PRESIDENT CLINTON ANNOUNCES NEW MEASURES TO INCREASE AVAILABILITY OF INFORMATION ON SAFE USE OF MEDICATIONS USED TO TREAT CHILDREN

August 13, 1997

Today, President Clinton unveiled a new FDA regulation that will protect children by requiring manufacturers to study the safety and appropriate dosage levels of drugs for pediatric populations. The regulation also requires proper labeling of drugs for use in children. Even though many drugs affect children differently than adults, most drugs have not been tested on pediatric populations. Under this rule, manufacturers of prescription drugs likely to be used by children will be required to complete studies and place information on drug labels to help pediatricians and other health care providers make scientifically-based treatment decisions when prescribing drugs to children.

WHY THIS REGULATION IS NEEDED

Most drugs -- even those commonly used in children -- have not been widely tested on pediatric populations. According to the American Academy of Pediatrics, only a small fraction of drugs and biological products marketed in the United States have had clinical trials performed in pediatric patients. Despite evidence that drugs affect children differently than adults, 80 percent of all drugs marketed in the United States have been labeled for use by infants, children, and adolescents. Forty-two percent of drugs that are widely used in pediatric populations have been tested on children.

- Many drugs commonly given to children under the age of six including Prozac, Zoloft, Ritalin, and drugs for asthma, allergic reactions, and ear infections are inadequately tested and labeled for use in children. These drugs, taken together, are given to over five million children each year.

- Less than half of the drugs used in the treatment of HIV infections carry any safety or effectiveness information for children. Of those that do, the data is often incomplete.

- Safety and effectiveness information is especially sparse for the over seven million children under the age of two.

- The percentage of drugs being tested on children decreased by over one-third between 1996 and 1991.

Drugs are likely to have a different impact on children than on adults. The appropriate use and dosage levels of medication for children and adults is usually different because of disparities in organs, the immune system, and metabolism.

Children who take prescription drugs that have not been tested on pediatric populations are at serious risk for unexpected adverse reactions. Evidence suggests that prescribing drugs that have not been adequately tested on children can be extremely dangerous. One example of the possible harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Some physicians are reluctant to prescribe much needed therapies to children because they have not been tested on pediatric populations. Physicians report that they have denied children important new drugs because, in the absence of adequate testing and labeling, they would have to guess at an appropriate dosage, and they do not want to take that risk. As a result, too many children do not receive the treatment they need and deserve.

SUMMARY OF THE RULE

Pediatric Studies for New Drugs. Under this proposed rule, manufacturers of new drugs would have to do studies on pediatric populations under two circumstances: when the product represents a meaningful therapeutic benefit over existing treatments; or when the product is expected to be widely used on pediatric patients. The FDA anticipates that about twelve new drugs each year would meet this requirement. Manufacturers could receive waivers from the requirement to do a pediatric study under any one of the following circumstances:

(1) The product does not represent meaningful benefits over existing treatments and is not likely to be used on a substantial number of pediatric patients as a whole; or

(2) Necessary studies are impossible or highly impractical-- i.e., the number of patients is too small or geographically diverse; or

(3) There is evidence strongly suggesting that the product would be unsafe or ineffective in pediatric populations.

Pediatric Studies For Existing Drugs. For drugs that are already on the market, the new FDA regulation requires additional testing on the pediatric population only if there is a "compelling need for more information." The criteria used is:

(1) If the product is widely used in pediatric populations and the absence of adequate labeling could pose significant risks to pediatric populations; or

(2) If the product is indicated for very significant or life threatening illness, but additional dosing or safety information is needed to permit its safe and effective use in pediatric patients.

Pediatric Labeling File

Fact Sheet
Proposed Regulation on Pediatric Labeling

August 13, 1997

"This is an important time for America's children. They're growing up in a world that is changing rapidly. They need our help more than any generation before them. As Hillary says, children are not rugged individualists; they depend upon us -- their parents and others in the community who love them -- to give them love and guidance and discipline, to provide for them, and to defend them. That's as it should be. Their future and ours depends upon how well we do our job."

-- President Bill Clinton, Radio Address, June 1, 1996

Today, President Bill Clinton announced a proposed plan that would increase the amount of information about new drugs used to treat children. The proposed regulation would require that most new drugs that will be used to treat sick children will be studied in children prior to approval. The regulation also requires data to be submitted on approved drugs that are used in children but which lack information on how to safely use the drugs in this patient population.

The proposed plan was published today in the Federal Register and includes the following key points:

- Many new drugs and biological products represent treatments that may be the best available treatment for children. Many of them have not been adequately tested in children when they are approved, however, this regulation would require these sorts of new drugs to have information on how the drugs should be used in children.

- For drugs that are already marketed, this regulation also would codify FDA's authority to require, in compelling circumstances, that manufacturers conduct studies that the product is safe and effective in children.

- The requirement could be waived if (1) FDA found that the product was likely to be unsafe or ineffective in pediatric patients; (2) that pediatric studies were impossible or highly impractical; or (3) that reasonable efforts to develop a pediatric formulation had failed.

- Because this rule has just been proposed, the Administration invites written comments on the proposal from the public and industry, which may be submitted to the Dockets Management Branch, HFA-305, Food and Drug Administration, 12410 Parklawn Drive, Room 1-23, Rockville, MD 20857, until Nov. **XX**, 1997.

Improving American Children's Health Care

In 1963, Dr. Harry Shirkey coined the phrase "therapeutic orphans" to describe children. Shirkey was alluding to the plight of children for whom many drugs have not been studied. Pharmaceutical firms have had little incentive to study drugs for use in children because the population--and therefore the financial return--is likely to be small. Moreover, testing drugs in children can be more complicated than in adults.

In 1994, the Food and Drug Administration issued a regulation to encourage drug manufacturers to submit pediatric data voluntarily for review. However, many new drugs are still being approved without information on how they should be used in children.

Today's proposal would require data that could then be put on a drug's label to help pediatricians and other health care providers make treatment decisions based on scientific information aimed at their patient population.

When drug labels do not include pediatric information, health care providers may be forced to guess at the appropriate dose or forego possibly the best treatment available. Likewise, without pediatric data, these health care providers may have limited information on potential side effects that might occur specifically in this patient population.

More information on this proposed rule is available at http://www.fda.gov/cder/regguide.htm.

Executive Office of the President
August 13, 1997

Draft Press Release

FDA PROPOSES TO REQUIRE PEDIATRIC DATA
PRIOR TO DRUG AND BIOLOGIC PRODUCT APPROVALS

FDA has proposed a rule to provide physicians with more information on using new drugs in children. Published in today's Federal Register, the proposed rule would require pediatric-use data for any medicine which may offer improved treatment for children over existing therapies.

For drugs that are already marketed, this regulation also would codify FDA's authority to require, in compelling circumstances, that manufacturers conduct studies to support pediatric-use labeling for the approved indications.

Despite FDA efforts in recent years, many prescription drugs commonly prescribed for children have labeling that states the safety and effectiveness in children has not been established. Without adequate information, physicians may be reluctant to prescribe certain drugs for their pediatric patients, or they may prescribe them inappropriately. As a result, children may be exposed to an increased risk of adverse reactions or decreased effectiveness of the drugs, or they may be denied access to valuable therapeutic agents.

Today's proposal would require data that could then be put on a drug's label to help pediatricians and other health care providers make treatment decisions based on scientific information aimed at their patient population.

"Kids deserve the same access to newly developed drugs that their parents get," said Donna E. Shalala, secretary of Health and Human Services. "With this proposal, we will have the power to ensure pediatricians and other health care providers who treat children have the best scientific information available on which to base their medical decisions."

"When drug labels do not include pediatric information, health care providers are forced to play a guessing game and may not properly dose their patients," said Michael A. Friedman, M.D., FDA lead deputy commissioner. "Not only does this mean sick kids sometimes don't get better, but they also have the potential to get worse as a result of unexpected adverse events."

The proposed rule would allow post-approval submission of pediatric data if FDA had safety concerns about testing the drug
on children prior to approval.

Likewise, the requirement could be waived if:

- FDA found that the product was likely to be unsafe or ineffective in pediatric patients
- that pediatric studies were impossible or highly impractical
- that reasonable efforts to develop a pediatric formulation had failed.

FDA invites written comments on the proposal from the public and industry, which may be submitted to the Dockets Management Branch, HFA-305, Food and Drug Administration, 12410 Parklawn Drive, Room 1-23, Rockville, MD 20857. The closing date for comments is Date, 1997. All comments received will be reviewed and considered by the agency in developing the final rule.

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PEDIATRIC LABELING Qs and As

1. Why are you doing this now?

Despite efforts in recent years to address this issue, most drugs still lack adequate pediatric labeling. Every year about one half of all new drug and biologic products approved, that are likely to be used in children, lack information to support their safe and effective use in children. Pediatricians initially lack information necessary to prescribe these products to children who may need them. For products already on the market, information is eventually made available to physicians by journal articles, handbooks and other references, but usually years after a drug is approved (and even then the information isn't available on the label).

2. Can't you achieve the same effect through voluntary compliance?

FDA has taken a number of steps in recent rears to address inadequate pediatric labeling, including issuing a rule in 1994 requiring drug manufactures to survey existing data and determine whether those data are sufficient to give information on how to use a drug in pediatric populations. Most drugs, however, still lack adequate pediatric labeling.

3. Given that the draft FDA reform legislation, pending in Congress, contains financial incentives to encourage voluntary compliance, why is this rule necessary?

This rule is intended to complement the financial incentives for market exclusivity that are currently being proposed in Congress. Because financial incentives may work in some cases, but offer no guarantees, this rule is needed to give FDA the authority to ensure that products widely used or offering a clinically significant use in children carry adequate labeling for their safe and effective use in children.

4. Have children been at risk in the past?

The lack of adequate pediatric labeling has resulted in the use of many products that have only been tested for adults, causing an increased risk of inappropriate and unexpected adverse effects. Also, sometimes useful drugs not have been used in children because their effects in kids were uncertain..

5. How many drugs that are commonly used in children lack this data?

FDA estimates that one-half of the drugs approved in the past five years that had potential usefulness in kids had no pediatric labeling at the time of approval.

6. How many products will be affected by the rule?

FDA approves approximately 30 major new drug advances each year. About half of those products will need pediatric studies under this rule. The agency will also review drugs already on the market to determine which ones should have pediatric studies. The effect of this rule will that in a few years most drugs important to children will have directions for use in kids on their labels.

7. What kinds of drugs are commonly missing this pediatric data?

Drugs such as anti-asthmatics, steroids, drugs to treat gastrointestinal problems, strong pain medications, antidepressants, and antihypertensives commonly lack appropriate pediatric labeling.

8. What do doctors do when they don't have this information?

Many physicians rely on referenced pediatric handbooks for dosing and use information. Others are reluctant to prescribe certain products to children without adequate pediatric labeling on the product.

9. When can parents expect that information to support safe and effective use of products in children will become available.

We believe that, in some cases, the information already exists and the drug companies merely need to analyze and compile it. In these cases, the information can be made available on the labeling of the products fairly quickly. In other cases, studies need to be conducted. Under the requirements of our 1994 regulation, where the effects of the product and the disease for which it is indicated are sufficiently similar in both adults and children, these studies can be done within one year.

10. What drugs now have the best pediatric data?

Vaccines and antibiotics are the most adequately labeled drugs for children.

11. Why haven't companies provided this information in the past?

Some companies do provide this information, however, pediatric labeling has not been required until now. Lack of familiarity with pediatric studies, need for a pediatric formulation, and cost may account for the lack of adequate pediatric information.

12. How much will this cost drug manufacturers?

The costs of pediatric studies will be less than 1% of the total costs of developing a drug. FDA estimates that the total annual industry costs will be less than $20 million per year (for a multi-billion dollar industry).

13. Will drug prices increase as a result of this regulation?

Because the cost of pediatric studies to manufacturers is expected to be small, it is anticipated that there will be little or no price increases to patients

14. Does this regulation cover all drugs?

It covers all drugs that are widely used in, or important to, children.

15. Will this requirement hold up drug approvals?

No, the proposal allows for postapproval submission of pediatric data if concerns about pediatric testing arise prior to approval. Additionally, the requirement may be waived in certain cases.

16. How will these waivers work and won't they make the regulation meaningless?

The waivers are only intended to be used in those cases in which the drug would not be widely used and would not represent a meaningful benefit over existing treatment or where the studies are impossible or highly impractical or pose undue risks to pediatric patients.

17. Why doesn't it cover medical devices? Do we not have this kind of problem with medical device pediatric data?

Once the agency gains experience in requiring pediatric studies for drugs and biologics, it will assess the need for such labeling for devices.

18. What kind of improvement can we expect in our childrens' health as a result of this regulation?

We expect safer and more effective medicines for children. The primary benefits expected are the reductions in avoidable adverse drug reactions and under or over treatments that would result from better informing health care practitioners about whether, and in what dosages, a given drug was safe and effective for use in children.

19. When will this regulation go into effect?

There is a 90 day period for comment on the proposed rule after which the agency will evaluate and respond to the comments and publish a final rule. The final rule will take effect 3 months after issuance. At that time, for drugs and biologics already on the market, FDA, in compelling circumstances, may request that pediatric studies be initiated. Manufacturers of new drug and biologic products, under review at the agency, will have 2 years to comply with the pediatric study requirement. Manufacturers of new products, not yet submitted for review, will have 18 months to comply with the requirement.

20. What kind of "legal action" can FDA take to force companies to provide this data on approved drugs?

FDA can go to court and ask the court to order the company to comply with the regulations. If the company does not comply, the court can impose penalties.

21. Would pediatric study participants' lives be at risk without having all the adult data from the start?

Pediatric participants are not enrolled in studies until enough data on the drug have been obtained so that the risk to the pediatric participants is low.

PEDIATRIC LABELING Qs and As

Q: WHY ARE YOU DOING THIS REGULATION NOW?

A: Despite efforts to increase the number of studies on pediatric populations, still too many children take prescription drugs that have not been tested on children. Over 80 percent of drugs manufactured in the United States have not been tested on children and over 50 percent of drugs that are known to be widely tested in children have not been tested.

As a result, some physicians are reluctant to prescribe much-needed therapies to children. Physicians report that they have denied children important new drugs because, in the absence of adequate testing and labeling, they would have to guess at an appropriate dosage, and they do not want to take that risk.

In some cases, guessing can be extremely dangerous. One example of the possible harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children have had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Q: CAN'T YOU ACHIEVE THE SAME EFFECT THROUGH VOLUNTARY COMPLIANCE?

A: FDA has already implemented reforms to encourage voluntary compliance. However, as 80 percent of drugs manufactured in the United States and over 50 percent of drugs widely used in children still do not have a adequate pediatric labeling, FDA has concluded that this new rule is necessary to ensure that children get the protection they need.

Q: GIVEN THAT THE DRAFT FDA REFORM LEGISLATION, PENDING IN CONGRESS, CONTAINS FINANCIAL INCENTIVES TO ENCOURAGE VOLUNTARY COMPLIANCE, WHY IS THIS RULE NECESSARY?

A: The Congressional approach, while thoughtful and worthy of serious consideration, would not assure that most or all of prescription drugs used by children are tested and labeled appropriately. We believe that the Dodd/Dewine legislation has the potential to complement the regulation the President is unveiling today, but it is not a replacement for it.

Q: DO YOU SUPPORT THE DODD LEGISLATION AS CURRENTLY DRAFTED AS A COMPONENT OF THIS EFFORT?

A: We are reviewing this legislation to determine if it can be designed to compliment and bolster our efforts today. We believe that it has great potential to compliment the legislation but we are not prepared to accept it as currently drafted before we consider all of the ramifications of overlaying the important regulation the President is announcing today.

Q: HAVE CHILDREN BEEN AT RISK IN THE PAST?

A: Yes. In some cases physicians do not prescribe drugs because they determine that it is simply not worth taking the risk of prescribing drugs that have not been tested in children.

In other cases, physicians choose to prescribe treatment, because it is the only means to cure a child's nagging illness or even a life threatening disease. Those physicians are left to make their best guess at the appropriate doses -- rather than rely on the through studies and information that the rest of us take for granted.

In some cases, however, guessing can be devastating. One example of the potential for harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Q: HOW MANY PRODUCTS WILL BE AFFECTED BY THE RULE?

A: FDA anticipates that this will impact about 12 new drugs each year. The agency will also review drugs already on the market to determine which ones should have pediatric studies. FDA will work as quickly as possible to ensure that in a few years the drugs most important to children will have directions for use in kids on their labels.

Q: WHAT KINDS OF DRUGS ARE COMMONLY MISSING THIS PEDIATRIC DATA?

A: Drugs such as anti-asthmatics, steroids, drugs to treat gastrointestinal problems, strong pain medications, antidepressants, and antihypertensives commonly lack appropriate pediatric labeling.

Q: WHAT DO DOCTORS DO WHEN THEY DON'T HAVE THIS INFORMATION?

A: In some cases they choose not to prescribe the drugs at all. In other cases, they take their best guess -- without the assistance of information that we rely on for adult medications. Sometime, however, guessing can have dangerous consequences, such as seizures, heart problems, or even death.

Q: WHEN CAN PARENTS EXPECT THAT INFORMATION TO SUPPORT SAFE AND EFFECTIVE USE OF PRODUCTS IN CHILDREN WILL BECOME AVAILABLE?

A: We believe that, in some cases, the information already exists and the drug companies merely need to analyze and compile it. In these cases, the information can be made available on the labeling of the products fairly quickly. In other cases, studies need to be conducted. Under the requirements of FDA's 1994 regulation, where the effects of the product and the disease for which it is indicated are sufficiently similar in both adults and children, these studies can be done within one year.

Q: HOW MUCH WILL THIS COST DRUG MANUFACTURERS?

A: FDA estimates that the costs of pediatric studies will be less than 1% of the total costs of developing a drug.

Q: WILL DRUG PRICES INCREASE AS A RESULT OF THIS REGULATION?

A: Because the cost of pediatric studies to manufacturers is expected to be small, it is anticipated that there will be little or no price increases to patients.

Q: WILL THIS REQUIREMENT HOLD UP DRUG APPROVALS?

A: Clearly we will provide every incentive to complete the study before the drug is approved. However, the rule explicitly ensures that a drug's entrance into the market is not held up even if all studies on pediatric populations have not yet begun. We will rely on other legal and financial remedies to ensure that companies comply as soon as possible.

Q: WHEN WILL THIS REGULATION GO INTO EFFECT?

A: There is a 90 day period for comment on the proposed rule after which the agency will evaluate and respond to the comments and publish a final rule. The final rule will take effect 3 months after issuance. At that time, for drugs already on the market, FDA, in compelling circumstances, may request that pediatric studies be initiated. Manufacturers of new drug and biologic products, under review at the agency, will have 2 years to comply with the pediatric study requirement. Manufacturers of new products, not yet submitted for review, will have 18 months to comply with the requirement. Drugs already on the marketplace will have 3 months to comply.

Q: WHAT IS THE ENFORCEMENT MECHANISM FDA WILL TAKE TO FORCE COMPANIES TO PROVIDE THIS DATA ON APPROVED DRUGS?

A: FDA can go to court and ask the court to order the company to comply with the regulations. If the company does not comply, the court can impose penalties.

President Clinton Continues to Fight to Improve the Health of Our Nation's Children

- **Children and Prescription Drug Testing.** Today's announcement requiring manufacturers to do studies on pediatric populations for new prescription drugs and those currently on the market builds on an impressive array of children's initiatives advocated by President Clinton.

- **Children and Insurance Coverage.** The President fought hard to ensure that the Balanced Budget Act included $24 billion -- the largest investment in children's health care since the passage of Medicaid in 1965 -- to provide meaningful health care coverage to as many as five million of our nation's uninsured children. He also fought to include revenue from a 20 cent tobacco tax which will not only further reduce the number of uninsured children, but it will also serve as a financial barrier to help prevent our children from starting to smoke in the first place.

- **Children and Tobacco.** The President issued guidelines to eliminate easy access to tobacco products and to prohibit companies from advertising tobacco to kids. Each day about three thousand children become regular smokers and 1,000 of them will die from a tobacco-related illness. According to former FDA Commissioner David Kessler, the possibility of a comprehensive, public health oriented settlement with the tobacco industry could not have come about without the President's leadership in this area.

- **Children and Insurance Reform.** By signing the Kassebaum-Kennedy bill into law last year, the President helped millions of American children keep their health care coverage when their parents lose or change jobs.

- **Children and Juvenile Diabetes.** The President fought to include $150 million ($30 million annually for five years) for research to help find the cure for diabetes. Americans with this disease often suffer severe consequences, such as blindness and kidney disease, even when they receive the best treatment and care. The HHS Secretary will have discretion to target the new funds toward the best scientific opportunities. This represents the largest single new investment in Juvenile Diabetes.

- **Children and Immunization.** As the President recently announced, over 90 percent of America's toddlers in 1996 received the most critical doses of each of the routinely recommended vaccines -- surpassing the goal set by the President in 1993.

- **Children and the Environment.** Earlier this year, the President signed an Executive Order to reduce environmental health and safety risks to children by requiring agencies to strengthen policies and improve research to protect children and ensure that new regulations consider special risks to children.

- **Children and Medicaid.** Throughout his Administration, the President has fought to preserve and strengthen the Medicaid program; its coverage of about 20 million children, makes it the largest single insurer of children. The Administration has partnered with states through Medicaid waivers to expand coverage to hundreds of thousands of children.

Pediatric Labeling Event
The Rose Garden
Wednesday, August 13, 1997

Thank you, Secretary Shalala. In a few moments, President Clinton will announce new steps he is taking to help parents and pediatricians care for our children -- to have the information they need to provide the very best care available. But today's announcement represents a commitment that is much broader, and much deeper, for this administration.

As President Clinton has said so often, the toughest job in the world -- the most important job in the world -- isn't being President; it's being a parent. Providing the love, support, and caring that strengthen future generations. Passing on our values, and our ideals. And any parent knows that the greatest responsibility of all is caring for a child when he or she is sick.

Government can't do those jobs -- nor should it try. But government can make it a whole lot easier for parents to succeed, and raise the kinds of healthy, strong children that make us all proud. That's our purpose here today -- and that's what President Clinton has been fighting to achieve these past four and a half years.

The First Lady has very eloquently described our achievements in expanding health care for children and families. But this administration's commitment to children's health goes far beyond the doctor's office. That's why this President has enacted the toughest-ever measures to cut off children's access to tobacco -- and a crackdown on cigarette ads aimed at our children. If it weren't for this President, Joe Camel would still be puffing away.

President Clinton dramatically expanded meat inspections, so parents can be sure the food they serve their children is safe. Our tough new air quality standards will make sure that the air our children breathe is clean and safe -- especially for those children who have respiratory difficulties. Thanks to those new regulations, children like **insert new name when we get it** Frances Doyle, a four-year-old with asthma, can breathe a lot easier.

But as Frances's father Johnthan will tell you in just a few moments, there are a lot of parents who want to do the right thing for their children -- especially when it comes to prescription medicines -- but they just don't have the right information. Two out of three drugs that Frances has to take for her asthma do not have adequate pediatric information. That means Frances's parents often have to guess -- even though Frances's mother, Kristen, is a nurse. When it comes to our children's health, guessing isn't good enough. And I'm pleased to introduce Johnthan Doyle, who will tell us more about what this problem means to his family...

Pediatric Labeling

Elizabeth R. Newman
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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release August 13, 1997

PRESS BRIEFING BY
PRESIDENT'S PRINCIPAL HEALTH CARE ADVISOR, CHRIS JENNINGS

The Briefing Room

12:50 P.M. EDT

MR. MCCURRY: Good afternoon, ladies and gentlemen. Today's daily press briefing will begin with the President's principal Health Care Policy Advisor, Chris Jennings, to tell you more about the event soon upcoming.

Chris, come on up here, help us out.

MR. JENNINGS: Later this afternoon at I believe it's 1:45 p.m., the President is going to unveil a new FDA regulation which will require pharmaceutical manufacturers for new and current drugs to do both testing and labeling for medications that are widely used by pediatric populations, or of course, children.

And this is something -- a regulation that the Department of Health and Human Services and FDA have been working on for a good time now. It follows in an effort by HHS to do this on a voluntary level, on a voluntary basis. Unfortunately, over the last several years we've noted that we've actually seen a decline in the amount of testing and labeling done for children, despite the voluntary efforts. So we have been working with the industry, pharmacists, providers, and of course, consumer groups to develop a regulation that the President will be unveiling.

This is just the unveiling of the reg. There will be a 90-day comment period, and then we will go to final. We think it works to complement legislation that is on the Hill, or it can complement legislation on the Hill that also tries to deal with this initiative. And the President will be with the Vice President, the First Lady, and the Secretary of Health and Human Services, and the parent of a child who has had great difficulty for herself and their pediatrician to have adequate information on labeling.

So that's it. Any questions?

Q How much is this going to cost --

MR. JENNINGS: Well, it's unclear. The FDA assumes it's about one percent of the current cost of drug development. It's a very, very modest amount according to them. I think the industry may say it's more. We will certainly be getting comments during the upcoming period, but we do anticipate it being very, very modest because, one, it does not necessarily require clinical studies. They can do pharmakenetic studies, which means they don't necessarily have to have populations of children in order to get the type of information that's necessary. Also, there has been some information for current drugs that are already out there that drug companies can access to get the type of information necessary and required under this legislation.

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Q Does it apply to all medicines?

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MR. JENNINGS: It applies to all prescriptions that will be used widely by children or are meaningful to children. We anticipate for new drugs that's about 12 to 14 new drugs a year and current drugs, too. And the regulation itself it will mention a category of about 10 drugs that are currently on the market that have inadequate testing.

Q . Did the drug companies fight this?

MR. JENNINGS: Well, the drug industry has indicated today and last night that they look forward to working with us in a collaborative effort. I think that they are not overly thrilled about the concept of it being required or mandated. We would only point out that in the last five years we've actually seen a decline in necessary testing and that we see no other way to address the problem. I anticipate that over the next 90 days we'll have even more serious discussions with them. And I hope by the end of the day they will be supportive of other regulation by the time it goes final.

Q Did you say you identified just 10 drugs that are currently on the market that need --

MR. JENNINGS: The regulation itself lists 10 categories of drugs ranging from asthma to antibiotics to pediatric AIDS and particularly these protease inhibitors that are being used in a significant way. There may well be others but we will go ahead and review. Of course, many of these drugs have been on the market for so long that some information has become available, and pediatricians feel that they have the information they need and getting the adequate clarifications will not be difficult.

Q So is this a problem -- are kids being over-medicated?

MR. JENNINGS: I think that you'll see that the major problem is that there are three categories -- what happens is really three choices for a physicians. One, because they don't have the information they need, they don't prescribe medications that children may benefit from, which obviously is an unfortunate outcome. Secondly, and what I would anticipate happens most frequently, is they guess. Frequently, they guess right. They've had lots of experience. Physicians know -- have a good sense of their patients and their needs. And third, they guess wrong. They either under-medicate or over-medicate, sometimes with tragic consequences. There have been some cases of deaths that have been reported because of the lack of information. That's why the American Academy of Pediatricians and many other physicians throughout the country, the Family Physicians, the College of Physicians, strongly, strongly endorse this information being made to them -- and this regulation.

Q Chris, are there any liability concerns? Are the companies concerned that if they say that this drug might be all right to use on children under 18 or under 12 and it turns out that it isn't, then all of a sudden they've got a problem.

MR. JENNINGS: They actually raised liability concerns during the vaccine compensation debate several years ago, then they dropped that as a major concern of them. We have no indication or no evidence whatsoever that information on such testing has created any liability concerns. We've asked in the past for specific examples. They have given us none. I don't anticipate that being a very

significant concern. We will talk to them about that the during the comment period, but, again, I do not think that is a serious concern.

Q How many children take these medications?

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MR. JENNINGS: Millions. Certainly we're talking about everything from asthmatics -- children with asthma, to children who have AIDS, to every known disease that children access. So we're talking about probably anywhere between millions to even more than 10 million children.

Q Why aren't drug companies are already doing something that sounds like it makes so much sense?

MR. JENNINGS: Well, I think that they would say that they have some -- I don't know exactly what they would say. I think you should ask them. My personal belief is that they think that a lot of the information they have obtained for adults is somewhat adequate, that it's not necessary to impose additional costs on the industry, and that they've raised concerns. They would also argue that they're doing better, notwithstanding some of the data to the contrary.

Q If I could switch that question just a little bit, why is it that the FDA hasn't done this before?

MR. JENNINGS: Well, the FDA, and before Dr. Kessler left, he worked very hard on this regulation. He consulted with the industry for a number of years. They asked for us to go voluntary compliance and to come up with some incentives for them to do it on a voluntary basis. We did that. We released a reg in 1994. It clearly has not had the desired effect, and so we're going beyond that today.

Q You mentioned prescription drugs, but how does this apply to over-the-counter medications?

MR. JENNINGS: Well, this is for prescription drugs that doctors prescribe frequently. A lot of over-the-counter drugs do have pediatric labeling information, but that's something that I will tell you I have not looked into or is not part of this regulation today.

Q Secretary Shalala yesterday was indicating that so many OTC medications just simply say, ask your doctor, and that she indicated that this may move to clear that up.

MR. JENNINGS: Well, this is for prescription drugs, and, certainly, if there is a major concern on OTC level, we will be consulting with the FDA about that.

Q You mentioned protease inhibitors. What is the problem there with the drug companies -- they are not adequately providing information to patients, or doctors, or who?

MR. JENNINGS: Well, as you may know the protease inhibitors are some of the most difficult to use medications and to prescribe. They are very complicated. They deal with regimens of prescriptions. They are usually and sometimes called drug cocktails. They have very, very differential impacts on children. There have been drug companies, and I'm sorry there was one Angoram or a smaller drug company that did do pediatric studies much to the praise of the AIDS community and others recently, but many other companies have not. This is very, very significant and absolutely essential information for any pediatrician for treating a child who has AIDS.

Q Chris, does this mean that a lot of parents will be asking to have their children tested?

MR. JENNINGS: No, not necessarily, because a lot of this testing can be done on information currently available. Pharma-kinetic testing, which does not require that I have actual children doing testing. It's based on computer simulations of differential metabolism rates of patients. So we don't anticipate it to be a major population although there will be some of that testing. And,
obviously, all of that testing is done on a voluntary basis in trials throughout the country.

Q Do you expect that the industry will try to block the regulation?

MR. JENNINGS: We would be very disappointed if they blocked this regulation. We would fight very, very hard, and I doubt that they would want to do that this year in this Congress. But I think you better ask them. But my general sense after conversations with the pharmaceutical manufacturers association last evening was that their desire was to work with the administration on this regulation in a collaborative, constructive way. We anticipate that they will live up to that commitment.

Q You mentioned categories of drugs. In what categories of drugs do you see most of the over-prescribing or the guessing by physicians that --

MR. JENNINGS: You know, I think that that's a question better answered by some of the physicians groups who will be here later this afternoon, so -- I'm not a doctor and I wouldn't want to guess some specific data in that area.

Q Chris, Mike indicated we could run a couple other health-related questions by you today.

MR. JENNINGS: It would be my pleasure. Thank you, Mike.

Q On the Medicaid situation with New York, there are some accounts saying you're trying to get together with New York legislators to fashion another solution. Is it accurate to say you're backtracking on this, or what are you trying to do exactly?

Mr. President, Mrs. Clinton, Vice President Gore, Secretary Shalala, and other guests:

Sam, my husband and I are very honored to be here today. This is a day I'll never forget and, quite frankly, one Sam may never remember. But the occasion is one that marks a tremendous advance for children and one that will yield benefits for millions of children for decades to come.

Mr. President, thank you for the strength and commitment you have demonstrated by issuing these regulations today--I thank you as a parent and a citizen.

Just 21 months ago I became a mother for the first time. It came with all the joy and chaos that parenthood brings. I barraged my pediatrician with all the first time questions: Should he sleep on his side or his back? How do I cut those tiny little fingernails? and WHEN will he sleep through the night???

When Sam was just four months old he had his first asthma attack. I was petrified. I was still working on the diaper rash questions and now he needed medication so his little lungs could sustain him. Before his first birthday he had been in the emergency room several times.

Sam's pediatrician prescribed a couple drugs to try and control his asthma--albuterol and Intal. So far, they seem to be working for Sam, he hasn't been hospitalized for about seven months.

It wasn't until recently that I learned that those drugs have not had extensive clinical trials in children Sam's age. If Sam were older, those drugs would have labeling but for his age, my pediatrician had to rely on limited medical studies, rather than comprehensive clinical trials.

I must thank Dr. Jeralyn Bernier, Sam's pediatrician. She has been with us every step of the way during Sam's illness. She was able to determine how much medication to give Sam but she should have been able to rely on a proper pediatric label to make that determination.

Mr. President, asthma drugs are only one example of the medications that need proper labeling for children. Scores of other drugs need to have pediatric clinical trials done--drugs for pediatric AIDS, heart conditions, infections, and allergies just to site a few.

These regulations being announced today will help Dr. Bernier and thousands of other pediatricians and health care professionals make medical decisions with the precise information they need so that the best drug and the correct dose can be prescribed and my son and millions of other children can get the high quality treatment they need and deserve.

Now it is my honor to introduce to you the President of the United States, William Jefferson Clinton.

Mr. President, Mrs. Clinton, Vice President Gore, Secretary Shalala and other guests:

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Elaine Holland