þ FDA0428.99 TRANSCRIPT
>>> I'M MARK BARNETT, COMMUNICATIONS DIRECTOR
WITH FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.
AND I'LL BE SERVING AS YOUR MODERATOR TODAY FOR THIS
LIVE INTERACTIVE TELECONFERENCE FOR FDA STAKEHOLDERS.
TODAY'S BROADCAST, WHICH IS A FOLLOW-UP TO THE STAKEHOLDER
MEETINGS WE HAD LAST SUMMER, IS PART OF A LARGER ONGOING EFFORT
TO IMPROVE COMMUNICATION BETWEEN THE AGENCY AND THE PEOPLE
AND GROUPS IT MOST DIRECTLY AFFECTS --
CONSUMERS, PATIENTS, PRACTITIONERS AND MANUFACTURERS.
AS YOU KNOW, THIS BROADCAST IS BEING HELD IN CONJUNCTION
WITH REGIONAL STAKEHOLDER MEETINGS HOSTED BY THE FDA THAT
ARE TAKING PLACE IN EIGHT LOCATIONS ACROSS THE
COUNTRY TODAY.
DEPENDING ON THE TIME ZONE IN THOSE LOCATIONS, THE REGIONAL
MEETINGS MAY TAKE PLACE DIRECTLY BEFORE OR
DIRECTLY AFTER THE BROADCAST.
FDA'S GOAL IN ALL THESE OUTREACH EFFORTS IS A
REGULATORY PROCESS THAT'S MORE TRANSPARENT TO YOU
AND MORE ACCOUNTABLE TO THE PUBLIC.
WE'RE TRYING TO ACCOMPLISH THAT BY FOSTERING A REAL INTERCHANGE
WITH STAKEHOLDERS, IN WHICH THE AGENCY MAKES ITS PRIORITIES
AND ITS EXPECTATIONS CLEAR TO THOSE WHO WILL BE AFFECTED
BY THEM, AND, IN TURN, RECEIVES MEANINGFUL FEEDBACK ABOUT WHETHER
ITS PROGRAMS ARE ON THE RIGHT TRACK.
A LIVE INTERACTIVE TELECONFERENCE LIKE THIS ONE CAN
BE AN EFFECTIVE WAY TO DO THAT, BECAUSE IT ALLOWS
THE FDA FOLKS TO EXPLAIN WHAT THEY'RE DOING
AND WHAT THEY PLAN TO DO.
AND THEN IT ALLOWS STAKEHOLDERS ALL ACROSS THE COUNTRY TO ASK
QUESTIONS AND OFFER COMMENTS.
IN OTHER WORDS, IT ALLOWS REAL INTERACTION TO TAKE PLACE
AND IN REAL TIME.
ONE OF OUR SPECIFIC GOALS FOR TODAY IS TO HELP
STAKEHOLDERS BETTER UNDERSTAND OUR STRATEGIC PLANNING
AND OUR BUDGET, PARTICULARLY, AS THEY RELATE TO THE FDA
MODERNIZATION ACT, OR FDAMA.
LET ME BRIEFLY EXPLAIN THE FORMAT WE'RE
GOING TO USE THIS AFTERNOON.
TO SET THE STAGE FOR THE DISCUSSION, WE'LL FIRST HEAR
FROM DR. JANE HENNEY, THE COMMISSIONER OF FOOD
AND DRUGS.
WE'LL HEAR ABOUT HER PLANS AND PRIORITIES, AND
ABOUT HER VIEWS AS TO WHERE THE AGENCY SHOULD BE GOING
IN THE NEW MILLENNIUM.
THEN WE'LL HEAR FROM DR. LINDA SUYDAM, FDA SENIOR ASSOCIATE
COMMISSIONER, ABOUT THE PROGRESS THE AGENCY'S MADE IN ITS EFFORT
TO IMPLEMENT THE FDA MODERNIZATION ACT.
AT THAT POINT, WE'LL TAKE A 15-MINUTE BREAK, AND THEN
WE'LL BEGIN THE INTERACTIVE PORTION OF THE BROADCAST.
AND DURING THAT SEGMENT, WE'LL BE RESPONDING TO
QUESTIONS AND COMMENTS THAT YOU PHONE OR FAX IN TO US.
NOW, SINCE YOU MAY BE THINKING ABOUT QUESTIONS OR COMMENTS
DURING THE EARLY PART OF THE BROADCAST, LET ME BRIEFLY
EXPLAIN THAT THEY SHOULD BE FOCUSED ON THE FIVE QUESTIONS
POSED TO FDA STAKEHOLDERS IN THE MARCH 22nd FEDERAL
REGISTER NOTICE.

A COPY OF THOSE FIVE QUESTIONS IS AVAILABLE AT THE REGIONAL
MEETINGS.
BUT FOR THOSE WATCHING THE BROADCAST FROM OTHER
LOCATIONS, HERE ARE THOSE QUESTIONS.
NUMBER ONE --
WHAT ACTIONS DO YOU PROPOSE THE FDA TAKE
TO EXPAND ITS CAPABILITY TO INCORPORATE STATE-OF-THE-ART
SCIENCE INTO ITS RISK-BASED DECISION MAKING?
OF COURSE, IMPROVING FDA'S
SCIENCE BASE IS ONE
OF DR. HENNEY'S TOP PRIORITIES.
AND WE'RE GOING TO BE DISCUSSING THIS
ISSUE WITH HER IN JUST A FEW MINUTES.
THE SECOND QUESTION IS --
WHAT ACTIONS DO YOU PROPOSE TO FACILITATE
THE EXCHANGE AND INTEGRATION OF SCIENTIFIC
INFORMATION TO BETTER ENABLE FDA TO MEET ITS
PUBLIC HEALTH RESPONSIBILITIES THROUGHOUT A
PRODUCT'S LIFE CYCLE?
THIS QUESTION GOES BACK
TO PREVIOUS STAKEHOLDER COMMENTS
THAT THE FDA SHOULD CONSIDER
SCIENTIFIC EXCHANGE TO IMPROVE
ACCOUNTABILITY AND TRANSPARENCY.
THE THIRD QUESTION IS --
WHAT ACTIONS DO YOU PROPOSE
OR EDUCATING THE PUBLIC ABOUT THE CONCEPT
OF BALANCING RISKS AGAINST BENEFITS IN PUBLIC
HEALTH DECISION MAKING?
AND THAT ONE GOES BACK
TO AN ANALYSIS OF PREVIOUS
STAKEHOLDER RECOMMENDATIONS THAT
CONSUMERS NEED BETTER
INFORMATION ABOUT THE RISKS
AND BENEFITS OF THE PRODUCTS
THEY USE AND ABOUT HOW
RISK/BENEFIT DECISIONS ARE MADE
BY THE FDA.
THE FOURTH QUESTION IS --
WHAT ACTIONS DO YOU PROPOSE TO ENABLE FDA
TO FOCUS RESOURCES ON AREAS OF GREATEST RISK
TO PUBLIC HEALTH?
AND THIS ONE RELATES TO THE NEED
FOR FDA TO MAKE MAXIMUM USE
OF A LIMITED BUDGET TO GET
ITS CONSUMER PROTECTION JOB DONE.
AND THE FIFTH AND FINAL QUESTION IS --
WHAT ADDITIONAL ACTIONS TO YOU PROPOSE FOR ENHANCING
FEEDBACK OR EVALUATION OF FDA'S MODERNIZATION EFFORTS?
THIS ONE GOES BACK TO PREVIOUS STAKEHOLDER COMMENTS THAT FDA
SHOULD SET UP A SYSTEM TO GET FEEDBACK
FROM STAKEHOLDERS ABOUT ITS PROGRESS
IN MODERNIZING THE AGENCY.
NOW, WE'LL SHOW THESE FIVE QUESTIONS
ON YOUR SCREEN AGAIN DURING THE BREAK.
DURING THE INTERACTIVE SESSION, WE'D ALSO LIKE TO HEAR
FROM YOU ABOUT A COUPLE OF BROADER ISSUES.

FIRST OF ALL --
HOW ARE WE DOING IN IMPLEMENTING FDAMA?
AND SECONDLY --
HOW CAN WE FURTHER ENHANCE OUR EFFORTS TO MODERNIZE
THE AGENCY, AND HOW CAN YOU AS A STAKEHOLDER
HELP IN THAT EFFORT?
WE'LL ALSO GOING TO BE RESPONDING TO QUESTIONS AND
COMMENTS FROM OUR STUDIO AUDIENCE.
THE STUDIO AUDIENCE IS MADE UP OF REPRESENTATIVES
OF BROAD-BASED STAKEHOLDER ORGANIZATIONS FROM PATIENT
AND CONSUMER GROUPS, THE CLINICAL AND ACADEMIC
COMMUNITIES, AND THE REGULATED
INDUSTRIES.
BY THE WAY, THOSE FAX LINES ARE
OPEN RIGHT NOW, AND THEY'RE GOING TO STAY
OPEN ALL THROUGH THE BROADCAST.
SO YOU CAN GO AHEAD AND START FAXING QUESTIONS TO US ANYTIME.
WE'LL ANSWER THEM DURING THE INTERACTIVE SESSION
LATER ON IN THE BROADCAST.
OR YOU CAN CALL A QUESTION IN AND LEAVE
IT WITH US TO BE ANSWERED LATER ON.
THE NUMBERS FOR FAXES AND PHONE CALLS SHOULD BE APPEARING
ON YOUR SCREEN, AND THEY'RE GOING TO REAPPEAR FROM
TIME TO TIME ALL THE WAY THROUGH THE BROADCAST.
IF YOU WANT TO CALL YOUR QUESTION IN AND SPEAK
DIRECTLY WITH THE PANEL --
THAT COMES LATER, AND I'LL TELL YOU WHEN YOU
CAN START MAKING THOSE LIVE CALLS.
WHICHEVER METHOD YOU USE TO GET YOUR QUESTIONS TO US, IF YOU'RE
AT ONE OF THE EIGHT REGIONAL MEETINGS, YOU'LL BE USING
A STANDARD FORM TO WRITE THEM DOWN ON, AND THAT HOLDS TRUE EVEN
IF ITS A PHONED-IN QUESTION.
THAT WAY, IF A QUESTION DOESN'T GET ANSWERED ON THE AIR, WE HAVE
A RECORD OF IT AND WE CAN ANSWER IT LATER ON.
AND NOW LET ME INTRODUCE THE TWO PEOPLE SITTING WITH ME HERE
IN THE STUDIO.
DR. JANE HENNEY IS COMMISSIONER OF THE FOOD AND DRUG
ADMINISTRATION.
SHE BEGAN AS COMMISSIONER IN NOVEMBER.
AND PRIOR TO THAT, SHE WAS VICE PRESIDENT FOR HEALTH
SCIENCES AT THE UNIVERSITY OF NEW MEXICO.
THAT WAS FROM 1994 TO 1998.
DR. HENNEY IS NO STRANGER TO THE FDA.
SHE SERVED AS FDA'S DEPUTY
COMMISSIONER FOR OPERATIONS FROM 1992 TO 1994.
AND SHE'S ALSO NO STRANGER
TO GOVERNMENT SERVICE, HAVING
SERVED AS DEPUTY DIRECTOR
OF THE NATIONAL CANCER INSTITUTE
AT NIH IN THE EARLY 1980s.
DR. HENNEY IS AN ONCOLOGIST,
AND SHE WAS VICE PRESIDENT
FOR HEALTH AFFAIRS
AT THE UNIVERSITY OF KANSAS
MEDICAL SCHOOL FROM
1985 TO 1992.
DR. LINDA SUYDAM IS FDA'S SENIOR

ASSOCIATE COMMISSIONER.
ONE OF HER TASKS IS TO DEVELOP
AND PUT INTO PRACTICE NEW
REGULATORY STRATEGIES FOR FDA.
AND ONE OF HER PRINCIPAL
RESPONSIBILITIES RIGHT NOW IS
TO DEVELOP THE FDA PLAN THAT'S
REQUIRED UNDER SECTION 406-B
OF THE FDA MODERNIZATION ACT.
PRIOR TO HER PRESENT POSITION,
DR. SUYDAM WAS ASSOCIATE VICE
PRESIDENT FOR PLANNING
AND DEVELOPMENT AT THE HEALTH
SCIENCES CENTER AT
THE UNIVERSITY OF NEW MEXICO.
LIKE DR. HENNEY, DR. SUYDAM HAS
A LONG HISTORY OF GOVERNMENT
SERVICE.
PRIOR TO 1995, SHE SPENT
17 YEARS IN THE FDA.
AND BEFORE LEAVING THE AGENCY TO GO
TO NEW MEXICO, SHE WAS FDA'S
INTERIM DEPUTY COMMISSIONER
FOR OPERATIONS.
DR. HENNEY, WELCOME TO YOUR
FIRST TELECONFERENCE.
DID YOU NOTICE THE FLOWERS?
WE HAVE DONE -- I WANT -- THE
PEOPLE WATCHING WHO ARE REGULAR
VIEWERS WILL KNOW THIS.
WE HAVE DONE 50 OF THESE, OVER 50.
THIS IS THE FIRST TIME WE HAVE
HAD A FLORAL ARRANGEMENT.
SO THIS IS FOR YOUR DEBUT.
[LAUGHTER]
WE WERE GOING TO HAVE THE
CAMERAMAN SCATTER THEM ON THE SET.
>> OH.
>> LIKE AT BULL FIGHTS AFTER, BUT THAT
WAS KIND OF DRAMATIC.
I WANT TO START OUT BY TALKING
TO YOU ABOUT SCIENCE AND THE FDA.
ONE OF YOUR TOP PRIORITY, AND
YOU'VE SAID IT OVER AND OVER -- MAYBE IT'S
YOUR NUMBER ONE PRIORITY -- IS STRENGTHENING THE SCIENCE BASE
OF THIS AGENCY.
AND I WANT TO KNOW WHY THAT'S SO IMPORTANT TO
YOU, PARTICULARLY IN VIEW OF THE
FACT THAT THIS IS, AFTER ALL,
PRIMARILY A REGULATORY AGENCY.
IT'S NOT NIH.
THIS IS THIS IS NOT A RESEARCH
ORGANIZATION.
AND YET, SCIENCE, IN YOUR MIND, IS VERY HIGH.
WHY IS THAT?
>> WELL, MARK, I THINK IT'S NOT
JUST MY PRIORITY.

I THINK TO KEEP THE AGENCY
REALLY AT THE TOP OF WHAT IT
SHOULD BE, WHICH IS A
SCIENCE-BASED REGULATORY AGENCY,
WE ALL REALLY NEED TO FOCUS ON
HOW WE CAN BEST DO THAT.
BECAUSE IT SEEMS TO ME, EVERY
DECISION THAT GETS MADE BY THE
AGENCY AND THE STAFF WITHIN THE
AGENCY MUST BE GROUNDED IN
SCIENCE.
AND WHETHER YOU'RE
TALKING ABOUT OUR REVIEWERS WHO
ARE REVIEWING APPLICATIONS AND
DEVICES OR DRUGS OR BIOLOGICS,
THEY NEED TO BE FIRMLY GROUNDED
IN SCIENCE AS THEY MAKE
JUDGMENTS ABOUT APPLICATIONS
THAT ARE COMING IN FROM SOME OF THIS
NATION'S BEST SCIENTISTS.
SO THEY REALLY NEED TO BE AT THE TOP OF
THE GAME SCIENTIFICALLY, STRONG IN TERMS OF THEIR
CURRENCY AND CREDENTIALS IN THE SCIENTIFIC WORLD.
BUT IT GOES FAR BEYOND OUR REVIEWERS.
I THINK OUR INSPECTORS IN THE
FIELD, CLEARLY, AS THEY COME INTO
THE AGENCY HAVE A REQUIREMENT
THAT THEY HAVE A CERTAIN NUMBER
OF SCIENCE BACKGROUND HOURS IN
THEIR COLLEGE EXPERIENCE AND
TRAINING.
BUT WE NEED TO MAKE SURE THAT THEY ARE ALSO CURRENT
AS THEY GO OUT AND INSPECT INDUSTRY AND HAVE TO MAKE
DECISIONS ABOUT COMPLIANCE OR ENFORCEMENT DECISIONS.
AND IT IS TRUE ALSO IN OUR POLICY ARENA.
OUR POLICIES NEED TO BE GROUNDED IN SCIENCE.
SO IT IS FOR ME VERY IMPORTANT THAT ALL ASPECTS OF
THIS AGENCY BE ALL THAT THEY REALLY CAN AND SHOULD BE IN
TERMS OF SCIENTIFIC EXPERTISE, BECAUSE IT IS ONLY THAT THAT
WILL MAKE OUR DECISIONS MEANINGFUL.
I THINK IF OUR DECISIONS ARE
GROUNDED IN GOOD SCIENCE, THEN
OTHER THINGS CAN TRY TO SWAY US, BUT WE'LL
HAVE A FIRM FOOTING ON WHICH WE CAN STAND.
AND SO THAT IS WHY I'M VERY HEAVILY INVESTED
IN THIS ISSUE.
>> YOU TALKED ABOUT REVIEWERS.
THE PRODUCTS THEY REVIEW ARE MORE AND MORE COMPLEX.
THE TECHNOLOGY THAT UNDERLIES THEM IS MORE AND MORE COMPLEX.
ARE YOU CONCERNED THAT AS TIME GOES BY, THERE MAY BE A GAP
DEVELOPING BETWEEN THE KNOWLEDGE
BASE OF THE SPONSOR AND THE
KNOWLEDGE BASE OF THE PEOPLE
THAT REVIEW THE PRODUCT?
>> WELL, I THINK THAT I HAVE
USED THE WORDS "MAINTAIN AND
ENHANCE THE SCIENCE STRENGTH OF

THE AGENCY."
I THINK THAT WE HAVE TO PAY
ATTENTION NOT ONLY AT THE TIME
WE RECRUIT STRONG SCIENTISTS TO
THE AGENCIES, BUT WE NEED TO
MAKE EVERY EFFORT TO MAKE SURE
THAT OUR CURRENCY, IF YOU WILL, OR OUR CREDIBILITY IN SCIENCE IS
STILL STRONG.
WE CAN DO THAT IN A NUMBER OF WAYS, EITHER
THROUGH THE STAFF COLLEGES THAT WE HOLD WITHIN THE
REVIEWING CENTERS IN TERMS OF
THEIR TRAINING AND ONGOING
ASPECTS, CLEARLY, LEVERAGING
WITH THE INSTITUTIONS THAT HAVE
A TREMENDOUS AMOUNT OF INTELLECTUAL CAPITAL, THE OTHER
FEDERAL RESEARCH AGENCIES, NIH, NSF THAT YOU MENTIONED,
CERTAINLY WITH ACADEMIA AND OUR
PARTNERSHIPS THERE THAT WE HAVE
IN TERMS OF BRINGING IN EXPERTS
FOR OUR ADVISORY COMMITTEES, BUT
ALSO EXCHANGES BETWEEN AND AMONG
THE FACULTY AND THE -- OF THOSE
INSTITUTIONS AND OUR OWN STAFF, AND CERTAINLY
THE INTERACTIONS THAT WE CAN HAVE WITH REGULATED
INDUSTRY.
I KNOW WITHIN THE CENTER FOR
DEVICES, THE EXPERIENCE AND
STRENGTH OF HOLDING VENDOR DAYS
HAS BEEN A VERY STRONG ONE FOR
THE AGENCY.
SO I'M REALLY
LOOKING AT A BROAD RANGE OF
OPPORTUNITIES THAT WE CAN HAVE
IN TERMS OF MAKING SURE WE KEEP
OUR SCIENTISTS STRONG.
>> YOU'RE PARTICULARLY INTERESTED IN THE
MOFFETT CENTER IN CHICAGO, TOO, AS AN
EXAMPLE OF WHAT CAN BE DONE.
YOU WANT TO TALK ABOUT THAT A LITTLE?
>> WELL, THE MOFFETT CENTER IS
VERY UNIQUE, AND I HOPE THAT IT
WON'T BE SO UNIQUE IN DAYS AHEAD.
>> NOT ONE OF A KIND.
>> NOT ONE OF A KIND, BECAUSE IT
DOES REALLY REPRESENT A VERY
STRONG PARTNERSHIP IN -- I GUESS
IT'S A THREE-WAY PARTNERSHIP.
BUT IT IS AMONG THE AGENCY
ACADEMIA, THE TECHNOLOGY
INSTITUTE AT ILLINOIS AND
REGULATED INDUSTRY.
WE'RE NOT DEVELOPING ANY
PRODUCTS THERE, AND THAT'S NOT
REALLY WHAT WE'RE LOOKING AT.
BUT WE ARE CONFIRMING PROCESSES
THERE THAT INDUSTRY HAS -- LOOKS AT
DIFFERENT ASPECTS OF MAKING FOOD SAFE.

IT STARTED SOME YEARS AGO.
I THINK IT HAS BEEN A HIGHLY
SUCCESSFUL VENTURE, AND WE'RE
USING IT AS A PROTOTYPE FOR WHAT
WE COULD BE DOING IN OTHER AREAS
AS WELL.
>> ARE YOU LOOKING FOR IDEAS
FROM STAKEHOLDERS ON THIS AS TO HOW WE CAN --
>> OH, ABSOLUTELY.
AS I'VE BEEN GOING OUT TO
OUR DIFFERENT DISTRICT OFFICES, I'VE TRIED TO
TAKE THE OPPORTUNITY TO MEET
WITH STATE OFFICIALS, BOTH
PUBLIC HEALTH AND OUR PARTNERS
FROM THE DEPARTMENTS OF
AGRICULTURE, MEET WITH MEMBERS
OF THE REGULATED INDUSTRY, MEET
WITH PATIENT AND CONSUMER
GROUPS.
I'M TRYING TO TAP THE IDEAS OF
ALL OF THOSE GROUPS IN TERMS OF
MAKING THE AGENCY AS STRONG AS
IT SHOULD BE.
>> FOR SEVERAL YEARS THIS AGENCY
WAS CRITICIZED HEAVILY FOR
PERCEIVED SLOWNESS IN GETTING
NEW PRODUCTS TO MARKET.
>> I THOUGHT WE WERE BEING
DELIBERATIVE, MARK.
[LAUGHTER]
>> DELIBERATIVE, RIGHT, RIGHT.
IT'S ALL IN HOW YOU LOOK AT IT, RIGHT?
>> YEAH.
>> ANYWAY, THAT HAS STILLED NOW BECAUSE
THE AGENCY HAS, IN FACT, TURNED THINGS
AROUND, AND REVIEW TIMES ARE DOWN.
YOU DON'T HEAR A LOT OF THAT CRITICISM NOW.
WHAT YOU HEAR NOW IS SOMETHING ELSE.
AND IT'S EXEMPLIFIED, I'VE GOT A "WALL STREET JOURNAL"
FROM LAST WEEK.
THE HEADLINE SAYS --
"FDA FINDS TRIES TO FIND RIGHT BALANCE ON
DRUG APPROVALS."
AND THEN IT SAYS IN THE SECOND PARAGRAPH --
"THE AGENCY IS CAUGHT IN PINCERS
BETWEEN TWO PRESSURES."
THAT MUST BE VERY PAINFUL.
"DEMANDS TO MOVE FASTER AND
FASTER IN APPROVING DRUGS AND
RISING INSISTENCE TO SHOW MORE
CAUTION."
ARE YOU, INDEED, CONCERNED THAT
THE EXTRA SPEED THAT WE'VE PUT
ON HAS OR COULD RESULT IN
COMPROMISING PUBLIC HEALTH?
>> WELL, LET ME RESPOND TO YOUR
QUESTION IN A NUMBER OF WAYS.

I WOULD BE VERY CONCERNED IF I
DIDN'T THINK THE STANDARD, THE
STRONG STANDARD THAT WE HAVE FOR
APPROVAL, SAFETY AND
EFFECTIVENESS WAS NOT BEING MET.
AND AS LONG AS THAT'S BEING MET,
THE TIMELINESS IN WHICH WE DO IT, I THINK, CAN
ONLY BENEFIT PATIENTS AND CONSUMERS THAT ARE
GOING TO USE OUR PRODUCTS.
SO IF THE STANDARD IS STILL HIGH
AND WE ARE MEETING THAT STANDARD
AS WE MAKE APPROVALS, THE TIME
IS OF CRITICAL IMPORTANCE TO
MANY OF THE POPULATIONS THAT
NEED THESE PRODUCTS.
SO I'M NOT AS CONCERNED ABOUT SPEED.
IN FACT, I THINK YOU ALLUDE TO
DAYS GONE BY WHEN THE AGENCY WAS
HEAVILY CRITICIZED FOR SLOWNESS IN REVIEW, FOR
NOT ONLY BEING DELIBERATIVE, BUT HAVING THE PROCESS TAKE TOO LONG.
I THINK THAT THE EXPERIMENT THAT
THE AGENCY ENGAGED IN WITH THE
INDUSTRY AND CONGRESS IN TERMS
OF THE DESIGN OF THE USER FEE
PROGRAM IN THE AREAS PARTICULARLY OF PRESCRIPTION
DRUGS AND BIOLOGICS WHERE AN
ADEQUATELY RESOURCED AGENCY AND, IN THIS CASE, THE RESOURCES CAME
FROM USER FEES, ALLOWING US TO
HIRE THE KIND -- THE KIND AND
THE NUMBERS OF PEOPLE THAT WE
NEEDED AT THE AGENCY TO APPLY
THEIR SKILLS TO THE REVIEW
PROCESS AND BE HELD TO TIMELY
AND ACCOUNTABLE REVIEWS HAS BEEN
A VERY SUCCESSFUL EXPERIMENT.
AND I THINK THAT WE CAN LOOK
BACK ON THAT WITH GREAT PRIDE, THAT THAT
EXPERIMENT HAS WORKED, THAT THE SAFE AND EFFECTIVE
PRODUCT IS STILL BEING DELIVERED
TO THE MARKET NOW IN A TIMELY WAY.
AND YOU ALLUDE TO MY PAST EXPERIENCE
AS A MEDICAL ONCOLOGIST.
TIME IS OF THE ESSENCE FOR MANY
OF THE PATIENT POPULATIONS WE SERVE.
AND SO WE MUST KEEP IT AS AN ISSUE, BUT WE MUST ALSO KEEP
AS AN ISSUE BEFORE US THE FACT THAT WE ARE CHARGED WITH DOING A
FAIR -- A VERY CAREFUL SAFETY AND EFFICACY REVIEW.
AND THAT'S ALWAYS FINDING THE BALANCE OF RISK AND BENEFIT.
>> EVEN WITH THE BEST PREMARKET
REVIEW SYSTEM WE COULD HAVE,
THERE IS NO WAY THAT WE CAN
GUARANTEE SAFETY, NO WAY THAT WE CAN
GUARANTEE, IN FACT, THAT RARE
ADVERSE EFFECTS UNFORESEEN WILL
NOT OCCUR ONCE A PRODUCT IS ON THE MARKET.
SO THE QUESTION GETS TO BE, DO
WE HAVE A SYSTEM IN PLACE

NATIONWIDE STRONG ENOUGH AND
QUICK ENOUGH TO DETECT THESE
ADVERSE EFFECTS IN A TIMELY
WAY SO WE CAN TAKE CORRECTIVE ACTION?
>> WELL, MARK, I WOULD SAY THAT
AS ONE OF THE REASONS WHY
YESTERDAY WHEN I APPEARED BEFORE
THE APPROPRIATIONS COMMITTEE --
>> THIS IS, INDEED, LIVE TELEVISION.
>> THIS IS, INDEED, LIVE TELEVISION -- THAT I WAS ASKING FOR
MONEY TO ENHANCE WHAT WE DO IN THE
POST-MARKETING ARENA IN
TERMS OF INJURY REPORTING.
WE DO HAVE SOME INJURY REPORTING
SYSTEMS AT THE AGENCY.
ARE THEY AS COMPREHENSIVE AS THEY SHOULD BE?
ARE THEY AS INTEGRATED AS THEY SHOULD BE?
THE ANSWER IS NO.
AND THAT'S WHY WE NEED MORE INVESTMENT IN THAT AREA.
WE WILL ALWAYS HAVE WITH ANY
PRODUCT THAT WE APPROVE FOR
MARKET, AS IT GOES INTO A WIDER
MARKETPLACE AND HAS MORE USE,
EITHER BY THE POPULATIONS IT WAS
TESTED IN OR BY OTHER
POPULATIONS, THE ADVERSE
REACTION BEYOND THAT USUAL AND EXPECTED
SIDE EFFECT.
WE NEED A WAY IN WHICH WE CAN
CAREFULLY MONITOR THOSE ADVERSE
REACTIONS, SO THAT IF THERE IS A
PROBLEM THAT WE NEED TO TELL
THE GREATER PHYSICIAN COMMUNITY,
PATIENT COMMUNITY OR GENERAL
CONSUMER COMMUNITY ABOUT, WE CAN
DO THAT IN TERMS OF ALERTS.
IF WE NEED TO GO BACK AND
REASSESS WHERE WE ARE IN TERMS
OF THE LABELING SO THAT IT'S
COMMUNICATED CLEARLY OR, IN THE WORST OF CIRCUMSTANCE, WE HAVE TO
TAKE A PRODUCT OFF THE MARKET, WE NEED
TO BE RESPONDING TO REAL
TIME AND STRONG DATA.
>> THE LOGISTICS ARE DAUNTING.
IT'S 300,000 ADVERSE EVENT REPORTS PER YEAR NOW.
AND IF PEOPLE ARE ENCOURAGED TO REPORT MORE, THERE WILL BE MORE.
AND SO PART IS A DATA MANAGEMENT THING, AND PART OF IT
IS A SYSTEMS APPROACH, ISN'T IT?
>> IT'S BOTH.
BUT I THINK WHAT WE ARE LOOKING FOR HERE IS
ADVERSE EVENT REPORTING.
NOT SIMPLY ANY EXPECTED SIDE
EFFECT THAT IS ALREADY KNOWN
ABOUT THE PRODUCT.
WE'RE ALSO TRYING TO USE NEW SYSTEMS.
AND I THINK IN THE DEVICE ARENA, WE ARE LOOKING AT
SENTINEL SYSTEMS.

AND WE HOPE TO EXPAND THE NUMBER OF SITES THAT
WE HAVE IN THE DEVICE SENTINEL SYSTEM TO REALLY GIVE US THOSE
STRONG SIGNALS WE CAN ACT UPON.
>> IN THE FDA, THERE IS A NATURAL TENSION
BETWEEN, ON THE ONE HAND, PATIENTS WANTING TO MAKE
THEIR OWN HEALTH CARE DECISIONS, TO USE PRODUCTS AND HAVE PRODUCTS
USED ON THEM OF THEIR CHOICE.
AND ON THE OTHER HAND, THE FDA'S MANDATE TO
PROTECT THEM AGAINST DEVICES OR PRODUCTS OF ANY KIND
THAT DON'T WORK OR THAT AREN'T SAFE.
HOW DO YOU DEAL WITH THAT IN
YOUR OWN MIND?
NOW, YOU TALKED ABOUT YOUR BEING AN
ONCOLOGIST.
I'M SURE THAT WAS A FACTOR WHEN PEOPLE
HAVE LIFE-THREATENING ILLNESSES FOR
WHICH THERE IS NOT AN APPROVED
TREATMENT THAT REALLY WORKS VERY WELL.
HOW DO YOU HANDLE THAT AND HOW
DOES THE AGENCY HANDLE THAT KIND
OF PRESSURE?
>> WELL, THAT IS A REAL
CHALLENGE.
I THINK THAT THE AGENCY
CERTAINLY IS CHARGED WITH THE
MANDATE TO LOOK AT SAFETY AND
EFFICACY FOR ANY PRODUCT IN A
PARTICULAR POPULATION.
WE NEED TO MAKE SURE, AS I SAID
BEFORE, THAT WE ARE DOING THAT
IN A TIMELY WAY, SO THAT THE
BENEFITS CAN BE ENJOYED BY ALL
OF THOSE THAT COULD IN TERMS OF
MOVING THINGS TO MARKET.
AND I THINK FOR THOSE
POPULATIONS, THE CANCER PATIENTS
THAT WE HAVE MENTIONED, BUT
THERE ARE MANY OTHERS THAT
DON'T EVEN HAVE THAT KIND OF
TIME LUXURY, WE'VE TRIED TO OPEN
UP SEVERAL DIFFERENT AVENUES OF
ACCESS TO PRODUCTS EARLY.
>> WHICH WE DIDN'T HAVE A WHILE BACK.
>> THAT'S CORRECT.
THE SORT OF THE COMPASSIONATE USE,
THE HUMANITARIAN DEVICE PROVISIONS, THE PARALLEL TRACK
PROVISIONS THAT I THINK GREATLY EXPANDED THE AVAILABILITY OF
PRODUCTS, PARTICULARLY IN THE AIDS PATIENTS.
ALL OF THESE, I THINK, ARE TRYING TO STRIKE THAT
RIGHT BALANCE IN TERMS OF SAFETY
BUT ACCESS AND MEETING REAL NEEDS.
>> IF I'M A CONSUMER READING A
NEWSPAPER AND WATCHING TELEVISION, I ALMOST HAVE TO
CONCLUDE THAT THE NATION'S FOOD SUPPLY IS
NOT AS SAFE NOW AS IT WAS.
I MEAN, I DON'T REMEMBER READING ABOUT
OUTBREAKS LIKE I'M READING ABOUT

NOW 15 OR 20 YEARS AGO.
SO THE QUESTION GETS TO BE, IS THE
AMERICAN FOOD SUPPLY ACTUALLY
LESS SAFE THAN IT WAS, OR IS THAT AN ILLUSION?
AND IF IT IS, WHY IS THAT SO?
AND WHAT FDA PREPARED TO DO ABOUT IT?
>> OH, MARK, I THINK THE AMERICAN FOOD
SUPPLY BY AND LARGE IS VERY SAFE.
BUT WE ARE AT A PERIOD OF TIME
WHEN MANY THINGS HAVE CHANGED
WITH RESPECT TO OUR FOOD SUPPLY
AND FOOD IN GENERAL.
LET ME CITE A FEW EXAMPLES.
I GREW UP IN A VERY SMALL TOWN
IN INDIANA, PROBABLY THE ONLY
THING YOU DIDN'T MENTION IN MY BIO.
BUT I DO REMEMBER -- AND IT WASN'T
THAT MANY YEARS AGO -- THAT MOST OF
US GOT FOODS FROM EITHER LOCAL
GROWERS OR LOCAL SOURCES.
OUR MOMS USUALLY PREPARED OUR MEALS.
DAD FLIPPED PANCAKES ON SUNDAY, BUT
OUR MEALS WERE PREPARED IN OUR HOME.
WHEN WE ATE OUT AT A RESTAURANT,
I MEAN, IT WAS A REAL TREAT.
AND ABOUT THE ONLY OTHER TIME
WHEN SOMEBODY ELSE PREPARED OUR
FOOD WAS WHEN WE WENT TO
SOMEBODY ELSE'S HOME THAT WE
KNEW OR WE WENT TO A CHURCH
SUPPER OR SOMETHING LIKE THAT.
SO THE FOOD PREPARERS WERE WELL KNOWN TO US.
WHEN WE HAD STRAWBERRIES, IT WAS
FOR TWO WEEKS IN JUNE.
I MEAN, IT WAS THE STRAWBERRY SEASON.
NOW WE GET STRAWBERRIES ALL YEAR LONG.
>> FROM OTHER COUNTRIES.
>> THROUGH MANY COUNTRIES, ALL YEAR LONG.
SO, I MEAN, JUST THINK ABOUT IT.
NOW ACTUALLY ALMOST 90% OF OUR
FOOD SUPPLY IS IN SOME WAY
REGULATED BY THE FDA.
LOTS MORE FRESH FRUITS,
VEGETABLES, BUT ALSO MUCH MORE SEAFOOD.
SO THE COMPOSITION OF OUR FOOD THAT WE EAT IS
DIFFERENT.
WE EAT OUT AS AMERICANS OR HAVE
FOOD PREPARED BY OTHERS MORE THAN 50% OF THE TIME.
WHEN YOU CONSIDER TAKE-OUT FOOD
OR FOOD THAT'S PREPARED BY
SOMEONE ELSE OR GOING OUT TO EAT IN A RESTAURANT.
>> SO THIS IS CONDUCIVE TO MASS
OUTBREAKS AS OPPOSED TO BEING
SICK ALONE IN YOUR HOME?
>> WELL, YES.
[LAUGHTER]
HOME ALONE, YES.

>> YEAH.
>> AND WE HAVE ALL KINDS OF THINGS
NOW AVAILABLE TO US BECAUSE OF
FOOD THAT CAN COME INTO US FROM
ALL OVER THE WORLD.
IT'S TRANSPORTED ALL OVER THIS
COUNTRY AND COMES IN FROM ALL
OVER THE WORLD.
SO THAT CREATES A DIFFERENT SET
OF CHALLENGES, I GUESS, THAN WE
HAD IN THE PAST.
AND WE DO HAVE AN INCREASED
NUMBER OF BACTERIA AND OTHER
MICROBES THAT SEEM TO CAUSE
PROBLEMS FOR US.
WHAT IT HAS CREATED FOR US IS A
CHALLENGE AS AN AGENCY.
BUT IT HAS ALSO CREATED, I THINK, A NEW
ENGAGEMENT BY BOTH ALL OF THE
AGENCIES AT FEDERAL
GOVERNMENT LEVEL THAT ARE
CHARGED WITH THIS WHOLE ISSUE OF
SAFETY OF THE FOOD SUPPLY, BE IT
THE DEPARTMENT OF AGRICULTURE,
BE IT THE CDC OR BE IT THE FDA, TO
ALSO PARTNER WITH THOSE PEOPLE WHO WORK WITH THIS ISSUE
DAY IN AND DAY OUT IN THE STATES, IN THE DEPARTMENTS OF
AGRICULTURE, DEPARTMENTS OF HEALTH IN OUR STATES.
SO WE ARE HAVING TO CREATE A NEW WAY OF
MONITORING THE SAFETY ISSUES
RELATED TO THE FOOD SUPPLY IN OUR COUNTRY.
>> WHAT ABOUT COORDINATING THE
EFFORTS OF THESE VARIOUS AGENCIES YOU'RE TALKING ABOUT SUCH
THAT THEY'RE NOT STEPPING ON EACH OTHER'S TOES AND THAT
THERE ARE NO GAPS?
IS THAT AN IMPORTANT ISSUE?
>> WELL, I CAN SAY FROM MY OWN
EXPERIENCE WHAT OCCURS NOW IN
TERMS OF COORDINATION, COOPERATION AND COMMUNICATION
BETWEEN AND AMONG THE FEDERAL AGENCIES WHO HAVE ADOPTED ONE
FOOD POLICY UNDER A PRESIDENTIAL INITIATIVE AND STRONGER
PARTNERSHIPS WITH THE STATE OFFICIALS THAT DEAL WITH FOOD
ISSUES, IS AT AN ALL-TIME HIGH.
AND IT MAKES FOR THOSE OUTBREAKS THAT DO
HAPPEN EASIER TO TRACK, EASIER TO FOLLOW.
DO WE HAVE A WAYS TO GO IN TERMS
OF GETTING IT BETTER?
PROBABLY, YES.
BUT THIS IS ANOTHER SYSTEM THAT I THINK CAN
ALWAYS BE CONTINUOUSLY IMPROVED.
>> WE'RE TALKING A LOT TODAY
ABOUT RESOURCES.
AND ONE WAY TO DO MORE WITH LESS
RESOURCES IS TO OUTSOURCE, TO
USE SUBCONTRACTORS.
AND WE CALL IT THIRD PARTIES, THAT IS, GETTING PEOPLE OUTSIDE THE
GOVERNMENT TO DO SOME OF THE WORK IN TERMS OF PREMARKET

REVIEW AND IN TERMS OF INSPECTION.
DO YOU VIEW THAT AS A KIND OF
WAVE OF THE FUTURE?
AND IF SO, DO YOU WORRY ABOUT THE IDEA THAT
THIS MAY COMPROMISE THE QUALITY, THE
THOROUGHNESS, THE INTEGRITY OF THE FDA PROGRAM?
>> I DON'T THINK THAT WITH ANY
OF THESE KIND OF INITIATIVES, MARK, THERE IS AN INTENT TO
LOWER THE STANDARD THAT IS EXPECTED BY THE AMERICAN PUBLIC
OF THIS REGULATORY AGENCY.
AND I THINK EVEN IF YOU GO BACK
TO THE MODERNIZATION ACT, WHEN
SOME OF THESE ISSUES WERE REALLY
RAISED, LIKE THIRD-PARTY REVIEW,
IT WAS ALWAYS WITH THE RECOGNITION THAT THE STANDARD
STILL BE THE SAME AND STILL BE HIGH.
COULD THE WORK BE DONE BY OTHERS
LOOKING AT PRODUCTS, PARTICULARLY IN THE DEVICE AREA
THAT PERHAPS DIDN'T POSE AS GREAT A RISK, COULD THEY BE
REVIEWED BY OTHERS?
AND WERE WE ALSO CHARGED WITH MAKING SURE
THAT WE OVERSAW THAT EXPERIMENT TO MAKE
SURE THAT IT WAS WORKING?
THE ANSWER TO THAT IS YES.
IN TERMS OF THE INSPECTIONAL
AREA, WE HAVE, I THINK, HAD
SOME VERY STRONG SUCCESS IN THAT REGARD,
AND THE MAMMOGRAPHY PROGRAM COMES TO MIND.
SO I THINK WE HAVE TO USE THESE KIND OF
OPPORTUNITIES FOR PARTNERING
WISELY AFTER WE SELECT THEM, AND
WE ALWAYS NEED TO MAKE SURE THAT
THE STANDARD BY WHICH WE ARE
USING IS NEVER LOWERED.
>> EVERYBODY INVOLVED WITH
MEDICAL PRODUCTS, WHETHER IT'S
THE PATIENT, WHETHER IT'S THE
PRACTITIONER, WHETHER IT'S THE
MANUFACTURER OR THE AGENCY, IS
CONCERNED THAT PEOPLE WHO ARE
USING THESE PRODUCTS UNDERSTAND BENEFITS AND RISKS.
AND IT GOES TO IN A GENERAL WAY TO PATIENTS
UNDERSTANDING THE FEDERAL GOVERNMENT CAN'T ENSURE ABSOLUTE
SAFETY AND, THEREFORE, YOU DO HAVE TO CONSIDER BENEFITS AND
RISKS IN MAKING DECISIONS.
IN A MORE SPECIFIC WAY, UNDERSTANDING THE BENEFIT AND
THE RISK OF THIS PARTICULAR PRODUCT BEING USED ON YOU AND DECIDING
ACCORDINGLY.
EVERYONE AGREES ON THAT, AND
EVERYONE HAS A ROLE TO PLAY.
WHAT'S FDA'S ROLE, AND HOW DOES
IT TIE IN WITH OTHER STAKEHOLDERS?
>> WELL, THE ISSUE OF SAFETY DOESN'T MEAN "NO RISK."
IT MEANS THAT A RISK AND BENEFIT
HAS BEEN ANALYZED, BALANCED AND
TAKEN INTO ACCOUNT.
SO OFTENTIMES WE TALK ABOUT

SAFETY AND EFFICACY.
AND I THINK IT HAS BECOME SHORTHANDED
TO "SAFE, NO RISK," AND UNFORTUNATELY THAT'S NOT THE CASE.
ALMOST ANY PRODUCT YOU THINK
ABOUT, AT SOME LEVEL, HAS A RISK.
WHAT WE AT THE AGENCY ARE CHARGED TO DOING, AS WE REVIEW NEW
PRODUCTS FOR THE MARKETPLACE, IS LOOKING AT THIS BALANCE, THIS
ANALYSIS OF RISK/BENEFIT FOR A PARTICULAR POPULATION OF
PATIENTS IN WHICH THE PRODUCT HAS BEEN TESTED.
AND FOR THAT POPULATION, IS THE RISK BENEFIT
EQUATION RIGHT TO PERMIT THIS PRODUCT ON THE MARKET?
ONCE A PRODUCT GETS ON THE MARKET, OUR ISSUE IS LESS OF
CONTROL TO THE MARKETPLACE AND IT BECOMES MUCH MORE AN ISSUE OF
INFLUENCING THE REST OF THE SYSTEM.
AND, WHEN YOU THINK ABOUT WHAT A
PHYSICIAN DOES OR A HEALTH
PROVIDER DOES WITH AN INDIVIDUAL
PATIENT EVERY DAY IN A PHYSICIAN/PATIENT ENCOUNTER,
THEY'RE WEIGHING RISKS AND BENEFITS FOR THE INDIVIDUAL PATIENTS.
DOES THIS PRODUCT FOR MY PATIENT -- IS THERE A
STRONG BALANCE OF RISK AND BENEFIT?
AND WHEN YOU THINK ABOUT CONSUMERS WHO ARE USING
OVER-THE-COUNTER PRODUCTS, THEY'RE BALANCING -- THEY'RE
CHARGED WITH BALANCING THEIR OWN RISK AND BENEFITS.
HOPEFULLY, WE AID THEM BY WHAT'S ON THE LABEL SO THAT WHEN THEY
WALK INTO THE DRUGSTORE LATE AT NIGHT OR THE GROCERY STORE AND
THEY'RE LOOKING FOR SOMETHING THAT MIGHT HELP THEM, THEY CAN
LOOK AT, WHAT ARE THE USES FOR THIS PRODUCT?
WILL IT HELP ME?
AND WHAT ARE THE THINGS I MIGHT
HAVE TO LOOK OUT FOR?
SO IN WAYS THEY BECOME THEIR OWN RISK/BENEFIT MANAGER.
ALL THE WAY THROUGH THAT SYSTEM,
WHEN THINGS HAPPEN OUTSIDE OF
THOSE PARAMETERS.
WE NEED STRONG FEEDBACK LOOPS SO THAT WE CAN
CONTINUOUSLY IMPROVE THE QUALITY OF RISK/BENEFIT
MANAGEMENT, THAT EACH ONE IN THAT CONTINUUM CAN
MAKE EITHER FOR THEMSELVES OR FOR A NEW PRODUCT TO THE MARKETPLACE.
>> SEEMS OUT OF ALL THE THINGS YOU'RE
TALKING ABOUT, THIS IS ONE THAT WAS REALLY CONDUCIVE TO A PARTNERSHIP
WITH
OTHER PEOPLE, OTHER STAKEHOLDERS, BETWEEN THE FDA AND OTHERS.
>> OH, IT HAS TO BE.
I MEAN, THIS IS SOMETHING THAT
WE, AS AN AGENCY, CONTROL ONE
PIECE AND INFLUENCE ANOTHER, AND
A PLACE WHERE OUR STAKEHOLDERS
CONTROL ANOTHER PORTION OF THE
SEQUENCE AND INFLUENCE US.
SO THAT BALANCING HAS TO BE RIGHT,
THAT ENGAGEMENT, THE INTEGRATION,
THE INTERACTION HAS TO BE STRONG
OR THE WHOLE SYSTEM DOESN'T
BENEFIT IN THE WAY THAT IT SHOULD.
>> LET ME ASK YOU A MANAGEMENT
QUESTION.

YOU'VE HAD TOP LEADERSHIP
POSITIONS IN GOVERNMENT AND ALSO
IN THE PRIVATE SECTOR.
IN GOING THROUGH THAT AND IN
TERMS OF GETTING AN ORGANIZATION
TO GET THE JOB DONE, IS THERE A
COMMON THREAD THAT RUNS THROUGH
ALL THAT YOU'VE BEEN ABLE TO
KIND OF PICK UP AND APPLY IN
YOUR ROLE AS COMMISSIONER?
>> I WOULD THINK THAT BOTH
IN GOVERNMENT SERVICE AND IN
ACADEMIA, I HAVE BEEN CHARGED
WITH HAVING VERY COMPLEX
ORGANIZATIONS FUNCTION WELL ON
BEHALF OF OTHERS.
AND I THINK IF THERE HAS BEEN -- IF I HAVE
BEEN SUCCESSFUL, AND IF THERE'S BEEN ANY SECRET TO THAT,
IT'S TO TRY TO MAINTAIN ORGANIZATIONAL FOCUS.
I HAVE USUALLY DONE THAT BY ESTABLISHING VERY CLEAR
PRIORITIES FOR AN ORGANIZATION, MAKING SURE THAT THE INTERNAL
PEOPLE WITHIN THE ORGANIZATION KNEW WHAT THOSE PRIORITIES ARE,
AS WELL AS ALL OF THE CONSTITUENCY GROUPS THAT WERE
EITHER SERVED OR SERVED BY OR PARTNERED WITH THE ORGANIZATION.
AT THE FDA, I HAVE ESTABLISHED FIVE.
ONE IS THIS WHOLE ISSUE OF FULL IMPLEMENTATION OF THE FDA
MODERNIZATION ACT.
SECOND, AND IT'S RUNNING VERY
CLOSE TO THE NUMBER ONE, IS THIS
WHOLE ISSUE OF THE SCIENCE BASE
OF THE AGENCY AND MAKING SURE
THAT IT'S MAINTAINED AND ENHANCED.
THE THIRD AND FOURTH CRUCIAL
ISSUES OF SAFETY AND IMPORTANCE,
IT SEEMS TO ME TO THE AMERICAN
PUBLIC, THE SAFETY OF OUR BLOOD
SUPPLY, THE SAFETY OF OUR FOOD
SUPPLY, AND THE FIFTH, THE
TOBACCO ISSUE, AND MAKING SURE
THAT WE'RE DOING OUR PART, ALL
OF OUR PART, IN KEEPING YOUTH
FROM STARTING SMOKING AND
RESTRICTING THEIR ACCESS TO TOBACCO.
THOSE ARE THE THINGS THAT I HAVE
ESTABLISHED AS PRIORITY AREAS FOR THE AGENCY.
WILL WE BE CALLED UPON TO DO
THINGS OUTSIDE THOSE PRIORITY
AREAS THAT ARE OF CRITICAL
IMPORTANCE?
SURE.
I MEAN, WE'RE BOMBARDED ALL THE
TIME WITH IMPORTANT ISSUES.
BUT I THINK THAT WHAT WE SHOULD DO
IF WE TAKE ONE OF THOSE KIND OF
ISSUES ON IS TO DO IT BY DELIBERATION, NOT BY DRIFT, NOT
JUST BY -- DO IT BY INTENT, NOT JUST GOOD INTENTION.
AND IN THAT WAY, WE CAN MAINTAIN OUR ORGANIZATIONAL

FOCUS AND USE OUR LIMITED RESOURCES MORE WISELY.
IT'S GOING TO BE VERY HARD TO DO AT AN AGENCY LIKE THE FDA,
BECAUSE I'VE BEEN HERE BEFORE, I KNOW THE KIND OF PEOPLE THAT WORK HERE.
THEY PRIDE THEMSELVES ON BEING
CAN-DO, CAN DO ANYTHING.
BUT IT'S VERY CLEAR TO ME THAT WE
CAN'T DO EVERYTHING WITH THE
LIMITATIONS WE HAVE ON OUR RESOURCES.
AND THAT'S WHY I'M REALLY
LOOKING TO BUILDING THE BRIDGES
THAT WE NEED TO OUR PARTNERS IN
THE STATES, IN REGULATED INDUSTRY, WITH CONSUMERS, WITH
PATIENTS, AND SO THAT WE CAN BUILD A STRONGER SYSTEM FOR ALL
OF OUR BENEFIT.
>> DR. HENNEY, THANKS FOR THAT INSIGHT.
LINDA, LET'S START TALKING NOW SPECIFICALLY ABOUT FDAMA.
>> OKAY.
>> EVERY PIECE OF LEGISLATION HAS KIND OF AN OVERARCHING THEME,
AN INTENT OF CONGRESS.
IN A GENERAL WAY, WHAT WAS CONGRESS'S INTENT HERE, WHAT DO THEY
WANT FDA TO DO DIFFERENTLY, WHAT WAS THE PROBLEM AS THEY
PERCEIVED DO YOU THINK?
>> WELL, I THINK THE REAL KEY THEME TO
FDAMA FOCUSES ON THAT WORD "MODERNIZATION."
I THINK CONGRESS WANTED US TO
BE -- TO REALIZE WE NEED TO CONTINUALLY BE
CREATIVE AND INNOVATIVE IN HOW WE APPROACH THE WORK THAT WE DO.
BUT MORE SPECIFICALLY, THE LAW GAVE US REALLY THREE DIRECTIONS.
THE FIRST IS THAT WE NEED TO
MAKE SURE THAT WE'RE ENGAGING
OUR STAKEHOLDERS, THAT WE KNOW WHAT PEOPLE WANT
FROM THE AGENCY, THAT WE UNDERSTAND THEIR EXPECTATIONS
AND CAN COMMUNICATE WHY WE'RE DOING SOMETHING.
THE SECOND THING IS THAT I THINK IT CODIFIED A LOT OF THE
RE-ENGINEERING THAT THE AGENCY HAD BEEN DOING FOR REALLY THE
LAST FIVE YEARS.
A LOT OF EFFORT HAD GONE ON IN THE AGENCY TO
MAKE SURE THAT WE WERE STREAMLINED, RE-ENGINEERED,
REALIGNED, AND ALL OF THAT WORK WAS CODIFIED BY THIS LAW.
AND THEN THE THIRD THING WAS
THAT THE FDA HAD TO REALIZE THAT
WE WERE OPERATING WITHIN A GLOBAL ECONOMY.
AND THAT WE HAVE AN OPPORTUNITY FOR THE HIGH STANDARDS FOR
QUALITY AND SAFETY THAT THE AGENCY HAS.
WE HAD A STAND -- WE A HAD AN OPPORTUNITY TO
INFLUENCE THAT WORLDWIDE.
>> YOU TALKED ABOUT THE FACT
THAT THE CONGRESS WANTED US, OR
GAVE US, THE OPPORTUNITY REQUIRED
THAT WE CODIFY THE CHANGES THAT WE HAD BEGUN TO
MAKE WITH RE-ENGINEERING AND SO ON.
WERE THEY ALSO THINKING ABOUT
PREVENTING US FROM BACKSLIDING?
IN OTHER WORDS, YOU CAN SAY, "IF
IT'S IN THE LAW, YOU CAN'T GO
BACK TO OUR OLD WAYS AGAIN"?
IS THAT -- WAS THAT PART OF IT?

>> WELL, YOU KNOW, THAT'S HARD FOR ME TO SAY, MARK.
I'M NOT SURE I CAN GUESS WHAT WAS IN THE
MINDS OF THE PEOPLE AS THEY WERE
PASSING THAT LAW.
BUT I DO THINK THAT IT RATIFIED THE HARD WORK
THAT THE AGENCY HAD ALREADY PUT INTO THINKING CREATIVELY ABOUT
HOW WE DO OUR JOBS.
AND SO I THINK, FROM A PROCESS STANDPOINT, IT IS
PUTTING INTO LAW THE THINGS THAT WE FELT NEEDED TO BE DONE.
>> YOU ALSO MENTIONED THE IDEA THAT THIS GIVES THE FDA THE
OPPORTUNITY TO, IN A SENSE, EXPORT ITS HIGH STANDARDS AROUND THE WORLD.
ANOTHER POSSIBILITY WOULD BE, TOO, THAT THE CONGRESS
HAD IN MIND PERHAPS THAT THEY WANTED TO BE SURE THAT FDA
REGULATIONS DID NOT NEEDLESSLY IMPEDE AMERICAN MANUFACTURERS
FROM COMPETING WORLDWIDE.
IS THAT VALID, DO YOU THINK?
>> WELL, I'M SURE THAT'S AN IMPORTANT
CONSIDERATION.
I THINK THAT WE DO HAVE AN
IMPACT ON A LARGE INDUSTRY.
AND, IN FACT, IT'S IMPORTANT FOR THAT
INDUSTRY TO BE GLOBALLY COMPETITIVE.
BUT I THINK THE REALLY KEY ISSUE
IS THAT KEY CAN EXPORT FDA'S
HIGH STANDARDS THROUGHOUT THE WORLD.
>> THIS IS A VERY SPECIFIC PIECE
OF LEGISLATION.
ONE OF THE THINGS IT REQUIRES IS
THAT WE DEVELOP A PLAN AND THEN
MEASURE PERFORMANCE AGAINST THAT PLAN.
WHAT PROGRESS HAVE WE MADE SO FAR IN THAT AREA?
>> WELL --
>> AND THERE IT IS.
[LAUGHTER]
>> THERE'S THE PLAN.
IN NOVEMBER OF '97 -- OF '98, WE PUT OUT THE FDA PLAN
FOR STATUTORY COMPLIANCE.
AND THIS PLAN DOES A VARIETY OF THINGS.
IT WAS DONE, FIRST OF ALL, AFTER
CONSULTATION WITH OUR STAKEHOLDERS.
WE HELD A SERIES OF MEETINGS
LAST SUMMER, AND WE MET WITH
PEOPLE IN ALL OF OUR PRODUCT AREAS.
AND WE HAD MORE THAN A COUPLE HUNDRED PEOPLE TALKING TO
US ABOUT WHAT THEY EXPECTED FROM FDA.
WE TOOK THAT, WE PUT THAT -- TOOK THAT INTO
CONSIDERATION AND DEVELOPED A
PLAN THAT TALKS VERY CLEARLY
ABOUT THE MISSION STATEMENT, THE
NEW MISSION STATEMENT OF THE
AGENCY TO PROMOTE AND PROTECT
THE PUBLIC HEALTH, THAT DESCRIBES THE CHALLENGES
THAT FDA FACES, THAT THE KIND OF
ENVIRONMENT WE'RE LIVING IN RIGHT NOW.
IT LAYS OUT THE GAP THAT WE
CURRENTLY HAVE BETWEEN WHAT IS
EXPECTED OF US, BOTH IN OUR

STATUTORY REQUIREMENTS AND WHAT
THE PUBLIC EXPECTS IN GENERAL,
AND THE RESOURCES WE HAVE TO
MEET THAT GAP.
AND THEN FINALLY, IT DEVELOPS
SOME STRATEGIC DIRECTIONS FOR
WHAT -- FOR HOW THE AGENCY CAN
MANAGE OUR WORKLOAD AS WE MOVE
INTO THE NEXT CENTURY.
>> SO IT'S KIND OF A BLUEPRINT AS
TO WHAT TO DO IN THE FUTURE?
>> YEAH, I REALLY THINK IT IS.
IT GIVES US A FRAMEWORK FOR HOW WE CAN OPERATE
WITHIN -- AND MEET THE LIMITS OF THE LAW.
>> THAT'S -- DESPITE THE FACT THAT IT'S VERY
BEAUTIFUL, IT IS A WORK IN PROGRESS.
I MEAN --
[LAUGHTER]
>> YEAH.
>> YOU KNOW, IT'S SOMETHING YOU
WILL BE CHANGING, I ASSUME, BASED UPON --
>> YES, AND THAT'S WHY WE'RE HAVING
THESE MEETINGS TODAY.
I THINK WE'VE CONTINUED TO RECEIVE INPUT FROM OUR STAKEHOLDERS.
AND WE ARE EXPECTED TO PRESENT AN ANNUAL
PLAN -- AN ANNUAL REPORT -- TO CONGRESS EVERY YEAR ON HOW WE'RE
MEETING THE PERFORMANCE MEASURES WE'VE ESTABLISHED UNDER THIS PLAN.
>> THE AGENCY HAS MADE A LOT OF
PROGRESS SO FAR IN IMPLEMENTING FDAMA.
AND YOU CAN'T GO THROUGH -- I WOULDN'T WANT YOU TO -- BUT, IN A
GENERAL WAY, WHAT'S HAPPENED?
>> WELL, YOU'RE RIGHT.
WE'VE MADE -- WE'VE DONE A TREMENDOUS NUMBER OF THINGS.
AND THERE'S BEEN AN AMAZING AMOUNT OF EFFORT PUT
INTO EVERY ASPECT OF THIS LAW DUE TO, IN A LARGE PART, ALL THE
HARD WORK THAT THE FDA EMPLOYEES HAVE PUT INTO MEETING THE
REQUIREMENTS OF THIS LAW.
WE MET ALMOST EVERY STATUTORY DEADLINE.
WE'VE PUT OUT 16 FINAL REGULATIONS -- 18 FINAL REGULATIONS, 6 PROPOSED
REGULATIONS, 38 GUIDANCE DOCUMENTS.
THE NUMBERS JUST GO ON AND ON.
BUT WE ALSO HAVE SOME VERY
SPECIFIC THINGS THAT I'D JUST
LIKE TO HIGHLIGHT.
BECAUSE, AS YOU SAID, IF I MENTIONED EVERYTHING, WE'D
BE HERE ALL AFTERNOON.
>> WE'LL DO WORD ASSOCIATION LIKE ON THE
PSYCHIATRIST'S COUCH.
I'LL SAY SOMETHING AND YOU SAY
THE FIRST --
>> OKAY.
[LAUGHTER]
>> THE FIRST THING THAT COMES TO YOUR MIND.
BIOLOGICS.
>> YEAH.
IN THE BIOLOGICS PROGRAM, AS
A RESULT OF THE CONCERNS WE

HEARD FROM A LOT OF PEOPLE, THE
LAW SAYS THAT WE MUST HAVE A
UNIFIED BIOLOGICS APPLICATION.
AND SO WE'VE TAKEN 17 DIFFERENT
FORMS TO MODERNIZE THE BIOLOGICS
PROGRAM.
>> FAST TRACK.
>> THE -- IN THE DRUGS AREA, WE
HAVE TAKEN WHAT WE HAD DEVELOPED
AS AN INITIAL PROGRAM BEFORE
FDAMA AND MOVED INTO A FAST-TRACK PROGRAM THAT WILL GET
DRUGS TO THE MARKET FASTER THAN
THEY HAVE IN THE PAST.
>> THIRD PARTY.
>> IN THE DEVICE AREA, WE'VE
IMPLEMENTED A NEW INITIATIVE AS
DR. HENNEY ALLUDED TO EARLIER
THAT WE HOPE WILL BE A PILOT THAT WE
CAN EXPAND WHERE LESS RISKY DEVICES WILL BE REVIEWED BY
THIRD PARTIES ON THE OUTSIDE.
>> STANDARDS?
>> IN -- ALSO IN DEVICES, WE'VE
TAKEN THE 510-K PROGRAM, THE DEVICE INDUSTRY CAN
NOW REFERENCE 300 STANDARDS THAT ARE ALREADY EXISTING
AS OPPOSED TO COMING IN WITH A WHOLE NEW RANGE OF DATA TO
SUPPORT THEIR PRODUCT APPLICATION.
>> FOOD IRRADIATION.
>> IN THE FOODS AREA, AS
WE ALSO -- AS DR. HENNEY ALSO MENTIONED, WE
HAVE CONCERNS, GREATER CONCERNS ABOUT FOODBORNE PATHOGENS.
AND THE FOOD IRRADIATION REGULATION WAS
FINALIZED SO THAT WE CAN LIMIT SOME OF THOSE PATHOGENS.
>> DISSEMINATING INFORMATION ON UNAPPROVED USES.
>> THAT'S ANOTHER THING THAT --
>> THAT'S A THORNY ONE.
>> YEAH, IT'S BEEN A LITTLE CONTROVERSIAL.
BUT I THINK IT SAYS THAT WE CAN, IN FACT, HAVE
A SYSTEM WHEREBY INFORMATION CAN BE PROVIDED TO
PATIENTS ABOUT OFF-LABEL USES.
>> FDAMA REQUIRES, IN ADDITION TO
HAVING THE REPORT, THAT YOU INTERACT WITH STAKEHOLDERS, THAT
YOU HAVE MEETINGS.
OBVIOUSLY, THE FIRST STEP WAS THE MEETING LAST SUMMER.
THIS TELECONFERENCE IS ANOTHER STEP.
>> MM-HMM.
>> BETWEEN THOSE TWO EVENTS, WHAT'S
HAPPENED IN TERMS OF WORKING WITH STAKEHOLDERS AND GETTING THE
BALL MOVING?
>> MARK, THERE'S A WHOLE SERIES OF THINGS.
AND I THINK I'D LIKE TO JUST HIGHLIGHT A FEW OF THEM.
WE HAVE, IN FACT, IMPROVED HOW INFORMATION IS BEING PROVIDED TO
CONSUMERS.
ONE OF THE THINGS WE HEARD AT
LAST YEAR'S MEETINGS WAS THAT
CONSUMERS WANT INFORMATION
THAT'S BALANCED, THAT THEY CAN
TRUST FROM THE FDA.

AND AS A RESULT, WE HAVE HAD THIS YEAR
TWO LABELING DOCUMENTS THAT HAVE BEEN FINALIZED.
ONE IS OVER-THE-COUNTER LABELING
INFORMATION WHICH IS NOW IN A STANDARDIZED FORMAT.
AND THE OTHER IS A LABELING REQUIREMENT
THAT IS A STANDARDIZED EASY-TO-READ FOR
THE DIETARY SUPPLEMENTS AS WELL.
WE'VE ALSO HAVE PROVIDED MORE ACCESS OPPORTUNITIES FOR
STAKEHOLDERS TO THE FDA.
WE HAVE ELECTRONIC SUBMISSIONS NOW OF NDAs.
WE HAVE ELECTRONIC -- WE HAVE MORE WEBSITES.
WE HAVE ONLINE ACCESS TO -- FOR AGENCY RECORDS.
WE HAVE HAD A ROUNDTABLE IN CEDAR WITH HEALTH PROFESSIONALS.
WE'VE HAD NATIONAL CONSUMER FORUMS AROUND THE COUNTRY.
OUR WOMEN'S HEALTH ORGANIZATION HAS INCREASED AWARENESS OF FDA
BY IMPLEMENTING A VERY COMPREHENSIVE WEBSITE FOR WOMEN.
WE HAVE MORE PATIENT REPRESENTATIVES ON OUR AGENCY
ADVISORY COMMITTEES.
WE'VE ALSO DEVELOPED MORE PARTNERSHIPS WITH SOME OUTSIDE GROUPS.
FOR EXAMPLE, WE'RE WORKING WITH THE STATE HEALTH DEPARTMENTS TO
DEAL WITH INTERSTATE OUTBREAKS OF FOODBORNE ILLNESSES.
WE'VE HAVE COLLABORATED WITH USDA TO HAVE A BETTER -- TO BETTER
INTEGRATE
OUR SAFETY INSPECTIONS IN THE -- WITHIN THE JURISDICTION OF BOTH
AGENCIES.
AND WE HAVE WORKED COOPERATIVELY WITH OTHER PUBLIC
HEALTH SERVICE AGENCIES TO PROVIDE INFORMATION TO HIV/AIDS
TREATMENT ISSUES, PATIENTS, SO THAT THEY HAVE SOME GREATER
INFORMATION.
WE'VE ALSO ESTABLISHED SYSTEMS THAT'LL HELP US CATCH HEALTH
RISKS MORE QUICKLY.
FOR EXAMPLE, PULSENET IS AN INTERAGENCY COMPUTERIZED DNA
FINGERPRINTING PROGRAM WHERE WE CAN NOW REDUCE THE INCIDENCE OF
FOODBORNE DISEASE.
AND THIS WILL MORE RAPIDLY IDENTIFY THE
SOURCES OF CONTAMINATION OF FOOD.
AND THE SEAFOOD HACPP AREA, WE'VE WORKED EXTENSIVELY
TO TRAIN STATE INSPECTORS SO THAT WE CAN HAVE A BETTER COVERAGE OF OUR
SEAFOOD INDUSTRY.
WE'VE ALSO INCREASED OUR EFFICIENCY BY HAVING MRAs
WITH THE EUROPEAN UNION.
AND WE HAVE A DEVICE ACTION PLAN IN THE BIOLOGICS
AREA THAT WILL HARMONIZE OUR REGULATION OF DEVICES.
AND FINALLY, WE'RE DEVELOPING THE CAPABILITY TO
ADDRESS NEEDS FOR SPECIAL CONSUMERS AND PATIENTS.
WE'VE HAD TREATMENT ADVOCACY CONFERENCES.
AND FOR THE FIRST TIME, WE'VE DEVELOPED A BROCHURE
THAT WILL ENCOURAGE PARTICIPATION OF MINORITIES IN
CLINICAL TRIALS.
SO I THINK WE HAVE AN IMPRESSIVE LIST.
>> I THINK IT SOUNDS IMPRESSIVE, TOO.
LET'S TALK ABOUT MONEY NOW FOR A WHILE.
>> OH, ONE OF MY FAVORITE TOPICS.
>> YOUR FAVORITE TOPIC, I KNOW.
IF YOU'RE AN OUTSIDER AND YOU'RE THINKING
ABOUT THE FDA, IT'S CONFUSING.
ON THE ONE HAND, I HAVE A QUOTE HERE'S

FROM AN ARTICLE IN A MAGAZINE CALLED "GOVERNMENT EXECUTIVE."
AND IT SAYS, AND I'M QUOTING, "THE FDA HAS A
PROBLEM THAT EVERY AGENCY WOULD LIKE TO SHARE.
ITS BUDGET IS RISING BY MORE THAN 6% PER YEAR SINCE 1992,
WHICH SOUNDS GOOD.
THEN ON THE OTHER HAND, THEIR
AGENCY PRONOUNCED SOMETHING ABOUT THE FACT THAT, AT LEAST IN
CERTAIN AREAS, THERE IS NOT ENOUGH MONEY
TO GET THE JOB DONE."
SO WHERE, IN FACT, DOES THE TRUTH LIE?
IS THERE OR IS THERE NOT ENOUGH MONEY
ON HAND TO DO FDA'S JOB?
>> WELL, I THINK BOTH OF THOSE THINGS ARE TRUE, MARK.
THE AGENCY'S BUDGET, AS YOU LOOK
AT IT FROM 1992, IT DOES LOOK
LIKE IT'S GOING UP.
BUT WHAT IS HAPPENING IS THOSE -- THAT
INCREASES -- THOSE INCREASES HAVE BEEN TARGETED FOR VERY
SPECIFIC PROGRAMS.
AND SO THE BASE PROGRAMS OF THE FDA HAVE ACTUALLY BEEN
DECREASING.
SO WHAT WE HAVE IS NEW PROGRAMS THAT WE'VE BEEN
GIVEN THE RESPONSIBILITY FOR, AND WE HAVE OUR CORE
RESPONSIBILITIES, WHICH HAVE HAD
THEIR BASE ERODED OVER A PERIOD
OF FIVE YEARS.
>> ARE THERE PLACES IN THAT BASE
PROGRAM WHERE THERE REALLY ISN'T
ENOUGH MONEY TO DO THE BASELINE
JOB THAT'S REQUIRED?
>> WELL, I THINK WE'RE GETTING
TO A POINT WHERE WE HAVE VERY
LIMITED RESOURCES IN MANY OF OUR
PROGRAMS.
I THINK WE'VE BEEN HELPED IN
SOME AREAS BY HAVING THE USER
FEE PROGRAM FOR PRESCRIPTION
DRUGS.
BUT IN OTHER AREAS, IN
ORDER TO MAINTAIN THAT BASE FOR
PRESCRIPTION DRUG USER FEES, WE
HAVEN'T BEEN ABLE TO HAVE SOME
OF THE BASICS.
SO, YOU KNOW, WE
HAVE PLACES WHERE OUR SCIENTIFIC
PERSONNEL HAVEN'T BEEN ABLE TO
GO TO A PROFESSIONAL MEETING FOR
THREE OR FOUR YEARS.
AND WHEN YOU'RE REALLY TRYING TO IMPROVE
AND ENHANCE THE SCIENCE BASE, THAT'S
NOT THE KIND OF THING THAT YOU
WANT TO HAVE HAPPEN.
>> IS THE SOLUTION TO LEARN HOW
TO DO MORE WITH LESS?
>> WELL, YOU KNOW, MORE WITH LESS TO
ME IS A MYTH.
I DON'T THINK YOU CAN DO MORE WITH LESS.

YOU CAN DO THINGS DIFFERENTLY.
AND I THINK THIS AGENCY HAS BEEN
INCREDIBLY INNOVATIVE IN HOW
IT'S LOOKED AT ITS PROCESSES, AND
HOW IT'S MADE PROGRESS OVER TIME
AND HOW IT HAS BEEN DOING OUR
JOB IN A MORE EFFICIENT AND
EFFECTIVE WAY.
WE'VE RECEIVED MORE THAN 50
HAMMER AWARDS THAT ARE BEING
GIVEN OUT TO THE GOVERNMENT FOR
RE-ENGINEERING THE WORKLOAD THAT
WE HAVE.
>> ARE WE ALSO TALKING ABOUT A
CULTURAL SHIFT HERE, I MEAN, THE IDEA OF
LOOKING AT HIGH-RISK, HIGH-IMPACT PRODUCTS AS
OPPOSED TO ROUTINE THINGS FOR
COST INSPECTIONS, MORE AND LESS
ROUTINE?
IS THAT PART OF A SHIFT IN THE
FDA CULTURE?
>> I THINK THAT'S PART OF IT.
I THINK THAT ONE OF THE
STRATEGIC DIRECTIONS IS TO LOOK
AT OUR WORKLOAD IN TERMS OF
RISK-BASED PRIORITIES.
AND CLEARLY THE FDAMA GAVE US THAT
RESPONSIBILITY WHEN IT STARTED
GIVING US SOME OF THE
AUTHORITIES THAT WE HAVE, LIKE,
YOU KNOW, BEING ABLE TO USE
STANDARDS INSTEAD OF -- INSTEAD
OF DEVELOPING YOUR OWN
INFORMATION ABOUT 510-Ks AND
BEING ABLE TO USE THIRD PARTIES.
SO, YES, PART OF THAT IS LOOKING AT RISK
AND THINKING ABOUT CHANGING.
>> AN OBVIOUS PLACE TO LOOK FOR RESOURCES IS
USER FEES.
THEY'VE BEEN SUCCESSFUL WITH PRESCRIPTION DRUGS,
WHAT ABOUT THE POSSIBILITY OF
EXPANDING THAT?
>> WELL, THE 2000 BUDGET, WHICH
IS THE ONE THAT WE WERE TALKING
ABOUT, DR. HENNEY WAS TESTIFYING
ABOUT YESTERDAY, DOES INCLUDE AN
OPPORTUNITY FOR USER FEES INTO
OTHER AREAS.
BUT LET ME SAY A FEW THINGS ABOUT
HOW -- WHY THE PRESCRIPTION DRUG
USER FEE HAS BEEN SO SUCCESSFUL.
IT'S BEEN SUCCESSFUL BECAUSE,
NUMBER ONE, WE'VE HAD INDUSTRY
SUPPORT.
NUMBER TWO, WE'VE DEVELOPED
PERFORMANCE MEASURES AND
PERFORMANCE GOALS.

AND WE'VE SAID
THESE ARE THE THINGS THAT WE'RE GOING
TO DO.
AND THE THIRD THING IS THAT
WE'VE HAD CONGRESSIONAL SUPPORT
AND COOPERATION IN DEVELOPING THAT
PIECE OF LEGISLATION.
SO ALL OF THOSE THINGS ARE
ESSENTIAL TO MAKE -- AND IT
PROVIDED A BASE OF MONEY, MONEY
ON TOP OF A BASE THAT WE ALREADY
HAD.
ALL OF THOSE THINGS ARE
ESSENTIAL TO MAKE ANY USER FEE
PROGRAM WORK.
SO WE'RE HOPEFUL THAT IN THE
AREA OF FOOD CONTACT SUBSTANCES
AND FOOD ADDITIVES IN FOODS,
THAT WE WILL HAVE AN OPPORTUNITY
TO DEVELOP A USER FEE PROGRAM
FOR SOME OF THEIR NEEDS.
AND, ALSO, IN THE AREA OF
MEDICAL DEVICES, WE'VE BEEN VERY
CAREFUL TO LISTEN TO THE
INDUSTRIES INVOLVED AND
UNDERSTAND THEIR CONCERNS.
AND EVEN THOUGH WE KNOW THAT THEY'RE
NOT WIDELY ENTHUSIASTIC ABOUT
THE POSSIBILITY, WE THINK IT IS
A WAY TO GIVE THE AGENCY SOME OF
THE VERY NECESSARY RESOURCES WE
NEED TO REVIEW THOSE PRODUCTS.
>> THERE IS TALK THAT FDA WILL
BE RECEIVING -- GETTING A
SIZABLE INCREASE IN BUDGET FOR
FISCAL YEAR 2000.
IF THAT HAPPENS, HOW FAR WILL
THAT GO TO SOLVING THE PROBLEM?
>> WELL, WE'RE HOPEFUL.
THE PRESIDENTIAL BUDGET THAT
WENT FORWARD REALLY DID GIVE THE
AGENCY ONE OF THE LARGEST
INCREASES IN ITS HISTORY.
AND AS A PERCENTAGE OF BUDGET
WAS CLOSE TO 18% INCREASE.
AND WE'RE HOPEFUL THAT CONGRESS WILL PUT
FORWARD THAT BUDGET WHEN THEY DO
THEIR MARKUP AND SEND IT
FORWARD.
IT STILL DOESN'T MEET ALL OF OUR
NEEDS.
THIS IS AN AGENCY THAT HAS AN
INCREDIBLE BREADTH AND DEPTH OF RESPONSIBILITY.
AND WE HAVE A LOT OF UNMET NEEDS AT THIS
POINT IN TIME.
AND I THINK IT'S THE BEGINNING --
IT'S THE DOWN PAYMENT, IS A NICE WAY TO SAY IT, ON

ALLOWING US TO HAVE THE KIND OF
SCIENTIFIC REGULATORY AGENCY THAT I THINK THE
AMERICAN PEOPLE EXPECT.
>> LINDA, ONE LAST QUESTION BEFORE WE GET
READY FOR A BREAK, AND THAT IS THE USEFULNESS,
OR HOW WE'RE GOING TO USE TODAY'S MEETING.
WE'VE TOLD PEOPLE, OF COURSE, THAT THIS IS IMPORTANT, WE'RE
GOING TO USE IT.
HOW, IN FACT, CAN WE USE WHAT WE LEARN TODAY FROM
STAKEHOLDERS IN FDA'S PROGRAMS?
>> I THINK THAT'S VERY IMPORTANT, MARK.
THERE ARE SO MANY WAYS WE'RE GOING
TO BE USING --
WE'VE ALREADY USED THE INFORMATION THAT WE RECEIVED
LAST YEAR, AND THIS YEAR WE'RE FACTORING THIS
INFORMATION INTO OUR CURRENT BUDGET PROCESS.
IF YOU WERE -- REMEMBER, THE TIMING LAST YEAR WASN'T
RIGHT TO DO OUR BUDGET FOR THIS YEAR, BUT
NOW WE ARE RIGHT AT THE TIME WHEN WE CAN,
IN FACT, INFLUENCE WHAT WILL BE IN OUR
YEAR 2001 BUDGET.
SO THAT'S BUDGET, PLANNING AND THEN FINALLY WE
NEED TO DO OUR ANNUAL REPORT TO CONGRESS, BUT EVEN MORE IMPORTANTLY, IT
ALLOWS US TO LOOK AT OUR PROCESSES AND SEE
IF WE'RE USING THE RIGHT ONES.
>> THANK YOU BOTH FOR A GOOD DISCUSSION.
DON'T GO AWAY.
WE'RE GONNA BE BACK IN A LITTLE BIT.
WE'RE READY NOW TO TAKE A 15-MINUTE BREAK.
DURING THE BREAK, WE'LL BE SHOWING ON YOUR
SCREEN THE FIVE STAKEHOLDER QUESTIONS -- THE ONES WE
TALKED ABOUT -- THAT WE'D LIKE YOUR FEEDBACK ON.
AND ALSO, WE'LL BE GIVING YOU SOME IMPORTANT ADDRESSES AND
OTHER INFORMATION.
WHEN WE COME BACK, WE'LL BEGIN THE
INTERACTIVE PORTION OF THE BROADCAST, IN
WHICH WE'LL BE TAKING QUESTIONS AND COMMENTS FROM YOU,
AS WELL AS FROM OUR STUDIO AUDIENCE.
SO YOU MIGHT WANT TO USE THE BREAK TO
FAX SOME QUESTIONS TO US, OR COMMENTS, OR TO PHONE THEM
IN AND LEAVE THEM HERE TO BE ANSWERED, ALONG WITH THE FAXES.
WE'LL SEE YOU BACK HERE IN 15 MINUTES.
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>>> OKAY, WE'RE BACK LIVE, AND WE'RE READY TO
BEGIN OUR INTERACTIVE SESSION.
WE HAVE SEVERAL SENIOR FDA PEOPLE
IN THE STUDIO THIS AFTERNOON, AND THEY MAY BE
JOINING DRS. HENNEY AND SUYDAM IN RESPONDING TO
QUESTIONS AND COMMENTS.
SO LET ME INTRODUCE THOSE PEOPLE BEFORE WE BEGIN.
DENNIS BAKER IS FDA'S ASSOCIATE COMMISSIONER FOR REGULATORY
AFFAIRS.
JANICE OLIVER IS DEPUTY DIRECTOR OF FDA'S CENTER
FOR FOOD SAFETY AND APPLIED NUTRITION.

LINDA KAHAN IS DEPUTY DIRECTOR FOR REGULATIONS
AND POLICY IN FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.
DR. MURRAY LUMPKIN IS DEPUTY DIRECTOR FOR
REVIEW MANAGEMENT IN FDA'S CENTER FOR DRUG EVALUATION AND RESEARCH.
DR. DAVID FEIGAL IS DEPUTY DIRECTOR FOR MEDICINE IN FDA'S
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.
DR. BERT MITCHELL IS ACTING DEPUTY DIRECTOR IN
FDA'S CENTER FOR VETERINARY MEDICINE.
AND DR. BERN SCHWETZ IS DIRECTOR OF FDA'S NATIONAL CENTER
FOR TOXICOLOGICAL RESEARCH.
BEFORE WE START TAKING QUESTIONS AND COMMENTS,
LET ME EXPLAIN OUR GOALS FOR THIS SESSION.
AS I SAID EARLIER, WE WANT YOUR INPUT AND IDEAS
ON THE FIVE QUESTIONS THAT APPEARED IN THE FEDERAL REGISTER NOTICE,
PLUS YOUR FEEDBACK ON HOW WE'RE DOING WITH FDAMA AND WHAT ELSE
WE MIGHT DO TO MODERNIZE THE AGENCY.
THAT'S THE KIND OF FEEDBACK WE NEED FROM YOU
AS WE PLAN FOR THE FUTURE, AND THOSE ARE THE KINDS
OF QUESTIONS AND COMMENTS THAT ARE MOST
APPROPRIATE AND MOST USEFUL IN THIS BROADCAST.
CONVERSELY, WHAT'S INAPPROPRIATE FOR THIS BROADCAST
ARE QUESTIONS OR COMMENTS ABOUT INDIVIDUAL PRODUCTS OR
COMPANIES, OR ISSUES RELATED TO THOSE PRODUCTS OR COMPANIES.
WE'RE ALWAYS HAPPY TO ANSWER THOSE QUESTIONS USING REGULAR
CHANNELS OF COMMUNICATION, BUT WE CAN'T RESPOND TO THEM
DURING THIS BROADCAST.
I SHOULD MENTION BEFORE WE BEGIN THAT, GIVEN OUR TIME LIMIT,
WE MAY NOT BE ABLE TO GET TO EVERY QUESTION OR COMMENT.
THAT'S A FACT OF LIFE WITH ANY CALL-IN SHOW.
BUT THOSE UNANSWERED QUESTIONS AREN'T GOING
TO SIMPLY EVAPORATE IN THE WIND.
IF YOU HAVE SOMETHING IMPORTANT TO SAY, WE WANT
TO HEAR IT.
WE'LL HAVE A RECORD OF ALL THE QUESTIONS AND
COMMENTS THAT WERE PHONED OR FAXED IN,
INCLUDING THE ONES THAT DIDN'T GET ON THE AIR.
AND IN ADDITION, IF YOU'RE AT ONE OF THE EIGHT LIVE
MEETINGS WE'RE HOSTING ACROSS THE COUNTRY
AND YOU HAVE A QUESTION THAT WE DON'T HAVE TIME FOR ON THE AIR, WRITE
IT ON ONE OF THE STANDARD FORMS WE'RE DISTRIBUTING
AND GIVE IT TO YOUR FDA HOST.
WE'RE GONNA COMPILE ALL THE LEFTOVER QUESTIONS, AND
WE'LL TRY TO RESPOND TO THEM IN A KIND OF THEMATIC WAY ON
OUR WEBSITE IN THE WEEKS TO COME.
THAT INTERNET ADDRESS, BY THE WAY, SHOULD BE APPEARING
ON YOUR SCREEN.
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OKAY, LET ME BEGIN WITH A COMMENT, OR QUESTION
FROM THE STUDIO AUDIENCE.
THE AMERICAN SOCIETY FOR HEALTH SYSTEMS PHARMACISTS HAD TWO
ISSUES THEY WANTED TO RAISE ABOUT INFORMATION TO
PRACTITIONERS AND PATIENTS.
DO WE HAVE SOMEBODY HERE FROM THAT ORGANIZATION?
DO YOU WANT TO IDENTIFY YOURSELF FIRST?
>> YES, THANK YOU.
MY NAME IS BILL ZELMER WITH THE AMERICAN SOCIETY OF HEALTH SYSTEM
PHARMACISTS.

FIRST OF ALL, COMMISSIONER HENNEY, THANK YOU
VERY MUCH FOR HOSTING THIS SESSION TODAY.
IT'S VERY INFORMATIVE.
I'D LIKE TO ASK YOU TO COMMENT A BIT FURTHER, PLEASE,
ON THE ROLE OF THE AGENCY IN SAFETY MANAGEMENT AT
THE PATIENT CARE LEVEL AFTER A PRODUCT HAS BEEN APPROVED FOR MARKETING.
WE CERTAINLY AGREE THAT HEALTH PROFESSIONALS HAVE
THEIR PRIMARY RESPONSIBILITY FOR HELPING
PATIENTS BALANCE RISK AND BENEFIT
INFORMATION, BUT IT DOES SEEM TO US THAT OCCASIONALLY
THERE ARE INSTANCES WHERE IT'S VERY IMPORTANT FOR
THE AGENCY TO HAVE A ROLE AT THE PATIENT CARE LEVEL.
JUST TO GIVE YOU A COUPLE OF EXAMPLES, THERE ARE
INSTANCES WHERE PRODUCTS, AFTER THEY'RE APPROVED, IT'S
DISCOVERED THAT PERHAPS THE NAME OF THE PRODUCT, THE
PACKAGING OF THE PRODUCT, THE DESIGN OF THE
LABELING IS CONTRIBUTING TO MEDICATION ERRORS, PERHAPS
AT THE PRESCRIBING, THE DISPENSING OR THE MEDICATION
ADMINISTRATION LEVEL.
AND WE WOULD HOPE THAT THE AGENCY WOULD BE QUITE ACTIVE IN WORKING WITH
THE MANUFACTURER AND WITH HEALTH PROFESSIONALS IN
RESOLVING THOSE PROBLEMS.
ANOTHER EXAMPLE THAT'S OF GREAT CONCERN TO OUR MEMBERS
DEALS WITH DIRECT-TO-CONSUMER ADVERTISING AND THE FACT
THAT OCCASIONALLY THIS CAN INDUCE OVERWHELMING PATIENT DEMAND FOR A
PRODUCT THAT MAY NOT BE IN
A PARTICULAR PATIENT'S BEST INTERESTS.
AND WE WOULD APPRECIATE YOUR PERSPECTIVES ON
CURRENT THINKING WITHIN THE AGENCY ON THESE ISSUES.
>> LET ME RESPOND TO THE TWO ISSUES AND, PERHAPS,
DR. LUMPKIN WOULD WANT TO ADD TO MY COMMENTS.
I THINK, WITH RESPECT TO THE FIRST ISSUE THAT YOU RAISE IN
TERMS OF THE NEED FOR CONTINUED ACTIVITY BY THE
AGENCY, EVEN AFTER A PRODUCT IS MARKETED, IS WELL TAKEN.
AND I THINK THAT I WOULD STRESS THAT WE
NEED A STRONG FEEDBACK LOOP FROM NOT ONLY
THE HEALTH PROFESSIONALS, BUT CONSUMERS AND PATIENTS
AT LARGE, ABOUT ISSUES THAT COME UP THAT ARE CONFUSING
TO THEM, LIKE THE SIMILAR NAMES OF PRODUCTS AND/OR ADVERSE
REACTIONS, AND I WOULD HOPE THAT WE HAVE
ESTABLISHED STRONG WAYS IN WHICH WE CAN RECEIVE
AND THEN ACT ON THAT INFORMATION.
IN THAT WE MIGHT HAVE TO ENHANCE THAT, I WOULD WELCOME YOUR
SUGGESTIONS, BUT WE HAVE IN THE PAST AND CURRENTLY AND HOPEFULLY
IN THE FUTURE, TRIED TO STRESS THIS STRONG FEEDBACK THAT'S
REALLY NEEDED BY THE AGENCY TO REALLY MAKE SURE
THAT WE ARE CONTINUOUSLY IMPROVING WHAT THE CONSUMER, THE
PATIENT, ACTUALLY TAKES AS IT USES ONE OF THESE PRODUCTS.
I THINK A RECENT EXAMPLE WAS THE ISSUE BROUGHT
TO OUR ATTENTION WHERE A SIMILAR NAME WAS VERY
CONFUSING AND WE HAD TO TAKE THE PRETTY
DRASTIC STEP OF ASKING A COMPANY TO GO BACK AND
RENAME A PRODUCT, SOMETHING THAT WE THINK THAT WE
DO A GOOD JOB OF AS WE REVIEW PRODUCTS THROUGH
THE SYSTEM, BUT THERE ARE FROM TIME TO TIME CASES
WHERE WE HAVE TO MAKE THOSE KIND OF CHANGES.
TO THE ISSUE OF DIRECT-TO-THE-CONSUMER ADVERTISING, I THINK,

LIKE MANY OF THE ISSUES THAT MARK MENTIONED
BEFORE, THERE ARE TWO SIDES OF THAT.
WE CERTAINLY WANT CONSUMERS, PATIENTS, TO BE
WELL-INFORMED IN THIS COUNTRY.
WE WANT TO MAKE SURE THAT THEY HAVE ADEQUATE
INFORMATION AVAILABLE TO THEM, AND I THINK
THAT THERE HAS BEEN AN UPTICK, IF YOU WILL, IN THE
AMOUNT OF DIRECT CONSUMER ADVERTISING.
WHETHER PEOPLE CAN SORT ALL OF THAT INFORMATION
OUT IS, I THINK, ONE ISSUE.
WHETHER THAT CREATES SITUATIONS IN WHICH PATIENTS
OR CONSUMERS WILL GO TO THEIR HEALTH PROFESSIONAL AND
ASK ABOUT A PRODUCT, BUT AT LEAST INITIATE
THE DIALOGUE WITH THE HEALTH PROFESSIONAL SO THAT THEY CAN
SAY THIS IS EITHER RIGHT OR NOT FOR YOU, OR LOOK AT AN ARRAY OF
OTHER APPROACHES TO THE SPECIFIC QUESTIONS A PATIENT HAS.
YOU KNOW, THOSE ARE SOME OF THE PLUSES AND MINUSES
IN ALL THIS.
FOR THE AGENCY, OUR BIGGEST POINT OF CONCERN IS
THAT ANY INFORMATION THAT IS PRESENTED IS BALANCED AND THAT IT'S
NOT MISLEADING.
BUT I DO THINK THAT WE ALL ARE GOING TO HAVE
TO WORK TOGETHER AS WE MAKE SURE THAT WE STRIKE
THAT GOAL OF BALANCE --
NOT MISLEADING, BUT NOT INFORMATION OVERLOAD, AND PRESENT IT IN SUCH A
WAY THAT IT REALLY IS HELPFUL
AT THE END OF THE DAY TO A CONSUMER OR A PATIENT.
AND I DON'T KNOW IF DR. LUMPKIN WOULD WANT TO ADD --
>> BEFORE WE GO ON, LET ME GIVE YOU A BOX SCORE AS TO WHERE WE STAND, IN
TERMS OF TIME AND WORKLOAD HERE.
WE HAVE A FAIRLY LARGE STACK OF FAXES THAT HAVE COME IN ALREADY.
>> I CATCH THE DRIFT, MARK.
[LAUGHTER]
>> HOWEVER, WE DON'T HAVE PHONE CALLS, AND I WANT TO REMIND OUR
STUDIO AUDIENCE, GO AHEAD, MAKE THE CALLS NOW AND SPEAK
LIVE TO OUR PANELISTS.
WE REALLY ENCOURAGE YOU TO DO THAT.
SO WE'RE WAITING TO HEAR FROM YOU.
AND WE WILL GIVE PRIORITY TO LIVE PHONE CALLS.
NOW, DR. LUMPKIN, DID YOU WANT TO ADD BRIEFLY?
>> VERY BRIEFLY, MARK, RIGHT?
[LAUGHTER]
THE ONLY THING I WOULD ADD IS THE FACT THAT WHEN YOU TALK ABOUT
MEDICATION ERRORS, WE WOULD BE THE FIRST TO SAY THAT
WHEN YOU LOOK AT THE WHOLE ISSUE OF MEDICATION ERRORS, THEY CAN
HAPPEN ANYWHERE WITHIN THE HEALTH DELIVERY SYSTEM.
AND I THINK WE RECOGNIZE THIS, THIS IS A SYSTEMS ISSUE,
AND THERE ARE CERTAIN AREAS WITHIN THAT SYSTEM
THAT YOU POINTED OUT THAT ARE AREAS WHERE, INDEED, WE CAN HAVE
A ROLE.
AND WE HAVE CREATED WITHIN OUR POST-MARKETING GROUP
A STAFF WHOSE SOLE RESPONSIBILITY, WHOSE DAY JOB RESPONSIBILITY,
IS TO DEAL WITH THE ISSUE OF MEDICATION ERRORS AND TO TRY
TO SORT OUT THOSE THAT WE CAN HAVE AN IMPACT ON.
AND THE PERSON WHO HEADS THAT IS ALSO OUR PERSON WHO
IS ON SEVERAL DIFFERENT STAKEHOLDER ORGANIZATIONS WHO ARE INTERESTED
IN MEDICATION ERRORS, AND HE IS OUR REPRESENTATIVE TO THAT.

SO I THINK IT'S ONE OF THOSE AREAS WHERE WE REALLY CAN WORK
TOGETHER AND WE'VE GOT A WAY TO DO IT.
>> THANK YOU.
>> LET'S GO TO A FAX.
THIS ONE'S FROM CHICAGO, IT SAYS "WHAT INITIATIVES HAS FDA
TAKEN TO ENCOURAGE THE PARTICIPATION OF MINORITY GROUPS IN
CLINICAL DRUG TRIALS?"
DO YOU WANT TO START ON THAT, OR -- ?
>> MARK, LET ME START WITH THAT.
I THINK THE ISSUE OF INCLUSION IN CLINICAL TRIALS IS A
VERY IMPORTANT ONE.
I THINK THAT IN THE EARLY '90s,
WE WERE FOCUSED AS AN ORGANIZATION, POSSIBLY
EVEN AS A SOCIETY, ON THE ISSUE OF GENDER INCLUSION, AND WE
TOOK SEVERAL ACTIVE STEPS AT THE AGENCIES TO MAKE SURE
THAT THERE WAS STRONG GENDER INCLUSION IN CLINICAL TRIALS.
NOT JUST THINKING ABOUT THE SPECIFIC ISSUES THAT MAY AFFECT
WOMEN DIFFERENTLY AND MEN FOCUSED ON REPRODUCTIVE SYSTEM
IN CHILDBEARING YEARS, BUT ISSUES THAT WERE MUCH BROADER
THAN THAT.
AND I THINK THAT WE HAVE COME A LONG WAY IN TERMS
OF MAKING SURE THAT WOMEN COULD BE INCLUDED IN CLINICAL TRIALS,
THAT THEY COULD MAKE THEIR OWN CHOICES ABOUT INCLUSION.
AND I THINK THAT WE ARE, IN THAT SUBSET ISSUE OF MINORITY POPULATIONS,
STILL HAVING A WAYS TO GO.
CERTAINLY, WE WANT MINORITIES TO BE INCLUDED IN
CLINICAL TRIALS.
WE REALIZE THAT SOME OF THE --
BOTH THE CULTURE AND THE HISTORY OF INCLUSION IN CLINICAL
RESEARCH FOR MINORITIES IS A VERY DIFFICULT ISSUE.
THEIR INCLUSION IN THE PAST IN SOME VERY TRAGIC
EXPERIENCES IN THIS COUNTRY HAS LED THEM TO BE
MORE RELUCTANT TO PARTICIPATE IN CLINICAL RESEARCH AND IN
CLINICAL TRIALS.
BUT INSOFAR AS WE CAN SUPPORT AND CREATE AN ENVIRONMENT
WHERE THEY ARE INCLUDED SO THAT WE CAN MAKE SURE THAT
AS NEW PRODUCTS ARE TESTED, THAT THEY ARE WELL UNDERSTOOD BEFORE
THEY ARE JUST SIMPLY USED IN A POST-MARKET SETTING.
SO I WOULD SAY THAT THE AGENCY'S THRUST IS TO MAKE SURE
THAT WE HAVE STRONG DEMOGRAPHIC REPRESENTATION WITHIN THE
CONTEXT OF CLINICAL TRIALS, RECOGNIZING THAT WE HAVE TO BE
SENSITIVE TO SOME VERY IMPORTANT ISSUES THAT
MINORITY GROUPS HAVE FACED AS THEY HAVE BEEN INCLUDED
PERHAPS -- WELL, NOT JUST PERHAPS -- WITHOUT INFORMED CONSENT AND IN
INAPPROPRIATE WAYS IN THE PAST.
I THINK WE DO HAVE SPECIFIC GUIDANCE AND REGULATION
TO THAT POINT THAT IS ACTIVE WITHIN THE AGENCY, AND IF ANYBODY IS
INTERESTED IN THAT PARTICULAR GUIDANCE, OF COURSE,
WE CAN GET THAT OUT TO THEM.
>> OKAY.
ANOTHER FAX.
THIS ONE SAYS, "SECTION 406-B OF FDAMA REQUIRES THE AGENCY TO
ESTABLISH MECHANISMS BY JULY 1st, 1999 FOR ELIMINATING
BACKLOGS AND FOR MEETING STATUTORY TIME FRAMES FOR SUBMISSIONS.
WHAT'S THE STATUS OF FDA'S IMPLEMENTATION
OF THIS SECTION?"
>> MARK, I THINK THAT'S A VERY IMPORTANT QUESTION,

AND I THINK THE 406-B PLAN WAS THE FIRST STEP TO LOOKING AT
HOW WE ARE GOING TO MEET THE BACKLOGS AND WHAT OPPORTUNITIES
WE HAVE TO, IN FACT, TO INCREASE OUR PERFORMANCE.
SO WHAT WE HAVE DONE IN 1999 BUDGETS, WE'VE ESTABLISHED THE
PERFORMANCE GOALS FOR ALL OF OUR STATUTORY WORKLOAD, AND WE
WILL BE LOOKING AT THOSE PERFORMANCE GOALS IN RELATIONSHIP
TO THE 2000 BUDGET, AND WE WILL BE ISSUING A REPORT THAT SAYS
WHAT OUR PLAN WILL BE IN JULY OF '99.
>> LET'S GO TO A COMMENT OR QUESTION
FROM THE STUDIO AUDIENCE.
THE AMERICAN PHARMACEUTICAL ASSOCIATION HAD
SEVERAL QUESTIONS, BUT I WANT TO CONCENTRATE ON ONE
THAT HAD TO DO -- BECAUSE IT REFERS TO SOMETHING THAT
DR. HENNEY SAID ABOUT COMMUNICATING WITH PATIENTS.
STEPS THE FDA MIGHT TAKE TO WORK WITH HEALTH
PROFESSIONALS IN THAT DIRECTION.
IS THERE SOMEBODY HERE?
IDENTIFY YOURSELF, PLEASE.
>> THANK YOU, I'M LUCINDA MAINE, WITH NPHA,
THE NATIONAL PROFESSIONAL SOCIETY OF PHARMACISTS.
AND OUR QUESTION, REALLY, IT APPEARS THAT THERE IS
DIVERGENT OPINION AMONG STAKEHOLDERS WITH RESPECT TO
THE AGENCY'S DIRECT ROLE IN PROVIDING CONSUMERS INFORMATION.
YES, I'D BE INTERESTED IN HAVING YOU REFLECT ON WHY YOU THINK
THE DIVERGENCE OF OPINION EXISTS, AND WHAT STEPS
THE AGENCY IS ANTICIPATING IN RESOLVING SOME OF THESE OUTSTANDING
ISSUES?
>> COULD YOU BE MORE SPECIFIC IN OUTLINING
THE DIVERGENCE THAT YOU SEE?
>> I THINK THAT THERE IS A DIFFERENCE FROM
THE PERSPECTIVE OF THE ROLES.
I THINK THE CONSUMER IS HUNGRY FOR INFORMATION, CREDIBLE
INFORMATION FROM A VARIETY OF SOURCES, AND I BELIEVE THAT THEY
SEE THE AGENCY AS ONE OF THOSE SOURCES.
ON THE OTHER HAND, HEALTH PROFESSIONALS HAVE
THE ROLE IN THE PROVISION OF INFORMATION, PARTICULARLY ABOUT
THERAPEUTICS TO THEIR PATIENTS, AND I THINK
THAT'S AT LEAST ONE EXAMPLE OF WHERE THE TENSIONS MAY EXIST.
>> WELL, LET ME RESPOND IN THIS WAY.
I THINK THAT CONSUMERS WANT NOT JUST INFORMATION,
BUT THEY WANT INVOLVEMENT.
AND I THINK INSOFAR AS WE CAN PROVIDE CREDIBLE INFORMATION TO
CONSUMERS AND THAT THEY CAN HAVE STRONG INTERACTION
WITH THEIR HEALTH PROFESSIONAL, BE THAT A PHYSICIAN, A NURSE
PRACTITIONER, A PHARMACIST IN TERMS OF HELPING
THEM SORT OUT THAT INFORMATION, HOWEVER CREDIBLE IT MIGHT BE,
AND ITS APPLICABILITY TO THEM, I THINK THAT THAT IS WHERE
YOU HAVE TO STRIKE THAT BALANCE.
THERE IS SO MUCH INFORMATION OUT THERE, WHETHER IT
IS CREDIBLE OR NOT, I THINK IS ONE ISSUE, AND
THEN HAVING THAT SORT-OUT OF CREDIBLE INFORMATION IN
TERMS OF AN INTERACTION WITH SOMEONE AND AN INVOLVEMENT
WITH SOMEONE, I THINK ONLY ENHANCES THE ULTIMATE
DECISIONMAKING BY THE CONSUMER IN TERMS OF
WHETHER THEY ARE GOING TO
USE THE INFORMATION OR NOT.
>> LET'S GO TO ANOTHER FAX.

THIS ONE SAYS "PLEASE COMMENT ON THE CREATION OF A
CVM, ANIMAL HEALTH PRODUCT INFORMATION WEBSITE DATABASE SIMILAR TO THE
CDER CONSUMER DRUG AND INFORMATION SITE FOR HUMAN DRUGS, AND WHAT ELSE
CAN BE DONE TO IMPROVE CONSUMER VETERINARIAN MANUFACTURER
RELATIONSHIPS WITH REGARD TO INFORMING CONSUMERS
ABOUT POSSIBLE ADVERSE SIDE EFFECTS OF MEDICATION."
>> I THINK THAT WE REALLY SHOULD ASK AN EXPERT
FROM CVM TO TALK TO THE AUDIENCE ABOUT THE POSSIBILITIES OF A DATABASE.
I THINK THAT WE HAVE A STRONG WORKING RELATIONSHIP BETWEEN THE
COLLEAGUES IN THE CENTER FOR DRUGS AND THE CENTER FOR
VETERINARY MEDICINE.
SO TAT KEEPING THAT DIALOGUE AND INFORMATION FLOW WITHIN
THE AGENCY IS SOMETHING THAT WE WORK HARD AT EVERY DAY.
BUT MAKING AVAILABLE INFORMATION ON A DATABASE,
LET ME ASK DR. MITCHELL TO PERHAPS ADDRESS THAT.
>> WELL, WE ARE WORKING TOWARD CREATING A WEBSITE, AND AS THE
COMMISSIONER HAS SAID, WE'RE WORKING VERY
CLOSELY WITH THE CENTER OF DRUGS FOR AN INFORMATION DATABASE
THAT WILL PROVIDE MUCH MORE INFORMATION ON
REACTIONS TO ANIMAL DRUGS.
WE ARE DOING THAT TO THE BEST OF OUR RESOURCES, AND
WE'RE QUITE INTERESTED IN PROCEEDING WITH THAT JUST AS FAST AS WE CAN.
>> PERHAPS OUR ONLY LIMITATION IS THAT WE
DON'T HAVE MORE 15-YEAR-OLDS OR 13-YEAR-OLDS OR 8-YEAR-OLDS TO
HELP US ON ALL THIS WEBSITE DEVELOPMENT.
WE'RE ALL FAIRLY ARCHAIC USER HOSTILE TYPES
THAT HAVE TO COME AROUND TO THIS NOTION OF DOING THINGS BY WEB.
>> WELL, HERE'S ANOTHER FAX.
THIS ONE HAS TO DO WITH --
IT SAYS, "THE MEDICAL DEVICE INDUSTRY APPLAUDS
THE INSPECTION EVALUATION THAT THE MEDICAL DEVICE INITIATIVE
GRASSROOTS TASK FORCE IS DOING IN CONJUNCTION WITH
THE UNIVERSITY OF CALIFORNIA AT IRVINE ON COMMUNICATION DURING
THE FDA INSPECTION PROCESS.
IS THE FDA INTERESTED IN WORKING WITH INDUSTRY AND ACADEMIA
TO GET FEEDBACK ON OTHER PROGRAMS, SUCH AS A PRODUCT
REVIEW PROCESS OR OTHER POST-MARKET SURVEILLANCE INITIATIVES?"
ANYONE WANT TO GRAB THAT?
>> WELL, LET ME TAKE A STAB AT IT.
>> SURE.
>> I KNOW THAT CALIFORNIA WAS REALLY INVOLVED
WITH A GRASSROOTS EFFORT, BUT I THINK IT STARTED IN
DENVER, IF I'M NOT MISTAKEN, AND CALIFORNIA CAME ALONG.
BUT THAT NOTWITHSTANDING, I ONLY KNOW THAT BECAUSE ONE OF MY
FIRST DISTRICT OFFICE VISITS WAS TO GO OUT
TO THE DENVER DISTRICT OFFICE AND ACTUALLY
MEET WITH A DEVICE GRASSROOTS GROUP FROM
REGULATED INDUSTRY IN THAT AREA.
AND THEY POINT WITH PRIDE TO THIS AS AN
INITIATIVE WHERE WE DID NOT HAVE A HEALTHY RELATIONSHIP WITH THE
INDUSTRY, PARTICULARLY OVER THIS ISSUE OF INSPECTION,
GETTING REPORTS IN A TIMELY FASHION, UNDERSTANDING,
I THINK, BETWEEN AND AMONG ALL PARTIES ABOUT WHAT
THE PROCESS WAS, WHAT ITS INTENT WAS AND HOW WE MIGHT
MAKE IT MORE CONSTRUCTIVE.
I THINK THAT THEY REALLY LED THE WAY IN TERMS
OF DEVELOPING A RELATIONSHIP OF RESPECT BOTH BY

THE REGULATED INDUSTRY AND BY THE AGENCY
FOR REALLY UPGRADING THIS PARTICULAR PROCESS.
THAT HAS FLOWED THROUGH NOW TO A NATIONWIDE INITIATIVE,
WHETHER WE CAN SPREAD IT TO OTHER AREAS, I THINK, IS
SOMETHING THAT WE VERY MUCH WANT TO DO.
>> OKAY.
ANYONE WANT TO ADD TO THAT?
>> I JUST WANTED TO SAY THAT I THINK THE SHORT
ANSWER TO THAT QUESTION IS, YES, WE'RE VERY INTERESTED IN
PURSUING THESE KIND OF PARTNERSHIPS AND COLLABORATIONS
ACROSS THE BOARD, NOT JUST WITH INSPECTIONS BUT WITH
POST-MARKET SURVEILLANCE.
WE HAVE LOTS OF INITIATIVES TO TRY TO DO THAT
AND LEVERAGE OUR RESOURCES SO THAT WE CAN GET MORE ACCOMPLISHED.
>> LET'S GO TO A STUDIO AUDIENCE QUESTION NOW.
THE HEALTH INDUSTRY MANUFACTURER ASSOCIATION HAD A
QUESTION ABOUT THE EFFECTIVE STRENGTH AND SCIENCE ON
THE FDAMA PROVISION ABOUT LEAST BURDENSOME.

DO WE HAVE SOMEBODY HERE FROM --
YES, CAN YOU IDENTIFY YOURSELF?
>> YES, I'M JANET TRUNSEAU WITH THE HEALTH
INDUSTRY MANUFACTURERS ASSOCIATION AND FDA REVIEW
TIMES HAVE SHOWN SIGNIFICANT IMPROVEMENT OVER THE LAST SEVERAL YEARS.
YET, A MAJOR CONCERN FOR THE MEDICAL DEVICE INDUSTRY IS
THAT PRODUCT DEVELOPMENT TIMES HAVE NOT IMPROVED.
SECTION 205 OF THE MODERNIZATION ACT REQUIRES THE AGENCY TO
CONSIDER THE LEAST BURDENSOME MEANS OF SHOWING DEVICE EFFECTIVENESS.
WE AT HEMA BELIEVE THAT FULL IMPLEMENTATION OF THE LEAST BURDENSOME
PROVISION, WITHOUT LOWERING THE STANDARD FOR
EFFECTIVENESS, WOULD ULTIMATELY HAVE A POSITIVE IMPACT ON
THE PRODUCT DEVELOPMENT TIME.
SO THE QUESTION IS, WHAT EFFECT WOULD THE INCREASED AND ENHANCED
SCIENCE BASE AT THE AGENCY HAVE ON THE IMPLEMENTATION OF THE
LEAST BURDENSOME PROVISION?
>> LET ME TRY IT FOR STARTERS, MARK, AND THEN TURN
IT OVER TO THE REAL EXPERT.
I THINK THAT THE CLINICAL RIGOR WITH WHICH DEVICES
ARE EVALUATED IS A VERY IMPORTANT ISSUE, AND I
THINK THAT THE STANDARD BY WHICH DEVICES ARE EVALUATED
WILL NOT CHANGE, HAS NOT AND WILL NOT CHANGE.
I THINK THAT WE HAVE UNDERTAKEN A NUMBER OF
LOOKS AT THIS WHOLE ISSUE OF WHAT IS THE APPROPRIATE
STUDY TO MATCH THE NEED AT THE TIME.
I THINK PERSONALLY, IF THE TERMS "MOST REASONABLE"
RATHER THAN "LEAST BURDENSOME" WOULD HAVE BEEN
SELECTED, I WOULD HAVE BEEN A MUCH HAPPIER CAMPER, 'CAUSE I
THINK THAT IT STRIKES AT THE HEART OF WHAT WE'RE
TRYING --
WE'RE BOTH TRYING TO GAIN, AND THAT IS TO APPLY THE MOST
REASONABLE STUDY DESIGNED THAT WILL GET A
DEVICE THROUGH THE PROCESS KNOWING THAT ULTIMATELY THE STANDARD
HAS TO BE MET.
BUT I THINK THAT THE STAFF IN THE CENTER HAVE
WORKED VERY HARD AND VERY HARD WITH MANY GROUPS
OVER THIS ISSUE OF HOW DO YOU ACTUALLY GO ABOUT THIS, AND ARE
READY TO ISSUE OR SOON WILL ISSUE GUIDANCE IN THAT REGARD.

>> I JUST WANTED TO ADD THAT I ACTUALLY THINK THAT DR. HENNEY'S
VISION ABOUT SCIENCE ENHANCEMENT FOR THE AGENCY REALLY
COMPLEMENTS AND GOES ALONG VERY WELL WITH WHAT WE'RE CALLING
LEAST BURDENSOME PATHS TO MARKET.
BECAUSE I THINK THAT REVIEWERS AND SCIENTISTS THAT ARE
AT THE TOP OF THEIR FORM, AS DR. HENNEY HAS
SAID, AND WHO ARE WELL-EDUCATED AND HAVE A CHANCE TO DO
CONTINUED EDUCATION AND ARE COMFORTABLE WITH
THE LATEST IN SCIENCE AND TECHNOLOGICAL AND
MEDICAL DEVELOPMENTS ARE THE MOST ABLE TO CALIBRATE
WHAT THEY ASK FOR, WITH THE RISK PRESENTED BY THE PRODUCT IN
FRONT OF THEM.
LESS LIKELY TO SECOND-GUESS AND MOST LIKELY TO
KNOW WHAT THE RIGHT FIT IS BETWEEN WHAT NEEDS TO COME IN
AND WHAT NEEDS TO BE REVIEWED.
>> WELL, LET'S GO TO A FAX.
IT SAYS "DRUG INTERACTIONS AND ADVERSE EFFECTS OF DRUGS CONTINUE TO BE A
MAJOR PROBLEM.
WHAT'S THE FDA'S ROLE NOW, AND ARE THERE NEW INITIATIVES
ON THIS IN THE FUTURE?"
>> WELL, SINCE I'M ALWAYS IN CHARGE OF THE LENGTHY ANSWERS,
THE ANSWER ON THIS ONE WILL BE DR. LUMPKIN.
[LAUGHTER]
>> I THINK THE PERSON WHO FAXED IN BRINGS UP SOME
OBVIOUSLY SOME VERY, VERY PERTINENT ISSUES HERE.
I THINK THE ISSUE OF DRUG/DRUG INTERACTIONS IS PARTICULARLY
IMPORTANT AND GROWING WITH THE NUMEROUS DRUGS THAT
ARE NOW AVAILABLE, AND THE FACT THAT WE HAVE SUCH A
WONDERFUL PIPELINE OF NEW DRUGS COMING DOWN THE PIKE.
WHEN WE'VE GOT A POPULATION THAT'S AGING, WHEN WE'VE
GOT A POPULATION THAT HAS POLYPHARMACY, OBVIOUSLY THE INTERACTIONS
ARE COMING FORWARD.
I THINK OUR BIGGEST CHALLENGE IS TWOFOLD --
ONE, FIGURING OUT THE PROPER WAY TO STUDY THE
DRUG/DRUG INTERACTIONS, AND SECONDLY, TO FIGURE OUT THE
WAY TO COMMUNICATE IT.
AND I THINK THE SECOND ONE IS THE BIGGER CHALLENGE BECAUSE
IT'S SOMETHING WE'RE CONTINUING TO LEARN ABOUT, AND I
THINK WE'RE HAVING TO THINK AS IT WERE OUTSIDE THE BOX
ON WAYS TO COMMUNICATE THIS.
AND THE QUESTION IS, IS LABELING REALLY THE MOST EFFICIENT
WAY TO DO IT?
OR TO GO TO WHAT DR. HENNEY WAS TALKING ABOUT
AND THINKING ABOUT IN TERMS OF WEBSITES AND WAYS OF GETTING
INFORMATION UP QUICKLY, SO THAT PEOPLE KNOW WHERE TO GO TO
FIND THE LATEST INFORMATION ON DRUG/DRUG INTERACTIONS
MIGHT BE THE MORE APPROPRIATE WAY TO COMMUNICATE IT.
>> LET'S GO TO THE STUDIO NOW.
THE COALITION FOR REGULATORY REFORM HAD A QUESTION ABOUT
STAKEHOLDER INPUT ON REGULATORY GUIDANCES.
IS THERE SOMEONE HERE FROM THAT ORGANIZATION?
>> YES, I'M KAY GREGORY, AND I'M FROM THE AMERICAN ASSOCIATION
OF BLOOD BANKS.
THE OTHER MEMBERS OF THE COALITION FOR REGULATORY REFORM ARE
THE AMERICAN BLOOD CENTERS, THE AMERICAN BLOOD RESOURCES
ASSOCIATION AND THE AMERICAN RED CROSS.
AND I'M HERE REPRESENTING ALL OF THEM.

AND WE BELIEVE THAT IT WOULD BE BENEFICIAL FOR THE AGENCY
TO SEEK INPUT FROM INDUSTRY EARLY ON IN THE DEVELOPMENT,
PARTICULARLY OF GUIDANCES AND REGULATIONS.
WE APPRECIATE THE FACT THAT WE CAN COMMENT AFTER YOU'VE
PUBLISHED THEM, BUT WE THINK WE COULD ADD MAYBE EVEN TO THE
SCIENCE AND THE RISK MANAGEMENT DECISIONS IF WE COULD BE INVOLVED
A LITTLE BIT EARLIER IN THE PROCESS.
AND WE'VE HAD LIMITED SUCCESS IN DOING THAT, BUT WE WONDER
WHETHER YOU'RE OPEN TO THIS KIND OF EARLY INTERACTION DURING
DEVELOPMENTAL PHASES AND IF SO, HOW CAN CMRR BEST WORK
PARTICULARLY WITH CBER?
>> LET ME START IT OUT AND ASK DR. FEIGAL TO FOLLOW.
I THINK IF I HAVE HEARD ANYTHING THAT LEADS TO SUCCESS IN
TERMS OF DEALING WITH A REGULATORY AGENCY, AND MOST PERSONALLY,
THE FDA, IT'S THREE LITTLE WORDS -- "EARLY AND OFTEN."
TALKING, INTERACTING, SEEING THAT COMMUNICATION IS CLEAR AND
WHETHER THAT'S A COMPANY COMING IN WITH AN IDEA WAY BEFORE
THEY HAVE EVERY IDEA WORKED OUT IN TERMS OF THEIR STUDY, THAT
EARLY AND OFTEN COMMUNICATION IS VERY IMPORTANT TO SUCCESS.
WITH RESPECT TO POLICY OR REGULATION DEVELOPMENT, WE HAVE
NUMEROUS FORUMS, I THINK, WHERE WE DO OUR PRELIMINARY
THINKING, PERHAPS, AND THEY AREN'T TITLED THAT WAY.
AND PERHAPS WE COULD DO SOME OF OUR OWN THINKING ABOUT
HOW WE COULD IMPROVE THAT.
I THINK THE REALITIES ARE, AS YOU POINT OUT, ONCE WE GO
INTO THE MODE OF REGULATORY WRITING, ONCE THAT PROCESS
IS ENGAGED, THAT'S NOT THE TIME FOR LOTS OF BACK AND
FORTH, BUT IN THE FRONT END OF DOING SOME OF OUR BRAINSTORMING
AND THEN THE MORE FORMAL PROCESS, ONCE A PROPOSED REG COMES
OUT, THE BACK AND FORTH COMMUNICATION THAT YOU'RE USED TO
SHOULD GO ON.
BUT PERHAPS WE NEED TO MAKE THIS FRONT-END PROCESS MORE TRANSPARENT,
MORE IDENTIFIABLE FOR YOU, SO THAT YOU'LL KNOW WHEN WE'RE TRYING
TO PICK YOUR BRAINS OR NOT.
[LAUGHTER]
BUT MAYBE DAVID COULD RESPOND A LITTLE BIT MORE TO THAT.
>> WELL, I'D LIKE TO THANK YOU FOR THE QUESTION.
IT'S A VERY GOOD ONE.
IT'S MADE COMPLICATED BY THE FACT THERE'S MANY DIFFERENT WAYS
THAT REGULATIONS COME INTO BEING.
AND THEY'RE USUALLY BASED ON EVOLUTION OF THE SCIENCE OR IDENTIFICATION
OF A NEW THREAT TO THE BLOOD SUPPLY.
AND THE WAY WE SEEK INITIAL INPUT IS OFTEN TO PRESENT PRELIMINARY
FINDINGS AND ASK FOR COMMENTS AT PUBLIC ADVISORY COMMITTEES
OR AT WORKSHOPS OR BRING UP THE ISSUE LIAISON MEETINGS THAT
WE HAVE WITH INDUSTRY GROUPS.
THERE HAVE BEEN TIMES, IN FACT, WHEN INDUSTRY GROUPS HAVE
BROUGHT, FOR US, PROPOSALS OF NEW GUIDANCES, NEW VOLUNTARY
STEPS THAT THEY WOULD LIKE TO TAKE TO CHANGE, AND WE'VE PRESENTED
THINGS THAT WE HAVEN'T BEEN THE FIRST AUTHOR OF TO OUR ADVISORY
COMMITTEE TO GET SUGGESTIONS ON THOSE.
SO WE DO VERY MUCH WELCOME THE -- WELCOME THE INPUT.
I THINK IT'S ALSO VERY IMPORTANT, GIVEN THE WAY THAT THE ADMINISTRATIVE
PROCEDURES ACT TELLS US HOW TO WRITE REGULATIONS, THAT WHEN WE HAVE
THE COMMENT PERIODS, EITHER ON ADVANCE NOTICE OF PROPOSED RULEMAKING
OR PROPOSED RULES, THAT WE GET THE COMMENTS BECAUSE IT'S -- WE
OFTEN WILL RECOGNIZE WHEN WE'RE WRITING A NEW REGULATION THAT

THERE ARE OPTIONS, OR THAT A SUGGESTION'S BEEN MADE THAT HAS PROBLEMS.
AND WE'RE PUBLISHING IT SPECIFICALLY TO GET THE COMMENTS, GET
THE FEEDBACK, AND IT HELPS US DECIDE IN THOSE CLOSE CASES WHICH
DIRECTION TO GO.
SO WE VERY MUCH VALUE THE INPUT, AND WE APPRECIATE THE FACT
THAT SUCH A BROAD GROUP OF ORGANIZATIONS HAS FORMED TOGETHER TO
MAKE OUR TASK A LITTLE BIT EASIER.
>> THANK YOU.
I'M ABOUT TO GO TO ANOTHER FAX.
BUT I WANT TO REMIND OUR AUDIENCE AGAIN, PLEASE CALL US.
WE'RE LONESOME HERE, WAITING TO HEAR FROM YOU.
[LAUGHTER]
THE FIRST CALLER WILL GET A PBS TOTE BAG AND A --
[LAUGHTER]
CD OF THE THREE TENORS.
[LAUGHTER]
OKAY.
>> THEY'RE ALL CALLING INTO THEIR RADIO TALK SHOW THAT
RUN AROUND NOONTIME.
>> THAT'S RIGHT.
THIS FAX SAYS, "WHILE FUNDS WERE AVAILABLE, CVM PROVIDED
INTERN -- EXTERNSHIPS TO ITS STAFF.
THESE WERE GREATLY APPRECIATED BY BOTH CVM AND BY THE INDUSTRY.
I ENCOURAGE THE FDA TO BUILD UPON THIS MODEST BEGINNING WITH
ONE OR TWO-WEEK DURATION EXTERNSHIPS.
THAT IS A COMMENT, NOT A QUESTION.
DOES SOMEONE WANT TO RESPOND TO THAT -- FROM CVM?
>> WELL, I WOULD COMMENT THAT WE ARE INTERESTED IN THAT PROGRAM.
IN FACT, WE HAVE SUCH GOING ON TO A LIMITED EXTENT AT THIS TIME.
AND IF THERE'S A WAY OF US CONNECTING SPECIFICALLY WITH THAT -- THE
SOURCE OF THAT COMMENT, WE'D BE GLAD TO DEAL WITH IT.
>> MM-HMM.
>> OKAY.
HERE'S ANOTHER FAX THAT SAYS, "WHAT IDEAS DOES THE AGENCY HAVE
FOR THE DISSEMINATION OF UNBIASED, UNDERSTANDABLE INFORMATION ON
THE RISK AND BENEFITS OF PRESCRIPTION DRUGS TO CONSUMERS?"
THAT'S A THEME WE HEARD BEFORE, BUT THIS IS A SPECIFIC QUESTION.
>> MATT, DO YOU WANT TO --
>> WELL, I THINK THERE ARE TWO DIFFERENT ELEMENTS TO THAT.
ONE IS CLEARLY THE GIVING OF INFORMATION TO CONSUMERS FOR PRODUCTS
WHICH THEY ARE SELECTING THEMSELVES, AND I WOULD SAY THAT THE NEW
OTC LABELING IS PROBABLY THE MOST VISIBLE INITIATIVE THAT WE HAVE
TO TRY TO MAKE THAT INFORMATION CLEARER AND MORE EASILY OBTAINABLE
AND MORE EASILY UNDERSTOOD.
THE SECOND ONE IS THE ISSUE OF TRYING TO GET CONSUMER-FRIENDLY
INFORMATION AND UNBIASED INFORMATION ON PRESCRIPTION DRUG PRODUCTS.
AND I THINK DR. HENNEY TALKED A LITTLE BIT ABOUT THAT.
AS EVERYONE KNOWS, WE HAVE -- WE'RE IN THE MIDDLE OF AN INITIATIVE
TO SEE WHAT ELEMENTS CAN OCCUR AS FAR AS PRIVATE SECTOR IS
CONCERNED ON THAT, AND WE WILL BE EVALUATING THE PRIVATE SECTOR
EFFORTS HERE OVER THE NEXT SEVERAL YEARS.
WE'VE ALSO JUST PUBLISHED A FINAL RULE ON CERTAIN KINDS OF
MED GUIDES THAT WE WOULD BE REQUIRING IN SOME VERY SPECIFIC SITUATIONS,
SO I THINK WE'RE LOOKING AT AS THREE DIFFERENT THINGS AT THIS POINT
IN TIME THAT I'VE JUST MENTIONED.
AND THOSE WOULD BE THE THREE SPECIFIC THINGS I WOULD PUT OUT
ON THE TABLE.

>> MARK, IF YOU DON'T MIND IF I COULD TIE A COUPLE OF QUESTIONS OR RESPONSES TOGETHER, IT'S -- YOU RAISE THE ISSUE OF THE OTC LABEL. ACTUALLY, A GOOD THRUST FOR THAT INITIATIVE REALLY CAME FROM THE STAKEHOLDER GROUP OF THE NDMA, NOW CHPA, THE CONSUMER HEALTH PRODUCTS ASSOCIATION, RAISING CONCERNS ABOUT THE UNIFORMITY OF THE LABEL, MAKING SURE THAT CONSUMERS COULD UNDERSTAND WHAT WAS ON THE LABEL, LOOKING FOR CLEARER LANGUAGE THAT COULD BE USED.
I THINK THAT THE AGENCY HAS ACTED UPON THAT IN AN APPROPRIATE WAY.
BUT IT SHOWS THE KIND OF, I THINK, INTERACTION THAT WE SEE AS BOTH HEALTHY BUT ULTIMATELY BENEFICIAL FOR CONSUMERS.
AND SO I THINK THAT TYING THE LAST TWO QUESTIONS TOGETHER IS A WAY THAT WE ACTED VERY MUCH ON SOMETHING THAT WAS BROUGHT FORWARD BY THE STAKEHOLDER GROUP.
>> HERE'S ANOTHER FAX THAT SAYS, "WE REALLY APPRECIATE THE NEW WARNING LETTER PROGRAM.
DO YOU PLAN TO PUT THE POST-INSPECTION LETTERS ON THE WEB?"
>> IS THAT DEVICES?
[LAUGHTER]
>> WELL, THIS ONE IS FROM C.R. BARD, IN FACT.
>> MM-HMM.
LET ME CLARIFY.
FOR PEOPLE WHO MAY NOT KNOW WHAT WE'RE TALKING ABOUT, WE HAVE A WARNING LETTER PILOT IN WHICH DEVICE INSPECTORS WHO FINISH AN INSPECTION ARE -- AND HAVE CHARGES THAT MAY RESULT IN A WARNING LETTER GIVE THE FIRM AN OPPORTUNITY TO RESPOND, AND IF CORRECTIONS ARE MADE WITHIN 15 DAYS -- OR SOMETHING LIKE THAT, I'LL CHECK WITH LILLIAN OVER THERE -- THEN WE WON'T BE ISSUING THE WARNING LETTER.
AS FAR AS PUTTING THOSE RESPONSES, I DON'T KNOW WHETHER THE CALLER IS ASKING ABOUT THE AGENCY'S RESPONSE OR THE FIRM'S RESPONSE.
BUT I DON'T THINK OUR PLAN IS TO PUT ANY OF THAT INFORMATION ON THE WEB.
THE PURPOSE OF THIS IS REALLY TO MAKE THE INSPECTION AS MUCH OF A LEARNING EXPERIENCE AND AN EFFECTIVE CHANGE FOR THE FIRM, RATHER THAN TO PUBLICIZE ANY KIND OF WEAKNESSES.
>> THANKS.
LET'S GO TO THE STUDIO AUDIENCE.
THE CONSUMER HEALTH CARE PRODUCTS ASSOCIATION HAD A QUESTION ON THE MECHANISM FOR ENSURING PRODUCTIVE MEETINGS BETWEEN THE FDA AND STAKEHOLDERS.
>> YES, I'M BILL ZOELLER WITH THE CONSUMER HEALTH CARE PRODUCTS ASSOCIATION, AND I DON'T KNOW WHETHER THIS IS ALSO OPEN TO OUR OTHER QUESTIONS THAT WE ASKED AS WELL.
THAT PARTICULAR POINT RELATED TO AN INTERACTION THAT WE HAD WITH CDER, PARTICULARLY MAC LUMPKIN, AND AGAIN, THANKS FOR THOSE VERY PRODUCTIVE INTERACTIONS WHEN WE WORKED OUT THE MEETINGS MAP 4512.1.
OUR POINT THERE, AS ONE OF OUR -- PART OF OUR WRITTEN COMMENTS, RELATED TO THINKING ABOUT HOW DIFFERENT AGENCIES HAVE INTERACTED WITH STAKEHOLDERS AND USING THOSE GOOD PRACTICES AND APPLYING THEM OVER INTO ANOTHER CENTER SUCH AS CISSAM.
AND WE WOULD THINK THAT PERHAPS HAVING A SIMILAR TYPE OF MEETINGS MAP WITH EXTERNAL CONSTITUENCIES MIGHT BE WORTHWHILE.
I'M WONDERING WHETHER YOU ENTERTAINED OUR OTHER QUESTIONS AS WELL.
>> WELL, WE TRY TO PICK THE ONES THAT WERE, IN FACT, ADDRESSING THE FIVE ISSUES, AND SO THAT'S WHY WE PICKED THAT ONE BECAUSE IT WAS, IN FACT, PERTINENT.
DOES SOMEONE WANT TO RESPOND TO THAT NOW?
YES?

>> YES, I'D LIKE TO RESPOND.
I'VE TALKED TO MAC ABOUT THE PROCEDURES THEY HAVE IN DRUGS.
AND THEY HAVE A SPECIFIC PROCEDURE SET UP FOR INTERACTIVE MEETINGS.
AND WE'RE GOING TO GET TOGETHER SO I CAN FIND OUT A LITTLE BIT MORE
ABOUT HOW DRUGS OPERATE IN THE INTERACTIVE MEETINGS TO SEE IF IT
MIGHT BE A PROCEDURE WE MIGHT BE ABLE TO USE BETTER IN THE CENTER,
BECAUSE WE'RE ALWAYS LOOKING FOR BETTER WAYS TO INTERACT WITH
THE INDUSTRY.
AND THAT MIGHT BE A HELPFUL WAY.
>> THAT SOUNDS GREAT.
>> THANK YOU.
>> THIS IS A FAX ABOUT THE POSSIBILITY OF GETTING POST-MARKET
SURVEILLANCE INFORMATION FROM THE PUBLIC.
IT SAYS, "DOES THE FDA HAVE ANY SPECIFIC PLANS TO ENHANCE
POST-MARKETING SURVEILLANCE?
IN PARTICULAR, I'M INTERESTED IN EFFORTS TO ENHANCE TIMELY AND
WIDESPREAD REPORTING FROM THE PUBLIC AT LARGE."
APPARENTLY SIMILAR TO THE MED WATCH FOR PROFESSIONALS.
ANY THOUGHTS ON THAT?
>> MATT, COULD YOU RESPOND?
>> WELL, I THINK AS FAR AS MED WATCH, OUR MESSAGE OUT THERE IS NOT
ONLY TO HEALTH CARE PRACTITIONERS, BUT CLEARLY TO CONSUMERS.
AND WE GET A FAIR NUMBER OF OUR REPORTS FROM CONSUMERS.
AND I THINK PARTICULARLY WHEN YOU'RE LOOKING AT PRODUCTS SUCH
AS OVER-THE-COUNTER PRODUCTS, CONSUMERS ARE GOING TO BE OUR
MAJOR SOURCE OF INFORMATION.
CLEARLY, CONSUMERS, I THINK, BRING A PARTICULAR PERSPECTIVE ON
HOW THEY PERCEIVE WHAT HAS HAPPENED TO THEM WITH THE DRUG.
AND OBVIOUSLY THE BEST OF ALL WORLDS IS WHEN WE HAVE A GIVEN
SUSPECTED ADVERSE EVENT THAT WE HAVE BOTH THE CONSUMER PERSPECTIVE AND
THE HEALTH CARE PROFESSIONAL PERSPECTIVE IF THERE WAS A HEALTH CARE
PROFESSIONAL INVOLVED IN THAT CASE, BECAUSE WE GET DIFFERENT KINDS
OF INFORMATION THAT HELP US UNDERSTAND IT BETTER.
I WOULD HOPE THAT CONSUMERS OUT THERE AND THE PERSON WHO SENT THIS
PARTICULAR FAX WOULD BE AWARE OF, AND MAYBE THAT IS ONE OF THE MESSAGES
TO US -- WE NEED TO MAKE IT MORE AWARE THAT, THAT INDEED, UNDER MED WATCH
WE ARE INTERESTED IN GETTING CONSUMER REPORTS, AND THEY SHOULD USE
THOSE FACILITIES JUST AS OTHER REPORTERS DO.
>> HERE'S ANOTHER ONE RELATED TO CONSUMERS.
IT SAYS, "WHAT RESOURCES ARE AVAILABLE FOR THE FDA TO WORK
WITH LOCAL HIGH SCHOOLS ON EDUCATIONAL PARTNERSHIPS?"
>> WELL, WE DO HAVE RELATIONSHIPS WITH SEVERAL LOCAL HIGH SCHOOLS.
AT LEAST WE USED TO AND JANET HAS HER HANDS UP, SO SHE CAN --
>> WE'VE HAD RELATIONSHIPS WITH LOCAL HIGH SCHOOLS IN THE D.C. AREA AND
SOME OF THE DISTRICTS DO IN A NUMBER OF AREAS IN SCIENCE AND CHEMISTRY
AND VARIOUS AREAS LIKE THAT.
BUT IN THE FOOD SAFETY INITIATIVE, THE FIGHT-BACK PROGRAM, WHICH IS
A PUBLIC/PRIVATE PARTNERSHIP WITH INDUSTRY, WITH THE STATES, WITH USDA,
FDA CONSUMERS HAS ONE ELEMENT IN IT THAT WE'RE TRYING TO GET MORE
INFORMATION ON FOOD SAFETY TO THE HIGH SCHOOLS, AND WE HAVE SOME RESEARCH
THAT'S BEEN DONE OVER THE PAST YEAR, AND PROGRAMS ARE GOING OUT FROM
FIGHT-BACK THROUGH THE HIGH SCHOOLS AND SCHOOLS THIS COMING YEAR.
>> I SHOULD MENTION THAT WAS FROM A HIGH SCHOOL, IN FACT.
[LAUGHTER]
>> GREAT.
>> THERE ARE A COUPLE OF OTHER THINGS WE DO.
AND HAVING JUST SIGNED A NUMBER OF CERTIFICATES TO HIGH SCHOOL STUDENTS

WHO PARTICIPATE IN SCIENCE FAIRS.
I AM WELL AWARE THAT WE BOTH HAVE, FROM TIME TO TIME, HIGH SCHOOL STUDENTS WORKING IN OUR LABS, NOT ONLY HERE IN HEADQUARTERS IN WASHINGTON, BUT FROM TIME TO TIME IN SOME OF OUR DISTRICT OFFICES AS WELL.
>> HERE'S A FAX THAT SAYS, "FDA IS LOOKING AT STRONGER INTEGRATION OF FOOD SAFETY PROGRAMS FROM THE FEDERAL, STATE AND LOCAL JURISDICTIONS IN ORDER TO LEVERAGE ALL AVAILABLE RESOURCES TO MAXIMIZE EFFECTIVENESS. WHERE ARE WE WITH RESPECT TO BRINGING ALL STAKEHOLDERS, FOR EXAMPLE INDUSTRY CONSUMER AND ACADEMIA, INTO THE DISCUSSION?"
>> JANICE, DO YOU WANT TO TAKE A SHOT AT THIS?
WE CLEARLY WILL BE DOING THIS IN A -- AN EVEN MORE VISIBLE WAY THIS YEAR AS THE FEDERAL AGENCIES ARE CHARGED WITH DEVELOPING THEIR STRATEGIC PLANNING PROCESS, AND IT CLEARLY WILL INVOLVE A LOT OF INTERACTIONS WITH ALL OF THE STAKEHOLDERS.
BUT, JANICE, PERHAPS YOU COULD RESPOND.
>> SURE.
ONE OF THE FIRST THINGS WE DID IS, IN LOOKING AT OUR INTERACTIONS WITH THE STATE AND LOOKING AT HOW CAN WE BETTER PROVIDE FOOD SAFETY THROUGHOUT THE COUNTRY, WHEN STATES AND LOCAL AGENCIES AND ALL THE FEDERAL AGENCIES ALL HAVE A PIECE OF THE PIE AND CONSIDERABLE RESOURCES INTO IT IS TO GET TOGETHER WITH REPRESENTATIVES OF THE STATE AND LOCAL AGENCIES TO TRY AND SEE WHAT PROGRAMS THEY HAVE, WHAT THE NEEDS WERE, AND TO DEVELOP PARTICULAR WORKING GROUPS IN THAT AREA.
WE STARTED WITH THE STATES AND LOCALS TO SEE THEIR INTEREST BECAUSE THEY WERE THE ONES WE WANTED TO WORK WITH AND TO SEE WHAT THE NEEDS WERE.
WE'VE DONE SOME OUTREACH.
WE HAVE NOT DONE ENOUGH OUTREACH YET TO CONSUMER GROUPS AND TO INDUSTRY, AND THAT IS OUR NEXT STEP BEFORE WE PROCEED ON.
OUR -- THE MOST OF WHAT WE'VE DONE -- OUR HIGHLIGHT HAS BEEN IN THE OUTBREAK RESPONSE AREA.
AND THAT STARTED INITIALLY WITH THE FOOD SAFETY INITIATIVE AND WE DID START AT THAT LAST YEAR.
AND SO THIS YEAR, WE WERE LOOKING AT, ARE THERE OTHER AREAS AS WE MOVE DOWN THE ROAD?
BUT INDEED, AS DR. HENNEY SAID, WE'LL BE DOING A LOT MORE INTERACTION IN STAKEHOLDER INPUT, AND THERE WILL BE PUBLIC MEETINGS AND ASSOCIATION WITH THE AFDO, ASSOCIATION OF FOOD AND DRUG OFFICIALS.
THEY'RE HOLDING A WORKSHOP TO DISCUSS THIS IN JUNE.
>> HERE'S A FAX ABOUT ADVERSE EVENT REPORTING.
IT SAYS, "HOW DOES FDA MONITOR POST-MARKET SURVEILLANCE IN RELATION TO DRUGS TREATING LIFE-THREATENING ILLNESSES, SUCH AS HIV/AIDS?"
AND HERE'S THE KEY PART OF THE QUESTION --
"HOW DOES THE ADVERSE REPORTING SYSTEM GET RELAYED TO CONSUMERS?"
>> I'M GOING TO ASK DR. LUMPKIN TO ANSWER THAT.
>> IT'S A VERY GOOD QUESTION.
I MEAN, AS FAR AS THE GENERAL PROCESS ITSELF IS CONCERNED, IT'S PART OF THE OVERALL SPONTANEOUS REPORTING SYSTEM THAT WE HAVE.
THAT'S BASICALLY, AS PEOPLE WHO HAVE LOOKED AT THIS OVERALL PROCESS UNDERSTAND, THAT'S KIND OF THE CATCH-ALL TO TALK ABOUT SOME OF THE SERIOUS UNEXPECTED KINDS OF ADVERSE EVENTS THAT ARE RARE IN THE POST-MARKETING AREA.
WE ALSO HAVE SEVERAL OTHER METHODOLOGIES, THOUGH, THAT WE USE TO LOOK FROM AN EPIDEMIOLOGICAL PERSPECTIVE AT OTHER ISSUES THAT MIGHT ARISE IN CERTAIN PATIENT POPULATIONS.
WE HAVE A CONTRACT, FOR EXAMPLE, WITH A DATABASE THAT LOOKS AT ADVERSE EVENTS IN PATIENTS WHO ARE HIV POSITIVE, BECAUSE WE KNOW THAT'S A VERY SPECIAL GROUP OF INDIVIDUALS WHO HAVE VERY SPECIAL DRUG-RELATED ISSUES

IN THEIR HEALTH CARE.
SO WE'VE GOT SEVERAL DIFFERENT MECHANISMS TO LOOK AT SPECIAL POPULATIONS.
THE QUESTION ABOUT HOW IS THAT THEN COMMUNICATED BACK, I THINK, IS REALLY WHERE PEOPLE ARE LOOKING AT THIS POINT IN TIME.
IT'S ONE THING TO GET THE INFORMATION, TO ASSEMBLE IT AND TO DIGEST IT.
THE REAL CRUX IS IT DOES NO GOOD FOR IT TO STAY IN ROCKVILLE.
IT'S GOT TO GET BACK OUT TO THE POPULATION.
WE HAVE SEVERAL DIFFERENT MECHANISMS THAT WE'VE STARTED TO USE.
ONE IS USING OUR WEBSITE, WHICH I THINK WE FOUND IN PARTICULAR SITUATIONS HAS BEEN VERY EFFECTIVE FOR GETTING INFORMATION OUT AT A CERTAIN PERIOD OF TIME.
ONE OF THE ONES IN THE HIV POPULATION THAT WE USED WAS THE LIPODYSTROPHY ISSUE WITH SOME OF THE PROTEASE INHIBITORS.
SO THERE ARE WAYS THAT WE HAVE.
WE ALSO HAVE DIRECT RELATIONSHIPS WITH DIFFERENT PROFESSIONAL ORGANIZATIONS AND DIFFERENT PATIENT GROUPS THROUGH THE MED WATCH PARTNERS PROGRAM, WHO, WHEN WE HAVE ISSUES THAT ARE RELATED TO THEIR POPULATION OR TO THEIR PRACTICE, WE THEN GET BACK WITH THEM AND FEEDBACK TO THEM.
AND WE'VE FOUND THEY'VE BEEN WONDERFUL FOR THEM GETTING OUT TO THEIR CONSTITUENCIES THE INFORMATION THAT WE THINK IS IMPORTANT AND THAT WE FOUND OUT.
>> THANK YOU.
I WANT TO CALL ON THE NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION FOR NOT A QUESTION BUT A COMMENT.
IS SOMEONE HERE?
YES?
>> YES, MY NAME IS RAY BOWLMAN WITH THE NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION.
LAST FALL, THE NATIONAL COUNCIL ON PATIENT INFORMATION ENCOURAGED FDA TO SUPPORT THE DEVELOPMENT OF A NATIONAL COLLABORATIVE AND SUSTAINED CONSUMER MEDICINE SAFETY AND EDUCATION PROGRAMS.
THE GOALS OF A CONSUMER MEDICINE SAFETY AND EDUCATION PROGRAM COULD BE, FOR EXAMPLE, TO EDUCATE CONSUMERS AND PROVIDERS ABOUT CHANGES AND IMPROVEMENTS IN MEDICINE INFORMATION AND BETTER EQUIPPED CONSUMERS AND CAREGIVERS TO RECOGNIZE AND REPORT MEDICINE-RELATED ERRORS, FOR EXAMPLE.
THERE IS A QUESTION, IF I COULD.
[LAUGHTER]
WHY NOT BROADEN THE SCOPE OF FDA'S PUBLIC EDUCATION CAMPAIGN TO HELP CONSUMERS UNDERSTAND THE NEW OTC LABELS -- MEDICATION LABELS -- INCORPORATING MORE COMPREHENSIVE MEDICINE INFORMATION AND EDUCATION OBJECTIVES TO HELP CONSUMERS ALSO UNDERSTAND, FOR EXAMPLE, THE FDA'S APPROVED MEDICATION GUIDES THAT WILL BEGIN APPEARING IN -- FOR SELECT PRODUCTS THIS SUMMER, ACTIONS CONSUMERS SHOULD BE TAKING REGARDING THE IMPACT OF Y2K ON THEIR MEDICINE SUPPLY, FOR EXAMPLE, AND THEIR OWN ROLE AND RESPONSIBILITIES AND ENSURING SAFE AND APPROPRIATE MEDICINE USE?
>> THANK YOU.
>> MM-HMM.
>> LET ME TAKE AT LEAST TWO ASPECTS OF THE QUESTION.
AND IF OTHERS WANT TO MAKE COMMENTS, AS WELL, THAT WILL BE GREAT.
THE ASPECT OF EDUCATIONAL EFFORTS TO CONSUMERS, PARTICULARLY ABOUT THE OTC LABEL, BUILT INTO THAT INITIATIVE IS A MORE GENERAL EDUCATIONAL CAMPAIGN.
WILL IT BE AS ROBUST AS WE ALL WOULD LIKE?
IT'S GOING TO BE, PERHAPS, LIMITED ONLY BECAUSE OF RESOURCES, BUT WE ARE LOOKING FORWARD TO PARTNERING WITH OTHER GROUPS WHO CAN ALSO CARRY THIS MESSAGE, SO I WOULD HOPE THAT WE WOULD KEEP INTERACTING WITH YOU AND THE OTHER ASSOCIATIONS IN TERMS OF HOW WE MIGHT DO THIS BEST IN

TERMS OF EDUCATING THE CONSUMER ABOUT WHAT IS ON THE LABEL.
THE ISSUE THAT YOU RAISE ABOUT Y2K, I THINK, IS A VERY IMPORTANT ONE.
AND THE ISSUES RANGE, I THINK, FOR THE AGENCY ANYWHERE FROM, ARE WE READY TO MEET THE CHALLENGE?
AND I WOULD HAPPILY REPORT TO YOU THAT ALL OF OUR CRITICAL SYSTEMS HAVE BEEN JUDGED TO BE COMPLIANT WITH THE CHALLENGE OF Y2K.
WE ARE -- WE HAVE BEEN IN DIRECT INTERACTION WITH THE DEVICE INDUSTRY IN TERMS OF PUTTING UP A WEBSITE, NOT ONLY OF THOSE THAT FEEL LIKE THEIR SYSTEMS MIGHT NOT BE COMPLIANT OR COMPLIANT YET, AS WELL AS THOSE NOW THAT ARE COMPLIANT.
AND WE HAVE RECENTLY BEEN SERVING THE PHARMACEUTICAL, BIOLOGICAL, BIOTECH INDUSTRIES TO GET ASSURANCE ABOUT THE INDIVIDUAL COMPANIES' STATES OF COMPLIANCE, TO LOOK AT THAT END OF THE PIPELINE.
THE OTHER INITIATIVE THAT IS GOING ON THAT WE ARE A PART OF AND THAT IS TO WORK WITH ALL OF, REALLY, THOSE THAT HAVE TO BE IN PARTNERSHIP, ALL THE WAY DOWN THIS CONTINUUM FROM THE TIME OF MANUFACTURE TO THE TIME WHEN A PILL REACHES YOUR MEDICINE CHEST, AND ALL THOSE THAT INFLUENCE WHAT THE SUPPLY WILL BE LIKE.
AND WE'VE HAD SEVERAL MEETINGS WITH PEOPLE WHO RUN THE DRUGSTORES, PEOPLE WHO WRITE THE PRESCRIPTIONS, INTERACTING WITH CONSUMERS AND SEEING WHAT THE GENERAL SENSE OF THE PUBLIC IS ABOUT THIS ISSUE.
WE BELIEVE THAT WE WILL BE IN A REASONABLE STATE WITH RESPECT TO SUPPLY COMING OUT OF THE MANUFACTURERS.
WE ARE FOCUSING OUR OWN AGENCY ATTENDANCE ATTENTION, PARTICULARLY IN THOSE AREAS WHERE WE HAVE ONLY ONE MANUFACTURER OR THE CRITICAL NEED OF A DRUG.
BUT AS WE GET MORE INFORMATION, WE WILL CERTAINLY GET IT OUT TO THE GENERAL PUBLIC, SO WE DON'T HAVE THIS -- A STATE OF PANIC.
WE DON'T NEED THAT.
THE COUNTRY DOESN'T DESERVE IT.
STOCKPILING, WE WOULD STRONGLY DISCOURAGE.
>> THANK YOU.
AND THANKS TO EVERYBODY IN THE STUDIO FOR A GOOD DISCUSSION.
WE'RE JUST ABOUT OUT OF TIME.
AND IN FACT, IT'S TIME TO WRAP UP THIS BROADCAST.
WE DON'T WANT TO IMPINGE ON THE LIVE MEETINGS GOING ON AROUND THE COUNTRY.
I WANT TO THANK DRS. HENNEY AND SUYDAM, AND THE FDA PANEL, AS WELL AS EVERYBODY WHO TOOK THE TIME TO COME TO ONE OF OUR REGIONAL MEETINGS OR TO THE STUDIO.
AND I PARTICULARLY WANT TO THANK THOSE OF YOU WHO, I WAS GOING TO SAY PHONED OR FAXED IN, BUT I'LL SAY FOR THOSE OF YOU WHO FAXED QUESTIONS.
AS DR. HENNEY SAID EARLIER, WE TAKE THIS KIND OF FEEDBACK SERIOUSLY.
WE'VE TAKEN CARE TO RECORD WHAT YOU'VE SAID TODAY, AND AGENCY MANAGERS ARE GOING TO TAKE YOUR VIEWS INTO ACCOUNT AS THEY MAKE PROGRAM PLANS FOR THE FUTURE.
AS I SAID EARLIER, WE'RE GOING TO BE RESPONDING TO MANY OF THE QUESTIONS WE DIDN'T HAVE TIME FOR -- THAT IS, THE FAXES THAT WE DIDN'T GET TO -- ON THE WEBSITE.
ALSO, TODAY'S BROADCAST IS GOING TO HAVE AN AFTERLIFE.
IT'S GOING TO BE AVAILABLE AS A WEBCAST ON OUR FDA WEBSITE THROUGH THE NEXT 30 DAYS.
AND ALSO VIDEOTAPE COPIES ARE GOING TO BE AVAILABLE FOR PURCHASE THROUGH THE NATIONAL TECHNICAL INFORMATION SERVICE, OR NTIS.
AND THAT INFORMATION SHOULD BE APPEARING ON YOUR SCREEN RIGHT NOW.
WE HOPE THIS BROADCAST WAS HELPFUL TO YOU IN UNDERSTANDING FDA'S

PLANS AND PRIORITIES.
I KNOW IT'S GOING TO BE HELPFUL TO US IN UNDERSTANDING YOUR VIEWPOINTS AND YOUR SUGGESTIONS.
IF WE'RE GOING TO BE SUCCESSFUL IN IMPLEMENTING FDAMA, WE'RE GOING TO HAVE TO CONTINUE TO WORK CLOSELY WITH STAKEHOLDERS.
AND TODAY'S TELECONFERENCE AND THESE MEETINGS ACROSS THE COUNTRY IS GOING TO BE AN IMPORTANT STEP IN THAT DIRECTION.
THEY CERTAINLY ARE NOT GOING TO BE THE LAST STEP, BECAUSE THIS HAS TO BE A CONTINUING PROCESS.
AND IN FACT, AS PART OF THAT ONGOING PROCESS, WE'RE GOING TO CONTINUALLY RE-EVALUATE THE FDA PROGRAMS BASED ON STAKEHOLDER INPUT.
AS PART OF WORKING WITH STAKEHOLDERS, WE MAY DO MORE OF THESE TELECONFERENCES IN THE FUTURE.
AND THAT DEPENDS LARGELY ON YOUR REACTION TO TODAY'S BROADCAST, WHICH WE CONSIDER AS A KIND OF TRIAL RUN, SO WE'RE REALLY INTERESTED IN YOUR FEEDBACK.
TO GET YOUR FEEDBACK TO US -- AND WE WANT YOU TO TELL US WHAT YOU LIKED, WHAT YOU DIDN'T LIKE AND SO ON -- IF YOU'RE AT ONE OF THE EIGHT REGIONAL MEETINGS AROUND THE COUNTRY, PLEASE FILL OUT THE BRIEF EVALUATION FORM THAT WAS DISTRIBUTED BY YOUR MEETING COORDINATOR.
AND IF YOU'RE WATCHING THE BROADCAST AT ANOTHER SITE, YOU CAN E-MAIL YOUR COMMENTS TO US AT THE ADDRESS WE'VE BEEN SHOWING ON YOUR SCREEN ALL THROUGH THE PROGRAM.
AGAIN, THANK YOU FOR TAKING THE TIME TO PARTICIPATE TODAY.
UNTIL WE MEET AGAIN, THIS IS MARK BARNETT.
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