AND IT'S PART OF OUR CULTURE AND
IF YOU LEAN AWAY IT'S GOING TO BE A PROBLEM. YOU HAVE TO KIND OF FIT INTO AN ENVIRONMENT. YOU HAVE TO UNDERSTAND IT. I THINK THAT'S EXTREMELY IMPORTANT.
>>THANKS VERY MUCH, JOSE. CRAIG, YOU'RE THE GUY THAT HAS TO WORRY ABOUT RISKS HERE. DOES
THIS SORT OF KIND OF GET YOUR ANTENNA UP?
>>YEAH, I MEAN, NORMALLY IT WOULD. BUT LISTENING TO THE CONVERSATION TODAY HEARING FROM
DEVEN AND JOSE IN PARTICULAR, I FEEL A LITTLE BETTER BELIEVE IT OR NOT. LET ME TELL YOU
WHY. . BECAUSE YOU HEARD VID MENTIONED PERIMETER AND 0 TRUST AND DIFFERENT THINGS. WE'RE
DOING A LOT OF GREAT THINGS AROUND OUR INFRASTRUCTURE TO MODERNIZE SO WE CAN DO THESE
THINGS. I'M VERY, VERY HAPPY ABOUT THAT. I'M TELL YOU WHERE WE'RE EVOLVING TO, CLIFF.
WE'RE TALKING ABOUT ACCESS TO TOOLS AND ACCESS MANAGEMENT AND YOU HEARD DEVEN AND JOSE
TALK ABOUT THAT. WHAT I WAS WRITING DOWN, I STARTED THINKING ABOUT OUR CDO BECAUSE
WE HAVE DATA CONTROLS AND DATA MANAGEMENT. AS WE GET OUR ARMS AROUND THIS

DATA MANAGEMENT
AND THE CONTROLS AROUND THAT BECAUSE ACCESS IS IN A BUCKET THIS BIG AND THEN THE DATA
MANAGEMENT IS THIS, I THINK WE'RE EVOLVING TOWARDS THAT. ALL THE CONVERSATIONS FROM HHS
PROTECT AND THINGS THAT WE'RE DOING I THINK WE'RE EVOLVING TOWARDS THAT. FROM A SECURITY
PERSPECTIVE, I FEEL PRETTY GOOD.
>>OKAY. IF YOU FEEL GOOD, I FEEL BETTER. THANK YOU, CRAIG.
>>THANK YOU.
>>SO, TIM, WITH THIS FEEDBACK NOW, YOU KIND OF LAID OUT A GREAT CASE FOR INTERDISCIPLINARY
APPROACHES AND REALLY HIGHLIGHTED THE UTILITY OF VISUALIZATION HERE. TAKING ACCOUNT OF
ALL THAT WHAT WOULD YOU SAY NOW BACK TO FDA LEADERSHIP ABOUT THE GOT TO DOS FOR PULLING IN
MULTIPLE STAKEHOLDERS AND MAKING VISUALIZATION A PRIORITY, WHAT WOULD BE YOUR MESSAGE BACK
TO THE AGENCY?
>>I THINK WHAT'S REALLY IMPORTANT IS TO REALIZE WE DON'T KNOW WHAT WE WILL NEED TO KNOW IN
FIVE TO TEN YEARS. WE HAVE TO BUILD WHATEVER IT IS THAT WE'RE BUILDING IN A VERY FLEXIBLE
WAY. WE NEED TO THINK FIVE AND TEN YEARS OUT, BUT DON'T KNOW WHAT THE QUESTIONS WILL
LOOK LIKE THEN, LIKE A YEAR AGO WE DIDN'T KNOW WE'D HAVE TO BE ANSWERING ALL THESE
QUESTIONS ABOUT COVID. SO WE HAVE TO DEVELOP THAT FLEXIBLE DATA INTEGRATION LAYER ON TOP
OF THINGS LIKE DATA LAKES AND DATA WAREHOUSES AND WE CAN DO THAT WITH A SEMANTIC DATA
MATCH OR DATA FABRIC THAT CAN SUPPORT THINGS LIKE NEW TYPES OF VISUALIZATIONS WE NEED TO
PRODUCE. WE CAN TAKE THAT DATA WAREHOUSE AND DATA LAKE TO THE NEXT LEVEL. SO I THINK
THERE'S HUGE POTENTIAL THERE. AND I HOPE THAT THOSE TYPES OF CONSIDERATIONS WILL BECOME
AN INTEGRAL COMPONENT OF WHAT THE FDA ROADMAP IS TO TAKE US TO THAT NEXT LEVEL AND TO DO
THAT, WE ALSO NEED TO CONSIDER PARTNERSHIPS WITH TECHNOLOGY COMPANIES OUTSIDE OF OUR
INDUSTRY, WHAT'S GOING ON IN DATA VISUALIZATION THAT'S -- IN OTHER INDUSTRIES LIKE
FINANCIAL OR EVEN OTHER GOVERNMENT AGENCIES. WHILE WE STILL INCLUDE OUR INDUSTRY THOUGHT
LEADERS THAT INCLUDE VARIOUS VENDORS, PARTNERS IN THE PRECOMPETITIVE SPACE BECAUSE ALL
THESE CHALLENGES NOT JUST THE VISUALIZATION OF COMPLEX DATA, BUT HOW WE CAN INTERPRET OUR
DATA, THESE ARE QUESTIONS THAT ARE JUST TOO LARGE FOR ANY ONE INDIVIDUAL OR ORGANIZATION
TO SOLVE. WE REALLY NEED THAT COLLABORATION FOR SUCCESS. I'M VERY PLEASED TO SEE THE A
OF ENGAGEMENT WE'RE HAVING IN THE PRECOMPETITIVE SPACE WITHIN PHARMA BUT ALSO TALKING TO
FOLKS LIKE AT THE FDA AND OTHER REGULATORS ACROSS THE GLOBE AND I THINK COVID IS HAS

STARTED TO HIGHLIGHT THE NEED TO DO THIS AND GIVEN US THE IMPETUS TO COME TOGETHER AND
TRY TO SOLVE SOME OF THESE CHALLENGES.
>>MARY ANN, HAS COVID ACCELERATED YOUR SLIDE DECK? BASICALLY WHAT YOU PRESENTED TO US
A LITTLE EARLIER TODAY, IT SEEMS AS THOUGH THE PANDEMIC IS REALLY SAYING, LOOK APPEALED
TO THE METAL. DOES THAT STRIKE YOU?
>>YES. IT HAS INDEED. AS A MATTER OF FACT [WHAT WE FOUND ALMOST INSTANTLY IS THE
INSTANT NEED FOR RESPONDING AND FINDING REALLY CREATIVE WAYS DO THINGS VERY, VERY QUICKLY.
NOW, OUR BIGGER PICTURE IS MORE SOPHISTICATED, IT'S ROBUST, WE'RE MOVING FORWARD WITH
THAT, BUT, YES, IT REALLY HAS TAUGHT US THAT WE NEED TO AND WE CAN MOVE FASTER
>>DEVEN VERYBODY'S
ARE YOU STILL RETAINING THIS OPTIMISM ABOUT WE CAN RETAIN THAT PROPER BALANCE BETWEEN A PROTECTION AND ACCESS
ON LARGE SCALE? I WANT TO AMP THIS UP A BIT. WE HAVE TO REMIND OURSELVES THE AGENCY
CARES ABOUT DRUGS AND BIOLOGICS AND DEVICES AND DIAGNOSTICS AND FOODS, AND VETERINARY --
IS IT STILL GAIN THIS INTERDISCIPLINARY ENGAGEMENT AND MAKE THINGS ALL VISUALIZED FOR
ALL? THIS IS A REALLY TALL ORDER. IS IT DOABLE, DEVEN
>>YEAH, IT IS. I MEAN, I'M PROBABLY A BIT MORE OPTIMISTIC ABOUT THIS STUFF THAN MOST
PEOPLE BECAUSE I KNOW WHAT'S POSSIBLE. TOO OFTEN PEOPLE LOOK AT THE CHALLENGES AROUND BIG
DATA AND DATA GOVERNANCE AND JUST THROW IN THE TOWEL OR SAY THINGS LIKE WE CAN'T HAVE IT
BOTH WAYS. WE EITHER GET PRIVACY AND SECURITY OR WE GET DATA ACCESS BUT WE CAN'T HAVE
BOTH. I HAVE SEEN IT HAPPEN. I DO THINK THERE ARE CHALLENGES WITH GOVERNMENT. BUT THE
GOVERNMENT HAS A DEDICATED FEDERAL WORKFORCE, HAVING WORKED IN IT, YOU KNOW, I FEEL LIKE
PEOPLE DO THE BEST WITH WHAT THEY'VE GOT AND THE FDA HAS RESOURCES AND -- THAT ARE BOTH
IN TERMS OF MONEY AND PEOPLE THAT THEY CAN GET THIS DONE FRANKLY IN WAYS THAT I THINK I'LL
SAY THAT OTHER AGENCIES CAN'T. AND SO I THINK THE AGENCY IS REALLY WELL POSITIONED TO DO
THIS VERY, VERY WELL. AND I'M KIND OF EXCITED ABOUT THAT ACTUALLY BECAUSE THERE'S ONE
THING THAT AS A MEMBER OF THE GENERAL PUBLIC, WE GET FRUSTRATED NOT JUST WHEN PRIVACY OF
OUR DATA IS COMPROMISED OR NOT TAKEN SERIOUSLY BUT WHEN PEOPLE DON'T MAXIMIZE THE USE OF
OUR DATA TO DO SOMETHING GOOD. IT'S PART OF THE PUBLIC TRUST IN THESE AGENCIES THAT THEY
ARE NOT JUST GOOD STEWARDS FROM A PROTECTION STANDPOINT BUT THEY'RE LEVERAGING THIS DATA
IN THE WAY THEY NEED TO. FDA IS A PEOPLE AGENCY, NOT A DEVICE AGE, NOT A DRUG AGENCY,
THEY'RE ABOUT PEOPLE AND THE HEALTH OF PEOPLE. YOU CANNOT CONVERT ON THAT

MISSION WITHOUT
DATA AND YOU NEED TO BE ABLE TO COLLECT IT IN USE IT SUCCESSFULLY. SO I'M PRETTY,
AGAIN, I AT THE POINT TO BE AN OPTIMIST BUT I'M FEELING PRETTY GOOD ABOUT WHAT'S HAPPENING
HERE.
>>IF I MIGHT JUST CHIME IN,
>>SURE, MIKE.
>>SO I WOULD AGREE, I THINK THAT ONE OF THE KEY PIECES TO MAKE SURE THAT WE COMMUNICATE
NOT JUST AT THE FDA BUT WE WORK WITH CDO'S ALL THE TIME AND AS YOU KNOW, THERE'S A FEDERAL
MANDATE TO IMPLEMENT CDOS AT EVERY AGENCY. AND MANY AGENCIES ARE DOING THAT TO CHECK THE
BOX AND IMPLEMENTING CDOS WITHOUT APPROPRIATE RESOURCES, NO FUNDING, NO STAFF, AND THEN
SAYING, OKAY, MR. AND MRS. CDO, FIX THE PROBLEM. WHICH IS NOT POSSIBLE. . SO WE'RE --
ONE OF THE THINGS WE WANT TO BE CONSCIOUS OF JUST IN GENERAL IS NOT PROJECTING THIS AS A
HUGE COST SAVINGS. SO
Test TEST TO CHECK THE BOX. AND MANY CEOs WITHOUT APPROPRIATE RESOURCES, NO FUNDING OR STAFF AND SAYING OKAY, MR. AND MRS. CDO [INAUDIBLE] WHICH IS NOT POSSIBLE. SO WE'RE -- ONE OF THE THINGS I WANT TO BE CONSCIOUS OF IS NOT PROJECTING THIS AS A HUGE COST SAVINGS. SO MAYBE WE CAN SAY OKAY IT'S LESS EXPENSIVE THAN SAY MAINTAINING LEGACY TECHNOLOGY IN TERMS OF SHIFT MAINTENANCE TO THE CLOUD AND WE CAN PAY FOR WHAT WE USE. BUT ON THE OTHER HAND IT PUTS THE ONUS ON EVERYONE TO REALLY IMPROVE THE DATA GOVERNANCE. SO WE CAN KEEP TRACK OF WHAT DATA THERE IS AND MORE EASILY COMBINE THE DATA, PROTECT THE DATA. MAINTAIN PRIVACY.
>>: I'M GLAD YOU MADE THAT POINT. I'M GOING TO CHALLENGE OUR PANELISTS THIS WASN'T ANYTHING THAT ANYONE PLANNED. HERE'S WHAT I WANT TO ASK ALL OF YOU WE CAME IN HERE AS INTERNATIONAL EXPERTS IN OUR FIELDS AND WE TALKED ABOUT.
>>: HERE'S A BIT OF A CHALLENGE. IT'S HARD TO COME UP WITH ONE THING BECAUSE I'M HEARING A LOT OF REALLY GOOD THINGS ACROSS THE PANEL TODAY. AND I THINK IT'S MORE ABOUT HOW WE APPROACHED THE DATA. AND TAKING THE
UNDERCURRENT OF THE THEME HERE IT'S ABOUT COLLABORATION THAT'S REALLY GOOD TO HEAR. THE
$6 MILLION MAN, WE CAN BUILD IT BUT IT'S GOING TO TAKE THE COLLABORATIVE EFFORT.
THAT'S WHAT I'M HEARING FROM EVERYONE TODAY AND THAT'S BEEN MY TAKEAWAY SO FAR IS THAT WE
ARE THINKING ABOUT THIS IN THE RIGHT WAY AND I'M REALLY ENCOURAGED THAT THE FDA HOSTED
THIS TYPE OF MEETING BUT THIS IS WHAT WE NEED MOVING FORWARD.
>>: THANK YOU. AND JOSE, IN A SENTENCE, ONE OR TWO, ONE THING, JOSE.
>>: I THINK THE ENERGY IS THERE TO DRIVE CHANGE. I WAS PRETTY IMPRESSED BY THE
OPENNESS. SO WHEREVER THERE'S MOMENTUM YOU CAN DRIVE CHANGE AND CLEARLY WITH THIS GROUP
ENERGY AND MOTIVATION. SO THE TECHNOLOGY IS THERE. CULTURAL CHANGE IS HARD. YOU JUST
NEED A GROUP WITH THAT ENERGY TO PUSH IT.
>>: SOUNDS LIKE WE'VE GOT SOME HERE. CRAIG, WHAT'S YOUR ONE THING.

>>: AND I WILL SAY THAT FDA IS A PEOPLE AGENCY. AND IT RESONATED WITH ME COLLABORATION.
AS YOU SAID THAT I WROTE IT DOWN IMMEDIATELY, CHRIS, AND I THINK THAT'S SOMETHING THAT WE
JUST WILL NEED TO MOVE FORWARD WITH. THANK YOU FOR THAT.
>>: AND ONE THING.
>>: YES. SO I WAS ACTUALLY HEARTENED BY, CRAIG, YOUR COMMENT. IN TODAY'S SESSION MADE
YOU FEEL MORE POSITIVE. BECAUSE AS I SAID CULTURE CHANGES THE NUMBER ONE ISSUE ACROSS THE
BOARD AND TO SEE THAT IT'S JUST THIS DISCUSSION GIVES YOU A POSITIVE OUTLOOK I
THOUGHT WAS A BIG WIN FOR US.
>>: THAT'S GREAT. LET'S GO TO DEVEN AND MARYANN WILL CLEAN UP.
>>: IT WAS IMPRESSIVE TO ME BUT THING THAT STICKS WITH ME IS THE COMMITMENT OF THE
LEADERSHIP WITHIN THE FDA AND THAT REALLY GOES ACROSS NOT JUST DR. ABERNETHY BUT MARYANN,
CRAIG, JOSE, THE STAFF, YOUR NEW CDO, ALL OF THAT, THAT'S OFTEN WHAT IT TAKES TO REALLY
DRIVE -- YOU HAVE TO HAVE THE COMMITMENT OF EVERYONE IN THE WORKFORCE AND THE COLLABORATION. BUT WHEN LEADERSHIP IS BEHIND IT AND BOTH PUSHING AND SUPPORTING, THAT'S
PRETTY KEY.
>>: THANK YOU VERY MUCH, DEVEN MCGRAW. AND FINALLY MARYANN SLACK, YOU STARTED US
OFF. FINISH US OFF.
>>: SURE. I THINK THAT I DON'T HAVE SOMETHING NEW I REFLECT EVERYTHING THAT WE'VE JUST
HEARD, BUT WHAT REALLY DROVE THE WHOLE THING HOME TO ME, WHICH HAS BEEN RESONATING WITH ME
ANYWAY FROM THE BEGINNING, IS THIS SERIOUS, THE SITUATION THAT WE'RE IN RIGHT NOW WITH
COVID-19 HAS CAUSED US TO REALLY PARTNER UP MORE. AND DO IT FASTER AND MOVE MORE QUICKLY
AND TAKE OPPORTUNITY TO BREAK BOUNDARIES THAT WE WOULD ORDINARY WILL I TAKE A LOT OF TIME
TO TRY AND WORK OUR WAY THROUGH TO DO SOME MORE SHARING. AND WHAT I WANT TO DO, WHAT I
REALLY WANT AND I HEAR IT REFLECT IT IS TO NOT LET US LOSE ANY GROUND, BECAUSE WHAT WE'RE
DOING NOW IT'S REALLY -- IT'S GROUNDBREAKING. IT'S THE THING THAT'S GOING TO ENABLE US TO
MOVE OUT ON THE VISION WE HAVE HERE.
>>: WONDERFULLY STATED. THANKS, MARYANN. IN JUST A MOMENT WE'RE GOING TO TAKE A FIVE,
FIVE-MINUTE BREAK BEFORE OUR SECOND PANEL. OUR SECOND PANEL IS GOING TO BE ON DATA
EXCHANGE. NOW THAT WE'VE TALKED ABOUT SHARING, LET'S TALK ABOUT DATA EXCHANGE. THAT
WILL BE FIVE MINUTES FROM NOW. BUT BEFORE THAT I WANT TO OFFER OUR, MY CONGRATULATIONS AND THANKS TO MARYANN SLACK, DEVEN MCGRAW, CRAIG TAYLOR, JOSE ARRIETA,
TIM WILLIAMS, AND MIKE FLECKENSTEIN, GREAT WAY TO START US OFF. AND WE JUST PROVED THAT
EVEN THE EXPERTS LEARN SOMETHING NEW. THANK YOU ALL. WE'LL SEE YOU IN FIVE MINUTES. THANKS, EVERYBODY. GREAT START.

>>: WELCOME BACK, THAT WAS A GREAT SESSION FOR DATA SHARING FOR OUR FIRST PANEL. WE'LL
MOVE TO OUR SECOND PANEL ON DATA EXCHANGE. DATA EXCHANGE. AND THIS SESSION WILL GO UNTIL
ABOUT 11:50 EASTERN.
11:50 EASTERN TIME, AFTER WHICH WE'LL TAKE A 20 TO 25 MINUTE BREAK. AS WE DID BEFORE
WE'LL HAVE AN INITIAL STIMULUS DISCUSSION. THIS WILL BE LED OFF BY MEREDITH CHUK FROM THE
AGENCY AND SHE'LL BE FOLLOWED BY RAPID FIRE RESPONSE FROM DON RUCKER. I'LL ASK FIRST IF
MEREDITH WOULD INTRODUCE HERSELF AND GET US STARTED ON THIS STIMULATING INITIAL
DISCUSSION. MEREDITH.
>>: THANKS, CLIFF. GOOD MORNING, EVERYONE. I'M MEREDITH CHUK A PEDIATRIC ONCOLOGIST
WORKING WITH THE CDER ENSURING SAFETY OF DRUGS FOR PATIENTS WITH CANCER AND I LEAD THE
IND SAFETY REPORTING PROGRAM AN EXAMPLE OF THE FDA TO MODERNIZE THE WAY WE RECEIVE AND
REVIEW OUR REGULATORY DATA. THE PARTICULAR GOALS OF THIS PROGRAM ARE TO TRANSFORM THE WAY
THE SUBMISSION PROCESS FOR THESE IMPORTANT SAFETY INFORMATION FROM THAT SEA OF PDFS YOU
SEE ON THAT FIRST SCREEN INTO A DIGITAL SUBMISSION FORMAT WITH STRUCTURED DATA
ELEMENTS THAT WILL ALLOW US BOTH TO IMPROVE THE DATA QUALITY AND ALSO ALLOW US TO USE NEW
ANALYTIC TOOLS TO BE ABLE TO USE THIS DATA IN NEW AND IMPORTANT WAYS.
NEXT SLIDE, PLEASE. DRUG MAKERS WHO CONDUCT INVESTIGATIONAL TRIALS WITH DRUGS ARE
REQUIRED TO MONITOR THE SAFETY OF THE PROGRAM FOR PATIENT SAFETY. CERTAIN TYPES OF THESE
MORE SERIOUS EVENTS ARE REQUIRED TO BE SUBMITTED TO THE FDA IN AN IND SAFETY REPORT WITHIN
SEVEN OR 15 DAYS DEPENDING ON THE TYPE OF EVENT. CURRENT METHOD IS PDF FORMS AND IT'S
EXTREMELY INEFFICIENT AS FDA RECEIVES 30 TO 50,000 OF THESE PDFS PER YEAR. SO REVIEW AND
TRACKING OF THIS IMPORTANT SAFETY INFORMATION BY THE MEDICAL REVIEWERS IS CHALLENGING.
AND THE SOLUTION TO THIS PROBLEM IS TO CREATE A DIGITAL SUBMISSION PROCESS USING
INTERNATIONAL EXISTING DATA STANDARDS TO BE ABLE TO USE THIS INFORMATION AND USE ANALYTIC
TOOLS TO CONNECT THE DOTS IN A WAY THAT WE HAVEN'T PREVIOUSLY. IN THE NEXT FEW SLIDES
I'LL WALK YOU THROUGH WHAT THE CURRENT PROCESS LOOKS LIKE AND THE BENEFITS OF THE NEW
PROCESS. NEXT SLIDE, PLEASE. SO IN THE CURRENT PROCESS, ESSENTIALLY A SPONSOR TAKES
INFORMATION FROM THEIR SAFETY DATABASE, UNSTRUCTURES IT AND PUTS IT IN A PDF MEDWATCH
FORM. NEXT SLIDE. THESE PDFS ARE THEN TRANSMITTED TO FDA THROUGH THE ELECTRONIC
SUBMISSION GATEWAY. NEXT SLIDE. AND HOUSED INDIVIDUALLY IN FILE FOLDERS IN THE eCTD FILE

STRUCTURE. NEXT SLIDE. PHYSICIANS, PHARMACISTS, NURSES HAVE TO INDIVIDUALLY LOOK AT ALL
THESE PDF FORMS AND MAKE THE CONNECTIONS ON THEIR OWN INDIVIDUAL TRACKING SYSTEMS WHETHER
IT'S EXCEL FILES OR STICKY NOTES OR OTHER TYPES OF DECENTRALIZED TRACKING SYSTEMS. NEXT
SLIDE. EACH OF THESE STEPS IN THE PROCESSES TAKES TIME. NEXT SLIDE. ADDS
INEFFICIENCIES, NEXT SLIDE. AND CREATES CHALLENGES FOR EFFICIENT SAFETY SIGNAL TRACTION
AND DETECTION FOR THE IMPORTANT SAFETY INFORMATION FOR PATIENTS IN CLINICAL TRIALS. IN
THIS RESPONSE THE SPONSORS WILL STRUCTURE IT IN THE SAFETY DATABASES. NEXT SLIDE. SUBMIT
THIS INFORMATION THROUGH THE FDA GATEWAY. NEXT SLIDE. NEXT SLIDE. AND TO THE FDA
ADVERSE EVENT REPORTING SYSTEM. OR FAERS IT WILL HOLD IND SAFETY AND POST MARKET SAFETY
REPORTS. NEXT SLIDE. SO REVIEWERS WILL BE ABLE TO VIEW THIS DATA IN A STRUCTURED FORMAT AND APPLY ADVANCED ANALYTIC TOOLS IN LOOKING AT THE SAFETY DATA ACROSS
THE DEVELOPMENT PROGRAM, ACROSS THE LIFECYCLE OF THE DRUG HERE SHOWN AS A SNAPSHOT OF THE
FDA PUBLIC DASHBOARD DATA JUST TO GIVE AN EXAMPLE OF THE TYPES OF ANALYTICS THAT WILL BE
POSSIBLE IN TERMS OF LOOKING AT THE TYPES OF ADVERSE EVENTS AND SUBSETTING BY OUTCOME OR
DEMOGRAPHIC FACTOR OR LOOKING AT THESE TYPES OF EVENTS THAT HAVE BEEN REPORTED ACROSS A
DRUG CLASS. NEXT SLIDE. THIS NEW PROCESS IS MORE EFFICIENT FOR SPONSORS WHO
MUST ADHERE TO THE REGULATIONS OF SUBMITTING THESE REPORTS WITHIN SEVEN OR 15 DAYS.
SCALABLE FOR THE FDA. AND AS AN EXAMPLE OF TECHNOLOGY THAT REALLY ENHANCES THE ABILITY OF
OUR REVIEWERS TO CARRY OUT OUR REGULATORY MISSION OF ENSURING PATIENT SAFETY AND
MAKING CONNECTIONS WITH THIS DATA THAT HAD PREVIOUSLY NOT BEEN POSSIBLE WHEN THEY'RE
LOCKED IN PDF FORMS. NEXT SLIDE. SO DURING THE IMPLEMENTATION WE'VE CERTAINLY
ENCOUNTERED OUR SHARE OF CHALLENGES BUT HAVE ALSO SETTLED UPON SOME OPPORTUNITIES NOT ONLY
FOR IMPROVING THIS PROGRAM BUT ALSO DATA MODERNIZATION EFFORTS ACROSS FDA. NEXT SLIDE.
SO REGARDING THE INFRASTRUCTURE. WE WERE ABLE TO USE THE EXISTING FDA GATEWAY FOR
SUBMISSION OF THESE IND SAFETY REPORTS. HOWEVER, NEEDED TO CONNECT EXISTING FDA DATA
SYSTEMS IN ORDER TO PROPERLY PROCESS THEM. SUCH AS CODING INDIVIDUAL INVESTIGATIONAL
DRUGS AND REVIEWING TO THE APPROPRIATE REVIEW TEAMS. WE ALSO HAD TO ADOPT NEW REVIEW
TOOLS TO BE ABLE TO REVIEW AND ANALYZE SAFETY INFORMATION SUBMITTED IN THIS MANNER.
IN ADDITION, WE'RE EXPLORING NEW DATA EXCHANGE AVENUES SUCH AS APES, WHICH WILL ALLOW

FOR THE SUBMISSION OF THIS PARTICULAR SAFETY DATA FROM A VARIETY OF DATA SOURCES. IN
TERMS OF DATA STANDARDS, WHICH ARE CLEARLY IMPORTANT, WE THOUGHT IT WAS IMPORTANT TO USE
THE EXISTING DATA STANDARDS AS THE DRUG DEVELOPMENT PROCESS IS OBVIOUSLY A GLOBAL
PROCESS. BUT WE DID HAVE TO MAKE SOME MODIFICATIONS IN ORDER TO ENSURE THAT OUR
REGULATORY REQUIREMENTS AT FDA WERE MET WHICH ARE SOME DIFFERENCES FROM OTHER REGULATORY
AGENCIES. WE CONDUCTED A PILOT PROGRAM OF THIS PROCESS WITH INDUSTRY TO NOT ONLY TESTIFY
OUR OWN CAPABILITIES BUT ALSO TO DIALOGUE WITH EXTERNAL STAKEHOLDERS TO UNDERSTAND THEIR
PROCESS AND ALSO MINIMIZE THE IMPACT OF EXTERNAL SUBMITTERS. SECURE DATA EXCHANGE IS
OBVIOUSLY PARAMOUNT TO ANY PROGRAM AND IN PARTICULAR FOR THIS PROGRAM WE CREATED A
SEPARATE SUBMISSION PATHWAY TO FAERS FOR IND SAFETY REPORTS SO THEY WERE CONTAINED
SEPARATE FROM THE POST MARKET REPORTS. BECAUSE AS YOU SAY THE POST MARKET REPORTS ARE
POSTED ON A QUARTERLY BASIS THAT'S NOT THE INTENT FOR THE IND SAFETY REPORT SUBMITTED
THROUGH THAT NEWLY CREATED MARKET PATHWAY. AND LAST BUT NOT LEAST, BUT THE CHANGE IS
PARAMOUNT WITH ANY OF THESE PROCESSES TO INFORM THE STAKEHOLDERS AND INTERNAL AND EXTERNAL
STAKEHOLDERS AND SUBMITTERS THAT INCLUDES NEW INTERNAL PROCESSES NEW TRAINING NEW SOPs,
EXTERNAL GUIDANCES, COMMUNICATION WITH REGULATED INDUSTRY WHO WILL BE RESPONSIBLE FOR
SUBMITTING DATA IN THIS NEW WAY. SO AGAIN I TRIED TO FOCUS ON THINGS THAT WERE PARTICULAR
FOR OUR USE CASE AND OUR PROGRAM BUT REALLY THESE CHALLENGES I THINK APPLY TO ALL OF THE
DATA MODERNIZATION EFFORTS THAT WE'LL BE DISCUSSING HERE TODAY AT FDA, INCLUDING
AGGREGATING OUR DATA ASSETS AND BEING ABLE TO LOOK AT OUR DATA IN NEW EXCITING WAYS
THAT WE HAVEN'T BEEN PREVIOUS. THE CONSISTENT RELEVANT AND THOUGHTFUL USE OF APPROPRIATE
DATA STANDARDS IN ORDER TO BE ABLE TO CONNECT THESE DATA AND CONNECT THE DOTS SORT OF
ACROSS DISPARATE DATA SOURCES, PROVISIONS FOR SECURE DATA TRANSFER AND THE ABILITY TO
ACCEPT DATA FROM A VARIETY OF DATA SOURCES AS AGAIN ALLUDED TO IN THE LAST PANEL. AND
THEN REALLY CONTINUING THE DIALOGUE WITH OUR INTERNAL AND EXTERNAL STAKEHOLDERS TO
UNDERSTAND THEIR PROCESS, MAXIMIZE EFFICIENCY AND ALSO MINIMIZE THE DISRUPTION AND ANY
DOWNSTREAM IMPLICATIONS FROM THESE PROCESSES, REALLY AGAIN IN ORDER TO MAXIMIZE THE WAY
THAT WE RECEIVE AND REVIEW OUR REGULATORY DATA IN ORDER TO SUPPORT OUR STAFF FOR THEIR
REGULATORY WORK. SO THANK YOU FOR YOUR TIME. AND I'M REALLY LOOKING FORWARD

TO THE PANEL
DISCUSSION ON THIS AND OTHER RELEVANT CONSIDERATIONS.
>>: THAT'S GREAT. THANKS VERY MUCH, MEREDITH. GOT TO SAY THAT THAT SEA OF PDFS THE
COVER SLIDE REALLY CONVEYS THE ISSUE. WE REALLY NEED THIS INITIATIVE. THIS COULDN'T BE
BETTER TIMES GIVEN NOT ONLY THE DATA CAPABILITIES WE'VE GOT WE'VE HEARD ABOUT AND SO
FORTH AND ALL THE MODERNIZATION PUSH, BUT THIS IS THE TIME WHERE WE NEED TO MAKE THIS MUCH
MORE EFFICIENT AND YOU'VE OUTLINED IT JUST A GREAT WAY, VERY CLEAR. THANK YOU. DON,
PLEASE INTRODUCE YOURSELF TO EVERYONE AND TELL US HOW IT IS YOU FIND YOURSELF AS OUR
RESPONDENT.
>>: OKAY. HI, EVERYBODY. DON RUCKER, NATIONAL COORDINATOR FOR IT. WORK AND RUN THE
AGENCY KNOWN COLLOUQUALY AT IT. AND MEREDITH HAS DONE A NICE JOB IN THINKING ABOUT MODERN
DATA. COUPLE OF QUICK OBSERVATIONS ON WHAT WE'VE JUST SEEN. I THINK THIS GOES ALSO TO
THE FIRST PANEL, WHICH IS IN ALL OF THESE THINGS WE HAVE TO THINK IN ANYTHING HAVING TO DO
WITH CLINICAL DATA, WE HAVE TO THINK WHAT ARE WE GOING TO GET FROM STRUCTURED DATA. WHAT
ARE WE GOING TO GET FROM MORE LET'S SAY FREE TEXT DATA. AND IN THAT FREE TEXT DATA I
WOULD ACTUALLY LUMP SOME THINGS THAT ARE RELATIVELY UNSTRUCTURED IN THEIR PROGRESSION SUCH
AS THE DATA LAKE ISSUES WHICH WAS STRUCTURED BUT ARE NOW OFTEN BECAUSE OF THE MOVEMENT OF DATA OVER MULTIPLE TRANSFORMATIONS, HAVE A LITTLE BIT MORE OF AN UNSTRUCTURED
NATURE TO THEM. I THINK ONE OF THE CHALLENGES FOR THE FDA WILL BE CLEARLY GIVEN
THE 20, 25 PERCENT OF THE ECONOMY AS WAS MENTIONED THAT THE FDA COVERS IS FOR THE BACK END
HOW MANY SORT OF THESE DATABASES IF YOU WILL, DATA LAKES, WAREHOUSES, WILL THE FDA WANT TO
STAND UP. MY GUT TELLS ME YOU'RE GOING TO NEED VERY SEPARATE THINGS FOR CLINICALS VERSUS
ANIMALS VERSUS LET'S SAY COSMETICS AND FOOD. AND YOU'RE JUST GOING TO HAVE DIFFERENT
CAPABILITIES AND TOOLS. SO I THINK THAT BACK END IS GOING TO BE A BIG QUESTION AS THE FDA
MOVES FORWARD. ANOTHER BIG QUESTION IS AS WE HAVE MORE OF THIS OUTSIDE DATA, HOW
WILL THE FDA THINK ABOUT COMBINING THE DATA THAT IS CAPTURED ON THE REPLACEMENTS FOR THE
PDF WITH THINGS THAT ARE AVAILABLE, FOR EXAMPLE, IN HHS PROTECT OR IN, FOR EXAMPLE, THE
HEALTH INFORMATION EXCHANGES, WHAT ARE THE MECHANISMS THERE. SO THERE'S SOME BROAD
DATA POLICY ISSUES THAT OUGHT TO BE LOOKED AT BEFORE LOCKING INTO CONTRACT OR INTO
CONCRETE THE DESIGN OF EACH OF THESE INDIVIDUAL DATABASES TO PREVENT SUB OPTIMIZATION.
THE FINAL THING I WANT TO SAY IS WHENEVER YOU LOOK AT DATA, IT IS OFTEN THE

CONVERSATIONS
-- AND THIS HAPPENED WHEN I WAS IN THE COMMERCIAL WORLD SELLING EHR SYSTEMS -
- THE
CONVERSATIONS ARE OFTEN ABOUT WHAT TO DO WITH THE DATA, BUT THE ACTUAL HARD
WORK,
LIKE 99 PERCENT OF THE INVESTMENT, IS GETTING THE DATA. THAT'S REALLY
THE CHALLENGE
IN GETTING DATA THAT IS ROBUST. BECAUSE AS WAS POINTED OUT THERE'S ONLY 30
TO 50,000
OF THESE REPORTS WHEN YOU SPREAD IT OVER THE SCOPE OF WHAT'S BEING REPORTED
HERE, THESE
ARE TINY DATA SUBSETS TO BASE CONCLUSIONS ON. SO YOU WANT TO THINK ABOUT HOW
DID THE DATA
COME IN AND I WOULD, AS I'M SURE IS HAPPENING, ENCOURAGE THE FDA TO THINK
LONG AND HARD,
WHAT ARE THE APPS OUT IN THE COMMUNITY THAT WOULD BE ENTERING THIS DATA, HOW
IS THIS
TRANSFORMED BY THE MANUFACTURERS, WHAT IS THE EFFORT FOR CLINICIANS.
RIGHT NOW IN THE
U.S. CLINICIANS WHO ARE ULTIMATELY GOING TO BE ENTERING MOST OF THIS ARE
ALREADY SPENDING
THREE OR FOUR HOURS A DAY SITTING IN FRONT OF COMPUTER SCREENS DOING WORK
THAT IS BY
POLICY CONSIDERATIONS MOST OF THEM PAYMENT POLICY TRUTH BE TOLD. SO
WE'VE PUT A HUGE
BURDEN ON FOLKS ON MUCH OF THE DATA WE'RE GETTING THROUGH THIS IS
EXTRAORDINARILY LOW
QUALITY TRUTH BE TOLD. IT'S PLATED TEXT AND STUFF LIKE THAT. SO I WOULD
JUST
ENCOURAGE LOOKING AT THE NATURE OF HOW THE DATA IS CAPTURED, THE LIKELIHOOD
OF ACCURACY,
WHERE THE BURDEN FALLS, AND I THINK THAT WILL REALLY HELP THE FDA DRIVE TO A
MODERN THING
PROBABLY THE MOST IMPORTANT THING FOR FDA TO MINIMIZE BURDEN IS TO GET AS
MUCH DATA WE'RE
SEEING THE SAME THING WITH COVID IN THE PUBLIC HEALTH REPORTING. A LOT
OF REPORTING,
A LOT OF MANDATED REPORTING. VERY LITTLE USE OF OPERATIONAL DATABASES LIKE
HEALTH
INFORMATION EXCHANGES THAT ARE ALREADY CAPTURING THE DATA FOR THE PROVISION
OF CARE. AS
WE LOOK AT THE BIG, BIG PICTURE HERE, I WOULD ENCOURAGE THE FDA TO USE AS
MUCH OPERATIONAL
CLINICAL DATA THAT'S BEING GENERATED AS PART OF THE PROCESS OF CARE AND TO
RELY AS LITTLE
AS POSSIBLE ON MANDATED REPORTING. SO THOSE ARE A COUPLE OF TOP-LEVEL
OBSERVATIONS, BUT
I THINK IN THIS PARTICULAR IND SAFETY THING, HAS A FLAVOR OF A VERY NICE JOB
BEING DONE
HERE. SO, KUDOS TO THE FDA.
>>: THANK YOU VERY MUCH. BEFORE WE MOVE TO OUR PANEL, I JUST WANT TO KIND
OF CAPTURE
SOMETHING THAT YOU MENTIONED ASK YOU JUST TO EXPLAIN A BIT. YOU TALKED A FEW
TIMES ABOUT
THE BURDEN. IS THE BURDEN ONE OF MAGNITUDE? IS IT A BURDEN OF QUALITY OR
SOMETHING
ELSE? WE NEED TO HAVE THAT CHARACTERIZED BECAUSE A DATA STRATEGY HAD BETTER

ADDRESS THAT
BURDEN. WHAT IS IT?
>>: I SOMETIMES DESCRIBE THE BURDEN AS CONVERTING ENTROPY INTO ORGANIZED DATA. SO A
PATIENT COMES TO YOU ESPECIALLY FOR THIS NARRATIVE DATA WHICH MUCH OF THIS IS, THE VERY
NATURE OF DECIDING SOMETHING'S A SIDE EFFECT OF A HUMAN ACTIVITY. WE DON'T HAVE A
BLOOD TEST IS THIS A DRUG SIDE EFFECT. THERE'S A HUMAN BEING WHO IS PROCESSING AS AN
INTERMEDIARY THERE. AND THE BURDEN COMES IN THE COGNITION OF TRYING TO UNDERSTAND WHAT
THE LIKELIHOOD IS. OF COURSE, THE DATA FIELDS AREN'T PROBABILISTIC. SO THIS IS WHERE
DIAGNOSIS NOBODY KNOWS EVERY DIAGNOSIS. WHEN YOU SAY HERE'S THE PROBLEM LIST, PEOPLE
STRUGGLE WITH DESCRIBING THIS SOME ABSOLUTELY SOMETHING THAT'S PROBABILISTIC. THAT'S JUST
INTENSELY PROBLEMATIC FROM A HUMAN POINT OF VIEW, BECAUSE YOU SORT OF KNOW THAT WHAT
YOU'RE REPRESENTING IS ON SOME LEVEL AT SOME POINT NOT TRUE THEN FRANKLY IT'S JUST THE
SHEER VOLUME, BOTH QUANTITY AND QUALITY THAT NEED TO COME IN HERE. AGAIN, WHEN YOU LOOK
AT THE ANSWER, WE NOW HAVE SO MUCH EHR DATA THAT WE'RE GENERATING AND FLOWING THROUGH
OUR HEALTH INFORMATION EXCHANGES, GETTING MORE OF IT THAT WAY RATHER THAN THESE BESPOKE
WAYS LIKE REPORTING FORMS IS GOING TO BE THE LONG-TERM ANSWER.
>>: I WANT TO MAKE SURE YOU CLARIFY THAT. THAT HAS GOT TO BE ON THE TABLE FOR
CONSIDERATION. THANKS, DON. LET'S MAKE SURE OUR PANEL INTRODUCED EACH OTHER AND LET'S
START WITH MARK, YOUR AFFILIATION AND HOW YOU FIND YOURSELF ON THIS PANEL.
>>: THERE WE GO. HI MY NAME IS MARK BACH. AND BY TRAINING I'M A PEDIATRIC
ENDOCRINOLOGIST BUT I'VE BEEN WORKING IN PHARMA WITH JOHNSON & JOHNSON OVER 10 YEARS.
BUT THE PAST YEAR MY FOCUS HAS BEEN ON DEVELOPING A BROAD AND COLLABORATIVE CLOUD BASED
APPROACH THAT'S INTENDED TO TRANSFORM THE WAY SPONSORS AND HEALTH AUTHORITIES
EXCHANGE DATA. SO I THINK WHAT I'M CURRENTLY DOING IS RELEVANT TO THE DISCUSSION TOPIC
FOR TODAY.
>>: GREAT, THANKS VERY MUCH, MARK. AND DDANICA MARINAC-DABIC.
>>: I'M DDANICA MARINAC-DABIC. I'M THE ASSOCIATE DIRECTOR OF THE OFFICE OF EVIDENCE
CLINICAL ANALYSIS AT THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND I'M A PHYSICIAN
AND GYNECOLOGIST AND EPIDEMIOLOGIST. I'VE BEEN WORKING FOR THE PAST 10 YEARS OR SO IN
THE DEVELOPMENT OF THE BETTER METHODS AND INFRASTRUCTURE FOR UTILIZATION OF THE REAL WORLD
EVIDENCE DATA TO ADVANCE THE KNOWLEDGE THAT FDA HAS IN REACHING THE REGULATORY
DECISION-MAKING.
>>: THANK YOU VERY MUCH, DANICA. AND JONATHAN.
>>: THANK YOU, CLIFF, THANK YOU TO EVERYONE WHO HAS PRESENTED. I'M JONATHAN

SHOUGH. I
CURRENTLY WORK WITH LABCORP DEVELOPMENT BRANCH AND I'VE BEEN THE PROVERBIAL IT PERSON.
MOSTLY FOCUSED ON DATA STRATEGIES, INTEGRATIONS AND COMMERCIAL CAPABILITIES SUPPORTING CONTRACT RESEARCH CAPABILITIES WITHIN OUR INDUSTRY. I'M NOT QUITE SURE HOW I
DREW THE STRAW TODAY OTHER THAN THAT OBVIOUSLY CLOSE RELATIONS WITH A LOT OF PEOPLE AROUND
THIS CALL.
>>: A LOT OF ATTENTION AROUND LABORATORY TESTS THESE DAYS. JONATHAN. NOT SURPRISED
YOU'RE SITTING HERE.
>>: WE HAD PEOPLE SORTING FEDEX PACKAGES OVER THE WEEKEND THAT WERE IT PEOPLE IF YOU CAN
BELIEVE THAT.
>>: I'M NOT SURPRISED.
>>: THANKS, AND JEFF.
>>: I'M JEFF ALLEN PRESIDENT AND CEO OF FRIENDS OF CANCER RESEARCH. I AM A MOLECULAR
BIOLOGIST BY TRAINING BUT I'VE BEEN IN POLICY ABOUT A DOZEN YEARS. AND I THINK I AM
PART OF THIS CONVERSATION TODAY BECAUSE OVER THE PAST COUPLE OF YEARS OUR ORGANIZATION HAS WORKED WITH A NUMBER OF DIFFERENT STAKEHOLDERS, LARGELY IN THE REAL WORLD
EVIDENCE SPACE, LOOKING AT CREATIVE WAYS TO BRING TOGETHER DATA FROM DIFFERENT SOURCES
IN ORDER TO ANSWER COMMON AND KEY QUESTIONS TO LEVERAGE THEIR FINDINGS IN A COLLABORATIVE WAY. AND HOPEFULLY THAT CAN BE SOME LESSONS LEARNED ON HOW TO BRING
CURRENTLY DISPARATE SOURCES TOGETHER.
>>: JEFF, I KNOW YOU WERE LISTENING AND PRESENT FOR THE FIRST PANEL. WHEN WE TALKED
ABOUT VARIOUS STAKEHOLDERS MULTI-INTERDISCIPLINARY APPROACH AND ALL THE DATA STREAMING
FROM PATIENTS AND OTHER SOURCES. DID THAT PANEL KIND OF ENCOURAGE YOU TO SAY, GOSH,
THERE'S GOING TO BE A GREATER ROLE FOR PATIENTS AND PATIENT COMMUNITIES? OR WAS IT
A LITTLE CONCERNING TO YOU THAT GOSH MAYBE WE'RE GETTING INTO MORE THAN WE CAN HANDLE?
WHAT WAS YOUR REACTION, JUST CURIOUS AT THIS POINT?
>>: NO, I FOUND IT VERY ENCOURAGING. AND I THINK IT FOLLOWS VERY MUCH IN STEP WITH THE
ACTIVITIES THAT HAVE BEEN HAPPENING OVER THE LAST SEVERAL YEARS. STARTING BACK
AT THIS POINT ALMOST 10 YEARS AGO WITH THINGS LIKE PATIENT FOCUSED DRUG DEVELOPMENT
MEETINGS THAT FDA HAS INSTIGATED, ENCOURAGED AND LED. AND FINDING WAYS THAT SOME OF THOSE
VENUES AS WELL AS OTHER DATA SOURCES INCLUDING THINGS THAT WERE MENTIONED AROUND DIGITAL
HEALTH AND PATIENT EXPERIENCES BEING FED INTO CLINICAL DATA SOURCES MORE REGULARLY,
TRYING TO FIND A PATHWAY FORWARD FOR THAT INFORMATION TO BE LEVERAGED AND MORE READILY
INCORPORATED, I THINK, IS A POSITIVE AND THERE ARE VERY ACTIVE COMMUNITIES OUT THERE THAT

ARE EXTREMELY COMMITTED TO PARTNERING IN THIS.
>>: I THINK THAT'S A NICE BRIDGE TO THIS PANEL BECAUSE I KNOW THAT THOSE HAVE BEEN
SOME OF YOUR INTERESTS AND CONCERNS AS WELL. I WANT TO START WITH DON. BACK TO YOU,
DON. JUST THINKING THE ORDER OF OUR DISCUSSION HERE. DON, YOU'RE THE INTEROPERABILITY
GUY. AND SO I'M KIND OF CURIOUS. YOU MENTIONED SOME ASPECTS OF UNIDIRECTIONAL REPORTING
VERSUS OPERATIONAL DATA IN THIS CONTEXT. I WAS HOPING YOU COULD CLARIFY THAT AND THEN
THERE'S YOU TALK ABOUT EHRS TOO. SO THE CONCEPTS I HOPE YOU'LL ADDRESS EVER SO
BRIEFLY IS UNIDIRECTIONAL REPORTING. THESE ARE THE OPERATIONAL DATA AND WHY IS
LONGITUDINAL IMPORTANT? DON.
>>: OKAY, CLIFF. THANK YOU FOR ASKING. SO I THINK WHEN WE LOOK AT ELECTRONIC HEALTH
RECORDS, WHAT WE'RE INCREASINGLY REALIZING, WHAT WAS MADE INTO LAW IN THE 21st CENTURY
CURES ACT AND WHAT WE IMPLEMENTED AS OUR RULEMAKING THAT WE JUST FINALIZED TAKES EFFECT
IS REALLY A SET OF APPLICATION PROGRAMMING INTERFACES, APES THAT ALLOWS GETTING AT SORT
OF THE CORE PATIENT DATA TO START WITH. SO MED LISTS PROBLEM LISTS, REALLY THE DATA THAT
GIVES YOU NARRATIVE NOTES. THE DATA THAT GIVES YOU THE PATIENT PICTURE. SO AS WE
LOOK AT PATIENT SAFETY, PATIENT ANALYSIS THAT IS REALLY A WONDERFUL SUBSTRATE. AND
WE HAVE AS PART OF THE BROADER APE COMMUNITY A NUMBER OF TOOLS THERE TO USE THE CURES ACT
ALSO PROVIDES FOR SOMETHING TRUSTED EXCHANGE COMMON AGREEMENT THE HEALTH INFORMATION
EXCHANGES GETTING THEM TO TALK. IT TURNS OUT ALMOST NOT KNOWN TO A LOT OF PEOPLE, BUT IN
QUITE A FEW STATES, THE HEALTH INFORMATION EXCHANGES ARE BY FAR THE MOST ROBUST SOURCE
FOR DATA ON THE COVID OUTBREAK. AND YOU MIGHT ASK WHY IS THAT BESIDES THE OBVIOUS THEY
ROLL UP SOURCES OVER MULTIPLE EHRS, MOBILE EHR VENDORS AND MULTIPLE SITES OF SERVICE. ONE
OF THEM IS BECAUSE THROUGH THEIR TRUST RELATIONSHIPS AND THROUGH THEIR PATIENT INDICES
THEY CAN HAVE LONGITUDINAL DATA. WHAT'S THE DIFFERENCE BETWEEN LONGITUDINAL DATA AND
THE PANDEMIC AND THE CLASSIC REPORTING DATA? MUCH OF THE REPORTING DATA, FIRST
OF ALL, A LOT OF IT IS DEIDENTIFIED, NOT ALL OF IT BUT MUCH OF IT IS DEIDENTIFIED, IT'S
REALLY POINT-IN-TIME DATA. BUT IF WE WANT DATA TO KNOW, FOR EXAMPLE, WHAT'S THE TIME
DURATION BETWEEN WHEN SOMEBODY HAS A POSITIVE TEST AND THEY END UP IN AN ICU OR WHAT'S
THE TIME DURATION WHEN THEY HAVE A POSITIVE TEST AND THEY RECOVER ENOUGH TO HAVE A
NEGATIVE TEST. OR WITH IMMUNIZATION AND HOPEFULLY COMING UP, WHAT'S THE TIME

BETWEEN
POSITIVE TESTS AND NEGATIVE TESTS AND IMMUNIZATION. I KNOW THEY'RE NOT STRICTLY
RELATED. BUT THEY MAY BE. OR TIGHTLY WHAT'S THE TIME BETWEEN IMMUNIZATION AND CHANGES IN
SEROLOGY THOSE ARE ALL LONGITUDINAL QUESTIONS EACH OF WHICH GENERATES NOT A POINT IN
ESTIMATE BUT A CURVE. AND YOU HAVE TO FIGURE OUT THE SHAPE OF THAT CURVE. ALL OF THAT
CAN REALLY ONLY BE DONE AT A LONGITUDINAL LEVEL AT A CERTAIN LEVEL. TO HAVE LONGITUDINAL
STORES TO FOLLOW PEOPLE OVER TIME WHICH THE EXCHANGES DO THAT'S CRITICAL. I WOULD
LABEL THAT AS OPERATIONAL DATA RATHER THAN AS REPORTING DATA. SO IT ANSWERS MANY MORE
QUESTIONS, IMPORTANT FOR TODAY'S SESSION BECAUSE THOSE ARE THE KIND OF QUESTIONS THE FDA
IS LIKELY TO NEED TO BE ABLE TO ANSWER. AND HAVING POINT IN TIME REPORTING DOESN'T
DO THAT. IT ALSO DOES SOME VERY BASIC THINGS LIKE, FOR EXAMPLE, HELPING WITH DUPLICATES
AND JUST THINGS LIKE HELPING WITH DUPLICATES. SO THAT HOPEFULLY GIVES A FLAVOR BETWEEN
REPORTING DATA, OPERATIONAL DATA AND SORT OF MODERN DATA WORLD. AGAIN TO THE FIRST
PANEL, THIS REQUIRES INDIVIDUALLY IDENTIFIABLE DATA WHICH MEANS YOU HAVE TO MATCH UP
PATIENTS AND YOU HAVE TO HAVE AS THE HEALTH INFORMATION EXCHANGES DO, VERY ROBUST SECURITY
PRACTICES IN PLACE TO GET THE ENTIRE STACK, BUT IF WE GO THERE WE CAN HARNESS THIS
NATIONAL INVESTMENT IN EHRS AND NOT DOUBLE DOWN ON THE BURDEN ON THE CLINICIANS BECAUSE
THEY'LL BE USING DATA THEY'VE ALREADY ENTERED FOR OTHER PURPOSES. IT WILL BE RICHER.
IT WILL BE REAL TIME. IT WILL BE MORE ACCURATE. THIS IS AN IMPORTANT SET OF CONCEPTS WE
THINK OF UNIDIRECTIONAL SEND THE DATA IN SOMETHING HAPPENS. NOW WE'RE TALKING ABOUT
OPERATIONAL DATA WHICH IS REALLY MAKING USE OF IT AND ONE OF THE MOST IMPORTANT USES OF IT
IS FOLLOWING ON A LONGITUDINAL BASIS. AND SO THIS IS REALLY ADDING ANOTHER SORT OF
DIMENSION TO THE SORT OF DATA APPLICATIONS THAT THE AGENCY HAS TO KIND OF CONTINUE TO
SUSTAIN. AND SO VERY IMPORTANT POINT AND WITH AN INFLUX OF THE HR DATA AND ALL THE
LABORATORY DATA THAT WE'RE TALKING ABOUT AND THE EXAMPLE YOU GAVE ABOUT THE TIMING OF
TESTING AND SO FORTH IS A VERY GOOD WAY TO LAY THAT OUT. AND THIS IS PART OF A DATA
CAPACITY AND SET OF FUNCTIONS OF THE AGENCY. THANK YOU VERY MUCH DON ON THAT. I'VE
ALREADY HEARD A BIT ABOUT REAL WORLD DATA. I WANT TO MOVE TO LET'S CALL IT
MULTICHANNEL REAL WORLD DATA. RWD ROLLED INTO RWE AND THE DATA WAREHOUSES AND THE
LONGITUDINAL FOLLOW-UP WHAT CAN WE LEARN FROM REAL WORLD DATA. I WAS HOPING

JONATHAN
COULD START US ON ON THIS, JONATHAN, INSOFAR AS WHAT'S HAPPENING IN REAL WORLD DATA,
JONATHAN.
>>: I THINK DON PUT IT IN KEEN PERSPECTIVE TO THINK ABOUT ALL THE DIFFERENT TYPES OF DATA
THAT WE'RE DEALING WITH TODAY. IF YOU THINK BACK TO THE DISCUSSION THIS MORNING ABOUT
DATA WAREHOUSING OUR ABILITY TO CAPTURE THAT DATA AND BEGIN TO USE IT AS A WAY TO
ACTUALLY MAKE BETTER DECISIONS BUT ALSO BETTER CLINICAL DECISIONS AROUND OUTCOMES. IT'S
INTERESTING TO THINK ABOUT A PERSPECTIVE ON THE AMOUNT OF DATA I THINK. AND BEFORE COVID
THERE WAS AN ESTIMATE THAT WE WOULD GENERATE ABOUT 25,000 PETABYTES OF DATA IN 2020.
I CAN ONLY IMAGINE AND WE HOPE TO TALK TO MATHEMATICIANS AND STATISTICIANS ON THIS CALL
WHAT DID COVID ACTUALLY ADD TO THAT VOLUME OF DATA. THAT'S INCREDIBLY SIGNIFICANT, JUST
TO PUT IT INTO PERSPECTIVE. I HAVE COLLEGE AGED CHILDREN AND I HEAR A LOT OF MUSIC PLAYED
AROUND RIGHT NOW DURING COVID. IF YOU WILL THINK ABOUT A PETABYTE, IT WOULD TAKE ABOUT
2,000 YEARS TO PLAY A PETABYTE WORTH OF DATA OF MUSIC. TO PUT IT IN CONTEXT THAT THE
AMOUNT OF DATA COMING AT US ALREADY AND THEN YOU ADD THINGS LIKE COVID-19. YOU ADD A
WORLD HEALTHCARE CHALLENGE THAT DATA IS GOING TO CONTINUE TO INCREASE. IT'S NOT
INSIGNIFICANT TO THINK ABOUT HOW WILL WE ACTUALLY HANDLE THESE MULTIPLE CHANNELS BECAUSE
WHAT WE'RE ALSO SEEING IS VARIOUS AND SUBSTANTIVE NEW MEANS OF DATA TO YOUR QUESTION ABOUT
MULTICHANNEL. WE'RE SEEING PATIENT REPORTED DATA. WE'RE SEEING SYSTEM REPORTED DATA.
AND EMR. DON MENTIONED EMR, EHIs AND EHRS DATA EARLIER, THE DATA WE'RE GETTING FROM THE
SYSTEM AS MOST OF US AROUND THE CALL KNOW HAS LARGELY BEEN BUILT AROUND REIMBURSEMENT HOW
DO I ACTUALLY GET REIMBURSED FOR THE CARE PROVIDED. IF YOU LOOK AT THE DATA TODAY AND
THINK ABOUT THE LACK OF DATA WE HAVE IN EMR AND EHR, MANY OF US ARE SEEING IT NOW AS WE
BUILD DATASETS AND CAPABILITIES PARTICULARLY AS WE TIE TOGETHER THE DIAGNOSTICS
ACTIVITIES, THE THERAPEUTIC ACTIVITIES THAT WE'RE UNDERGOING WITH COVID-19, WE'RE
REALIZING A LOT OF INFORMATION THAT COULD BE USEFUL IN THE DELIVERY OF CARE TO PATIENTS
DOESN'T EXIST IN THE EMR BECAUSE IT HASN'T BEEN USED AS A CARE DELIVERY TOOL. IT'S BEEN
USED AS A BILLING TOOL. SO THAT'S GOING TO CHANGE AND IN FACT WHAT'S GOING TO HAPPEN
IS EVEN THOSE TRADITIONAL METHODS OF DATA ARE GOING TO SIGNIFICANTLY EXPAND. AS WE THINK
ABOUT WHAT THE FDA CAN DO AS WE REGULATE THERAPEUTIC OPPORTUNITIES, AS WE

REGULATE THOSE
CLINICAL ACTIVITIES THAT WE'RE UNDERGOING, IT REALLY IS ALSO HOW DO WE TAKE THOSE MULTIPLE
CHANNELS OF INTERACTION THAT WE MIGHT NOW SEE, WHETHER IT'S FROM SOCIAL NETWORKS. WHETHER
IT'S FROM EMR, EHR HEALTH SYSTEMS IF YOU WILL, THE PERSONAL AND PRIVATE DATA THAT AN
END USER CAN ACTUALLY OFFER AS PART OF A SAFETY EVENT OR AS PART OF AN OUTCOMES EVENT THAT
THEY MIGHT WANT TO REPORT AS WELL AS PUBLIC DATA AND OTHER ADVOCACY DATA THAT MIGHT BE OUT
THERE THAT CAN AGAIN HELP US FROM A REGULATORY PERSPECTIVE MAKE BETTER DECISIONS ABOUT THE SAFETY AND ABOUT THE CARE OF PATIENTS, IT'S ONLY GOING TO GET LARGER.
YOU ASKED THE QUESTION ABOUT GIVE US A PERSPECTIVE ON SORT OF THE AMPLITUDE OR THE SIZE
OF THE CHALLENGE. I THINK IT'S SIGNIFICANT, BUT I THINK COMMERCIAL GOVERNMENT AND
PRIVATE ENTITIES ARE ALL AT AN INTERSECTION WHERE WE REALLY DO HAVE AN OPPORTUNITY TO
IMPROVE CARE, TO IMPROVE SAFETY WITH THOSE MULTIPLE CHANNELS OF DATA.
>>: GREAT POINT, JONATHAN. MAKES US THINK HOW FAR FDA HAS HAD TO COME WHEN YOU THINK
ABOUT TAKE DRUGS OR BIOLOGICS, THERE WOULD BE SOME STREAM OF CLINICAL DATA AND MAYBE PHASE
ONE, PHASE TWO, PHASE THREE OF CLINICAL MANUFACTURER AND PHASE FOUR POST MARKET GT FOR
ADVERSE EVENTS SOMETIMES FROM SPOTTY SOURCES. NOW WHEN YOU PUT REAL WORLD DATA INTO THE
MIX AND AGENCY MADE A BIG MOVE I THINK IT WAS 2016 WHEN THEY REALLY RECOGNIZED THE
IMPORTANCE OF REAL WORLD DATA INTO REAL WORLD EVIDENCE. THAT JUST EXPANDS, EXPANDS THE IN
BOX FOR THIS AND YOU DESCRIBED THE MASSIVE MAGNITUDE OF THE DATA IS OVERWHELMING, THIS IS
A DATA MANAGEMENT PROBLEM. JEFF ALLEN, I KNOW YOU'RE ALL OVER THE CANCER RESEARCH END OF
THIS. WHETHER FROM THE CANCER RESEARCH SIDE FROM THE CHILD, WHAT DO YOU SEE AS THE ROLE
OF REAL WORLD DATA.
>>: AS JONATHAN DESCRIBED, THERE'S SUCH A LARGER RECOGNITION ON THE CAPABILITIES OF WHAT
CAN BE DONE WITH DIFFERENT DATA SOURCES IF PROPERLY ALIGNED. AND WE'VE SEEN THAT AT LEAST
TAKE SHAPE IN THE ONCOLOGY FIELD PRETTY RAPIDLY GIVEN LARGE INVESTMENTS, FRANKLY, INTO
AGGREGATING SOME OF THIS DATA AND EVEN CURATING IT AS A TOOL UP FRONT WHICH ALLOWS IT TO
BE USED MORE READILY TO REPEATEDLY ASK QUESTIONS. SOME OF THAT IS PUTTING STANDARDS IN
PLACE AND PUTTING COMMON METHODOLOGIES INTO PLACE THAT CAN BE READILY ADOPTED TOWARD OTHER
SCENARIOS. AND I THINK WE'RE SEEING THAT GO WELL BEYOND ONCOLOGY NOW. WE'VE BEEN WORKING
WITH FDA, FOUNDATIONS AND MANY STAKEHOLDERS MANY DATA PARTNERS AND ONCOLOGY THAT ARE ALSO
SEEING A LARGE PROPORTION OF THEIR POPULATION AFFECTED BY COVID-19 AS WELL AS

HOW SOME OF
THESE APPROACHES USING LARGE POPULATION-TYPE DATASETS CAN BE LEVERAGED IN ORDER TO ANSWER
QUESTIONS QUITE QUICKLY. BY NO MEANS IS THIS MEANT TO REPLACE CLINICAL TRIALS, BUT
I THINK WITH SOME STANDARD METHODOLOGY AND UNDERSTANDINGS OF THE LIMITATIONS IT CAN HELP
AUGMENT SOME OF THAT INFORMATION. I THINK ONE CHALLENGE THAT STILL REMAINS IS HOW TO
LAYER SOME OF THESE DIFFERENT DATASETS TOGETHER IN ORDER TO GET SOME OF THE INFORMATION
THAT YOU MAY NOT BE ABLE TO OBTAIN FROM DIFFERENT DATASETS. I THINK THAT'S TRUE IN
SOME OF THE PATIENT EXPERIENCE AND PATIENT REPORTED OUTCOMES, FOR EXAMPLE, AND
JONATHAN DESCRIBED HOW SOME OF THESE DATASETS FOR BILLING CONTRACT THINGS AROUND SAY
POTENTIAL USE OF A DRUG OR TIME ON TREATMENT, FOR EXAMPLE. BUT WHEN A PATIENT IN THE
ONCOLOGY SETTING STARTS STOPPING TAKING A TREATMENT PERHAPS THE TREATMENT WASN'T TOLERABLE
OR THE DISEASE PROGRESSED OR THEY BECAME A CANDIDATE FOR SURGERY. ALL THOSE ARE VERY
DIFFERENT REASONS. BUT IF YOU'RE ABLE TO BRING IN ADDITIONAL DATA SOURCES MAYBE IT'S NOT
EVEN FROM THE PATIENT'S EXPERIENCE TO BETTER ALIGN DIFFERENT INFORMATION ABOUT HOW THAT
BASELINE INFORMATION CAN BE LEVERAGED, YOU SHOULD BE ABLE TO DISTINGUISH BETWEEN SOME OF
THOSE AND THAT WOULD MAKE THESE ALL THE MORE POWERFUL.
>>: SO THERE ARE MULTIPLE SOURCES QUITE COMPLEX AND DIVERSE AND A LOT OF THEM, MOST OF
THEM WEREN'T DESIGNED TO DO RESEARCH. THERE IS SORT OF LIGHT AT THE END OF THIS TUNNEL OF
HOW DO YOU SORT OF PULL THESE TOGETHER INTO SOMETHING THAT'S A RICHER SOURCE OF
EVIDENCE AND PATIENTS HAVE HAD A BIG ROLE IN THAT AS WELL, OF COURSE.
>>: AND I THINK LAYING THE GROUND WORK IS REALLY IMPORTANTLY. AND I THINK THAT WAS A
MOTIVATION BEHIND FDA'S EFFORTS TO PROVIDE GUIDANCE AND TO THE USE OF REAL WORLD EVIDENCE
AND HAVING SOME JOINT RECOGNITION ABOUT WHAT'S POSSIBLE AND WHAT'S NOT AND THE
APPROACHES THAT CAN BE TAKEN IS A MOTIVATOR. WHEN YOU SEE DIFFERENT GOVERNMENT AGENCIES
LIKE FDA PERHAPS EVEN LIKE CMS EXPRESS THE INTEREST AND USING REAL WORLD DATA WHITTLED
DOWN TO QUALITY STANDARDS I THINK IT PUSHES THE PRIVATE INDUSTRY TO BE ABLE TO INVEST AND
RAISE THE BAR AROUND THESE KNOWING THAT THERE IS ADDITIONAL USES THAT THE INVESTMENTS WILL
PAY OFF IN ORDER TO INCREASE THE QUALITY AND THE BREADth OF SOME OF THESE SOURCES.
>>: GREAT POINT. YOU RAISED IT WELL FDA'S MOVE TOWARD REAL WORLD DATA HAS ACTUALLY
PROMOTED INNOVATION ON THE INDUSTRY SIDE, AS WELL AS THE IT SIDE, OF COURSE, SO THANKS

JEFF. DANICA, WE MOVE TO YOU, YOU'RE WITH CDRH AND THERE'S SUCH A DIVERSE ARRAY OF
DIAGNOSTICS, COMPLEX FIELD. I'M WONDERING HOW YOU'RE SEEING NOVEL SOURCES OF REAL WORLD
DATA CONTRIBUTE TO THE REGULATORY SORT OF RESPONSIBILITIES OF THE CENTERS FOR DEVICES AND
RADIOLOGICAL HEALTH. WHAT'S YOUR PERSPECTIVE?
>>: I'D LIKE TO REMIND THE FOLKS THAT CDRH WAS THE FIRST CENTER AT THE FDA THAT ISSUED
THE FIRST DOCUMENT, EVIDENCE BACK IN 2016. AND THE FINAL DOCUMENT IN 2017. SO WHICH
DIDN'T COME REALLY AS SORT OF ONE-OFF EFFORT OBVIOUSLY. IT TOOK YEARS OF STRATEGIC
INVESTMENTS BY FDA INTO THE DEVELOPMENT AND PROMOTION AND ENABLING OF THE LARGER ECOSYSTEM
TO THINK ABOUT THE REAL WORLD EVIDENCE. SO WHEN YOU MENTIONED ABOUT THE DIVERSITY OF
MEDICAL DEVICES THAT CERTAINLY IS ONE OF THE IMPORTANT DRIVERS OF THE SELECTION OF DATA
SOURCES THAT ONE CAN USE FOR THE DECISION-MAKING, FOR EXAMPLE, THE DEVICE OF THE MEDICAL
PORTFOLIO SHOULD NOT BE UNDERESTIMATED. REGULATES OVER 100,000 DIFFERENT TYPES OF DEVICES
PRODUCED BY NEARLY 20,000 COMPANIES GLOBALLY, THAT'S A SUBSTANTIAL SIZE OF THE
PORTFOLIO OBVIOUSLY WITH THE DIVERSITY OF THE DEVICES, SOFTWARE AND MEDICAL DEVICES, THOSE
ARE VERY IMPORTANT DRIVERS OF WHAT CAN BE DRAWN FROM THE REAL WORLD EVIDENCE AND WHATNOT.
SO THEN ON TOP OF THAT ONE ALSO NEEDS TO THINK ABOUT THAT UNIQUE DEVICE IDENTIFIER, FOR EXAMPLE, IT'S NOT EMBEDDED IN ALL THE DATA SOURCES, FOR EXAMPLE. SO
CAN YOU IMAGINE HOW THAT DELIMITS THE USE OF SOME OF THE THE DATA SOURCES IF YOU'RE NOT
ABLE AS REGULATORY AGENCY TO IDENTIFY THE PARTICULAR DEVICE. THERE'S UNIQUE DEVICE
IDENTIFICATION SYSTEM BUT WE HAVE A LONG WAY TO HAVE IT EMBEDDED IN EHR AND OTHER
SYSTEMS. ANOTHER DRIVER I THINK IT'S IMPORTANT WHEN WE TALK ABOUT THE USE OF REAL WORLD
EVIDENCE AND DEVICE SPACE IN PARTICULAR, HAS TO DO WITH THE WAY DEVICES MEDICAL
DEVICES MAKE IT INTO THE MARKET. IT'S BEEN DONE THROUGH ITERATION OF A VARIETY OF MODELS
SO YOU ACTUALLY PUT THE FIRST MODEL IN THE MARKET AND THEN THERE'S A PROPER PREMARKET POST
MARKET BALANCE AND GENERATE A LOT OF EVIDENCE WHILE BEING IN POST MARKET. LOOPING IT
BACK TO THE INNOVATORS AND INDUSTRY AND OTHERS AND THAT CREATES THE NEW SORT OF BETTER
MODEL OF THE SAME DEVICE. THOSE ARE IMPORTANT DRIVERS AND UNIQUE TO THE DEVICE SPACE. SO
HAVING SAID ALL OF THAT, AND WITH THE DIGITAL HEALTH SOLUTIONS HAD BROUGHT TO THE ENTIRE
ECOSYSTEM, HEALTHCARE ECOSYSTEM. WE CERTAINLY ARE USING IN THE DEVICE SPACE AND HEALTH
TECHNOLOGY SPACE NUMBER OF NONTRADITIONAL DATA SOURCES IN ADDITION TO

RANDOMIZED CONTROL
TRIALS AND OBSERVATIONAL STUDIES AND ALL THAT, REALLY ARE MAKING DECISIONS AS WE SPEAK
BASED ON THE DATA COMING FROM PATIENTS THAT IS JUST OPERATIONAL REGISTRIES SURGERIES AND
OPERATIONS TYPE OF REGISTRIES, PRODUCT REGISTRIES. IN ADDITION TO THAT WE'RE PROMOTING THE CONCEPT OF COORDINATED REGISTRY EFFORTS BY LINKING REALLY THE REGISTRIES TO
CLAIMS DATA AND ELECTRONIC HEALTH RECORDS AND PATIENT DATA TO ENSURE LONGITUDINAL PROFILE
OF THE PAGE THAT RECEIVE A PARTICULAR MEDICAL DEVICE.
>>: DANICA, STOP A SECOND. CAN YOU JUST GO BACK A SECOND? I KNOW WHAT A REGISTRY IS,
WHAT IS A REGISTRY NETWORK AND HOW DOES IT PULL IN CLAIMS DATA, CAN YOU REHASH THAT FOR
US, PLEASE?
>>: SO THE COIN OF STRATEGIC EFFORTS WAS COINED BY THE DEVICE STRATEGIC TASK FORCE WHICH
ENSURED THE FUTURE OF TRADITIONAL REGISTRIES WOULD BE IN THE SPACE WHEN THEY'RE REALLY
INNER OPERABLE FOR THE HARMONIZING OF CORE DATA ELEMENTS TO LINK THEM TOGETHER AND ALSO
TO BE LINKABLE TO ELECTRONIC HEALTH RECORDS TO THE CLAIMS DATA AND OTHER NOVEL DATA
SOURCES THAT MIGHT BE COLLECTED IN THE FUTURE. SO IN ORDER TO DO THAT, AND WE'VE
CERTAINLY SUBSTANTIALLY INVESTED IN THE DEVELOPMENT OF THESE REGISTRY NETWORKS, SINCE 2014
WHEN THE REPORT CAME OUT BY THE TASK FORCE, SO THE BASIS FOR THE COORDINATED REGISTRY
NETWORK IS REALLY IN HARMONIZATION OF OTHER DATA SOURCES. AGAIN I'LL USE ONE EXAMPLE THAT
I THINK SHOWS WHAT GOVERNMENT AGENCIES CAN DO WHEN PARTNERED WITH PRIVATE SECTOR TO
ADVANCE THE DEVELOPMENT OF THE SPACE FOR UTILIZING THE REGISTRY WE HAVE IT. AND I'M GLAD
DR. RUCKER IS ON THE PANEL BECAUSE IT WAS FANTASTIC COLLABORATION IN THE SPACE OF WOMEN'S
HEALTH TECHNOLOGY THAT MBA, OFFICE OF NATIONAL COORDINATOR AND NATIONAL MEDICINE, PUT
TOGETHER UNDER THE FUNDING FROM THE CORE TRUST FUND LED BY THE SECRETARY OF ADVANCED
PLANNING AND COORDINATION. AND AS YOU CAN IMAGINE WE COULD HAVE CHOSEN ANY SPACE, THERE'S
LOTS OF GAPS IN THE HEALTHCARE SYSTEM, BUT WE CHOSE THE SPACE OF WOMEN'S HEALTH
TECHNOLOGIES BECAUSE, FIRST OF ALL, FDA HAD WRESTLED WITH A LOT OF RECENT SIGNALS AND
ADVERSE EVENT REPORTING, RANGING FROM ASSURE PERMANENT STERLIZATION AND SURGICAL MASKS AND
OTHER THINGS FOR THE APPROPRIATE TREATMENT. SO WE'VE REALLY RECOGNIZED THAT THERE NEED
TO BE BETTER INTEGRATED INFRASTRUCTURE FOR US TO TAP INTO IN ORDER TO BE ABLE TO
PROACTIVELY LOOK AT THE SAFETY AND EFFECTIVENESS OF THE TECHNOLOGIES THAT WE APPROVE. SO
BASICALLY WHAT WE'VE DONE, WE'VE STARTED WITH SORT OF A SPACE, WE HAD SOME

REGISTRIES,
TRADITIONAL REGISTRIES THERE WAS A REGISTRY AND A ORGAN FOLLOW UP REGISTRY BUT WHAT WE
WANTED TO DO WAS TAKE A HARD LOOK ON HOW THE REGISTRIES COLLECT THE DATA. IF WE COULD
IN FACT CREATE A COMMON DATA MODEL, MINIMUM CORE DATASETS THAT THESE REGISTRIES WILL AGREE
TO, NOT JUST BY TALKING TO CLINICIANS BUT HAVING PATIENT GROUPS IN PART OF THE ACTUAL
PORTFOLIO THAT EVALUATED THIS NEED FOR THE CORE DATASETS AND INDUSTRY AND PROFESSIONAL
SOCIETIES, REGULATORS REIMBURSEMENT AGENCIES. SO WE IN FACT PUT TOGETHER IN COOPERATION
WITH THE MEDICAL DEVICE EPIDEMIOLOGY PUBLIC/PRIVATE PARTNERSHIP WE PUT TOGETHER THIS
COMPREHENSIVE GROUPS THAT IN FACT WENT INTO THE FORMAL DATA TRUSSES, INCORPORATED THE
DATASET AND OFFICE OF NATIONAL KOREAEDER STEPPED IN HELPED BUILD THE GUIDE AND FASTENED
IT WITH PROFESSIONAL SOCIETIES. IT WAS FHIER ENABLED AND WE NOW HAVE A SYSTEM THAT'S
IN FACT CAN BE UTILIZED IN FUTURE WAYS LESS COSTLY WAY.
>>: THAT'S A GREAT EXAMPLE OF SORT OF AN INTERAGENCY AND INTERDIFFICULTIES MRINRY EFFORT
THAT WAS FDA AND NLM AND ALL TOGETHER ON THIS INITIATIVE. GREAT EXAMPLE OF WHY YOU NEED
THESE STREAMS AND ACTORS TO BRING A REAL WORLD SOLUTION. AND NOT TO MENTION THE UNIQUE
IDENTIFIERS, YOU DIs, WHICH STINT AND WHICH HIP. WITHOUT THE UDIs IT'S HARDER TO TAKE
ADVANTAGE OF REAL WORLD DATA. POINT'S WELL TAKEN. THANK YOU SO MUCH FOR THAT, DANICA.
MARK, I WANT TO MOVE BACK ON YOU, THE INITIAL PRESENTATION THAT MEREDITH CHUK MADE WHEN
SHE SHOWED US THE GRAND SEA OF PDFS AND I WANT TO ASK ABOUT THE ISSUE OF MODERNIZING
FILINGS. MODERNIZING FILINGS. I SEE YOU'RE SMILING BECAUSE YOU KNOW A BIT ABOUT THIS.
I THINK YOUR COMPANY'S INVOLVED IN TRYING TO MAKE THIS HAPPEN BETTER, PERHAPS A PLATFORM
TO MAKE IT MORE EFFICIENT. THAT'S WHAT MEREDITH WAS TALKING ABOUT. CAN YOU TELL US WHERE
WE ARE WITH HOW WE'RE MODERNIZING FILINGS TODAY AND TOMORROW.
>>: SURE. LET ME TALK A LITTLE BIT ABOUT WHAT WE'RE WORKING ON. THANKS FOR THAT. WHAT
WE'RE HEARING AS PART OF THE THEME FUNDAMENTALLY IN SOME WAYS THE WAY SPONSOR COMPANIES
AND HEALTH AUTHORITIES FORMULATE THIS HASN'T CHANGED OVER TIME. IN SOME CASES THEY'RE THE
ELECTRONIC EQUIVALENT OF TRUCKLOADS OF PAPERS. PDFS. AND PDFS ARE NOT AS HELPFUL AS THEY
COULD BE. THEY'RE NOT ANALYZABLE. THEY'RE DIFFICULT TO DEAL WITH. SO WE LOOK AT HOW DO
WE CHANGE THAT? AND TO ADDRESS THIS WE'RE WORKING WITH MULTIPLE PHARMA COMPANIES ON A
PROJECT CALLED ACUMULUS. IT'S HIGHLY ASPIRATIONAL FOR ASPIRATIONAL DON'T READ IMPOSSIBLE

BUT CHALLENGING. BUT IT'S ASPIRATIONAL PROJECT BUT COLLABORATIVE. LOOKING AT HOW WE
COULD MODERNIZE THE NATURE OF THE DATA EXCHANGE INCLUDING FILINGS BETWEEN SPONSORS AND
HEALTH AUTHORITIES GLOBALLY INCLUDING THE FDA. IN LOOKING AT THIS WE REALIZED THERE'S A
NUMBER OF CHARACTERISTICS THIS PLATFORM WOULD NEED TO HAVE. THIS IS NOT INCLUSIVE BUT A
NUMBER MUCH KEY THINGS IS THE POTENTIAL FOR ROLLING DATA RATHER THAN BOLUS OF DATA AT KEY
TIME POINTS. PARSING AND TAGGING OF DATA TO MAKE THINGS EASIER TO FIND AND EASIER TO
SORT. SHARED WORKSPACES TO BE USED POTENTIALLY WITHIN OUR ACROSS HEALTH AUTHORITIES. A
GLOBAL VIEW OF SOME KEY DATA. THERE'S ONE SOURCE OF THE TRUTH GLOBALLY FOR THINGS
SAFETY AND MANUFACTURER AND THE POTENTIAL FOR DATA SHARING. AND AGAIN THAT'S
SOMETHING THAT WOULD BE DONE BY ADVANCED PERMISSIONING BUT AT LEAST THE POTENTIAL BUILT
IN. WE'RE LOOKING THROUGH ACUMULUS TO LOOK AT MOVING THE FOCUS OF THE REGULATORY
CONVERSATIONS AWAY FROM DOCUMENTS AND MORE TO WHAT'S IN THE CONTENT THAT'S IMPORTANT. TO
LOOK AT ACTIONABLE DIFFERENCES. THE PURPOSE OF THE PROJECT IS TO BUILD AN
ARTIFICIAL INTELLIGENCE CLOUD AND ECOSYSTEM AND WORKING WITH EXPERTS ACROSS THE PHARMA
INDUSTRY BUT ALSO WITH FDA AND OTHER MAJOR HEALTH AUTHORITIES TO TOTALLY UNDERSTAND WHAT
ARE THE SPECIFIC DESIGN NEEDS IN BUILDING THIS PLATFORM. WE BELIEVE THAT THE BEST ENABLED
DATA SHARING. WE NEED TO BUILD SOMETHING THAT OBVIOUSLY IS VERY SECURE, A CLOUD BASED
ECOSYSTEM AND HAVE IT BROADLY ACCESSIBLE ACROSS A WHOLE DIVERSE SET OF STAKEHOLDERS,
WHICH MANY OF WHICH ARE REPRESENTED IN THE DISCUSSION HERE. THERE'S SOME BIG IMPLICATIONS
IN HERE DOING THIS. THERE'S IMPLICATIONS FOR ALL THE STAKEHOLDERS BUT ALSO FOR PATIENTS,
BECAUSE THE AMBITION IS REALLY TO HAVE THE CAPABILITY TO AGGREGATE FROM MULTIPLE SOURCES
RANGING FROM CLINICAL TRIAL DATA POTENTIALLY ELECTRONIC HEALTH RECORDS, WEARABLES AND
BRING THIS ALL TOGETHER IN ONE PLACE TO MAKE, TO REALLY HAVE THE ABILITY TO MAKE
SCIENTIFICALLY FOCUSED AND EFFICIENT REVIEW. AND THE LONG-TERM GOAL IS TO ACCELERATE SETS
BETWEEN PATIENTS. IT'S SOMETHING WE SHARE. AND DO IT IN A SAFE WAY, DOING VALUABLE WORK,
LOOKING AT THE SCIENCE AND THE DATA.
>>: YOU WENT OVER A COUPLE OF KEY CONCEPTS, ROLLING DATA FLOW IS QUITE INTERESTING AND
AGAIN IT ECHOES WHAT DON RUCKER SAID BEFORE ABOUT LONGITUDINAL ATTITUDE. ROLLING DATA NOT
ALL POINTS AT ONE TIME. YOU MENTIONED GLOBAL. ARE YOU SAYING A SINGLE PLATFORM
COULD ACCOMMODATE IN PUT FOR AND FOR MULTIPLE REGULATORY AGENCIES AROUND THE WORLD?

IS THAT WHAT YOU MEAN BY GLOBAL.
>>: YES, WE HOPE SO. WE'VE HAD A LOT OF DISCUSSIONS WITH THE FDA WHO HAVE BEEN VERY
GREAT PARTNERS IN THINKING ABOUT THIS, BUT WE'VE ALSO HAD DISCUSSIONS AT OTHER MAJOR
GLOBAL HEALTH AUTHORITIES WHO HAVE EXPRESSED INTEREST WORKING ON THIS. I KNOW PEOPLE
WONDER HOW IS THIS POSSIBLE WILL IT DRIVE US TO THE SAME STANDARDS OR NOT T THAT
I DON'T KNOW. BUT WORKING WITH A SYSTEM THAT'S SMART ENOUGH WE COULD ENABLE HAVING A
SOURCE OF TRUTH IN THE CLOUD THAT COULD THEN BE BUILT BY THE DATA THAT'S NECESSARY
FOR EACH HEALTH AUTHORITY OR MAYBE SOME POTENTIAL CONVERGENCE OVER TIME AND WHAT THE
NEEDS ARE.
>>: GOT IT. IN A MOMENT I WANT TO HEAR DON RUCKER'S TAKE ON THIS, BUT MARK YOU MENTIONED
A THING SAYING IT'S AI ENABLED. TELL US HOW IT'S AI ENABLED AND DOES THAT CONTRIBUTED TO
A LEARNING PLATFORM SYSTEM?
>>: ABSOLUTELY. SO THE OPPORTUNITY HERE IS NOT JUST EXCHANGING DATA BUT DO WHAT WE DO IN
MANY FIELDS TODAY FROM ONLINE TRAFFIC TO ANYTHING ELSE TO HAVE A SYSTEM THAT'S SMART AND
LEARNING AS IT GOES AND A LEARNING SYSTEM WILL HAVE REAL ADVANTAGES IN THAT IT CAN GET
BETTER OVER TIME. IT COULD EVEN OFFER RECOMMENDATIONS BASED ON HISTORICAL DATA. IT COULD
BUILD, BUILD A LEARNING SYSTEM WE'LL HAVE TO LOOK AT HOW DO WE LOOK AT THE KEY ISSUES HOW
THE DATA CAN BE USED TO ADDRESS QUESTIONS TO THINGS WE'RE NOT POSSIBLE AND PROTECTING
PRIVACY AND CONFIDENTIALITY. SO, YEAH, WE DO INTEND TO HAVE THAT KIND OF CAPABILITY.
CERTAINLY THAT COULD BE USED BOTH BY HEALTH AUTHORITIES BUT ALSO POTENTIALLY BY SPONSORS
PUTTING THEIR DATA IN THE SYSTEM.
>>: DON, WANT TO HEAR YOUR TAKE ON THIS. ARE YOU BUYING THIS? DOES IT SOUND VIABLE TO
YOU? AND YOU'RE ON MUTE, DON.
>>: I THINK THERE'S ALL KINDS OF CLEVERNESS WITH DATA ROLL-UPS. I THINK YOU JUST HAVE TO
HAVE A LOT OF RIGOR ABOUT WHO IS ENTERING WHAT DATA AT WHAT QUALITY ON WHAT ANALYTIC TOOLS
ARE YOU GOING TO USE, WHAT IS THE POWER OF THOSE TOOLS IN TERMS OF ANY SPECIFIC
SIGNAL THAT YOU MIGHT WANT TO GET OUT. I THINK ONE OF THE CHALLENGES THE DATA AND AI.
I'M A FAN OF AI I WENT AND GOT A MASTER OF SCIENCE BACK AT STANFORD AI LAB IN THE '80s
FAIR ENOUGH TIME TO PONDER AI WHAT IT DOES WHAT IT CAN'T DO. I THINK ONE OF THE
CHALLENGES AS WE LOOK AT THIS A LOT OF THE FDA STILL HAVE RELATIVELY SMALL DATASETS
LOOKING FOR VERY SMALL SIGNALS AND AI TOOLS CAN DISCOVER LOTS AND LOTS OF STUFF. SO THE

QUESTION IS THIS A REAL SIGNAL OR NOT A SIGNAL? SO I THINK YOU'RE GOING TO HAVE TO THINK
QUITE CLEARLY ABOUT THAT. THE OTHER CHALLENGE OF AI I WOULD JUST THROW OUT THERE,
THERE ARE PARTS OF THE GOVERNMENT THESE TOOLS ARE EVEN WALL RIGHT. I WOULD RETHINK
QUALITY MEASURES AT THE CMS TO GET TO THE WHOLE POINT HOW WE'RE PAYING FOR CARE AND
USING EHRS THAT JONATHAN MENTIONED. I THINK WHEN YOU LOOK AT AI YOU STILL HAVE TO REALIZE
THAT AI IS GREAT AT FIGURING OUT VARIOUS PATTERNS. IT IS NOT AS GOOD AT EXPLANATION WITH
THAT ARE VERY LEGAL, WHICH ULTIMATELY IS WHAT THE FDA IS OR EVEN ANY GOVERNMENT
AGENCY FOR THAT MATTER. I THINK WHEN YOU LOOK AT AI YOU ALSO HAVE TO LOOK AT HOW AM I
GOING TO EXPLAIN THIS THING THAT I'VE FOUND AND HOPE TO ACT ON. THAT IS AN AREA WHERE
THERE'S A LOT OF RESEARCH IN THE ARTIFICIAL INTELLIGENCE COMMUNITY BUT I THINK THAT
IS AS WE LOOK AT AI I THINK EVERY TIME YOU RAISE IT, YOU HAVE TO ASK YOURSELF HOW IS THIS
GOING TO BE EXPLAINED, WHAT'S THE ACCURACY, REPRODUCIBILITY OF THE EXPLANATION. SO I'M
BOTH OPTIMISTIC AND REALISTIC ABOUT THESE BIG DATA THINGS. THE OTHER THING I WOULD
JUST POINT OUT SIMPLY THAT WE ACTUALLY HAVE IN OUR INTEROPERABILITY ROLE. THAT GETS A LOT
OF THESE QUESTIONS, IS WE HAVE PUT IN A REQUIREMENT FOR WHAT'S CALLED A BULK FIRE API. SO
RIGHT NOW ANYBODY WHO DOES BIG DATA ACTUALLY HAS TO GO IN AND MANUALLY FIDDLE WITH EHR
DATASETS IF YOU'RE USING EHR DATA ON ONE OFF EXCHANGE SCREENS AND QUERIES. WE'VE PUT IN
OR REQUIRED FOR POPULATION LEVEL DATA EXTRACTION SO YOU CAN ACTUALLY FINALLY DO BIG DATA
OVER MULTIPLE PROVIDERS. SO AS WE THINK ABOUT A LOT OF THINGS AND TECHNIQUES IN THE PAST
A LOT OF THESE THINGS ARE WORK AROUND AROUND THE INABILITY TO GET LOTS OF DATA. I THINK
WE'RE VERY CLOSE TO GETTING LOTS OF DATA SO AGAIN MANY OF THE QUESTIONS THAT THE FDA HAS
HISTORICALLY LOOKED AT ESPECIALLY FOR THINGS OUT IN THE FIELD, NOT NEW DEVICES, BUT THINGS
OUT IN THE FIELD WILL HAVE A DIFFERENT ANALYTIC APPROACH TO BE ABLE TO BE EMPLOYED.
>>: THANKS. DON. DANICA, MARK'S COMPANY MAKES A LOT OF STUFF THAT GOES THROUGH YOUR
AGENCY HOW DO YOU TAKE HIS DESCRIPTION OF MODERNSED FILINGS DOES THAT HAVE A BIG UP SIDE
IN TERMS OF CDRH, IMPROVING EFFICIENCY AND SO FORTH.
>>: I THINK IT'S QUITE IMPORTANT. AND WHAT I HAVE TAKEN REALLY FROM THE PERSPECTIVE
OF THE GLOBAL APPLICATION, I'D LIKE MAYBE TO START WITH THAT. BECAUSE WE'VE INVESTED A
LOT OF EFFORTS WORKING TOGETHER WITH OUR PARTNERS ACROSS THE GLOBE. MEMBERS AS THEY

EXIST OF THE MEDICAL REGULATORS FORUM IN HARMONIZING EXPECTATIONS AROUND REAL WORLD DATA
SOURCES. IN TERMS OF THE ARTIFICIAL INTELLIGENCE, SOFTWARE, WE REGULATE MANY OF THESE
DEVICES AND THEY COME THROUGH OUR PROGRAMS. AND MORE RECENTLY FDA HAD OPENED A DOOR EVEN
WIDER TO THE DEVELOPERS OF SUCH SOFTWARES THROUGH OUR PRECIPITATION PROGRAM. IN FACT, IN
DOING THAT PROGRAM, YOU CAN ACTUALLY ENTER THE MARKET SOONER BUT OBVIOUSLY THERE WILL BE
LOT OF INFORMATION THAT'S COLLECTED IN THE POST MARKET SPACE IN ORDER TO MAKE SURE THAT WE
CONTINUE TO MONITOR THE PERFORMANCE OF THESE TECHNOLOGIES. AND SO LOOKING AT IT IN
TERMINOLOGY OF TECHNOLOGIES. ACTIVE SURVEILLANCE WHICH ACTUALLY BRINGS AGENCY
ATTENTION TO A PARTICULAR SIGNAL AND THEN THERE'S A HOLE NEXT PHASE WHICH IS CALLED SIGNAL
REFINEMENT IN WHICH YOU IN FACT NOT ONLY INTERPRET BUT YOU ACTUALLY DO ADDITIONAL
ANALYSIS, AND DIG DEEPER INTO WHERE THE SIGNAL IS COMING FROM TO UNDERSTAND BETTER
THE NATURE OF THE SIGNAL. AND THE WHOLE PRACTICE OF SIGNAL EVALUATION AND SIGNAL
MANAGEMENT EVOLVES WITH UTILIZATION OF OTHER METHODOLOGICAL APPROACHES. AND I THINK
THERE'S OPPORTUNITIES IN WHICH WE CAN UTILIZE THE ARTIFICIAL INTELLIGENCE CAPABILITIES,
BUT KNOWING VERY WELL THAT OFTEN STATISTICAL SIGNIFICANCE HAS TO TAKE THE TEST ALSO TO --
NEEDS TO TAKE THE TEST OF CLINICAL SIGNIFICANCE TOO. IT'S NOT REALLY ONE SIZE FITS IT ALL
IT HAS TO DO WITH THE COMPLEX OF THE MULTIDISCIPLINARY APPROACH.
>>: WELL TAKEN. AND I LIKE THE ANGLE YOU GIVE TO RESPOND TO MARK'S RESPONSE ON
GLOBALIZATION. JONATHAN, A LOT OF THESE HUGE STREAMS OF DATA ARE GENERATED BY STUFF YOUR
COMPANY DOES. IF YOU LOOK AT MODERNIZED FILINGS, A LOT OF THOSE HAVE TO BE DONE. DO
YOUR EARS PERK UP WITH, DOES IT SEEM YOU HAVE TO BE A COLLABORATOR OR BENEFITER AS FAR AS
WHAT YOU DO FROM THE LAB SLIDE.
>>: ABSOLUTELY, CLIFF. DANICA, ACTUALLY I WAS THINKING ABOUT THE THINGS I COULD TALK
ABOUT RELATIVE TO DON'S COMMENT ABOUT HOW AI CAN IMPACT BUT THAT FOCUS ON THE DATA IN THE
SYSTEM, NOT HOW THAT WILL AFFECT IT BUT THE DATA DELIVERY WE'RE SORT OF DELIVERING
BASED ON STANDARDS AND THAT WE'RE MANDATED TO DO, BUT THINK ABOUT NOW EXPANDING THAT TO
DEVICES THAT ARE NOW MANAGED BY A PATIENT. MANAGED BY A SUBJECT THAT ARE INTERROGATED BY
THAT PARTICIPANT SAY IN A CLINICAL OR THERAPEUTIC SETTING. THAT'S GOING TO HAVE A
SUBSTANTIVE CHANGE IN TERMS OF THE TYPES OF STATISTICS WE GET FROM THEM AS WELL AS HOW WE
APPLY THIS TO DETERMINE, WHAT SHOULD THE FACTORS SHOULD WE BE SCALING OUT OF

THERE. ADD
INTO THE DATA, WHETHER WE'RE TRAFFICKING EFFICACY PHASE AND I THINK IT'S GOING TO BE
DIFFERENT. AND I THINK ABOUT THE TERM OF A SEARCH CHODRIAC WHEN YOU REACH OUT TO THE
HUMAN FACTOR NOT ABLE TO PARTICIPATE IN WAYS THEY COULD PARTICIPATE, IT'S GOING TO CHANGE
THE CHANNEL I THINK IN DRAMATIC WAYS.
>>: I SAW JEFF ALLEN SMILE WHEN HE SAID SEARCH CHONDRIAC. I BET HE KNOWS WHAT YOU'RE
REFERRING TO. COULD YOU REFLECT FOR A MOMENT ON THE OTHER PANELISTS IN RESPONSE TO --
>>: I THINK THEY'RE FAIR COMMENTS. I'LL GIVE AN OVERALL WAY OF THE WAY WE'RE WORKING.
ABSOLUTELY I WORK FOR J AND J, BUT THIS THIS WORK I REPRESENT THE COLLABORATION OF
COMPANIES WORKING TOGETHER TO DO THIS. THERE'S A NUMBER OF MAJOR PHARMA COMPANIES
MAKING THIS EFFORT TOGETHER. NOT JUST J AND J ALONE. AND SECOND IS WE STARTED OUT BY
SAYING IN ANY TRANSFORMATIONAL PROJECT WHAT'S THE DISTANCE LOOKING 20 YEARS, FIVE YEARS
DOWN THE ROAD, WHERE DO WE WANT TO BE AND HAVE A VISION, WE RECOGNIZE ABSOLUTELY THERE'S A
LOT OF STEPS ALONG THE WAY. WE'RE LOOKING AT DOING THIS IN A STEP WISE CAPACITY BUILDING
SUBSEQUENT USE CASES ALONG THE WAY AND DOING THIS IN COLLABORATION WITH MULTIPLE
STAKEHOLDERS. WE ALSO ENVISION THIS AND WE'RE WORKING ON THIS NOW, IS ACTUALLY BUILDING
THIS INTO BASICALLY A STAND ALONE NOT FOR PROFIT COMPANY AS OPPOSED TO BEING OWNED BY
MAJOR PHARMA COMPANY. TO DO IT IN A WAY THAT WE CAN HAVE MULTIPLY STAKEHOLDERS ON THIS.
>>: POINT WELL TAKEN, INCREASE CHANGES OF A SUCCESS, MARK. JEFF, I'LL ASK YOU TO REFLECT
NOT ONLY WHAT YOU'VE HEARD IN THE LAST MINUTES, BUT PANEL ONE AGAIN, DATA EXCHANGE,
THERE'S A LOT OF DATA LIQUIDITY OUT THERE. AND THAT LIQUIDITY COMES FROM OR IS GOING TO
AFFECT PATIENTS. MY I'M CURIOUS TO WHAT EXTENT DO PATIENTS REALLY CARE ABOUT HOW THEIR
DATA ARE USED? THE PATIENTS -- I KNOW PATIENTS ARE DIVERSE AND HIGHLY HETEROGENEOUS
OF COURSE, BUT THE PATIENTS AND FAMILY COMMUNITIES WHETHER IN ONCOLOGY OR BEYOND, HOW
MUCH DO THEY CARE ONE WAY OR ANOTHER. AND I THINK IT MIGHT REFLECT ON POINTS DEVEN MADE
EARLIER, I'M SURE YOU'RE LISTENING TO THOSE TOO.
>>: I THINK THEY CARE VERY MUCH IN THE SENSE IT IS USED. AND I THINK MOST PEOPLE WOULD
BE SURPRISED IF NOT APPALLED TO WHICH IT MAY NOT BE FULLY USED. AND OBVIOUSLY WITH THAT
COMES THE DESIRE TO MAKE SURE IT'S APPROPRIATELY PROTECTED, BUT I THINK PARTICULARLY IN
DISEASES LIKE CANCER A HIGH AMOUNT OF ALTRUISM THAT ANY ONE INDIVIDUAL'S CARE CAN IMPROVE

OTHER PATIENTS IN THE FUTURE. SO I THINK THERE'S A DEGREE OF -- THREE MAY BE A DEGREE
OF SHOCK TO UNDERSTAND THE CHALLENGES AROUND IT. BUT I THINK THERE WOULD BE A MOTIVATION
TO BE PART OF THE SOLUTION IN TERMS OF CONTRIBUTING DATA. AND WE'VE SEEN THAT IN A
VARIETY OF DIFFERENT VENUES WITH A WHOLE HOST OF DATA SOURCES. WHETHER IT'S CONSENTING
FOR CLINICAL INFORMATION OR DIRECTLY PARTICIPATING AND SHARING INDIVIDUALS EXPERIENCES,
WHETHER IT BE WITH A MEDICAL PROFESSIONAL OR FRANKLY AMONG THEIR PEERS, WHICH CONTINUES TO
JUST SOAR IN TERMS OF THE INFORMATION AND BACK AND FORTH OF DATA SHARING BETWEEN
PATIENTS. BOTH FOR INFORMATION SEEKING AND THOSE AS A COPING MECHANISM AND SOMETHING
THAT'S BEING USED AS A RESEARCH TOOL IN ITSELF. SO I THINK GENERALLY I DO REMAIN
ENCOURAGED BY ALL OF THESE DISCUSSIONS, AND I'M CERTAINLY WOULD SUPPORT ALL OF THE EFFORTS
THAT ARE BEING TAKEN TO MAKE SURE THAT THIS DATA IS BRINGING TOGETHER IN A RESPONSIBLE WAY
AND MAKE SURE THAT IT IS NOT MISUSED TO THE FULLEST EXTENT POSSIBLE. AND WHILE NOT
ABDICATING FOR ANY DEGREE OF SLOPPINESS, BUT I THINK THERE'S A PERFECT WHERE PERFECT CAN
BECOME THE ENEMY OF THE GOOD IN TRYING TO GET EVERY FINITE DETAIL LINED UP EXACTLY AS IT
SHOULD AT THE PACE OF TECHNOLOGY MOVING, IT'S ONE OF THE EARLIEST PANELISTS POINTS WE MAY
NOT WHAT THESE QUESTIONS ARE IN FIVE TO 10 YEARS. IF WE TAKE FIVE TO 10 YEARS TOGETHER TO
ANSWER THE QUESTIONS FROM TODAY, I THINK WE'LL BE --
>>: GOOD POINT.
>>: CLIFF I'D LIKE TO ADD SOMETHING ON THAT, REAL BRIEF.
>>: THE OTHER THING THAT I THINK IS REALLY IMPORTANT IS PART OF THE MULTICHANNEL
DISCUSSION, AND THAT IS GIVING PATIENTS OR SUBJECTS BACK RESULTS OF PARTICIPATION IN
CLINICAL RESEARCH, PARTICIPATION IN THEIR CLINICAL PARTICIPATION. AS WAS MENTIONED
ONE OF THE TOP FOUR REASONS PEOPLE DON'T PARTICIPATE IN CLINICAL TRIALS, THEY DON'T KNOW
WHAT WAS GOING OR WHAT IMPACT WAS GIVEN. I THINK TO JEFF'S POINT I'D LIKED TO HAMMER THAT
HOME, THAT I THINK FROM A REGULAR PERSPECTIVE IT'S IMPORTANT TO THINK ABOUT HOW TO GIVE
PATIENT BACK SUBJECTS, PATIENTS INFORMATION.
>>: POINTS WELL TAKEN. THANK YOU JONATHAN. I GAVE YOU MY DATA, WHAT DID YOU DO WITH
IT. THANK YOU. SO CLOSING QUESTION FOR EVERYONE. AND WE DIDN'T TALK ABOUT THIS ONE A
AHEAD OF TIME. WITH THE INFORMATION, I'LL GIVE YOU A SCENARIO GIVE US YOUR RESPONSE IN
ONE SENTENCE. HERE'S THE SCENARIO.
>>: YEAR 2025, YEAR 2025, AND THE NEWSLETTERS AND PODCASTS AND BLOGS ARE SAYING FDA GOT

DATA EXCHANGE RIGHT. THEY GOT DATA EXCHANGE RIGHT. AND MY QUESTION TO YOU, STARTING WITH
DON RUCKER, WHO SET A GOOD EXAMPLE FOR BREVITY, ONE SENTENCE, DON, WHAT'S THE ONE THING THAT FDA GOT RIGHT ON DATA EXCHANGE BY 2025, WHAT IS IT?
>>: I WOULD SAY BASING DECISIONS ON IS AS MUCH OPERATIONAL DATA THAT THEY CAN GET A HOLD
OF, RATHER THAN ONE POINT OF REPORTING.
>>: THANK YOU, JONATHAN, WHAT DID THE FDA GET RIGHT.
>>: THAT THEY THEY ALSO ENABLED AND INFORMATION FOR DRUG SAFETY.
>>: POINT WELL RAISED. MARK, WHAT DID THE FDA GET RIGHT?
>>: I THINK WHAT I'VE SEEN PARTICULARLY REFLECTED IN THIS MEETING IS THIS BROAD
COMMUNITY. I THINK THAT'S CRITICAL.
>>: DANICA, WHAT DID YOUR DEAR AGENCY GET RIGHT IN REGARDS TO DATA EXCHANGE?
>>: THEY BASE THE DECISION ON THE DATA THAT ARE COLLECTED ONES AND CAN BE REUSED FOR
MULTIPLE DECISION-MAKING. THE DATA THAT REFLECTS THE INPUT OF MULTISTAKEHOLDERS PART
OF THE LEARNING SYSTEM. AND TO BE ABLE TO FEED THE DATA TO THE NEXT SORT OF CHANGE IN THE
SYSTEM IN ORDER FOR PEOPLE TO CONTINUE MAKING DECISIONS BASED ON THAT INCLUDING AGENCIES
AND OTHER GROUPS.
>>: THANK YOU YOU VERY MUCH, DANICA. DO YOU WANT TO SPEAK ON BEHALF OF PATIENTS AND
CONSUMERS MORE BROADLY. WHAT DID THE AGENCY GET RIGHT BY 2025 AND DATA EXCHANGE?
>>: I THINK THEY FOUND WAYS OR I HOPE THEY WILL FIND WAYS TO BE ABLE TO BRING IN VARIOUS
DIFFERENT SOURCES OF DATA. NOT NECESSARILY JUST TO -- BUT TO INVITE DATA IN A NUMBER OF
DATA SOURCES IN ORDER TO CONNECT THE PIECES TOGETHER TO BE ABLE TO ANSWER CRITICAL
QUESTIONS IN NEAR REAL TIME.
>>: VERY WELL STATED. THANK YOU. GREAT RESPONSES. ALL WELL DONE. IN A MOMENT WE'LL TAKE OUR LUNCH BREAK AS IT WERE DEPENDING ON THE TIME ZONE. WE'LL RECONVENE
AT
12:15 EASTERN TIME. AT WHICH TIME WE'LL START PANEL NUMBER THREE ON PUTTING DATA TO USE.
THAT'S THE TRAIN HERE, DATA SHARING, DATA EXCHANGE AND PUTTING DATA TO USE. BUT BEFORE WE
TAKE OUR BREAK I HOPE EVERYONE REALIZES AND RECOGNIZES THAT MARK BACH AND DDANICA MARINAC-DABIC, JEFF ALLEN, JONATHAN SHOUGH DID A GREAT JOB UNDERSTANDING HOW DATA
WORKS AND HOW THE AGENCY GOT IT RIGHT BY 2025. THANK YOU ALL. SEE YOU AT 12 EASTERN.
TAKE CARE. CLIFF, GO AHEAD. YOU'RE LIVE.
>>: WELCOME, EVERYONE, BACK FROM OUR SHORT BREAK HERE. WE HAD TWO GREAT PANELS HAVING TO
DO WITH DATA SHARING AND DATA EXCHANGE. NOW IT'S TIME TO PUT DATA TO USE. LET'S GET
ABOUT IMPLEMENTATION HERE. WE'RE GOING TO START OUT WITH A STIMULATING PRESENTATION,
AS IT SAYS IN OUR AGENDA, FROM DON PRATER. HE'S GOING TO TALK ABOUT THE PREDICT PILOT.
DON, IF YOU WOULD INTRODUCE YOURSELF, WE'D BE PLEASED TO FIND OUT YOUR KIND

OF SITUATION
AND HOW IT IS YOU FIND YOURSELF ON A PANEL OF THIS TITLE. DON?
>>: THANKS, CLIFF, AND WELCOME BACK, EVERYONE. CAN WE GO TO THE FIRST SLIDE, PLEASE. GOOD AFTERNOON, EVERYONE. I'M DON PRATER, AND I'M FDA'S ASSOCIATE COMMISSIONER FOR THE BOARD OF FOOD SAFETY. I WORK IN THE OFFICE OF FOOD POLICY AND RESPONSE AND HELP OVERSEE THAT PORTION OF THE U.S. FOOD SUPPLY THAT ARRIVES FROM OUTSIDE OUR BORDERS, WHICH IS CURRENTLY MORE THAN 15% OF THE TOTAL FOOD SUPPLY AND GROWING.
TODAY WE LIVE IN A FOOD WONDERLAND WITH UNPRECEDENTED DIVERSITY AND AVAILABILITY THROUGHOUT THE YEAR. DIFFERENT KINDS OF FOOD FROM DIFFERENT PLACES, PROCESSED AND PACKAGES IN DIFFERENT WAYS. FISH TACO, GUACAMOLE, THAT EXOTIC SPICE BLEND -- GOOD CHANCE THE MAJOR COMPONENTS WERE IMPORTED FROM ABROAD. NEXT SLIDE. IN FACT, THOUSANDS OF SHIPMENTS ARRIVE EVERY DAY FROM OUR PORTS. FOOD ARRIVES BY LAND, BY AIR, AND BY SEA.
NEXT SLIDE. HERE'S SOME STATISTICS THAT MIGHT SURPRISE YOU. IN 2019, THOSE SHIPMENTS INCLUDED 32% OF OUR FRESH VEGETABLES, 55% OF OUR FRESH FRUIT, AND A WHOPPING 94% OF THE SEAFOOD AMERICANS LOVE TO CONSUME. IN THE PAST YEAR, PAST TEN YEARS, WE'VE SEEN A REMARKABLE RISE IN THE NUMBER OF SHIPMENTS REACHING OUR BORDERS. IN 2019, FDA SCREENED OVER 45 MILLION SHIPMENT LINES, ABOUT A THIRD OF WHICH WERE FOOD. DATA SCIENTISTS THINK THROUGH THIS WITH ME. THIS IS HUNDREDS OF DIFFERENT FOODS PACKAGED IN HUNDREDS OF DIFFERENT CONTAINERS -- A CAN, A BOX, A BAG, A POUCH -- FROM OVER 200 COUNTRIES AND TERRITORIES, 125,000 FACILITIES AND FARMS, WITH THOUSANDS OF ENTRIES, OVER 40,000 SHIPMENT LINES PER DAY GOING THROUGH 300 PORTS WITH MINUTES OR SECONDS OR EVEN MILLISECONDS TO MAKE EACH ADMISSIBILITY DECISION. WHERE'S THE STINKY FISH? WHERE'S THE CONTAINER WITH THE ROTTEN TOMATO? HOW DO I FIND A JAR OF SAUCE THAT COULD MAKE ME OR MY FAMILY SICK?
THE CHALLENGE IS REALLY ENORMOUS. NEXT SLIDE. SO WHAT DATA DO WE HAVE TO HELP US FIND THAT STINKY FISH? I SAID THERE'S MILLIONS OF SHIPMENT LINES, EACH WITH ITS OWN SET OF ENTRY INFORMATION. THAT'S THE INFORMATION PROVIDED BY THE SHIPPER -- WHAT IS IT? WHO'S SENDING IT? WHERE'S IT COMING FROM? HOW'S IT ARRIVING? BY TRUCK OR TRAIN? BY PLANE OR BY SHIP? FOR EACH SHIPMENT, WE CAN START TO ASSOCIATE INFORMATION WE HAVE IN OUR FDA SYSTEMS. WHAT'S THE COMPLIANCE HISTORY OF THE FIRM? HAVE THEY HAD PROBLEMS BEFORE? HAVE WE VISITED THEIR FACILITY? HAVE WE EXAMINED THEIR PRODUCTS OR TAKEN A SAMPLE FOR

TESTING? WE ALSO KNOW CERTAIN PRODUCTS HAVE ASSOCIATIONS WITH PARTICULAR
HAZARDS. CYCLOSPORINE IN FRESH VEGETABLES, PESTICIDES ON FRUIT, DECOMPOSED FISH. AND
THERE'S A RAPIDLY EXPANDING EXTERNAL SOURCE OF INFORMATION, GENOMIC SEQUENCES AND
PATHOGENS THAT WE CAN ANALYZE. PUTTING THIS INFORMATION TO USE ON PRODUCTS IS HOW WE
PROTECT PUBLIC HEALTH. WHAT WE NEED TO DO, THEREFORE, IS TRANSLATE THAT ENORMOUS
AMOUNT OF DATA AND INFORMATION INTO HIGHLY ACCURATE AND EFFICIENT TARGETING. NEXT SLIDE,
5. ABOUT TEN YEARS AGO, WHEN IT BECAME APPARENT OUR VOLUME OF IMPORTS WAS
THREATENING OUR MODEL, FDA DEVELOPED OUR PREDICTIVE RISK-BASED EVALUATION FOR DYNAMIC
IMPORT COMPLIANCE TARGETING, OR PREDICT TOOL. IT'S A SOPHISTICATED ENGINE WITH AUTOMATIC
LINK-UPS TO FDA DATABASES THAT SCORES A RISK ASSESSMENT FOR EVERY PRODUCT COMING
INTO THE UNITED STATES. THESE RISK SCORES HELP OUR ENTRY VIEWERS DETERMINE WHICH
SHIPMENTS NEED FURTHER SCRUTINY. RELATIVE TO OTHER SYSTEMS CURRENTLY IN USE ACROSS
THE WORLD, PREDICT IS CONSIDERED AMONG THE BEST AND IS OFTEN HELD UP BY OUR
REGULATORY COUNTERPARTS AS A MODEL. SO WHAT DOES IMPORTED FOOD SCREEN LOOK LIKE IN THE
FUTURE, IN THE NEW ERA OF SMARTER FOOD SAFETY? WE THINK IT WILL LIKELY HARNESS NEW AND
EMERGING TECHNOLOGIES, LIKE ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING, AS PART OF
PREDICTIVE UNTIL. AND IT WILL EVALUATE STRUCTURED AND UNSTRUCTURED DATA. FOOD SUPPLY MAY
BECOME INTEROPERABLE WITH ENHANCED TRACEABILITY SYSTEMS THAT USE DISTRIBUTED LEDGERS OR
BLOCKCHAIN OR OTHER APPROACHES. SLIDE 6. NEXT SLIDE. SO AS YOU PROBABLY ALREADY
SURMISED, WE THINK ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING, IN PARTICULAR, HOLD MUCH
PROMISE IN BEING ABLE TO TURN THE MASSIVE AMOUNTS OF DATA FDA RECEIVES FROM A CHALLENGE
INTO AN OPPORTUNITY. UNDERSTANDING THE RELATIVE RISK OF DIFFERENT PRODUCTS AND SHIPMENTS
IN A DYNAMIC SETTING WILL HELP US ALLOCATE OUR RESOURCES MORE ACCURATELY TO HAVE THE BEST
CHANCE OF FINDING THAT STINKY FISH BY EXAMINATION AND SAMPLING. AND MACHINE LEARNING
HAS A NUMBER OF CHARACTERISTICS WHICH MAKE IT PARTICULARLY SUITABLE FOR LEVERAGING ALL
THAT DATA AND INFORMATION TO ADDRESS THE CHALLENGE OF IMPORT SCREENING. FOR EXAMPLE, THE
ACCURACY AND EFFICIENCY OF AI/ML MODELS IMPROVES AS MORE AND MORE DATA ARE PROCESSES.
A CONSIDERABLE AMOUNT OF THE DATA WE HAVE ARE STRUCTURED DATA. THE AI/ML MODELS MAY ALSO
ALLOW US TO EXAMINE UNSTRUCTURED DATA LIKE DIGITAL IMAGES AND VIDEO AND LARGE TEXT FIELDS,

HARNESSING THE SUPER COMPUTING POWER FOR ANALYSIS OF BIG DATA AND DYNAMIC SETTINGS, SUCH
AS SCREENING AT PORTS OF ENTRY, WILL ENHANCE THE WORK OF ENTRY WORKERS AND ALLOW
ADDITIONAL OPPORTUNITIES TO AUTOMATE DIFFERENT PARTS OF THE PRODUCTS, WHICH WE DO QUICKLY
AND ACCURATELY, SPEEDING SAFE PRODUCTS ON THEIR WAY. MACHINE LEARNING, ALSO QUITE
FAMOUSLY, HAS THE POTENTIAL TO IDENTIFY PATTERNS AND /SOERBSS WHICH MAY NOT BE READILY
APPARENT WITH CURRENT TECHNOLOGY. AND FINALLY, AND ALSO IMPORTANTLY, AS
ANTICIPATED INCREASES IN COMPUTING POWER AND DECREASES IN COMPUTING COSTS, AN AI MODEL
SYSTEM CAN POTENTIALLY BECOME MORE COST EFFICIENT OVER TIME. NEXT SLIDE. SO FOR ALL
THESE REASONS, ONE OF THE FIRST INITIATIVES WE IDENTIFIED WHEN WE LAUNCHED THE NEW ERA OF
SMARTER FOOD SAFETY IN APRIL OF LAST YEAR WAS A PILOT TO PUT OUR DATA TO USE, TO
DEMONSTRATE THE POSSIBILITY TO APPLY AN AI/ML MODEL TO IMPORT SCREENING. IN PARTICULAR,
TO EXAMINE THAT COMMODITY THAT WE IMPORT SO MUCH OF FROM ALL OVER THE WORLD. SEAFOOD.
SUCH A PILOT WOULD LEVERAGE OUR EXISTING DATABASES AND COULD TAKE ADVANTAGE OF NEARLY TEN
YEARS OF EXPERIENCE WITH OUR RULES BASED ENGINE PREDICT. WITH HISTORICAL DATA TO
TRAIN THE MODEL, INCLUDING THE OUTCOMES OF OUR EXAMINATION AND SAMPLING, AND THE CHALLENGE
OF DYNAMIC, NEAR REALTIME DATA COMING NEAR OUR PORTS OF ENTRY, WE THOUGHT WHAT A
PERFECT TEST ENVIRONMENT. NEXT SLIDE. SO WHAT ARE WE DOING? WE DEVELOPED AND
EXECUTED A PROOF OF CONCEPT USING HISTORICAL DATA AND SAMPLE RESULTS. WHILE THE PROOF OF
CONCEPT HAD SOME LIMITATIONS, IT DID SHOW SOME VERY PROMISING RESULTS AND PROVIDED
VALUABLE INSIGHTS FOR HELPING US TO DEVELOP A MORE REFINED MODEL THAT WE CAN TAKE TO THE
NEXT STEP, AN OPERATIONAL FUEL PILOT. WE ENCOUNTERED SOME FAMILIAR CHALLENGES WITH AI
MODELS, FOR EXAMPLE, INTEGRATION OF DATABASES, MINIMIZING SOURCES OF BIAS THAT COULD
IMPACT OUR ASSESSMENT OF THE RESULTS, AND IDENTIFYING MODIFICATIONS AND DATA
INFRASTRUCTURE THAT MAY BE NECESSARY TO WORK IN REALTIME. WE'RE ALSO IN THE PROCESS
OF EVALUATING OTHER OPERATIONAL CONSIDERATIONS, FOR EXAMPLE, HOW TO INCORPORATE AN AI/ML
MODEL INTO OUR ENTRY REVIEW PROCESSES. BECAUSE OUR ENTRY REVIEW PROCESS IS DONE BY HIGHLY
TRAINED STAFF, HOW CAN THE RESULTS BE INTEGRATED INTO THEIR WORKFLOW AND
DECISION-MAKING PROCESS? AND IMPORTANTLY, WE NEED TO CONSIDER THE IMPLICATIONS FOR PUBLIC
HEALTH. WE HAVE A REALLY GOOD TRACK RECORD OF MAKING GOOD DECISIONS, AND WE NEED TO
MAKE SURE THAT IT STAYS THAT WAY. ANOTHER IMPORTANT CONSIDERATION FOR AN OPERATIONAL

PILOT INVOLVING AI/ML IS THE SPEED AT WHICH GOODS ARE FLOWING THROUGH PORTS OF
ENTRY. WE NEED TO CAREFULLY EXAMINE THE PARAMETERS OF THE PILOT TO TO AVOID ANY
DISRUPTION IN THE FLOW OF GOODS. FINALLY, WE AIM TO EXECUTE THE PILOT FOR LEARNING.
THOSE OTHER 30 MILLION SHIPMENT LINES THAT ARE SCREENS EACH YEAR. SO IN SUMMARY. IMPORT
SCREENING IS A BIG JOB AT FDA. WHETHER IT'S STINKY FISH OR OTHER UNSAFE PRODUCTS
PRESENTED AT OUR BORDERS, WE BELIEVE THAT NEW TECHNOLOGY SUCH AS ARTIFICIAL INTELLIGENCE
AND MACHINE LEARNING AND OTHER PREDICTIVE APPROACHES TO ANALYTICS WILL ALLOW FDA TO PUT
DATA TO USE. DATA IS AT THE HEART OF FDA'S WORK AS A SCIENCE-BASED AGENCY, AND THIS IS
JUST ONE EXAMPLE OF HOW WE ANTICIPATE ONGOING RAPID INCREASES IN THE AMOUNT AND COMPLEXITY
OF DATA WILL INFORM FDA'S REGULATORY DECISION-MAKING PROCESS. AND HELP US ADVANCE OUR
PUBLIC HEALTH MISSION. THANK YOU.
>>: DON, THANK YOU VERY, VERY MUCH. GOSH, THE ENORMITY OF THE JOB IS IMPRESSIVE. YOU
MAKE A CLEAR CASE FOR WHY WE NEED ALL THESE TOOLS, ANALYTICAL APPROACHES, AND SO FORTH.
THE AI, THE ML TIE-IN. YOU ALSO BROUGHT IN STRUCTURED VERSUS UNSTRUCTURED DATA. YOU
BROUGHT IN THE LONGITUDINAL ASPECT ABOUT WHICH WE'VE HEARD SEVERAL TIMES TODAY. AND MORE
THAN ANYTHING, YOU JUST REMIND US ABOUT WHAT A GLOBAL ISSUE THIS IS. THE FDA HAS TO BE
24/7 EVERY BIT OF LATITUDE AND LONGITUDE, EVERY DEGREE AROUND THE EARTH TO KIND OF
KEEP MANAGING THIS. GOOD GOSH, THANK YOU VERY MUCH. A QUICK PROGRAM REMINDER, THIS
SESSION WILL GO TO
1:25 EASTERN. BUT FOR RIGHT NOW, I WANT TO ASK ZACH INTRODUCE HIMSELF. ZACH,
YOU'RE GOING TO BE OUR RAPID RESPONDENT. TELL US WHO YOU ARE AND HOW DID YOU FIND
YOURSELF IN THIS ROLE TODAY?
>>: YEAH, I'M ZACH KOHAN. I'M A PROFESSOR OF BIOINFORMATICS AT HARVARD MEDICAL SCHOOL.
TRAINED AS A NEUROSCIENCE AND PEDIATRIC ENDOCRINOLOGIST. I'VE BEEN INVOLVED WITH USING
DATA FOR MACHINE LEARNING NOW FOR 30 YEARS. IT'S CUT AND CHASE. THIS TRIAL THAT WE
JUST HEARD ABOUT, THE PREDICT TRIAL, IS AN AMAZING IMPRESSIVE SUCCESS, AND I THINK IT'S
BOTH A MICROCOSM OF THE OPPORTUNITIES BUT ALSO THE CHALLENGES THAT THIS KIND OF EFFORT IS
GOING TO HAVE. DON SPOKE ABOUT HAVING ACCESS TO THE DATA, AND WE HEARD FROM SOME
OF OUR PREVIOUS PANELS ABOUT SOME OF THE CHALLENGES OF GETTING ACCESS TO THE DATA. YOU
SPOKE ABOUT BEING ABLE TO USE PRIOR EXPERIENCE, AND THIS IS VERY IMPRESSIVE WE'RE ABLE TO

USE REALTIME DECISION-MAKING TO DATA, AS OPPOSED TO JUST THE EXPERT WRITTEN RULES,
WHICH WERE VALUABLE, BUT NOT PERHAPS AS RESPONSIVE AS THE DATA. I WOULD LIKE TO POINT OUT
THAT, WITH THESE OPPORTUNITIES, THERE ARE ALSO SOME SIGNIFICANT CHALLENGES, WHICH IS,
IN THE USE OF THESE MACHINE LEARNING METHODS, THEY'RE ONLY AS GOOD AS THE DATA ON
WHICH THEY'RE TRAINED. SO IF THINGS SHIFT, IF THERE'S A DATA SET SHIFT -- FOR EXAMPLE, TO
SWITCH TO THE ERA OF HEALTH CARE, WHEN OUR PATIENT MIX GOES FROM NORMAL CIVILIAN TIME
PATIENT CASE MIX TO COVID PATIENT CASE MIX, SOME OF THE DATA DRIVEN RULES DON'T WORK AS
WELL. SIMILARLY, WHEN THE PRACTICE OF MEDICINE CHANGES, WHETHER BECAUSE OF THE EVOLUTION
OF MEDICINE, WHETHER IT'S BECAUSE OF THE WAY MEDICINE IS REIMBURSED OR BECAUSE POPULATIONS
ARE SHIFTING, AGAIN, THE DATA OF THE PAST MAY NOT ALWAYS BE THE BEST INFORMANT. SO
AN ONGOING AND A VERY IMPORTANT CHALLENGE FOR ALL OF US USING THESE KINDS OF SYSTEMS IS TO
FIGURE OUT HOW DO WE COMPENSATE OR ADJUST FOR THESE DATA SHIFTS? HOW DO WE RETRAIN THE
SYSTEMS APPROPRIATELY? AND VERY TOPICALLY, UNFORTUNATELY, HOW DO WE ACCOMMODATE THE BIAS
THAT MAY OCCUR IN THESE SYSTEMS IF THEY'RE TRAINED ON DIFFERENT POPULATIONS? SO FOR
EXAMPLE, JUST TO BRING IT BACK TO PREDICT. WHAT IF THERE'S A CHANGING MARKET IN A CERTAIN
KIND OF FISH, A KIND OF FISH THAT'S VERY POPULAR? THERE MAY NOT BE A LOT OF HISTORICAL
DATA. HOW DO WE ACTUALLY ALLOW FOR THAT SHIFT TO BE REFLECTED IN MACHINE LEARNING
PROGRAMS? BUT IN THE END, I THINK THE REAL CHALLENGE IN HEALTH, BROADLY
SPEAKING, THE PUBLIC NEEDS TO UNDERSTAND THERE'S ENORMOUS VALUE IN THE CARING OF DATA. SO
IT BECOMES INCUMBENT, NOT JUST ON THE PUBLIC, BUT ON THE INSTITUTIONS THAT SERVE THE
PUBLIC, BY WHICH I MEAN, THE HEALTH CARE INSTITUTIONS, TO ACTUALLY SHARE THE DATA IN A
TIMELY FASHION AND NOT, UNFORTUNATELY, AS WE HAVE FOUND CURRENTLY, WHERE THEY'RE NOT QUITE
PREPARED TO SHARE THE DATA THAT, EVEN WHEN WE SO CALLED BREAK THE GLASS AND DECLARE AN
EMERGENCY, THE PIPES ARE NOT OPEN. SO I DON'T WANT TO MONTH /TPHOP LIES ANY MORE
TIME, BUT I HOPE WE CAN DISCUSS THIS MORE IN THE PANEL.
>>: WE WILL, ZACH. AND FOR THAT MATTER, DON, IF YOU COULD JUST PUT A BOOK MARK IN A
COUPLE THINGS ZACH SAID, I WANT TO COME BACK TO THEM. THE BOOK MARK WOULD GO IN THE PAGES
THAT SAY DATA SET SHIFT, BIAS, AND TIMELY DATA SHARING. IF YOU COULD KEEP ON THOSE
POINTS, WE'LL TURN ON THOSE IN A MOMENT. I DO WANT TO HAVE OUR PANELIST INTRODUCE

HIMSELF, AND WE'LL TAKE THIS, AS I SAID, TO
1:25 EASTERN. FRANK, DO YOU WANT TO INTRODUCE YOURSELF AND TELL US WHY YOU'RE ON
THIS PANEL.
>>: SURE, HI. MY NAME IS FRANK YIANNAS. I'M DEPOSITIONLY COMMISSIONER FOR THE OFFICE OF
FOOD POLICY AND RESPONSE AT FDA, AND I'M ON THIS PANEL BECAUSE I HAVE AN INTEREST IN USING
DATA IN NEW AND EMERGING TECHNOLOGIES TO TRY TO SOLVE SOME OF OUR REMAINING OR
GREATEST PUBLIC HEALTH CHALLENGES. I AM A BELIEVER THEY PRESENT GREAT HOPE, AND THEY'RE
GOING TO ALLOW US TO TACKLE SOME OF THE REMAINING PUBLIC HEALTH AND FOOD SAFETY ISSUES WE
WEREN'T ABLE TO TACKLE IN THE 21st CENTURY.
>>: SOUNDS LIKE PREDICT COULD BE THE WAY TO GET THERE. THANKS, FRANK. ANDY?
>>: HI, I'M ANDREA CORVOS. I WORK WITH ELEKTRA LABS, AND WE WORK WITH PHARMACY COMPANIES
THAT ARE USING DATA IN A NEW WAY FOR CLINICAL TRIALS. I PREVIOUSLY WORKED AROUND AI AND
MACHINE LEARNING AND HOW WE USE THESE DIFFERENT TYPES OF TOOLS. I'M HERE BECAUSE THE MATH
IS VERY DIFFERENT WHEN YOU GET STREAMS VERSUS SPOT DATA, SO YOU HAVE TO HANDLE THE DATA IN
A VERY DIFFERENT SORT OF WAY AND UNDERSTAND, NOT JUST DATA, BUT WHAT ARE THE INSIGHTS
WE'RE DERIVING FROM THOSE AS WELL?
>>: THE MATH IS VERY DIFFERENT. INTERESTING. OKAY. HEY, JOE.
>>: THANKS. MY NAME IS JOE GOODGAME. I'M THE CTO AND CO-FOUNDER OF REMARQUE SYSTEMS. I
THINK I'M HERE ON THIS CONFERENCE BECAUSE I'VE SPENT THE LAST 28 YEARS OF MY LIFE BEING A
DATA GEEK. I'M ABSOLUTELY PASSIONATE ABOUT MAKING IT USABLE FOR THE END USERS.
I'M DEFINITELY NOT A SCIENTIST OR A MATHEMATICIAN, BUT I KIND OF REALLY LIKE TO FOCUS ON
HOW THE END USERS EXPERIENCE DATA.
>>: THANK YOU, JOE GOODGAME. RON, CAN YOU REINTRODUCE YOURSELF.
>>: RAM IYER. I'M THE CHIEF DATA OFFICER FOR THE FDA. I'M PARTIALLY HERE BECAUSE OF MY
ROLE, AND ALSO BECAUSE I FAILED IN MY ATTEMPT TO BE JUST A LISTENER FOR THE WHOLE DAY.
ONE OF OUR PARTICIPANTS FOR THIS PANEL COULD NOT JOIN, SO I'M JUMPING IN.
>>: THANK YOU FOR PINCH-HITTING ON THAT, RAM. GREAT. PETER?
>>: HI, I'M PETER LEE. I'M A CORPORATE VICE PRESIDENT FOR RESEARCH AND INCUBATION AT
MICROSOFT. I HAVE RESPONSIBILITY FOR THE FUNDAMENTAL RESEARCH ARM OF MICROSOFT CALLED
MICROSOFT RESEARCH. SO WE'RE VERY MUCH INVOLVED IN MACHINE LEARNING AND DATA SCIENCE.
BUT I ALSO LEAD SEVERAL NEW BUSINESS INCUBATIONS, THE LARGEST OF WHICH IS THE HEALTH CARE
BUSINESS AT MICROSOFT. SO I'M VERY MUCH MIRED IN TRYING TO UNDERSTAND WHAT'S GOING ON
WITH HEALTH DATA.
>>: GREAT TO HAVE YOU HERE, PETER. JUST A QUICK UPDATE ON SOME OF THE TOPICS WE'D LIKE TO

GET TO IN THIS PANEL DISCUSSION. WE'RE GOING TO START OFF WITH SMARTER FOOD SAFETY.
YOU'LL HEAR MORE ABOUT THAT. JUST A QUICK HEADS UP TO FRANK. FRANK, I'M GOING TO
YOU WITH BLOCKCHAIN FOR FOOD SAFETY. GET READY FOR THAT. WE'RE GOING TO TALK ABOUT USING
DATA FASTER. SPEED AND EFFICIENCY HAVE COME UP A LOT. WE WANT TO TALK ABOUT CLINICAL
TRIAL DATA, MAKING USE OF CLINICAL TRIAL, HOW TRIALS HAVE CHANGED SOMEWHAT, AND HOW
WE'RE GOING TO ADAPT TO THAT. WE WANT TO PULL EHRs IN DECISION-MAKING. WE'VE HEARD A BIT
ALREADY ABOUT EHRs. WANT TO COME BACK TO DATA QUALITY IN THIS CONTEXT OF PUTTING DATA TO
USE. PROBABLY GOING TO RAM ON THAT ONE. AND FUTURE TECH -- AND I'M BASICALLY SETTING UP
PETER LEE ON THIS, BUT I HOPE HE'LL CHIME IN EVEN SOONER, WHICH IS WHERE OUGHT THE AGENCY
GO NEXT TO CAPITALIZE ON NEXT GENERATION ANALYTICS? THAT'S KIND OF THE LINEUP WE'D
LIKE TO GET TO. DON, BACK TO YOU. IN THE BOOK MARKS, JUST AS A REMINDER, BASED ON ZACH'S
FEEDBACK, HE TALKED ABOUT HOW DO YOU COPE WITH A DATA SET SHIFT? HOW ARE YOU
HANDLING INHERENT BIAS? AND HE EXPLAINED HOW THAT MIGHT ARISE. AND THEN TIMELY DATA
SHARING. DON, TAKE YOUR PICK OF ANY ONE OR MORE OF THOSE THREE. WHAT'S YOUR TAKE ON THEM
NOW?
>>: SURE. THANKS, CLIFF. IT'S A GREAT POINT THAT ZACH RAISES ABOUT SHIFTS IN THE DATA
SET. THIS IS SOMETHING THAT WE'RE CONFRONTED WITH CURRENTLY. WE HAVE SHIFTS IN IMPORT
TRENDS IN TERMS OF WHAT FOODS ARE COMING INTO THE COUNTRY. THAT'S SOMETHING WE'RE HOPING
OUR SYSTEMS WILL BE ABLE TO ADAPT TO. CURRENTLY, WITH OUR SYSTEM AS A RULES-BASED SYSTEM,
WE ARE ABLE TO ADD NEW RULES, CHANGE RULES, BUT WE BELIEVE THE AI/MACHINE LEARNING MODEL
MAY ALLOW US ADDITIONAL FLEXIBILITY TO DO THAT, AND MAYBE MORE ON A DYNAMIC BASIS. SO AS
MODELS CAN IMPROVE, THE MORE DATA THEY PROCESS, WE'RE HOPING THE MODEL WILL CONTINUE TO
IMPROVE AND WILL ADAPT TO SOME OF THE SHIFTS IN THE DATA SET, MAYBE EVEN TO A GREATER EXTENT THAN OUR PREDICTIVE ANALYTICS DO CURRENTLY. SO WE'RE LOOKING AT THAT AS
ONE OF THE OPPORTUNITIES, I THINK, WITH BEING ABLE TO UTILIZE NEW TECHNOLOGIES ON LARGE
DATA SETS. DATA SHARING IS AN INTERESTING POINT AS WELL. I'VE LISTENED WITH
GREAT INTEREST THIS MORNING TO SOME OF THE DIFFERENT PANELISTS. CERTAINLY, WE HAVE OUR
OWN DATABASES THAT WE'RE SEEKING TO LEVERAGE, FDA DATABASES, BUT AS I MENTIONED,
ADDITIONAL DATA STREAMS, NEW DATA STREAMS THAT WE CAN BRING INTO THE MODEL. ONLY
HAVE THE POTENTIAL TO IMPROVE IT. SOME OF THOSE DATA STREAMS POTENTIALLY HAVE OTHER DATA

OWNERS. IF WE WANT TO UTILIZE DATA SETS FROM INTERNATIONAL REGULATORY COUNTERPARTS, WHICH
IS SOMETHING THAT WE'VE HAD SOME DISCUSSIONS DOING, WE HAVE TO LOOK AT OUR ABILITY AND THE
ARRANGEMENTS WE HAVE IN PLACE TO THEN BE ABLE TO SHARE THAT DATA. WE'RE HAVING THOSE
DISCUSSIONS NOW, AND I THINK IT'S SOMETHING WE CONTINUE TO LOOK FORWARD TO AS AN
OPPORTUNITY TO REALLY IMPROVE THE SAFETY OF THE GLOBAL FOOD SUPPLY.
>>: EXCELLENT. THANKS, DON. HEY, ZACH, HOW DO YOU LIKE DON'S RESPONSES TO YOUR POINTS?
DID HE HIT THEM?
>>: I THINK HE HIT THEM. HE WAS THINKING A LITTLE BIT, AS HE SHOULD BE, POLITICAL WITH
THE DATA SHARING PART OF IT, BUT I ALSO THINK HE RAISES A VERY GOOD POINT, WHICH IS IN THE
NEAR TERM, HAVING THE RULES-BASED SYSTEM PART TO ACTUALLY BE ABLE TO ADD THE RULES IS VERY
VALUABLE, AND I SEE THERE A NICE INTERPLAY BETWEEN THE KNOWLEDGE BEYOND THE DATA, THAT THE
EXPERT CAN HAVE IN THE RULES, WHILE AT THE SAME TIME TAKE ADVANTAGE OF THE DYNAMICS OF THE
CHANGE OF THE RULES. I THINK DON'S FORESHADOWING, I THINK, FUTURE WORK IN HOW DO YOU
MAKE THE EXPERT, COMMON SENSE RULES DOVETAIL WITH THE DATA DRIVEN PART BECAUSE IT'S JUST
LIKE DRIVING YOUR TESLA. IT'S GREAT TO HAVE THE AUTOPILOT, BUT SOMETIMES THAT BIG BLUE
THING IN FRONT OF YOU IS NOT THE SKY. IT'S A BIG TRUCK. SO YOU NEED TO HAVE THAT HUMAN
SUPERVISION.
>>: THANKS, ZACH. WE'LL LOOK FORWARD TO RIDING IN YOUR TESLA AT SOME POINT. I'LL HAVE TO
LOOK IN MY DRIVEWAY TO SEE IF MINE'S BEEN DELIVERED YET. NOT SURE. HEY, DON, BEFORE
WE MOVE ON, IS ANYONE ELSE DOING PREDICT AROUND THE WORLD? IS ANYONE ELSE DOING SOMETHING
THAT LOOKS ANYTHING AT ALL LIKE PREDICT?
>>: YEAH, THANKS FOR MENTIONING THAT, CLIFF. AS I SAID, PREDICT IS CURRENTLY CONSIDERED
ONE OF THE BEST. WE HAVE DEPARTMENT REGULATORS REACHING OUT TO US, EVEN JUST RECENTLY, TO
SEE WHAT MORE CAN THEY LEARN FROM OUR EXPERIENCE IN PREDICTIVE ANALYTICS? BUT
CERTAINLY, AS WE HAVE CONVERSATIONS WITH OUR REGULATORY COUNTERPARTS, WE'RE AWARE THAT
THEY'RE INTERESTED IN PREDICTIVE ANALYTICS AS WELL, BEING ABLE TO LEVERAGE NEW
TECHNOLOGIES AND ADDITIONAL DATA STREAMS. SO WE'RE HAVING THOSE CONVERSATIONS IN A
VARIETY OF VENUES. SOMETIMES WE HAVE THOSE CONVERSATIONS TOGETHER WITH INDUSTRY. WHEN IT
COMES TO DATA SHARING, THOSE ARE QUITE SOME INTERESTING CONVERSATIONS. FROM A
REGULATOR'S STANDPOINT, WE REALLY WANT TO HAVE AS MUCH DATA AS WE CAN TO MAKE THE BEST
DECISIONS AND MAKE THOSE DECISIONS AS QUICKLY AS WE CAN, BUT WE RECOGNIZE

THAT BEING ABLE
TO ADDRESS DATA SHARING ISSUES IS SOMETHING THAT WE'LL NEED TO HAVE SOME FURTHER
CONVERSATIONS ABOUT.
>>: GREAT. THANKS, DON. ONCE AGAIN, THE THEME OF GLOBAL DATA SHARING, COLLABORATION
WITHIN INDUSTRY AND AMONG OTHER STAKEHOLDERS. THANK YOU, DON. FRANK, WE'VE ALREADY
HEARD A BIT ABOUT PREDICTIVE ANALYTICS AND SO FORTH. I'M JUST KIND OF WONDERING FROM YOUR
STANDPOINT, HOW ARE THE EVOLVING ANALYTICAL METHODS IMPROVING FOOD SAFETY? DON
MENTIONED SOME OF THEM, BUT I WANT TO HEAR YOUR TAKE ON THAT. THEN TAKE US INTO
BLOCKCHAIN AND KIND OF REMIND US WHAT BLOCKCHAIN IS AND TELL US HOW IT WORKS IN FOOD
SAFETY. FRANK?
>>: GREAT. WELL, LET ME ANSWER YOUR FIRST QUESTION, AND IT'S A REAL PLEASURE TO BE PART
OF THIS PANEL. I'VE ENJOYED THE CONVERSATION SO FAR. I'VE MENTIONED THAT WHAT WE'RE
TRYING TO DO IS SOLVE SOME OF THE REMAINING PUBLIC HEALTH CHALLENGES THAT EXIST
IN THE AREA OF FOOD SAFETY. WE BELIEVE THAT SOME OF THESE EMERGING ANALYTICAL TECHNIQUES
AND TECHNOLOGIES OFFER GREAT HOPE TO DO THAT. I LIKE TO PAUSE AND SAY THINK ABOUT WHAT WE
DO IN TERMS OF OVERSEEING FOOD SAFETY. WE REGULATE FOOD ESTABLISHMENTS AND
PRODUCTS. THEY ARE, IN ESSENCE, ASSETS. HISTORICALLY, THE WAY WE'VE TRIED TO REGULATE
THESE IS WE WRITE RULES AND PROCEDURES AND GUIDANCE DOCUMENTS ON HOW THOSE FACILITIES, THE
ASSETS HAVE TO OPERATE, AND WE HOPE THAT PEOPLE OPERATE IN COMPLIANCE. AND THEN
THE FOOD ITEMS. WE HAVE VERY LITTLE VISIBILITY TO SEE IF THOSE ITEMS ACTUALLY COMPLY WITH
REQUIREMENTS. WE WRITE STANDARDS OF IDENTITY, FOR EXAMPLE. WHAT'S DIFFERENT IN
THE 21st CENTURY WITH THE ANALYTICAL METHODS YOU'RE HEARING ABOUT TODAY OR SOME OF THESE
TECHNOLOGIES, WE HAVE THE HOPE AND PROMISE THAT WE CAN GIVE EVERY ASSET, WHETHER IT'S A
FACILITY THAT MANUFACTURES A REGULATED PRODUCT, OR THE PRODUCT ITSELF, TO GIVE IT A
DIGITAL FOOTPRINT AND A VOICE. SO YOU CAN TRACK AND TRACE, ALMOST IN REALTIME, WHAT'S
HAPPENING. SO IT'S A REAL PARADIGM SHIFT ON HOW WE COULD POTENTIALLY REGULATE
ESTABLISHMENTS AND PRODUCTS IN MY VIEW. BUT THE ONE SPECIFIC EXAMPLE YOU ASKED FOR
IS BLOCKCHAIN. FDA IS VERY INTERESTED AND COMMITTED TO USING NEW AND EMERGING
TECHNOLOGIES. IN FACT, YOU HEARD THIS ABOUT THE NEW ERA OF SMARTER FOOD SAFETY. I ASSURE
YOU IT'S NOT A SLOGAN. IT'S DEFINITELY A NEW WAY OF LOOKING AT FOOD SAFETY. AND WE
BELIEVE WE'RE GOING TO USHER IN, THE UNITED STATES, INTO AN ERA OF A MORE

DIGITAL, SAFER,
AND TRACEABLE FOOD SYSTEM. NOW, BLOCKCHAIN, LET ME BEGIN, AND I WANT YOUR AUDIENCE
TO REALLY TAKE THIS AWAY. IT'S NOT ABOUT BLOCKCHAIN. IT REALLY IS ABOUT WHAT IS THE
PUBLIC HEALTH CHALLENGE WE'RE TRYING TO ADDRESS OR SOLVE? IT'S THIS IDEA THAT, WHILE
TODAY'S FOOD SYSTEM IS PRETTY GREAT -- THINK ABOUT IT. YOU CAN GO INTO ANY GROCERY STORE
AND FIND 50,000 TO 70,000 FOOD SKUs, STOCK KEEPING UNITS, FOR A PORTION OF YOUR WELL
EARNED DOLLAR. WHEN THE FOOD SCARES HAPPEN, WE OFTEN FIND THERE'S ONE ACHILLES HEEL.
THAT ACHILLES HEEL IS A LACK OF TRANSPARENCY IN THE FOOD SYSTEM. I DON'T HAVE TO SPEND A
LOT OF TIME WITH THIS. IT'S ONE THAT'S NEAR AND DEAR TO EVERYONE'S HEART.
REMEMBER IN THE FALL OF THANKSGIVING, AN OUTBREAK OF E. COLI 15787, WE HEAR THEM SAY, WE
SEE THESE ILLNESSES OCCURRING ACROSS THE COUNTRY. WE KNOW IT'S ASSOCIATED WITH BAGGED
ROMAINE LETTUCE. BUT WHAT HAPPENED? NEITHER THE CDC NOR THE FDA COULD TRACE IT BACK TO
THE SOURCE OF CONTAMINATION FAST ENOUGH. WHAT RESULTED, WHICH WE'D EXPECT THE FDA
AND CDC TO DO, IS PUT OUT A FOOD ADVISORY WHICH ADVISED ALL AMERICANS EVERYWHERE TO NOT
EAT ROMAINE LETTUCE REGARDLESS OF WHERE IT'S GROWN BECAUSE WE DIDN'T KNOW WHERE IT WAS
COMING FROM. THAT'S THE PUBLIC HEALTH CHALLENGE WE'RE TRYING TO SOLVE. NOW, WHY
IS IT SUCH A BIG CHALLENGE? THE REALITY TODAY IS FOOD IS STILL LARGELY TRACED, OR
TRACKED, IF YOU WILL, FOOD TRACEABILITY, USING PAPER-BASED SYSTEMS. WE HAVE WHAT WE CALL
AROUND THE WORLD THE ONE STEP UP, ONE STEP BACK MODEL OF A PAPER-BASED TRACEABILITY
SYSTEM. YOU CAN SEE THEN HOW LONG IT MIGHT TAKE IF YOU HAVE A PRODUCT AND YOU'RE TRYING
TO TRACE IT BACK TO SOURCE BY FOLLOWING ONE STEP UP, ONE STEP BACK PAPER-BASED RECORDS.
SO WE BELIEVE THAT DIGITIZING THESE RECORDS COULD ACCELERATE TRACEABILITY. NOW, YOU
MIGHT ASK, WELL, WHY DON'T YOU DIGITIZE THEM? DIGITIZING RECORDS ISN'T ANYTHING NEW.
WE'VE BEEN DIGITIZING RECORDS IN SOCIETY FOR DECADES NOW. THIS IS WHERE THE PROMISE OF
BLOCKCHAIN, I THINK, IS VERY INTERESTING. WE OFTEN TALK ABOUT A FOOD CHAIN.
IN FACT, I TRY TO NOT USE THOSE WORDS IN MY VOCABULARY BECAUSE IT'S NOT A FOOD CHAIN
WHATSOEVER. IT'S NOT A LINEAR SYSTEM WHERE POINT A LEADS TO B. WHAT WE TRULY HAVE IS A
FOOD SYSTEM. FOOD AGRICULTURE IS LARGELY A DECENTRALIZED AND DISTRIBUTED FOOD SYSTEM
ACROSS THE U.S. AND OUR PLANET. THINK ABOUT -- AND I KNOW THE FOLKS ON THIS CALL
WILL HAVE GREAT KNOWLEDGE AND INSIGHTS INTO BLOCKCHAIN. WHAT IS BLOCKCHAIN? IT'S

A DISTRIBUTED AND DECENTRALIZED DIGITAL LEDGER, AND WHAT GOT ME INTERESTED IN BLOCKCHAIN
WAS AFTER I DID SOME STUDYING, SOME WORK, AND SOME PILOTS. THERE'S SOMETHING TO A
DISTRIBUTED LEDGER TECHNOLOGY THAT MATCHES THE STRUCTURE OF THE FOOD SYSTEM. THE
REALITY IS YOU CAN NEVER GET ALL OF THE FOOD SYSTEM PARTICIPANTS IN A SINGLE CENTRALIZED
DATABASE. SO THAT'S WHAT WE'RE TRYING TO SOLVE. I WILL TELL YOU I DID A PILOT
BEFORE I JOINED THE AGENCY ON THIS PARTICULAR SUBJECT. I TOOK PACKAGES OF SLICED MANGOS,
AND I WENT TO MY EMPLOYER -- I WORKED AT THE WORLD'S LARGEST RETAILER AT THE TIME. I
ASKED MY TEAM. I BROUGHT IN A SACK OF MANGOS AND PUT IT IN THE CENTER OF THE CONFERENCE
TABLE, AND I SAID THE TRACEABILITY EXERCISE STARTS NOW. TRACE THESE BACK TO SOURCE. YOU
KNOW HOW LONG IT TOOK THEM TO TRACE SLICED MANGOS BACK TO SOURCE? SIX HOURS, 28 DAYS, AND
16 MINUTES. THIS IS THE WORLD'S LARGEST RETAILER WITH SOPHISTICATED I.T. SYSTEMS. AND
THAT SPEAKS TO THE CHALLENGE OF ONE STEP UP, ONE STEP BACK, PAPER-BASED. WE STARTED
WORKING WITH A TECHNOLOGY PROVIDER, WORKING WITH FOOD SAFETY PARTICIPANTS. MANGOS TEND
TO BE GROWN BY SMALL FARMERS IN CENTRAL AND SOUTH AMERICA. WE STARTED CAPTURING DATA IN
VERY SIMPLE USER FRIENDLY APPS, STANDARDIZING KEY DATA ELEMENTS. I THEN DID THE SAME
TEST, SCANNED A PACKAGE OF MANGOS, AND TRACED IT BACK TO SOURCE IN 2.2 SECONDS. I CALL
THAT FOOD TRACEABILITY AT THE SPEED OF THOUGHT. NOW, MORE THAN TRACEABILITY AT THE SPEED
OF THOUGHT, WHAT IT GAVE US IS TREMENDOUS INSIGHT AS TO WHERE THOSE FOOD PRODUCTS CAME
FROM AND HOW THEY'RE GROWN. THAT'S HOW WE'RE INTERESTED IN WORKING WITH THESE NEW
AND EMERGING TECHNOLOGIES TO TRY TO SOLVE SOME OF OUR REMAINING PUBLIC HEALTH
CHALLENGES. SO BLOCKCHAIN HAS TREMENDOUS VALUE WITH REGARD TO DATA AND ANALYTICS. IT'S A
GREAT FUTURE OUT THERE. WE HAVE TO STAY FOCUSED ON THE PUBLIC HEALTH AND BUSINESS PROBLEM
WE HAVE AND MATCH IT UP WITH THE RIGHT TECHNOLOGY.
>>: THAT'S GREAT, FRANK. YOUR CONCEPTS OF DIGITAL FOOTPRINT AND DIGITAL VOICE. I HADN'T
HEARD THAT BEFORE. AND HOW YOU HIGHLIGHT THE IMPORTANCE OF GETTING OVER THE LACK OF
TRACEABILITY HERE. YOU'RE OFFERING BLOCKCHAIN. BLOCKCHAIN ISN'T KIND OF LOOKING FOR A
SOLUTION. WE HAVE A PROBLEM FOR WHICH BLOCKCHAIN MAY BE AT LEAST A PARTIAL SOLUTION AS A
DISTRIBUTED LEDGER, AND IT SOUNDS LIKE THE DISTRIBUTED LEDGER WORKS ACROSS, NOT SIMPLY A
FOOD SUPPLY CHAIN THAT SOUNDS LINEAR, BUT A FOOD SYSTEM THAT HAS TO OPERATE GLOBALLY
AND OVER TIME. AGAIN, THE LONGITUDINAL KIND OF COMPONENT THERE. SO,

DON, DID FRANK
REFLECT APPROPRIATELY ON WHAT YOU LAID OUT THERE FOR THE ENORMITY OF THIS
GLOBAL ISSUE?
DID IT SOUND RIGHT TO YOU, DON?
>>: ABSOLUTELY. ABSOLUTELY. I THINK THERE'S A LOT OF PROMISE IN THE FUTURE.
AGAIN, I
APPRECIATE FRANK'S POINT. IT'S THE PUBLIC HEALTH CHALLENGE THAT WE'RE REALLY
TRYING TO
SOLVE WITH THESE TECHNOLOGIES. SO I THINK WE'LL GET THERE. IT'S VERY
EXCITING
TIMES FOR US, AND WE'RE LOOKING FORWARD TO WHERE WE GO NEXT.
>>: YOU MIGHT HAVE NOTICED, WHEN FRANK WAS TALKING ABOUT THE MANGOS, HE WENT
FROM SIX DAYS
TO 2.2 SECONDS, I THINK IT WAS. WHICH RAISES THE ISSUE WE WANT TO POSE TO
ANDY, AND THE
ISSUE WE WANT TO POSE TO ANDI IS HOW DO WE USE DATA FASTER? FRANK LAID OUT
AN EXAMPLE,
ANDI. ANDI, REMIND US HOW YOU INTERACTED WITH THE AGENCY IN THE PAST AND WHY
USING DATA
FASTER MATTERS TO YOU. AND THEN HOW WOULD YOU CHARACTERIZE A MODERN DATA
APPROACH TO THE
SET OF REGULATED PRODUCTS THAT SPEED STUFF UP? ANDI?
>>: THANK YOU. SO, HI, I'M ANDI. SO I GOT INVOLVED -- I'M NO LONGER A PART
OF THE
AGENCY, SO I'M SPEAKING FROM MY OWN OPINION. HOW I DID FORMALLY GET INVOLVED
IS THE
AGENCY IS STARTING TO LOOK WITH SOFTWARE AS A MEDICAL DEVICE, PEOPLE ARE
LOOKING AT ALL
THESE DIFFERENT TYPES OF ALGORITHMS, THE AGENCY IS LOOKING AT BRINGING IN
MORE SOFTWARE
ENGINEERS AND PEOPLE THAT HAVE DONE THIS TYPE OF WORK INTO THE AGENCY.
SO THERE'S A
ROLE CALLED ENTREPRENEUR IN RESIDENCE THAT I HAD PREVIOUSLY SERVED AT, AND I
HAD COME IN
THROUGH THE SECURITY COMMUNITY. A NUMBER OF PEOPLE WHO ARE A PART OF DEFCON,
WHICH IS A
VERY BIG SECURITY RESEARCH COMMUNITY, HAVE ALSO SERVED. ONE THING I WOULD
SAY, FOR
ANYBODY WHO'S THINKING ABOUT THIS, IF YOU'RE QUESTIONING YOUR ROLE AND HOW
YOU'RE GOING TO
SUPPORT OUR GOVERNMENT DURING COVID, I WOULD HIGHLY RECOMMEND DOING A TOUR OF
DUTY IN
GOVERNMENT. AS THE GOVERNMENT IS THINKING ABOUT WHETHER OR NOT BLOCKCHAINS
ARE THE RIGHT
SORT OF SOLUTIONS, AND WHETHER OR NOT YOU WANT TO USE A RULES-BASED SYSTEM OR
THE
ALGORITHMS ARE THE RIGHT WAY, AS ZACH WAS TALKING ABOUT EARLIER, WE REALLY
NEED A LOT OF
TECHNICAL FOLKS WHO ARE PART OF THIS DECISION-MAKING PROCESS. SO I'D HIGHLY
RECOMMEND
THAT YOU SERVE, AND THERE ARE WAYS TO DO THAT IN SHORTER FORM. THERE
ARE GROUPS
LIKE AT&F OR THE DIGITAL SPECIALTY ROLES. I'M HAPPY TO TALK TO ANYBODY.
MY DMs ARE
OPEN ON TWITTER IF YOU'RE THINKING ABOUT SERVING IN GOVERNMENT, AND I'D
DEFINITELY
RECOMMEND DOING IT. ONE THING, IF YOU THINK ABOUT THE DIFFERENT TYPES

OF DATA,
SOMETHING THAT COVID TAUGHT US IS THAT A LOT OF THE WAYS WE RAN HEALTH CARE CAN'T SUSTAIN
IN SHELTER IN PLACE. SO ALL OF A SUDDEN, PEOPLE ARE AT HOME. THEY CAN'T CALL IN. THEY
HAD TO ADOPT NEW TELEMEDICINE SYSTEMS THAT WEREN'T REALLY WELL EQUIPPED, AND ALSO
THINGS LIKE DECENTRALIZED TRIALS, WHICH PEOPLE ARE USING MORE, ARE STARTING TO HAPPEN MORE
AND MORE. SO WHAT THIS MEANS IS HISTORICALLY, WHEN TRIALS ARE CENTERED AROUND
THE SITE, YOU WOULD HAVE TO GO INTO THE SITE AND GET YOUR DATA THERE. NOW PEOPLE ARE AT
HOME. HOW DO YOU COLLECT THAT AT HOME? HOW DO YOU SEND THE DATA BACK? NOW THAT WE HAVE
THINGS LIKE PHONES AND SMART WATCHES, YOU HAVE ALL THIS OPPORTUNITY TO COLLECT HIGH
QUALITY DATA. MUCH OF THAT DATA IS, IN FACT, IN MANY WAYS BETTER THAN THE TYPE OF DATA
THAT YOU MIGHT GET IN OTHER FORMS. SO IF YOU WOULD IMAGINE, YOU WOULD NEVER MANAGE
SOMEBODY'S BLOOD SUGAR WITH ONE DATA POINT A MONTH. THAT WOULD BE CRAZY. LIKE
DID YOU EAT SUGAR? DID YOU EAT LIKE SOME SORT OF PIZZA? WHAT HAPPENED? SO THE FACT THAT
WE'RE RUNNING CLINICAL TRIALS ON ONE DATA POINT FOR ONE VISIT OVER TIME IS REALLY INSANE,
AND SO IF YOU THINK ABOUT HOW PEOPLE SLEEP OR HOW THEY MOVE, IF YOU'RE EVEN GETTING YOUR
SLEEP MEASURE AT A HOSPITAL, YOU'RE NOT GOING TO SLEEP THE SAME THERE AS YOU DO AT HOME.
SO COLLECTING DATA USING DECENTRALIZED TOOLS LIKE CONNECTED SENSORS IS A REALLY POWERFUL
WAY TO RETHINK HOW THE PATIENT EXPERIENCE IS HAPPENING. WHEN WE THINK ABOUT DATA, IF
YOU'RE JUST GETTING ONE DATA POINT A MONTH WHEN SOMEBODY'S COMING IN, MAYBE YOU ONLY GET
12 DATA POINTS OVER THAT WHOLE YEAR, AND YOU'RE BASING YOUR MULTIBILLION DOLLAR
TRIAL ON 12 DATA POINTS, IF SOMEONE EVEN COMES INTO THE CLINIC AT THAT TIME. YOU CAN RUN
THESE A LOT FASTER IF YOU'RE GETTING 12 DATA POINTS IN 12 DAYS OR 12 DATA POINTS IN 12
HOURS. SO THERE'S A FUNDAMENTALLY DIFFERENT TYPE OF TRIAL YOU CAN RUN WHEN YOU CAN
COLLECT THIS SORT OF DATA.
>>: ANDI, WHAT'S SUCH A BIG, GOOD BREAK FOR US IN A WAY IS THAT WE'RE BEING FORCED TO DO
THINGS DIFFERENTLY. BUT WE END UP DOING THEM DIFFERENTLY MIGHT EVEN PROVIDE BETTER DATA.
YOU'RE KIND OF THE HEMOGLOBIN, THE HB1C EXAMPLE, DATA AS A STREAM. THIS IS A MORE
CLINICAL EXAMPLE THAN WE'VE DONE BEFORE. WE WERE FORCED INTO IT, BUT, GOSH, WE'RE BETTER
OFF. IT'S NOT ONLY FASTER. IT MIGHT BE BETTER.
>>: ONE OF THE THINGS THAT FOLKS TALK ABOUT IS IT BETTER, FASTER, AND CHEAPER? AND THE

ANSWER IS YES IN MANY INSTANCES ACROSS ALL OF THOSE. THIS ISN'T SOMETHING THAT WAS NEW.
OVER 55 DIGITAL DATA POINTS WENT THROUGH THE AGENCY IN THE LAST COUPLE OF YEARS. 15 OF
THEM WERE PRIMARY END POINTS. 50 OF THEM HAVE BEEN TRYING TO DO THIS, BUT WE NEED A
STIMULUS BECAUSE EVERYONE KNOWS THE SYSTEMS IN HEALTH CARE ARE PRETTY MESSED UP. SO LIKE
HEALTH CARE AND COVID HAS REALLY ALLOWED US TO RETHINK THE OLD INCENTIVE SYSTEMS AND DO
THE THINGS THAT PEOPLE HAVE REALLY NEEDED.
>>: GREAT, GREAT POINT. THANK YOU. SINCE ANDI BROUGHT UP COLLECTING CLINICAL DATA, I
WANT TO GO TO JOE NOW ON THIS. JOE, LET'S KIND OF MAKE THIS KIND OF STEP THAT ANDI SAID
INTO CLINICAL TRIALS. WHEN WE'RE THINKING ABOUT DATA THAT'S NOT ONLY GOOD QUALITY, BUT
FASTER AND CHEAPER, HOW CAN WE CHANGE HOW CLINICAL TRIALS GENERATE AND USE DATA MORE
EFFICIENTLY? WHAT'S GOING ON IN THE CLINICAL TRIAL SECTOR THAT'S POINTING THAT RIGHT
DIRECTION?
>>: THANKS FOR THAT, CLIFFORD. THANKS VERY MUCH FOR THE LEAD-IN, ANDI. I THINK THERE'S
TWO PARTS TO THIS. MAYBE I CAN KIND OF BREAK IT DOWN INTO A COUPLE OF DIFFERENT CHUNKS.
IF WE LOOK AT FOOD SAFETY AND THINGS LIKE THAT, OBVIOUSLY, MY EXPERIENCE IS IN THE
CLINICAL TRIAL PHASE. IT'S ABOUT TWO THINGS. WHAT YOU'RE TRYING TO DO IS PROVE SAFETY
AND EFFICACY. THAT'S WHAT IT BOILS DOWN TO. THAT'S THE WHOLE PURPOSE OF WHY WE RUN
TRIALS. TO DO THAT, YOU COLLECT DATA. WHEN I MOVED OUT OF -- I WAS IN FRAUD
DETECTION IN TELECOMS, AND WHEN I GOT THE OPPORTUNITY TO CHANGE, I HAD A CHANCE TO MOVE
INTO LIFE SCIENCES, AND I WAS ASTOUNDED THAT AN INDUSTRY THAT IS 100% RELIANT ON ANALYZING
DATA IN CLINICAL TRIALS IS SO BACKWARDS IN BOTH COLLECTING DATA AND MANAGING IT. FOR ME,
I LOOKED AT THAT AND SAID, RIGHT, THIS IS A CHALLENGE. I'M JUST GOING TO SPEND THE REST
OF MY CAREER IN LIFE SCIENCES TRYING TO MAKE THIS BETTER. IF YOU LOOK IN 2003, AT
LEAST 60% OF CLINICAL TRIAL DATA WAS STILL COLLECTED ON PAPER. AT THE TIME, THAT WAS THE
PROBLEM, BUT IF WE LOOK AT THE LAST 17 YEARS, THE ACTUAL COLLECTION OF DATA IS NOW A
LOT LESS OF THE A PROBLEM. I THINK ANDI POINTED OUT THE PHONES. WE LITERALLY WALK AROUND
WITH A DATA ENTRY PAD IN OUR POCKET NOWADAYS. WE'RE LITERALLY WEARING OUR DEVICES.
THERE'S SO MANY WAYS TO COLLECT DATA, AND WHETHER IT'S COMING FROM HR AND WE'RE
USING THAT AS A REAL LIFE STUDY, OR WHETHER IT COMES FROM A DEVICE AND WE'RE FEEDING THAT
AUTOMATICALLY INTO A SYSTEM. I THINK THE KEY THING FOR ME IS WE HAVE TO

EMBRACE THAT
DATA DIVERSITY. SO YOU THINK, OH, IT'S GREAT. WE'RE COLLECTING ALL THIS DATA. OTHER
COMPANIES AND OTHER INDUSTRIES DO IT GREAT. WE'VE BEEN MONITORING NUCLEAR POWER STATIONS
USING DATA FOR A LONG TIME. UBER STARTED A FEW YEARS AGO. THEY PULLED TOGETHER TRAFFIC
ALL OVER THE WORLD -- TRAFFIC PATTERNS, PROBLEMS, FINANCIAL DATA. SO WE'RE NOT
REINVENTING THE WHEEL HERE. WE'RE JUST TRYING TO APPLY IT TO A SPECIFIC INDUSTRY OF LIFE
SCIENCES. I THINK WHERE -- COVID IS A HORRIBLE THING THAT'S HAPPENING AROUND
THE WORLD, BUT WHAT IT IS DOING IS FORCING THIS INDUSTRY TO ACTUALLY CHANGE THEIR
MINDSET. IT'S NOT AS MUCH ABOUT CAN WE COLLECT DATA IN DIFFERENT WAYS? IT'S CAN I CHANGE
MY ENTIRE FINANCIAL MODEL WHICH IS BASED ON THE MANUAL COLLECTION OF DATA AT A SITE AND
THEN SENDING MONITORS OUT TO A SITE TO MANUALLY LOOK AT THAT DATA. SO I THINK THAT IS
WHAT IS REALLY, I BELIEVE, GOING TO CHANGE THE MINDSET AND HOW WE CAN IMPROVE THE USE OF
DATA. SO IF YOU THINK ABOUT THAT AND EMBRACE THAT DIVERSITY, THEN YOU'VE GOT -- MY
PASSION IS MAKING SURE IT'S USABLE. WITH THIS BEING SOME FANTASTIC PEOPLE ON THIS
SEMINAR, TALKING ABOUT DATA MARKS AND MACHINE LEARNING AND ALL THAT, I THINK WE NEED TO
LOOK AT THAT AND SAY THERE IS NO SILVER BULLET AND THERE IS NO POISON CHALICE. WE
NEED TO USE A BLEND OF THESE DIFFERENT METHODOLOGIES TO BE ABLE TO PROVIDE A BETTER USE OF
DATA. SO IF YOU THINK OF A CLINICAL RESEARCH ASSOCIATE WHO'S RESPONSIBLE FOR
MONITORING DATA COMING IN AT THE SITE, THEY HAVE NO IDEA WHAT A DATA LAKE IS OR A DATA
WAREHOUSE. WHAT DID WE IN I.T. TO? AND I'M JUST TO BLAME AS WELL. OVER THE LAST 30
YEARS, WHAT WE IN I.T. DID IS, OH, THAT'S OKAY. WE'LL CREATE A DATA WAREHOUSE AND GIVE
YOU A REPORT. THAT'S NOT THE WAY TO ENGAGE WITH SOMEONE. THAT'S WHY I THINK WE'VE
STRUGGLED FOR SO LONG. WE NEED TO THINK ABOUT THIS AS MUCH MORE ABOUT THE OPERATIONAL
TRANSACTIONAL SYSTEM THAT PEOPLE USE DAY IN AND DAY OUT. THAT'S WHY METHODOLOGIES LIKE
UBER OR LYFT HAVE BECOME SO SUCCESSFUL BECAUSE THEY BLENDED ANALYTICS, DATA
PLATFORMS, TRANSACTIONS ALL WITHIN A SINGLE USER EXPERIENCE. SO THE CLINICAL RESEARCH
ASSOCIATE DOESN'T NEED TO KNOW WHAT A DATA MARK IS OR WHAT A DATA LAKE IS TO BE ABLE TO
LONGITUDINALLY MONITOR A PATIENT THAT'S BEING SEEN BY A SITE AND GETTING DATA IN FROM
DEVICES, FROM HEALTH CARE SYSTEMS, DIRECT FROM SITE REPORTED OUTCOMES. I THINK THAT'S
WHERE WE'VE -- THAT'S WHERE WE AS AN INDUSTRY NEED TO CHANGE. I THINK COVID

HAS PROVIDED
A STIMULUS TO THE UNDERLYING ECONOMICS OF THIS INDUSTRY, BUT I THINK WE STILL NEED TO WORK
ON EMBRACING A SLIGHTLY DIFFERENT APPROACH, AND DON'T JUST THINK ABOUT THE DATA SCIENTISTS
AND THE STATISTICIANS AND THE MATHEMATICIANS BECAUSE HONESTLY THOSE GUYS KNOW WHAT TO DO
WITH DATA. UNLESS WE PUT THESE KIND OF DECISION-MAKING INTO THE HANDS OF THE MEDICS OR
INTO THE HANDS OF THE CLINICAL RESEARCH ASSOCIATES OR INTO THE HANDS OF PRODUCT MANAGERS,
WE JUST DON'T GET THE SAME TYPE OF VALUE.
>>: THAT'S HELPFUL COMING FROM SOMEONE WHO CAME UPON THE SCENE AND SAID IT WAS BACKWARDS.
>>: IT WAS A SHOCK WHEN I FIRST JOINED.
>>: THAT SOUNDS LIKE IT WAS. AND YOU TALK ABOUT EMBRACING DATA DIVERSITY, AND NOT ONLY
EMBRACING DATA DIVERSITY, BUT ULTIMATELY PUTTING IT INTO THE HANDS OF SOMEONE WHO CAN DO
SOMETHING WITH IT AND THEREBY ENHANCING INNOVATION AND UTILITY THERE. THANKS FOR
EMBRACING IT. WE HOPE IT WON'T STAY BACKWARDS FOR QUITE SO LONG.
>>: I THINK IT'S MOVING IN THE RIGHT DIRECTION.
>>: GLAD TO HEAR IT. SPEAKING OF DATA DIVERSITY, I WANT TO PICK UP ON A DATA SOURCE WE'VE
TALKED ABOUT A FEW TIMES BEFORE. I'M PROBABLY GOING TO ZACH FIRST ON THIS. THAT, ZACH,
IS ON ELECTRONIC HEALTH RECORDS IN DECISION-MAKING, EHRs AND DECISION-MAKING. I
KIND OF WANT TO CATCH UP ON THE STATE OF THE ART FOR USING UNSTRUCTURED AND STRUCTURED
DATA OUT OF EHRs, NOT JUST TO COMPILE MORE AND MORE DATA, BUT HOW WE MAKE SURE IT GETS
TARGETED TO THE DECISION-MAKING BETWEEN PATIENTS, FAMILIES, AND CLINICIANS. THE
EHRs IN DECISION-MAKING. WHERE ARE WE, ZACH?
>>: THANKS FOR THE QUESTION. IT SEEMS TO ME THAT, FIRST OF ALL, WE HAVE TO FRAME FOR
EVERYBODY WHAT WE'RE TALKING ABOUT. WE'RE TALKING ABOUT A TOOL, ELECTRONIC HEALTH
RECORDS, THAT DOCTORS USE TO DOCUMENT WHAT THEY'RE DOING WITH A PATIENT, WHAT THEIR PLAN
IS, AND FRANKLY, ALSO TO GET REIMBURSED FOR CARE. THERE'S TWO PARTS TO THE DATA, TO THIS
DATA. ONE IS THE CODIFIED PART, THE PARTS THAT ARE IN A DISCRETE, WELL-ESTABLISHED,
STANDARDIZED TERMINOLOGY LIKE DIAGNOSTIC CODES, LIKE LAB VALUES, AND THEN THERE IS THE
NARRATIVE PART OF IT, THE TEXT THAT DOCTORS USE AND OTHER CARE PROVIDERS USE TO DESCRIBE
WHAT THEY'RE GOING TO DO IN PLAIN ENGLISH. AND EACH HAS ITS OWN ROLE, BUT THERE ARE
CHALLENGES WITH EACH. ON THE CODIFY PART, WHAT IS THE STANDARDIZED VOCABULARY? IS
THAT BEING DONE ACCURATELY? AND, IN FACT, ARE EXTERNALITIES LIKE REIMBURSEMENTS,
DISTORTING THE PURPOSE FOR WHICH THESE THINGS ARE ENTERED? AND THEREFORE

MAYBE NOT QUITE
RENDERING THE TRUTH. THEN THERE'S THE NARRATIVE TEXT, WHICH IS NOT AS EASY AT FIRST BLUSH
TO USE LIKE THE CODIFIED DATA BY COMPUTERS BECAUSE COMPUTERS LIKE TO HAVE THESE DISCRETE
ENTITIES THAT THEY CAN WORK WITH. BUT THROUGH VARIOUS ADVANCES IN MACHINE LEARNING,
WE ARE ABLE TO MINE THAT NARRATIVE TEXT, A CLINICIAN'S RIGHT TO ACTUALLY BE ABLE TO
EXTRACT MEANING THAT IS ABSENT FROM THE CODIFIED DATA. SO THERE'S NOW AN OPPORTUNITY
TO SAY WHAT ARE WE GOING TO DO WITH THIS DATA? CERTAINLY, WE CAN USE IT TO SHARE IT WITH
OTHER CARE PROVIDERS TO IMPROVE CARE. WE CAN USE IT IN THE SAME SENSE AS PREDICT, TO BE
ABLE TO, WITH THE FOOD SAFETY, TO ACTUALLY LOOK AT PATIENT SAFETY, TO SEE WHAT'S GOING ON
WITH A PATIENT. BUT I'D LIKE TO QUICKLY PULL OUT SOME QUALITY ISSUES THAT ARE VERY MUCH
IN THE SPIRIT OF WHAT JOE SAID. SO I HAD THE PRIVILEGE OF RUNNING A QUICK FOUR-WEEK
SPRINT ACROSS FIVE COUNTRIES AND 96 ACADEMIC HEALTH CENTERS IN THE COVID ERA,
PUTTING DOWN A DATA SET, WHAT'S HAPPENING TO OUR PATIENTS ACROSS THESE TENS OF THOUSANDS
OF COVID PATIENTS ACROSS SIX COUNTRY -- OR FIVE COUNTRIES AND 96 HOSPITALS. WE WERE ABLE
TO GET ALL THIS DATA TOGETHER AND ANALYZE WITHIN FOUR WEEKS, BUT HERE'S THE PART THAT
WAS NOT QUITE AS OBVIOUS. EVEN THE CODIFIED DATA, THE PRECISELY CODIFIED DATA, WAS
ACTUALLY DIFFERENT, MEANT DIFFERENT THINGS AT DIFFERENT SITES, AND THE ONLY WAY WE WERE
ABLE TO FIGURE IT OUT WAS BY TALKING TO THE INDIVIDUALS AT THE LOCAL SITES. SO FOR
EXAMPLE, TRAPONIN, WHICH IS A MEASURE OF MUSCLES THAT LEAK OUT OF YOUR HEART, FOR EXAMPLE,
UNDERSTANDING WHETHER THEY'RE USING A HIGH SENSITIVITY ASSAY, A LOW SENSITIVITY ASSAY,
WHETHER IT'S DONE IN ICU OR OUTPATIENT, CHANGED THE MEANING OF THAT VALUE. AND IN THIS
IMPORTANT PERIOD OF TRANSITION, WHERE WE'RE GOING FROM A PAPER-BASED HEALTH INFORMATION
ECONOMY TO A DIGITAL HEALTH ECONOMY, THE PRACTICE IS FAR FROM STANDARDIZED. SO EVEN
THOUGH IT LOOKS LIKE THE SAME DATA ELEMENTS, UNDERSTAND WHAT THEY ACTUALLY MEAN BY
GOING BACK TO THE SITES BEING INVOLVED IS ABSOLUTELY ESSENTIAL. AND THEREFORE, I
WOULD SAY THAT ENGAGING THE HEALTH CARE SYSTEMS DIRECTLY IN A FEEDBACK LOOP, WHERE
THEY CAN EXPLAIN THEIR DATA AND CORRECT IT AND IMPROVE IT IS ABSOLUTELY ESSENTIAL IF WE'RE
GOING TO HAVE ADEQUATE DATA. IN THE FAR FUTURE, MAYBE WE WON'T NEED IT, BUT WE NEED THAT
LOOP NOW. I DON'T KNOW IF JOE WANTS TO AGREE OR DISAGREE.
>>: WELL, KEY POINT. ABSOLUTE KEY POINT IN THE FEEDBACK LOOP BECAUSE WE HAVE TO KEEP

TESTING AND RETESTING HOW IS THAT COMING ACROSS TO THE END USER? IS IT MAKING ANY
DIFFERENCE IN DECISION-MAKING IN HEALTH CARE OUTCOMES? I'M WONDERING, PETER, LET
ME ASK YOU SOMETHING. SET UP RAM FOR A SECOND. RAM, I'M GOING TO TELL YOU AHEAD OF TIME
THAT WE'RE GOING TO ASK YOU ABOUT WHAT DOES THIS ALL MEAN TO A CDO WHO CARES ABOUT DATA
QUALITY? SO I HOPE YOU'VE GOT -- YOU'RE THINKING ABOUT WHAT YOU'RE HEARING THAT WAY,
AND I'LL ASK YOU FOR A RESPONSE ON THAT PRETTY SOON. PETER, DO YOU GET JAZZED UP
HEARING ABOUT ALL THIS STUFF, ALL THESE ADVANCES? YOU'RE KIND OF A CUTTING EDGE GUY
HERE. I'M JUST KIND OF CURIOUS ABOUT WHERE SHOULD THE AGENCY GO NEXT IN YOUR VIEWPOINT
TO ENSURE, TO MAKE MOST EFFICIENT USE OF THESE FUTURE TECHNOLOGIES, EMERGING
TECHNOLOGIES? IN FACT, NOT JUST WHERE WE SHOULD GO NEXT FROM AN AGENCY STANDPOINT, BUT
HOW CAN THE AGENCY MAYBE LEAD THE WAY ON THE INNOVATION AND IMPLEMENTATION SIDE? PETER?
>>: SURE, THANKS. TO YOUR QUESTION, ON SOME DAYS I WAKE UP ON THE RIGHT SIDE OF MY BED
AND FEELING COMPLETELY JAZZED UP BY ALL THE OPPORTUNITIES HERE, AND THEN OTHER DAYS I WAKE
UP ON THE LEFT SIDE AND SCARED TO DEATH. WE'LL NEVER GET THIS RIGHT. I HAVE TO SAY
I'M EXTREMELY, LIKE THE OTHERS, EXTREMELY IMPRESSED WITH PREDICT. THAT'S A SOLUTION
THAT'S ACTUALLY AT SCALE SOLVING A PROBLEM. ROUGHLY SPEAKING, IF YOU THINK OF DATA AS THE
RAW MATERIAL MAYBE TO BUILD A HOUSE, TODAY'S TECHNOLOGY IS, LARGELY SPEAKING, A BIG BAG
OF TOOLS. BUT WHAT WE REALLY WANT IS THAT HOUSE, ARE THE SOLUTIONS LIKE PREDICT, AND
EMERGING FROM THE RAW MATERIAL, GETTING THE RAW MATERIAL, MAKING SURE IT'S HIGH QUALITY,
AND THEN BRIDGING FROM THAT USING THE TOOLS WE HAVE TO THOSE SOLUTIONS IS SUCH A BIG
CHALLENGE. I THINK THE THING THAT I WOULD SAY HERE, JUST IN TERMS OF WHERE
WE'RE GOING NEXT, I HAVE A TREMENDOUS AMOUNT OF OPTIMISM WITH WHERE THE FUNDAMENTAL
TECHNOLOGY IS GOING WITH RESPECT TO MAKING THE DATA PROBLEMS EASIER. FOR SURE, SOME
OF THE DRIVES TOWARDS MORE STANDARDIZATION OF DIGITAL DATA, INTEROPERABILITY, BLOCKCHAIN'S
OBVIOUSLY HELPED A LOT. BUT WE'RE ALSO SEEING MORE AND MORE AI TECHNIQUES SPECIFICALLY TO
WRANGLE, TO NORMALIZE, AND TO AGGREGATE DATA MORE INTELLIGENTLY. SO THE ISSUE OF SCHEMA
MAPPING, DEALING WITH HETEROGENEOUS DATA EXTRACTION, OR HDE, USING AI TECHNIQUES IS
SOMETHING THAT'S EMERGING RIGHT NOW THAT IS, IN ESSENCE, AI IN ORDER TO WRANGLE DATA.
THEN THERE ARE MAYBE TWO OTHER DEVELOPMENTS IN THE FUNDAMENTAL AI TECHNOLOGY THAT ARE

STARTING TO BECOME VERY REAL. ONE HAS BEEN THE EMERGENCE AT A PRACTICAL SCALE OF
SOMETHING CALLED TRANSFER LEARNING. SO WHEN WE TODAY USE SOMETHING CALLED LARGE
SCALE MLP PRETRAINED MODELS, THESE ARE PRETRAINED MODELS THAT ARE TRAINED ON VERY, VERY
LARGE AMOUNTS OF TEXT, RESULTING IN MACHINE LEARNED MODELS WITH TENS OF BILLIONS OF
PARAMETERS. AND WHILE THEY WERE TRAINED SPECIFICALLY ON TEXT, WHAT WE'RE FINDING IS USING
VERY SMALL AMOUNTS OF ADDITIONAL DATA FOR SPECIFIC TASKS, EVEN TASKS THAT AREN'T RELATED
TO TEXT, BUT MAYBE FOR COMPUTER VISION OR OTHER APPLICATIONS, WE'RE ABLE TO GET EXTREMELY
HIGH QUALITY, HIGHLY EFFECTIVE NEW MACHINE LEARNED MODELS THAT MAKE USE OF THE LARGE
EARLIER PRETRAINING. THAT HAS BEEN A MAJOR LEAP FORWARD, AND WE'RE SEEING IN COMMERCIAL
DEVELOPMENTS NOW HUGE ACCELERATION OF PROGRESS BECAUSE WE NEED NOW LESS DATA TO GET THE
SAME LEVEL OF QUALITY THAT WE HAD BEFORE. AND THEN ANOTHER ELEMENT BESIDES TRANSFER
LEARNING IS SOMETHING CALLED REINFORCEMENT LEARNING. WE'RE STARTING TO SEE THIS IN
LOGISTICS, IN SHIPPING, LARGE SHIPPING COMPANIES, WHERE IF YOU CAN BUILD A PRECISE REAL
WORLD SIMULATOR, LET'S SAY FOR A MARITIME SHIPPING COMPANY, YOU CAN ACTUALLY PLAY FORWARD
THOUSANDS OF YEARS OF SHIPPING SITUATIONS, WEATHER PATTERNS, WARS, AND SO ON. AND
GENERATE THE DATA SYNTHETICALLY FROM THOSE SIMULATIONS, AND THEN IN THAT PROCESS, BUILD A
MODEL ON WHICH YOU CAN DO TRANSFER LEARNING. WE'RE NOW STARTING TO SEE THE MAJOR
SHIPPING AND LOGISTIC SUPPLY COMPANIES BECOMING MUCH, MUCH LESS DEPENDENT ON DATA THAN
BEFORE. YOU STILL WANT INSTRUMENTATION IN ORDER TO BE ABLE TO OPERATE THOSE MODELS, BUT YOU'RE LESS DEPENDENT ON THAT FOR THE ACTUAL CREATION OF THE MACHINE LEARNING
MODELS. SO I HAVE SYMPATHY FOR THE HUGE DATA CHALLENGES WE FACE TODAY, BUT I DO SEE
THEM BECOMING LESS AND LESS OF A CONCERN OVER THE NEXT TEN YEARS.
>>: SO, PETER, I'M THINKING YOU'RE REMINDING ME MAYBE WE NEED A GLOSSARY FOR TODAY BECAUSE
ALL OF THESE WONDERFUL CONCEPTS ARE BEING INTRODUCED -- TRANSFER LEARNING, REINFORCEMENT
LEARNING, PLAYING THE FUTURE. CAN YOU JUST GIVE US AN IDEA ABOUT HOW THE FDA MIGHT PLAY
THE FUTURE FORWARD IN THE WAY THAT YOU JUST DESCRIBED? WHAT WOULD BE A CASE EXAMPLE OR AN
INSTANCE OF THAT? JUST IN THE CONTEXT OF THIS PANEL DISCUSSION, I DO THINK THAT SOME
OF THE CONCEPTS THAT BOTH JOE AND ZACH AND ANDI WERE TALKING ABOUT ARE FOCUS AREAS WHERE,
AS HAS BEEN DONE WITH PREDICT, WHERE WE COULD BRING THE BEST THINKING IN A FOCUSED WAY AND
REALLY MAKE SOME PROGRESS. SO IF FOLLOWING THE IDEAS FROM ANDI AND JOE,

WE'RE
ACTUALLY ABLE TO DO SOME IN THE HOME 24/7 MONITORING OF PARTICIPANTS IN CLINICAL
STUDIES AND REALLY START TO BRING IN A FOCUSED WAY, MAYBE A SMALL NUMBER OF LEARNING
STUDIES, THAT WOULD BRING FOCUS IN THE TECH INDUSTRY FOR SCIENTISTS AND WOULD PROVIDE
POSSIBILITY OF A CRUCIAL BUILDING BLOCK THAT MIGHT LEAD TO A PREDICT-LIKE CAPABILITY,
LET'S SAY, FOR CLINICAL STUDIES. THEN WHEN WE TALK ABOUT WHAT'S HAPPENING WITH EHRs,
ZACH AND I ACTUALLY WERE TRADING SOME EMAILS PRIOR TO THIS PANEL, TALKING ABOUT THE
PROGRESS THAT WE'RE SEEING IN UNDERSTANDING THE CONTENT IN ELECTRONIC HEALTH RECORDS.
THAT WOULD BE SORT OF A STEP 2 FOR THE FDA THAT WOULD START TO TRY TO BRING IN THAT REAL
WORLD EVIDENCE FROM THAT CLINICAL DATA. IT SEEMS TO ME THE FDA IS JUST SITTING ON SORT OF
TREASURE TROVE OF VERY, VERY FOCUSED EFFORTS THAT COULD BRING ALONG THE FUNDAMENTAL
TECHNOLOGY.
>>: THANK YOU VERY MUCH ON THAT. GREAT POINT, PETER. ZACH, A POINT ON THAT, SIR. ZACH?
>>: YES, SO ACTUALLY I HAVE A QUESTION FOR DON. ONE OF MY COLLEAGUES, JOHN BROWNSTEIN HAS
ACTUALLY USED FOR FOOD SAFETY YELP REVIEWS. I'M WONDERING IF -- AND ACTUALLY DID A PRETTY
GOOD JOB. OF COURSE WE WANT TO IDENTIFY THREATS TO OUR FOOD SAFETY BEFORE THEY HIT OUR
SHORES, BUT SOMETIMES WE ONLY SEE IT IN DOWNSTREAM EFFECTS. I'M WONDERING, AMONG THE DATA
FEEDS THAT YOU'RE CONSIDERING, IN ADDITION TO THINGS LIKE YELP, IS, IN FACT, A REPORT
OF FOOD POISONINGS FROM HOSPITALS. I IMAGINE THE HOSPITAL IS NOT SHARING IT, BUT WOULD
YOU CONSIDER DATA FEEDS FROM EMERGENCY ROOMS AND PUBLIC MEDIA AND SO ON?
>>: YEAH, THANKS, ZACH. THAT'S A GREAT SUGGESTION AND A GREAT QUESTION. IN FACT, WE ARE
LOOKING AT THE WHOLE RANGE OF NEW DATA STREAMS, BOTH FROM OTHER FEDERAL PARTNERS. SO
WE HAVE TYPES OF THOSE INFORMATION. WE'RE AWARE OF DATA THAT ARE AVAILABLE NOW THAT
PERHAPS WE COULD BRING TO BEAR IN OUR IMPORT SCREENING, WHEN IT COMES TO OUTBREAK
RESPONSE. THERE ARE OTHER DATA STREAMS THAT WE'RE LOOKING AT AS WELL. SO I THINK WE'RE
FAMILIAR WITH THE RESEARCH THAT YOU'RE SUGGESTED, AND IT IS ONE OF THE TYPES OF NEW
DATA STREAMS THAT WE'RE VERY MUCH INTERESTED IN TRYING TO LEVERAGE AND BRING TO BEAR. I
THINK THE BIGGEST THING TO THINK ABOUT WITH THIS IS A HEARTBEAT IS A HEARTBEAT. A LOT OF
THIS NEW DATA NEEDS TO BE USED IN DIFFERENT WAYS. IF WE ARE SPLIT IN OUR SILOS, IF
CLINICAL TRIALS ARE DIFFERENT FROM CARES, DIFFERENT FROM OTHER THINGS, IT'S DIFFICULT TO MAKE THE DATA WORK ACROSS. SO I THINK THE AGENCY IS SUPER

IMPORTANT TO WORK
TOGETHER ON THESE AND TO FORGET THE OLD RULES ABOUT HOW DATA IS HANDLED IN CLINICAL
GROUPS. AND SENSOR DATA IS REALLY IMPORTANT AND IT'S COLLECTED DIFFERENTLY. SO SENSOR
DATA WOULD LOOK DIFFERENT THAN OTHER ONES.
>>: IT LOOKS DIFFERENT WHEN IT'S COLLECTED DIFFERENTLY.
>>: YES, FOR EXAMPLE, IF YOU THINK ABOUT THE SENSOR, RIGHT? THIS USES A PPG, AND THAT
COLLECTS MY -- IT SEES HOW MUCH LIGHT GOES INTO MY SKIN. SO DIFFERENT TYPES OF SKIN TONES
MIGHT ABSORB THAT LIGHT DIFFERENTLY. SO THAT WOULDN'T BE INTENTIONAL, BUT AS
SOMEBODY IS TESTING THE DIFFERENT TYPES OF TOOLS, DIFFERENT TYPES OF SKIN TONES MIGHT
REGISTER HEART RATE DIFFERENTLY. SO IF WE'RE NOT THINKING ABOUT THE PATIENT AND HOW THESE
DIFFERENT TOOLS ARE BEING USED, YOU COULD ACCIDENTALLY END UP WITH A WHOLE BUNCH OF
DIFFERENT DATA IF IT WASN'T REALLY CONSIDERED ON DIFFERENT TYPES OF USE CASES.
>>: THANK YOU, ANDI. GREAT POINT. JOE, WHAT HAVE YOU GOT?
>>: YEAH, TWO MINOR THINGS. ONE, ISAAC, I TOTALLY AGREE WITH YOU. THE FEEDBACK LOOP IS
ESSENTIAL. THAT'S THE ONLY WAY IT MAKES IT SUCCESSFUL. BUT JUST TO PICK UP ON WHAT ANDI
SAID, THE FDA IS A UNIQUE REGULATOR. THE FACT THAT YOU COVER SO MANY DIFFERENT AREAS
FROM CLINICAL TRIALS TO FOOD SAFETY. WITH ALL THE PEOPLE YOU'VE GOT ON HERE, THIS IS WHAT
WE NEED TO DO BECAUSE NO ONE INDIVIDUAL GROUP IN INDUSTRY WILL SUCCEED IN THIS. I THINK
IT HAS TO BE A COMBINATION. WELL, IT MIGHT -- ONE GROUP MIGHT SUCCEED, BUT IT
MIGHT END UP BEING AN AMAZON OR A FACEBOOK BECAUSE THEY'LL BASICALLY BUY UP ALL THE
DIFFERENT COMPONENTS. BUT I THINK THE REGULATORS HERE HAVE A POINT TO PLAY THIS IS AROUND
PUBLIC HEALTH AND PROTECTING PUBLIC HEALTH. IT DOESN'T MATTER WHETHER IT'S FOOD OR
CLINICAL TRIALS. WORKING WITH THE DIFFERENT TECHNOLOGIES AND CUSTOMER BASES WILL ONLY
HELP US, AND I THINK IT'S A GREAT START TODAY.
>>: THANKS FOR THAT, JOE. GOOD POINT. THAT'S WHY WE'RE HERE TODAY. FRANK?
>>: JUST REAL QUICKLY, ZACH, I LOVE THE QUESTION YOU ASKED BECAUSE TRADITIONALLY FOOD
SAFETY PROFESSIONALS, PUBLIC HEALTH PROFESSIONALS TRY TO DETECT FOOD BORNE ILLNESSES BY
DETECTING WHAT WE CALL THE TIP OF THE FOOD BORNE SURVEILLANCE PYRAMID. ARE PEOPLE
SICK ENOUGH TO GO TO THE HOSPITAL TO THE DOCTOR, GET TESTED, AND GET TESTED FOR THE RIGHT
PATHOGEN? FOR EVERY CASE WE GET DETECTED, JUST LIKE WE'RE SEEING WITH COVID, A LOT OF
CASES GO UNDETECTED OR UNREPORTED. WHAT YOU'RE SUGGESTING IS COULD WE CHANGE THE
PARADIGM AND LOOK AT OTHER DATA STREAMS THAT GIVE THE SIGNAL? LITERALLY

FLIPPING THE
SURVEILLANCE ON ITS HEAD. THERE ARE INDICATIONS IT'S POSSIBLE. THERE WAS AN OUTBREAK OF
LISTERIOSIS IN CANADA. THEY WENT BACK AND LOOKED AT IT RETROACTIVELY, HAD WE BEEN
SEARCHING FOR IT ON SEARCH ENGINES LIKE GOOGLE, WE COULD HAVE DETECTED LONG BEFORE
TRADITIONAL HEALTH REPORTING. SO IT'S WIDE OPEN ON THINGS WE CAN DO AND THINGS WE SHOULD
CONSIDER.
>>: THANKS, FRANK. SO, RAM, WE DO THIS ON PURPOSE. WE NEED YOU TO INTEGRATE UNDER THE
CURVE. YOU'VE HEARD HOW WONDERFUL PREDICT IS AND IS GOING TO BE. YOU'VE HEARD ABOUT NEW
WAYS OF USING DATA FASTER, HOW WE REVAMP CLINICAL TRIALS, HOW WE'VE USED HEALTH
RECORDS TO INFORM DECISION-MAKING. WE TALKED ABOUT FUTURE TECH, INCLUDING SORT OF HOW YOU
GO FROM THE BAG OF TOOLS TO THE HOUSE. TRANSFER LEARNING, REINFORCEMENT LEARNING. WHAT
IS A CDO TO DO, RAM? WHAT ARE YOU THINKING NOW ABOUT DATA QUALITY? DOES THIS KIND
OF TURN THE PAGE ENTIRELY FOR YOU? WHERE DOES THIS LEAVE A CDO? FIRST OF ALL, HE'S GOT
TO NOT BE ON MUTE.
>>: YEAH, THIS HAS BEEN A GREAT DISCUSSION, AND I TOOK SOME NOTES. I'M ACTUALLY GOING TO
COMPARE THIS PROBLEM TO, I THINK IT WAS SIMON WARDLEY, WHO CATEGORIZED INNOVATORS INTO
THREE CATEGORIES -- PIONEERS, SETTLERS, AND TOWN PLANNERS. WE SOMETIMES MAKE A MISTAKE
OF JUST PUTTING ALL THE DATA INTO THIS ONE MONOLITHIC ENTITY AND ALL THE USERS INTO JUST
USERS, BUT ACTUALLY THERE ARE DIFFERENT ARCHETYPES IN THE USER. SO THE PIONEERS ARE
THE PEOPLE WHO WILL TOLERATE SOMEWHAT OF A BAD QUALITY IN DATA. THEY ARE HUNTING FOR
SIGNALS IN A LOT OF NOISE, AND THEY ARE ABLE TO TRY A LOT OF EXPERIMENTS AND FAIL, AND
THEY WILL NOT MAKE THEM AVAILABLE TO THE LARGER GROUP. THE NEXT LEVEL ARE THE PEOPLE WHO
ARE TAKING THE PROBLEMS THAT ARE USEFUL AND TURNING THAT INTO SOMETHING THAT CAN BE TRIED
IN A SLIGHTLY BROADER SCALE. AND THEN THE THIRD ONE ARE THE PEOPLE WHO WILL SCALE IT TO
A PUBLIC HEALTH LEVEL OR A SCALEABLE LEVEL, AND THEY WILL WORK ON THE EFFICIENCY THAT
COMES FROM THE MODEL GROUPS. SO IF WE TAKE OUR DATA QUALITY TO BE PRISTINE FOR ALL
OF THESE GROUPS, WE WILL BE HERE FOREVER. SO WHAT WE NEED TO DO IS A FIT FOR PURPOSE.
WHAT IS THIS DATA GETTING USED FOR? AN EXAMPLE I WOULD SAY IS, IF I'M PLANNING FOR A
PICNIC TOMORROW OR THREE DAYS FROM NOW, I CAN TOLERATE WITH SOME LEVEL OF WEATHER DATA,
BUT IF I'M LAUNCHING A SPACE SHUTTLE, I MAY NEED A DIFFERENT LEVEL OF ACCURACY. SO

WITHOUT KNOWING THAT FIDELITY OF THE QUALITY THAT WE NEED, OF THE FIT FOR PURPOSE, WE WILL
JUST BE OVER INDEXING ON ONE SIDE OR THE OTHER. SO THAT IS, I THINK, AN IMPORTANT PART
THAT WE NEED TO BE CLEAR. THAT DOES NOT APPLY JUST TO THE DATA QUALITY. I THINK IT
ACTUALLY APPLIES TO THE ENTIRE STACK OF DATA AND ANALYTICS, THE TOOLS THAT THEY USE AND
THE TYPE OF TALENT WE HAVE IN THE ORGANIZATION NEEDS TO GO ALL THE WAY TO THE HOUSE TO USE
PETER'S ANALOGY. I THINK THAT IS AN IMPORTANT PART. AND I HAVE A LITTLE BIT OF A
COUNTERPOINT ABOUT USING UBER AS AN EXAMPLE THAT, IF UBER CAN DO IT, WHY CAN'T WE DO IT?
JOE, YOU MAKE A VERY GOOD POINT FROM A USER INTERFACE PERSPECTIVE. WE JUST NEED
TO BE CAREFUL. IF MY CAR COMES THREE MINUTES LATE OR FIVE MINUTES LATE, IT'S NOT A HUGE
DIFFERENCE, BUT WHEN IT COMES TO HEALTH DATA, IT COULD HAVE LIFE CONSEQUENCES. SO I THINK
WE JUST NEED TO PUT A SLIGHTLY HIGHER BAR ON THE TYPE OF USE OF THOSE TYPES OF DATA. SO
THE TRIANGULATION AND INTERMEDIATION ARE ALL CRITICAL IN THAT SPACE. I ALSO FELT --
I THINK, PETER, YOU SAVED THREE MINUTES OF MY DISCUSSION BECAUSE THE TOPIC THAT YOU TALKED
ABOUT FROM A TRANSFER LEARNING, WHICH IS REALLY BASED ON SOME FORM OF DEEP LEARNING, IS
CRITICAL BECAUSE IN THE AI SPACE, SOMETIMES WE HAVE A TENDENCY TO CONFUSE PERFORMANCE FOR
COMPETENCE. JUST BECAUSE SOMETHING IS DETECTING A PARTICULAR LIGHT SOURCE AND SAYS IT'S A
CAT DOESN'T MEAN IT WILL FIND A TRUCK. SO THERE ARE SOME ITEMS OF IDENTIFYING
CONTOURS OF A CAT WHICH IS USABLE IN IDENTIFYING THE TRUCK, WHICH IS THE TRANSFER
LEARNING, BUT IT DOESN'T MEAN WE HAVE CREATED THE MASTER ALGORITHM, A GENERALIZED
ALGORITHM THAT IT CAN GO. SO I THINK WE'RE STILL IN THAT PHASE OF COMPETENCE, BUT
NOT GENERAL PERFORMANCE. WE JUST NEED TO BE CAREFUL, NOT JUST FROM A DATA QUALITY
PERSPECTIVE, BUT FROM AN AI ALGORITHM QUALITY AS WELL. AND THE LAST THING I WOULD
MENTION, PETER EXPLAINED IT REALLY BEAUTIFULLY, ABOUT WE SHOULD NOT CONSIDER AI JUST FOR
THE FINAL USE CASE. THE PREDICT IS A GREAT EXAMPLE. THE EXAMPLE THAT FRANK GIVES US IS A
FANTASTIC EXAMPLE, BUT AI CAN BE USED TO IMPROVE THE DATA QUALITY, TO IMPROVE THE FIDELITY
OF THE DATA TO IDENTIFY THE PAGEANTS THAT IMPROVE THE OVERALL SUPPLY CHAIN OF THE DATA
ITSELF. I THINK THAT'S AN IMPORTANT PART THAT WE SHOULD NOT IGNORE. TO THE POINT
THAT SOMEBODY MADE ABOUT THE RULES ARE CHANGING, HOW WILL YOU KNOW WHEN YOU HAVE A PREDICT
ALGORITHM THAT A PARTICULAR RULE HAS CHANGED? I THINK THE CONCEPT, SUCH AS

DATA OPS, JUST
LIKE WE HAVE DEV OPS OR AI OPS DO HAVE A PLACE. I'M SURE MICROSOFT AND OTHER COMPANIES
ARE LOOKING AT THAT AS WELL. TO SEE IF THERE'S A CHANGE IN A PARTICULAR PATTERN, MAKE
SURE THAT IT IS FLAGGED AND WE ARE ABLE TO CATCH THAT AHEAD OF TIME. THAT IS AN IMPORTANT
PART OF DATA AND DATA QUALITY. THEN THE LAST THING I WOULD MAYBE TAKE THIS OFFLINE
WITH PETER IS I WANT TO GET YOUR THOUGHTS ON THE CONCEPT OF LEARNING USING
HEURISTICS BASED LEARNING. IF HUMAN INTELLIGENCE IS BASED WITH LOTS AND LOTS OF
HEURISTICS, AND IF WE CREATE OUR OWN ALGORITHM FOR FAIRLY DIFFICULT PROBLEMS AND THEN LET
THAT RUN ON THE DATA, AND OVER TIME, THE WEAK ALGORITHMS KEEP DYING AND THEN THE STRONGEST
ONE, IN COMBINATION WITH THE HEURISTICS AND THE DATA EMISSION LEARNING BECOMES THE REAL
STRENGTH. I WOULD LOVE TO GET YOUR THOUGHTS. STANFORD IS PIONEERING SOME OF THIS. I
WANT TO HEAR YOUR THOUGHTS, PROBABLY NOT HERE BUT AS AN OFFLINE DISCUSSION.
>>: RAM, FIRST OF ALL, I'M GLAD WE WAITED FOR YOU. WE NEED YOU TO DO THE ROLL-UP IN
QUALITY BECAUSE WE NEED TO REMIND OURSELVES THAT WE NEED TO CONTINUALLY LOOK AT THIS
THROUGH THE LENS OF DATA QUALITY. SO MANY THINGS ARE CHANGING AROUND. EVEN HOW YOU MIGHT
ASSESS QUALITY MIGHT BE CHANGING, BUT THAT WAS A GREAT WRAP-UP. ALSO, I'M REALLY
CONFIDENT WE HAVE THE RIGHT CDO IN PLACE. PETER, DID YOU HAVE A COMMENT YOU WANTED TO
TOSS ON THIS, PETER LEE?
>>: I'M SORRY. ACTUALLY, JOE MADE IT ALREADY, BUT ONE THING I MAYBE JUST WOULD SAY AS A
CLOSING COMMENT IS I'M ALWAYS REMINDED IN THESE DISCUSSIONS OF THE OLD FAMOUS POEM, THE
RIME OF THE ANCIENT MARINER, WHERE AT SOME POINT IN THE STORY PEOPLE ARE MAROONED.
THERE'S NO WIND. THE SHIP IS JUST ADRIFT, AND THERE'S THE SAYING, WATER, WATER EVERYWHERE
NOR ANY DROP TO DRINK. SOMETIMES THESE DISCUSSIONS ABOUT DATA REMIND ME OF THAT.
IN FACT, DON'S SLIDE SHOWING ALL THE SHIPPING CONTAINERS REMINDED ME OF THAT AS WELL. I
DO FEEL VERY OPTIMISTIC THAT OVER THE NEXT DECADE WE'LL OVERCOME THESE DATA ISSUES.
>>: SO SPEAKING OF LAST WORDS, THAT IS NOT YOUR LAST WORD. I HAVE ONE LAST WORD REQUEST
OF ALL OF YOU, AND WE'LL TRY TO BE EFFICIENT ABOUT THIS. IF YOU CAN ANSWER THIS IN ONE
SENTENCE, WE'D BE DELIGHTED. HERE'S THE QUESTION. AND IT KIND OF PLAYS OFF OF
SOMETHING WE MENTIONED EARLIER. WE'VE HEARD ABOUT A LOT OF DATA TOOLS THAT ARE
AVAILABLE IN THE FIELD, AND FDA IS TRYING THEM OUT AND PUTTING THEM INTO DIFFERENT
MODELS AND SO FORTH. WE HEARD A LOT ABOUT PREDICT AND SO FORTH. ASIDE FROM

MAKING THE
BEST USE OF MODELS, ANALYTICS, AND TALENT, PUSH IT A LITTLE FURTHER. HOW CAN FDA LEAD THE
WAY GLOBALLY? HOW CAN FDA ACTUALLY LEAD THE WAY IN PUTTING DATA TO USE? LEAD THE
WAY. AND WHILE YOU'RE PANELISTS ARE THINKING ABOUT IT, I'LL REMIND YOU THAT IN JUST A FEW
MINUTES I'LL TURN IT OVER TO DR. AMY ABERNATHY. SHE HAS SUMMARY REMARKS AND OTHER
INSIGHTS SHE'LL PROBABLY ADD. BUT I WANT TO ASK EACH OF THE SEVEN OF YOU IN JUST A
SENTENCE HOW CAN THE FDA LEAD THE WAY NOW IN PUTTING DATA TO USE? DON PRATER, YOU SET US
OFF SO WELL IN THE BEGINNING. IN A SENTENCE, HOW CAN YOUR AGENCY LEAD THE WAY?
>>: THANKS, CLIFF. THAT'S A GOOD QUESTION. I THINK WE HAVE A UNIQUE PURVIEW AT THE
AGENCY, AND I THINK THE THING THAT WE CAN DO IS TO ALLOW EXAMPLES OF DIFFERENT TYPES OF
USES OF DATA TO EXPLORE AND PILOT THINGS. WE DID A PROOF OF CONCEPT PRETTY RAPIDLY, I
THINK, FOR THE SPEED THAT THE AGENCY WORKS. SO I THINK ABILITY TO TRY THINGS AND TO SHARE
WHAT WE LEARN.
>>: GOOD. THANKS VERY MUCH. ZACH, HOW CAN THE AGENCY LEAD THE WAY?
>>: BY USING SUCCESSES LIKE THE PREDICT PROJECT TO REACH OUT TO THE AMERICAN PUBLIC AND
SAY, WE WANT TO USE WITH OUR GOOD STEWARDSHIP YOUR DATA TO ADVANCE YOUR HEALTH. JOIN US
IN HELPING YOUR LOCAL INSTITUTIONS SHARE DATA WITH US SO THAT WE CAN ACTUALLY DO THE
RIGHT THING, AS YOU EXPECT US TO, FOR YOU, OUR CITIZENS.
>>: SETTING A GREAT EXAMPLE AS THE LEAD AND THE COLLABORATOR. THANKS, ZACH. JOE, WHAT DO
YOU HAVE? HOW CAN THE AGENCY LEAD THE WAY?
>>: THAT'S TOUGH. I WOULD SAY THE AGENCY IS ANOTHER USER. MY PASSION IS ABOUT MAKING
STUFF USABLE FOR THE USER. I WOULD SAY THE AGENCY SHOULD JUST -- I WOULD SAY ENFORCE
REQUESTING DATA EARLIER, ESPECIALLY IN CLINICAL TRIALS. YOU DON'T NEED TO WAIT UNTIL THE
LAST MINUTE OR SIX MONTHS INTO A TRIAL, AS LONG AS YOU'RE WILLING NOT TO MICROMANAGE THE
SPONSORS DEVELOPING THE DRUGS. REQUEST DATA EARLIER. THAT WILL ACTUALLY HELP EMBRACE
DATA USAGE.
>>: GREAT POINT. THANK YOU. VERY GOOD. ANDI, LEADING THE WAY, WHAT DO YOU HAVE?
>>: I THINK THE MOST IMPORTANT THING THAT THE AGENCY DOES IS IT BUILDS TRUST IN A SYSTEM.
SO JUST MAKING SURE THAT IT KEEPS DOING THINGS THAT BUILD TRUST. SO MAYBE RETHINKING THE
PREDICATE PROGRAM, THINKING ABOUT HOW WE HANDLE SECURITY, HOW WE HANDLE DATA RIGHTS, THINGS THAT HISTORICALLY THE AGENCY HASN'T TAKEN A FIRM OPINION ON, AND I THINK IT
WOULD HELP EVERYBODY IF IT SET SOME STANDARDS AROUND THOSE.
>>: WELL STATED. GOT IT. THANK YOU VERY MUCH, ANDI. RAM, I HOPE YOU CAUGHT

YOUR BREATH
BY NOW. WHAT'S THE ONE THING WE CAN DO TO KIND OF LEAD THE WAY?
>>: YEAH, I'M GOING TO SAY TWO THINGS. ONE IS WE HAVE TO ACT AS AN ORCHESTRATOR OF THESE
TYPE OF DISCUSSIONS SO THAT WE BRING THE REAL MIND MELD INTO THESE KINDS OF PROBLEMS. IT
CANNOT BE SOLVED BY JUST FDA. THE SECOND THING I WOULD SAY IS WE HAVE TO ACT ALMOST
LIKE A LIGHTHOUSE WHERE WE HAVE THE ABILITY TO SEE SO MANY THINGS AND SHINE LIGHT ON THE
THINGS THAT ARE IMPORTANT AND CORRECT THE COURSE SO THAT WE ARE GETTING ALL THE SHIPS
TO THE SHORE. I THINK THOSE TWO CRITICAL ROLES ARE IMPORTANT FOR FDA.
>>: EXCELLENT. FRANK, LEADING THE WAY, YOU ALREADY HAD SOME GOOD IDEAS ON THAT.
>>: YEAH, THERE'S BEEN SO MANY GOOD EXAMPLES HERE. YOU HEARD ABOUT LEADING THE WAY,
STUDYING THE EXAMPLE ROLE MODEL. I'LL GO WITH SOMETHING DIFFERENT. TO ME, ONE OF THE
THINGS THE AGENCY NEEDS TO DO IS LOOK AT OUR ROLE IN ALLOWING SOME OF THESE SOLUTIONS AND
TECHNOLOGIES TO SCALE. I THINK WE PLAY A UNIQUE ROLE IN THAT RESPECT. FOR EXAMPLE,
BLOCKCHAIN TRACEABILITY. LOTS OF DIFFERENT SOLUTIONS EMERGING IN THE PRIVATE SECTOR, BUT
THE AGENCY CAN TAKE A POSITION ON WHAT ARE THE KEY DATA ELEMENTS. WHAT ARE THE CRITICAL
TRACKING EVENTS THAT ARE NEEDED SO THAT, AS THE PRIVATE SECTOR WORKS ON THESE SOLUTIONS,
THEY WORK ON THEM IN A HARMONIZED FASHION AND HOPEFULLY ALLOW THEM TO BE INTEROPERABLE.
>>: PERFECT. GREAT POINT. PETER, BACK TO YOU. I TOLD YOU WE'RE GOING TO HAVE ANOTHER
LAST WORD. YOU'VE BEEN KIND OF OBSERVING THIS FROM THE INSIDE AND TAKING A LOOK FROM THE
OUTSIDE AND HEARING THIS FEEDBACK. IF THIS AGENCY IS GOING TO TAKE THE LEAD, WHAT
WOULD IT LOOK LIKE, PETER?
>>: I THINK JUST STAYING ON THE TECHNOLOGY TRACK, MAYBE TWO THINGS. ONE IS EMBRACE THE
EMERGING DATA INTEROPERABILITY STANDARDS, PARTICULARLY IN THE CLINICAL TRIAL SPACE THAT
DON RUCKER AND OTHERS TALKED ABOUT IN THE PREVIOUS PANEL. AND, TWO, I WOULD CONTEMPLATE
CREATING AN OPEN SOURCE COLLECTION OF MODELS, ALGORITHMS, AND DATA THAT ARE PERTINENT TO
SPECIFIC CHALLENGE PROBLEMS WITHIN FDA.
>>: GREAT POINT. THANK YOU. IN A MOMENT, I'M GOING TO GO TO RAVI GOUD, AND HE'LL SET US
UP FOR A CLOSING BY DR. ABERNATHY. BEFORE WE DO THAT, I JUST WANT TO POINT OUT THAT THIS
GROUP OF SEVEN, AS IT WERE, HAS REALLY OUTLINED, AS YOU JUST HEARD, NOT ONLY HOW CAN
THE AGENCY TAKE BEST ADVANTAGE OF EXISTING RESOURCES AND TALENT IN ANALYTICS, BUT WHAT IT
CAN DO TO LEAD THE WAY GLOBALLY TOWARDS PUTTING DATA TO USE. THIS IS A GREAT WRAP UP OF

DATA SHARING, DATA EXCHANGE, AND NOW DOING SOMETHING WITH IT AND DOING SOMETHING WITH
IT THAT WILL SET A GLOBAL STANDARD. SO THANKS ALL VERY MUCH. DON PRATER, FRANK YIANNAS,
ANDI CORVOS, JOE GOODGAME, RAM IYER, PETER LEE, AND ISAAC KOHAN. THIS HAS BEEN A SESSION
OF TAKING GOOD NOTES. WE REALLY APPRECIATE YOUR INNOVATION AND YOUR LEADERSHIP.
WITH THAT, I'M GOING TO THANK YOU AND TURN IT OVER TO RAVI GOUD. RAVI, TELL FOLKS WHO
YOU ARE AT THE AGENCY AND WHAT YOUR ROLE IS PLEASE, SIR.
>>: HI, MY NAME IS RAVI GOUD, AND I'M A MEDICAL OFFICER IN THE CENTER FOR BIOLOGICS,
EVALUATION AND RESEARCH. I'M HERE TO TALK TO YOU TODAY ABOUT FDA'S ANOMALY CHALLENGE. I
WORK WITH ADVERSE EVENT AND CLAIMS DATA SURVEILLANCE SYSTEMS TO DETECT, MONITOR, AND HELP
PREVENT ADVERSE EFFECTS OF BIOLOGICAL PRODUCTS REGULATED BY THE FDA. I WILL BE
TALKING TO YOU TODAY ABOUT HOW FDA IS ENGAGING EXTERNAL EXPERTS IN COMPETITIONS FOCUSED ON
REAL WORLD PROBLEMS TO GAIN INSIGHTS INTO HEALTH DATA AND TO INFORM REGULATORY SCIENCE.
IN ADDITION, I WILL BE ANNOUNCING THE TOP PERFORMERS OF THE PRECISION FDA DETECTING
ADVERSE EVENT ANOMALIES USING FDA OPEN DATA CHALLENGE. NEXT SLIDE, PLEASE. LET'S
FIRST TAKE A MOMENT TO TALK ABOUT PRECISION FDA, THE PLATFORM WHERE FDA RUNS THESE
COMPETITIONS. PRECISION FDA BEGAN IN 2015 AS A RESEARCH EFFORT TO SUPPORT DEVELOPMENT OF
FDA'S REGULATORY STANDARDS IN EVOLVING GENOMIC SCIENCE. IT HAS EVOLVED TO FOCUS
MORE BROADLY ON ALL AREAS OF OMICS, AND NOW IT'S A WIDELY USED SCIENTIFIC COLLABORATION
DATA SCIENCE PLATFORM. THE PRECISION FDA TEAM COLLABORATES ACROSS FDA AND WITH
OTHER GOVERNMENT AGENCIES TO SUPPORT THE FDA MISSION AND THE VISION AND INTENT OF THE
AMERICAN INNOVATION AND COMPETITIVENESS AND 21st CENTURY CURES ACT. PRECISION FDA
OFFERS A HIGH PERFORMANCE COMPUTING PLATFORM WITH ALMOST 5,000 USERS, OVER 76 TERABYTES OF
DATA, ACCESS TO A COMMUNITY OF EXPERTS, A LIBRARY OF TOOLS AND APPLICATIONS, A
COMPETITION FRAMEWORK, AND VIRTUAL LAB WORKSPACES TO ALLOW FDA SCIENTISTS AND REVIEWERS TO
COLLABORATE WITH EXTERNAL PARTNERS. NEXT SLIDE, PLEASE. PRECISION FDA FITS WITHIN A
LARGER DATA SCIENCE ECOSYSTEM. ORGANIZATIONS WITHIN THIS ECOSYSTEM ARE DIVERSE AND
GROWING. THEY INCLUDE ORGANIZATIONS SPONSORING CHALLENGES, THOSE HOSTING CHALLENGES, AS WELL AS THOSE SUPPORTING THE CHALLENGE ECOSYSTEM AS A COMMUNICATION
CHANNEL. FOR EXAMPLE, THE FEDERAL GOVERNMENT'S CHALLENGE.ORG SITE SERVES AS A CENTRALIZED
SOURCE OF GOVERNMENT SPONSORED COMPETITIONS. COMPETITIONS RANGE FROM SIMPLE

TO COMPLEX
AND TARGET A WIDE RANGE OF SKILL SETS. THE PRECISION FDA TEAM WORKS ACROSS THIS ECOSYSTEM
TO CONNECT BOTH INTERNALLY AND EXTERNALLY THROUGH A VARIETY OF COMMUNICATION CHANNELS.
IN ADDITION, THE TEAM CONNECTS WITH OTHER COMPETITION PROVIDERS TO COMMUNICATE OUR
CHALLENGES, DESIGN NEW CHALLENGES, PARTICIPATE IN COMPETITION EVALUATIONS, AND LEARN FROM
EACH OTHER'S EXPERIENCES. NEXT SLIDE, PLEASE. SO WHY DOES PRECISION FDA SPEND SO
MUCH TIME DESIGNING AND IMPLEMENTING BIOMEDICAL DATA SCIENCE COMPETITIONS? WE DO THIS
BECAUSE RUNNING COMPETITIONS IS AN IMPORTANT PART OF BUILDING A COMMUNITY OF EXPERTS.
THIS HELPS FDA TO DO THE FOLLOWING -- GAIN NEW INSIGHTS, SOLVE REAL WORLD PROBLEMS,
DEVELOP NEW DATA SCIENCE TOOLS AND TECHNIQUES, AND GENERALLY TO RAISE AWARENESS OF THE
CRITICAL ROLE OF REGULATORY SCIENCE. NEXT SLIDE, PLEASE. TO DATE, FDA HAS LAUNCHED
27 DATA SCIENCE COMPETITIONS ON PRECISION FDA. COMPETITIONS ALWAYS TEACH FDA AND OUR
COMPETITION PARTNERS SOMETHING, AND OFTEN THAT SOMETHING IS UNEXPECTED. IN THE CASE OF
THE CENTER FOR DEVICES AND RADIOLOGICAL RESEARCH BIOTHREAT CHALLENGE, WE LEARNED THAT AN
ENSEMBLE APPROACH PRODUCED BETTER RESULTS THAN ONE INDIVIDUAL SUBMISSION. IN THE CASE
OF THE NATIONAL CANCER INSTITUTE BRAIN TUMOR SAMPLE LABELING CHALLENGE,
PARTICIPANTS DEVELOPED TOOLS TO CORRECT THE NOT INFREQUENT PROBLEM OF TUMOR MISLABELING,
WHICH HELPS TO ENSURE THAT THE RIGHT DATA IS AVAILABLE FOR THE RIGHT PATIENT. THE
TRUTH CHALLENGES, IN COLLABORATION WITH THE NATIONAL INSTITUTES OF STANDARDS AND
TECHNOLOGY, HELPED US TO BENCHMARK GENOMIC PIPELINES USING PREVIOUSLY UNKNOWN REFERENCE
DATA. THE CURRENT VETERANS HEALTH ADMINISTRATION COVID-19 RISK FACTOR CHALLENGE,
WHICH APPEARS AT THE BOTTOM RIGHT HAND CORNER OF THE SLIDE, IS GEARED TOWARDS PREDICTING
THE RISK FACTORS OR HEALTH OUTCOMES IN RISK POPULATIONS -- IN HIGH RISK POPULATIONS. THIS
IS A PARTICULARLY RELEVANT CHALLENGE TO THE CURRENT PANDEMIC SITUATION. NEXT SLIDE,
PLEASE. BEFORE I BEGIN TALKING ABOUT OUR PUBLIC ADVERSE EVENT DATA CHALLENGE, IT MAY
BE HELPFUL FOR ME TO DESCRIBE THE LIFECYCLE OF FDA REGULATED PRODUCTS, INCLUDING
SURVEILLANCE FOR ADVERSE EVENTS AT FDA. FIRST, APPROVED PRODUCTS GO THROUGH DIFFERENT
STAGES BEFORE APPROVAL. THIS INCLUDES PRECLINICAL STAGES ALL THE WAY TO PHASE 3 CLINICAL
TRIALS. DATA COLLECTED ON ADVERSE EVENTS VARY AND STEADILY INCREASE FROM A FEW SUBJECTS
IN INITIAL STAGES TO AT THE MOST THOUSANDS IN VACCINE PHASE 3 TRIALS. WHEN

YOU GET TO THE
POST-MARKET PHASE, THE NUMBER OF PATIENTS EXPOSED INCREASES DRASTICALLY, AND FDA CONDUCTS
SURVEILLANCE ON POTENTIALLY MILLIONS. TO DO THIS, THERE ARE FDA AND HHS ACTIVE
SURVEILLANCE SYSTEMS USING HEALTH CARE DATABASES, AND THERE ARE PASSIVE SURVEILLANCE
SYSTEMS, SUCH AS THE FDA ADVERSE EVENT RECORDING SYSTEM OR FAERS. FOR THE PUBLIC ADVERSE
EVENT DATA CHALLENGE, WE FOCUSED ON THE PASSIVE SURVEILLANCE DATA SYSTEMS, WHICH ASKS
PATIENTS, PROVIDERS, AND FAMILY MEMBERS TO VOLUNTARILY SUBMIT REPORTS TO FDA. NEXT SLIDE,
PLEASE. ONE WAY INDIVIDUALS SUBMIT THESE REPORTS ARE THROUGH A MEDWATCH FORM, AS
PICTURED IN THIS SLIDE. DUE TO THE VOLUNTARY NATURE OF PASSIVE SURVEILLANCE, THE DATA HAS
SOME DRAWBACKS, SUCH AS THE POSSIBILITY OF DUPLICATE REPORTS, INCOMPLETE INFORMATION ABOUT
THE PATIENT OR THE EVENT, THE POSSIBILITY OF COMPOUNDING DUE TO UNDERLYING CONDITIONS, OR
BIAS TOWARDS REPORTING TEMPORALLY CLOSE EVENTS. STILL, ANALYSIS OF THESE REPORTS CAN LEAD
TO VALUABLE INSIGHTS ABOUT PRODUCTS AND UNRECOGNIZED ADVERSE EVENTS EITHER THROUGH THE
ANALYSIS OF A SPECIALLY DETAILED REPORT NARRATIVES OR THROUGH AGGREGATE METHODS LOOKING AT
CLUSTERING OR DISPROPORTIONATE REPORTING OF ADVERSE EVENTS. WHEN THIS OCCURS, FURTHER
INVESTIGATION IS FREQUENTLY REQUIRED TO INVESTIGATE THE HYPOTHESIS GENERATED BY THE
ADVERSE EVENT REPORTS. SOMETIMES FURTHER INVESTIGATION FINDS THAT THE ADVERSE EVENT IS
NOT ATTRIBUTABLE TO THE PRODUCT EVEN THOUGH REPORTS WERE SUBMITTED. SO DISTINGUISHING
BETWEEN NOISE AND SIGNAL WITHIN THE PASSIVE SURVEILLANCE SYSTEM IS VERY IMPORTANT.
TO DO THIS BETTER, FDA HAS INVESTIGATED VARIOUS TOOLS OR METHODOLOGIES TO TRY AND INCREASE
THE CHANCE OF DISTINGUISHING SIGNAL FROM NOISE, OR TO AUTOMATE PROCESSES AS THE NUMBER OF
PRODUCTS AND REPORTS ARE ALWAYS STEADILY INCREASING. NEXT SLIDE, PLEASE. THIS
BRINGS US TO THE PUBLIC ADVERSE EVENT DATA CHALLENGE. AT FDA, WE ARE ALWAYS INTERESTED TO
LEARN IF THERE ARE NEW METHODS AND TECHNIQUES THAT COULD BENEFIT PUBLIC HEALTH. THE FDA
OPEN DATA ANOMALIES COMPETITION WAS LAUNCHED AS PART OF TODAY'S MODERNIZING FDA'S DATA
STRATEGY PUBLIC MEETING AS A WAY TO ENGAGE EXTERNAL SCIENTISTS PRIOR TO THE MEETING. THIS
COMPETITION ASKS PARTICIPANTS TO DEVELOP AND EVALUATE COMPUTATIONAL ALGORITHMS FOR
THE AUTOMATIC DETECTION OF ADVERSE EVENT ANOMALIES. PARTICIPANTS HAD ACCESS TO PUBLICLY
AVAILABLE DATA, SUCH AS FAERS AND VAERS, AS WELL AS OTHER PUBLICLY AVAILABLE DATA, SUCH AS

INFORMATION FROM PRODUCT LABELING. NEXT SLIDE, PLEASE. CHALLENGE PARTICIPANTS COULD
ACCESS THE WIDE AND DIVERSE ARRAY OF PUBLIC DATA SOURCES TO TRY AND REVEAL INTERESTING
PATTERNS AND EVEN SURPRISES. ON THE LEFT SIDE OF THIS SLIDE, WE SEE AN ABBREVIATED
EXAMPLE OF AN ADVERSE EVENT REPORT. THIS REPORT SHOWS A 56-YEAR-OLD MAN TAKING A VARIETY
OF DRUGS AND EXPERIENCING SEVERAL ADVERSE EVENTS THAT LEAD TO HOSPITALIZATION.
PARTICIPANTS MAY COMBINE DATA AVAILABLE FROM PUBLIC SOURCES, SUCH AS DRUG LABELS,
THE FDA SUBSTANCE DATABASE, AND ADVERSE EVENT REPORTS TO DETECT A PATTERN. FOR EXAMPLE,
AN ALGORITHM MAY FIND AN ADVERSE EVENT REPORTED AT AN UNEXPECTED RATE FOR A SPECIFIC
DEMOGRAPHIC GROUP OR ONLY IN COMBINATION WITH ANOTHER PRODUCT OR FOR A CERTAIN TIME OR
ONLY FOR A CERTAIN TIME OF YEAR. IN ADDITION, AN ALGORITHM COULD DETECT POTENTIALLY
ERRONEOUS REPORTING, SUCH AS AN ADVERSE EVENT REPORT SUBMITTED PRIOR TO A PRODUCT'S
APPROVAL. TO ACCOMMODATE THE CHALLENGE'S SUBMISSIONS, WE BROUGHT TOGETHER A
TEAM OF EXPERTS FROM DIVERSE BACKGROUNDS SUCH AS COMPUTER SCIENCE, BIOSTATISTICS,
CHEMISTRY, EPIDEMIOLOGY, MEDICAL SCIENCE, PHARMACOVIGILANCE, AND MICROBIOLOGY. WE WORKED
WITH THE TEAM TO DEVELOP A RUBRIC WITH SCORES BASED ON THE ALGORITHMIC METHODS AND
THE SPECIFIC ANOMALIES DETECTED. METHODS WERE SCORED BASED ON ASSESSMENT OF QUALITY,
USEFULNESS, INNOVATION, AND REUSABILITY. AND EACH OF THE SURVEILLANCE OF THE ANOMALIES
WAS SCORED BASED ON IMPACT, SURPRISE, AND INNOVATION. IMPACT WAS DEFINED AS
APPLICABILITY TO FDA SURVEILLANCE ACTIVITIES OR DATA PROCESSING EFFORTS. SURPRISE ENCODES
WHETHER AN ANOMALY IS STATISTICALLY DISPROPORTIONATE OR UNEXPECTED IN NATURE. INNOVATION
ENCODES THE NOVELTY AND COMPLEXITY OF THE FINDING. TOP SUBMISSIONS WERE FURTHER
ANALYZED BY A TEAM OF MEDICAL OFFICERS, PHARMACISTS, AND PHYSICIANS FROM THE FDA CENTER'S
CREDITED. THIS CHALLENGE WAS UNLIKE OTHER CHALLENGES WE HAVE HOSTED ON PRECISION FDA, AND
BY DESIGN, IT WAS MORE OPEN-ENDED. IT IS PERHAPS NO SURPRISE THEN THAT WE RECEIVED
DIVERSE RESPONSES, AND SUBMITTERS USED DIFFERENT TECHNIQUES FOR DATA ANALYSIS, WHILE
FOCUSING ON A WIDE RANGE OF ANOMALIES. THE HISTOGRAMS TO THE RIGHT SHOW THE DISTRIBUTION
OF SCORES ACCORDING TO EACH CRITERIA FOR THE SUBMITTED ANOMALIES. AS YOU CAN SEE FROM THE
DISTRIBUTIONS ALONE, THE SUBMITTED ANOMALIES TENDED TO HAVE VERY WELL DESCRIBED METHODS,
AS CAN BE SEEN IN THE TOP LEFT GRAY HISTOGRAM, SOMEWHAT LOW ESTIMATED IMPACT, AS CAN BE

SEEN IN THE TOP RIGHT GREEN HISTOGRAM, SOMEWHAT HIGHER SURPRISE, AS IT EVIDENT IN THE
BOTTOM LEFT ORANGE HISTOGRAM, AND A POSITIVELY SKEWED INNOVATION SCORE AS SHOWN IN THE
BOTTOM RIGHT BLUE HISTOGRAM. COMBINING THESE VARIOUS INPUTS, /SW-LSZ INPUT FROM CBER
AND CDER HELPED US TO IDENTIFY TWO TOP PERFORMING SUBMISSIONS BASED ON INNOVATIONS AND
ENERGIES WITH EXISTING PRACTICES. NEXT SLIDE, PLEASE. I AM PLEASED TO ANNOUNCE
THAT THE EVALUATION TEAM IDENTIFIED THE FOLLOWING HIGH PERFORMERS. DR. LEIHONG WU FOR
MOST INNOVATIVE, AND THE COMBINED TALENTS OF KELVIN CHAN AND NICK BECKER FOR MOST
SYNERGISTIC. DR. LEIHONG WU RECEIVED HIS Ph.D. IN PHARMACOLOGY FROM XEIXING UNIVERSITY IN
2013. HIS CURRENT RESEARCH INTERESTS FOCUS ON ARTIFICIAL INTELLIGENCE, PARTICULARLY ON
FACILITATING ITS APPLICATION TO REGULATORY DATA ANALYSIS. KELVIN CHAN STARTED HIS
CAREER IN NEURODEGENERATIVE RESEARCH AT COLUMBIA UNIVERSITY AND LATER CONSULTED FOR
BIOTECHNOLOGY COMPANIES. CURRENTLY, HE BUILDS MODERN HEALTH CARE AND FINANCIAL
TRANSACTION SYSTEMS FOR THE MENTAL HEALTH SECTOR. NICK BECKER HAS A PROFESSIONAL
BACKGROUND IN FINANCE, GOVERNMENT, AND TECHNOLOGY. CURRENTLY, HE IS A SOFTWARE
ENGINEER AND DATA SCIENTIST FOCUSING ON BUILDING GPU ACCELERATED DATA SCIENCE PRODUCTS.
TO ACHIEVE MOST INNOVATIVE, DR. WU TOOK AN UNEXPECTED APPROACH OF DATA ANALYSIS THAT IS
POTENTIALLY VALUABLE TO FDA. HIS APPROACH USED STATISTICAL MEASURES, COMPLEX DATA SOURCES
WITH MULTIPLE VARIABLES, AND DIVERSE LOGICAL FRAMEWORKS TO IDENTIFY ANOMALIES.
CHEN AND BECKER ACHIEVED MOST SYNERGISTIC BY CREATING PROGRAMS THAT AUTOMATED MANUAL
REVIEW PROCESSES. THEY IDENTIFIED DISPROPORTIONAL REPORTING AND AUTOMATICALLY COMPARED
FINDINGS TO PRODUCT LABELING. IN ADDITION, THEIR APPROACH ALLOWED USERS TO SPECIFY
ASPECTS OF THE POPULATION USED FOR THE DISPROPORTIONALITY CALCULATION. BOTH OF
THESE APPROACHES ARE VALUABLE TO THE FDA. NEXT SLIDE, PLEASE. THANK YOU FOR YOUR
INTEREST AND ATTENTION TODAY. PLEASE DO NOT HESITATE TO REACH OUT BY EMAIL AT
PRECISIONFDA@FDA.HHS.GOV. FDA'S PRINCIPAL DEPUTY COMMISSIONER DR. AMY ABERNATHY WILL NOW
CLOSE OUT TODAY'S EXCITING AND INFORMATIVE MEETING.
>>: TERRIFIC. THANK YOU, RAVI. WHEN WE FIRST CONTEMPLATED THIS MEETING, WE PARTNERED
WITH PRECISION FDA TO SEE IF WE COULD PULL OFF A COMPETITION IN TIME FOR THE MEETING,
MEANING WE NEEDED TO WORK FAST AND TOGETHER INSIDE AND OUTSIDE THE FDA. IT'S REALLY

COOL TO SEE YOU PULLED THAT OFF. AS YOU CAN SEE, INNOVATION IN SERVICE OF PUBLIC HEALTH
IS IN OUR DNA. SO TO RECAP, DIGITAL TRANSFORMATION FDA IS TAKING PLACE IN PARALLEL
WITH DIGITAL TRANSFORMATION ALL ACROSS THE INDUSTRIES THAT WE REGULATE. AS WE EMBARK ON
THIS JOURNEY IN MODERNIZING FDA'S DATA STRATEGY, PUBLIC INPUT IS IMPORTANT, INCLUDING FROM
REGULATED INDUSTRIES, CONSUMERS, PATIENTS, AND ALL OUR STAKEHOLDERS -- YOU. THIS IS ABOUT
HOW WE MAKE DATA USEFUL, PUTTING DATA TO WORK. AS YOU KNOW, OVER THE COURSE OF THE
DAY, WE ASKED YOU WHAT YOU THOUGHT THROUGH SOME POLLING QUESTIONS. HERE'S SOME THINGS WE
LEARNED. CONSIDERING YOUR OWN ORGANIZATION, WE ASKED HOW EFFECTIVE IS YOUR ORGANIZATION
AT PUTTING DATA TO GOOD USE? 29% OF YOU ARE STILL TEENAGERS, 22% ADULTS, AND 20% WERE
YOUTH. BUT THEN CONSIDERING THE FDA, HOW EFFECTIVE ARE WE AT PUTTING DATA TO GOOD
USE? THE PATTERN WAS SIMILAR TO YOUR ORGANIZATIONS, BUT I NOTE THAT A FEW OF YOU THOUGHT
THAT YOUR ORGANIZATIONS WERE MORE MATURE THAN WE ARE HERE AT THE FDA. HMM, TELLS YOU
WE HAVE A LOT OF WORK TO DO, AND WE'RE HERE TO MAKE SURE IT GETS DONE. CONSIDERING
YOUR ORGANIZATION, WHAT ARE YOUR BIGGEST CHALLENGES WHEN IT COMES TO EXCHANGING DATA WITH
OTHERS? 25% OF YOU SAID IT'S ABOUT STANDARDS. 20% OWNERSHIP. AND 18% DATA QUALITY.
WHAT CAN THE FDA DO TO ENCOURAGE HEALTH CARE DATA EXCHANGE? 37% OF YOU SAID WE CAN
FACILITATE THE ESTABLISHMENT OF STANDARDS. WE WILL CONTINUE COLLECTING RESULTS OVER THE
NEXT WEEK AND INCORPORATE THAT INTO OUR THINKING, AND YOU HAVE OTHER IDEAS TOO. THE
INSIGHTS COMING TO US THROUGH THE PUBLIC DOCUMENT HAVE BEEN INCREDIBLE, AND WE'RE STILL
ACCEPTING SUBMISSIONS THROUGH THE 30th OF JULY. INFORMATION ABOUT REACHING THE PUBLIC
DOCKET IS ON OUR WEB PAGE, WHERE YOU CAN EMAIL US AT INNOVATION@FDA.HHS.GOV. TODAY'S
MEETING MIRRORED OUR GENERAL ORGANIZING FRAMEWORK FOR OUR MODERN ENTERPRISE DATA
STRATEGY. THREE AREAS -- UNITING DATA, SUCH AS AN EXAMPLE OF DATA SHARING AND AGGREGATION
USING A DATA LAKE PLUS DATA WAREHOUSE STRATEGY FOCUSING FIRST ON OPIOIDS AND PERHAPS
GOING TO BE EXPANDED IN THE FUTURE. IT'S ABOUT IMPROVING DATA, SUCH AS THE EXAMPLE OF
TRANSITIONING FROM UNRULY, UNSTRUCTURED DATA, TO DIGITIZED RAPIDLY ANALYZABLE DATA IN THE
SERVICE OF SAFETY FOR PATIENTS WHO ARE ON I&D STUDIES. AND THEN USING DATA, SUCH AS
EXAMPLES OF USING AI AND PREDICTIVE ANALYTICS TO IMPROVE FOOD PROVISIONS, THE STINKY
FISH. AND THEN EXAMPLES OF WHICH WE HEARD INCLUDE THE FOLLOWING. WE

HEARD ABOUT
STRIVING TOWARDS EFFICIENCY. WE WERE REMINDED TO SOLVE DAY TO DAY
OPERATIONAL PROBLEMS,
TO ACCELERATE REGULATORY TASKS, AND TO HELP EQUIP THE WHOLE ECOSYSTEM WITH
MODERN METHODS
TO IMPROVE PUBLIC HEALTH. WE WERE TOLD WE NEED TO USE DATA FASTER. WE
AGREE. 2020 AND
BEYOND MEANS WE NEED TO USE DATA FASTER. DATA SHARING MUST CONTEMPLATE
AGGREGATION,
LINKAGE, CLEANING, GOVERNANCE, STORAGE, DATA MANAGEMENT, AND PLANNED USE.
WE MUST
ENSURE THAT WE ATTEND TO CYBERSECURITY AND PRIVACY, BUT ATTENTION TO PRIVACY
NEEDS TO BE
BALANCED WITH PUTTING DATA TO WORK FOR IMPROVING HUMAN AND ANIMAL HEALTH.
LOCKING DATA
SETS IN AN IRON BOX IN THE BACKYARD MAKES THEM PRETTY SECURE BUT DOESN'T MAKE
THEM VERY
USEFUL. HMM, DATA QUALITY, DATA QUALITY, DATA QUALITY. I KNOW EVERY DATA
SET HAS WORTH
AND EVERY DATA SET HAS VALUE. WE SHOULDN'T HAVE AN EMOTIONAL REACTION TO
DATA QUALITY BUT
RATHER CONTEMPLATE HOW TO MANAGE OUR WAY THROUGH IT. BE PIONEERS AND THEN
SETTLERS AND
THEN TOWN PLANNERS. PERHAPS WE NEED A WAY TO SYSTEMATICALLY AND
CONSISTENTLY
CHARACTERIZE AND DOCUMENT DATA QUALITY. THIS IS SOMETHING TO BE SOLVED. WE
ALSO NEED TO
LEVERAGE TOOLS AND TECHNIQUES TO IMPROVE DATA QUALITY AND TO DEVELOP NEW
ONES. WE NEED TO
UNDERSTAND WHAT SYSTEMATIC BIAS EXISTS IN OUR DATA SETS AND HOW TO
ACCOMMODATE FOR
IT. WE HAVE TO SOLVE THESE PROBLEMS TOGETHER. AS WE DO OUR WORK AT
FDA, WE NEED TO
REMEMBER THAT WE DON'T EXIST IN A VACUUM. I REFLECT ON MEREDITH CHUK'S
PRESENTATION OF
DIGITIZATION OF THE UNSTRUCTURED IND SAFETY DOCUMENTS OR DON PRATER'S STINKY
FISH. THE
DECISIONS WE MAKE AT THE FDA AND HOW WE USE DATA AND EXPECT TO RECEIVE IT
IMPACTS THE
INDUSTRIES WE REGULATE. MORE ON THIS IN A MINUTE. AND WE HEARD A LOT
ABOUT PEOPLE.
HEALTH IS ABOUT PEOPLE AND ANIMALS. IT IS PEOPLE AND ANIMALS THAT WE SERVE.
WE ARE ALL
PATIENTS AT ONE POINT OR ANOTHER, AND OUR DATA SETS NEED TO REFLECT THE
PEOPLE, THE
PATIENTS THAT WE SERVE, AS WELL AS THEIR VOICES, OUR VOICES. ALSO, WE MUST
ENSURE PEOPLE
CENTERED DESIGN IN OUR WORK, AND USERS NEED TO INFORM THE WORK THAT WE'RE
DOING. I LOVE
THE CONCEPT THAT FDA IS A PEOPLE AGENCY. THANK YOU, DEVEN McGRAW. /*.
CLIFF ASKED
PANEL 2, WHAT DID THE AGENCY GET RIGHT IN 2025? WE HEARD OPERATIONAL DATA,
SYNTHETIC
DATA, COLLABORATION, REUSE OF DATA, COLLECT IT ONCE, INCORPORATE MANY
DIFFERENT DATA
SOURCES IN ORDER TO CONNECT THE PIECE TOGETHER IN THE OVERALL TIME. WE'VE
GOT

A LOT OF TASKS IN THE NEXT FIVE YEARS. PANEL 3 HIGHLIGHTED THAT THE FDA IS SITTING
ON A TREASURE TROVE OF DATA, AND WE NEED TO PLAN FOR HOW WE'RE GOING TO USE IT, INCLUDING
HOW TO LEVERAGE THE RIGHT CAPABILITIES LIKE AI. THERE'S SO MUCH MORE WE LEARNED FROM
TODAY, AND WE ARE LISTENING. AS ANDI CORVOS JUST REMINDED US, THE FDA IS RESPONSIBLE FOR
ENSURING TRUST. WE HAVE TO GET THIS RIGHT. TODAY'S MEETING WILL INFORM OUR DATA
MODERNIZATION STRATEGY. RAM, TEAM, I THINK WE HAVE A LOT OF WORK TO DO. AND AS I
MENTIONED IN OUR OPENING COMMENTS, THIS IS JUST THE BEGINNING. WE RECOGNIZE
THAT THE DECISIONS WE MAKE AT FDA, HOW WE MODERNIZE, WILL HAVE A RIPPLE EFFECT ACROSS THE
INDUSTRIES THAT WE REGULATE. SO WE NEED YOUR INPUT, AND WE NEED TO HAVE MANY
COLLABORATIVE DISCUSSIONS. THERE IS A NEED FOR AN ONGOING DIALOGUE AND PARTNERSHIP ALONG
THE WAY IN ORDER TO STAY IN TOUCH WITH OUR STAKEHOLDERS. WE NEED YOUR IDEAS AND
SUGGESTIONS. WE WILL BE CAREFUL ABOUT THE RIGHT BOUNDARIES OF ENGAGEMENT TO SUPPORT
APPROPRIATE MANAGEMENT OF CONFIDENTIAL INFORMATION, CONFLICTS OF INTEREST, GOVERNMENT
ACQUISITION POLICIES, AND ALL OF THE THINGS TO WHICH WE NEED TO ATTEND, BUT WE ARE NOT
GOING TO FORGET THE COLLABORATION AND PARTNERSHIP IS CRITICAL. THIS IS AN INAUGURAL
DIALOGUE TO BE FOLLOWED BY ADDITIONAL LARGE AND SMALL EVENTS FOCUSED ON SPECIFIC
CAPABILITIES AND NEEDS, ESPECIALLY THOSE THAT GOT SURFACED TODAY. SO PLEASE WATCH THIS
SPACE. SO AS WE END, I WANT TO THANK CLIFF GOODMAN, AWESOME. ALISON HOFFMAN, OUR
THOUGHTFUL PRESENTERS AND PANELISTS, THE FDA INNOVATION LAB, OUR TECHNICAL ORGANIZATION,
AND EVERYONE WHO PARTICIPATED IN MAKING TODAY A REALLY IMPORTANT INAUGURAL MEETING.
A HUGE AND HEARTY THANK YOU TO YOU, AND I AM #PROUD TO BE A PART OF THIS PROCESS AND
EFFORT ALONG WITH YOU. THANK YOU.