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8/18/97

THE WALL STREET JOURNAL

FDA Loves Kids So Much, It'll Make You Sick

By HENRY I. MILLER

If you've filled a prescription recently, you may have had a nasty surprise. A bottle of antibiotics or a tube of steroid cream used to cost a few bucks, but now you find drug prices like Epogen (erythropoietin for anemia) at between $324 and $486 per week, Rocalcitrol (a vitamin D derivative) at $55 to $385 a week, and Biaxin (the antibiotic clarithromycin) at $75 a week.

Why the huge prices? It's your tax dollars at work. Government regulation imposes enormous costs on drug development that must be passed along to consumers in higher prices.

They were at it again last week. President Clinton announced that drug companies will be required to test whether the medicines they sell for adults are safe and effective for children, and to put the pediatric dosages on the label. The new requirement will increase the already astronomical cost of drug development by more than $200 million annually, according to the FDA's own (conservative) estimate. The added cost was characterized as a "very, very modest amount" by Chris Jennings, President Clinton's principal health care adviser. Consumers who pay for their drugs may have other ideas.

* * *

A more measured approach to encouraging adequate pediatric testing and labeling would be simply to require a prominent label or logo on drugs whose safety and efficacy have not yet been determined in children. Or the FDA could simply publish a list of such drugs each year. This would make parents and physicians aware that such information is not available, and they, in turn, could exert moral and economic pressure on drug companies to obtain it. After all, it is in drug companies' own interest to expand the population that will purchase and benefit from their products.

The Clinton administration's new regulation is far more ambitious. It makes unreasonable demands on drug developers and would actually delay the availability of new drugs, if FDA withholds approval for adult uses while data from pediatric studies are being collected. Creating a dosage appropriate for children is often especially challenging, for a number of reasons. Can the active ingredient be incorporated in a chewable or syrup form? Will it have special storage requirements and adequate shelf life? Is the taste one that kids will take?

A pediatric form of Glaxo Wellocome's antibiotic Seftin, approved in 1990, required more than double the cost and man hours to develop than its adult form did. Glaxo also had tremendous problems in finding effective preservatives for the pediatric syrup form of Epivir, an AIDS drug, even after the adult form had been fully developed.

Clinical trials are difficult to perform with children. For ethical reasons, testing is done on patients, not on healthy volunteers. Study participants may be scarce because a given disease is rare in children, because the patient population is geographically diverse, or because parents are reluctant to enroll their sick children in an experiment.

Finally, for the purposes of drug testing, "children" is by no means a homogenous category. The term implies several groups that are physiologically and metabolically distinct: newborns, infants, preschoolers, schoolchildren and teens. Moreover, children may pass through two or more age groups during the course of a multiyear clinical study.

As FDA regulatory requirements for all age groups are ratcheted ever upward, drugs are moving more sluggishly through the clinical testing pipeline. The total time required for drug development, from synthesis of the molecule to marketing approval, has more than doubled since 1964, to 14.8 years from 6.5. And the $500 million tab for each drug approved in the U.S. is by far the most expensive in the world.

Why does FDA propose unnecessary regulations, which are expensive, rigid and inimical to market forces? For one thing, it's in the self-interest of bureaucrats to seek greater mandates and, thereby, to amass larger empires and budgets. It often seems as if it's simply in their nature—as former FDA Commissioner Frank E. Young once quipped, "Dogs bark, cows moo, and regulators regulate."

* * *

When regulation is excessive, everyone is a loser—except government regulators themselves. Money spent by the government, industry and consumers on FDA regulation is money not spent on something else, including the ability to protect public health in other ways—reduce poverty, improve highways, perform diagnostic testing.

Consider, for example, the potential benefits of spending the $200 million annual cost of FDA's new regulation on breast cancer screening—according to National Institutes of Health statistics, it would save between 60,000 and 140,000 years of U.S. women's lives. If it were spent on cervical cancer screening, it would save between 140,000 and 300,000 years of life.

The FDA's new regulation is the latest example of Big Brother deciding where private-sector research and development resources are to be spent. In the process, it increases costs to consumers and puts them at risk as the introduction of new drugs is delayed. More fundamentally, the policy illustrates that the Clinton administration has a greater commitment to the rhetoric than to the reality of protecting the public health.

Dr. Miller is a senior research fellow at the Hoover Institution and author of "Policy Controversy in Biotechnology: An Insider's View" (Academic Press, 1997). He was an FDA official from 1979 to 1994.

MEMORANDUM FOR THE PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

FROM: Regan Hall Reinerth

DATE: August 13, 1997

RE: Food and Drug Administration, HHS
Proposed Rule Requiring Manufacturers to Assess the
Safety and Effectiveness of New Drugs and
Biological Products in Pediatric Patients

I. Reasoning for Proposal

The FDA is proposing new regulations requiring pediatric studies of certain new drugs and biological products. The proposed rule would attempt to address the issue of the lack of pediatric use information on product labels by requiring that manufacturers of a limited class of new drugs and new biological products provide sufficient data and information to support directions for pediatric use for the claimed indications, before or soon after approval.

A recent survey by the FDA concluded that products used for treatment of diseases that occur both in adults and children have very little information about pediatric use in their labeling. ***Less than half of the FDA approved drugs for treatment of HIV infection or opportunistic infections carry ANY pediatric safety or effectiveness information.*** Those treatments that do are often limited to a certain pediatric age group. For example, there is almost no information on use in patients under 2 years of age for most drug classes.

Even after a drug has been used in pediatric patients for a long period of time and the drug has been successful, directions for safe and effective use for pediatric patients still do not appear on the label.

Inadequate dosing information may expose pediatric patients to dangerously high doses or to ineffective treatment.

II. FDA Initiatives to Improve Pediatric Use Information: The 1994 Rule

The 1994 rule requires drug manufacturers to survey existing data and determine whether those data are sufficient to support additional pediatric use information on the drug's labeling.

This rule recognizes that controlled clinical studies to support pediatric use information need not have been carried out in pediatric patients where the course of the disease and the effects of the drug are sufficiently similar in children and adults.

In these cases, controlled clinical studies in adults together with pharmocokinetic and adverse reaction data in pediatric patients may be sufficient to establish pediatric safety and effectiveness.

The 1994 rule does not impose a general requirement that manufacturers carry out studies if existing information is not sufficient to support pediatric use information. It only requires the manufacturer to include in the drug's labeling the statement: "Safety and effectiveness in pediatric patients have not been established."

III. Need for Additional Steps

The 1994 rule is one of the ways in which the FDA attempted to improve pediatric use information, but the results of this rule as well as other steps taken by the FDA have not shown consistent improvement. As a result, the FDA has:

- proposed another rule that would require the manufacturers of certain new and marketed drugs and biological products to evaluate the safety and effectiveness of their products in pediatric patients

- made plans to develop guidance on clinical trial designs for assessing pediatric safety and effectiveness

- proposed that a users fee be waved for supplements to add pediatric use labeling, unless the supplements contain adequate and well-controlled clinical trials - this is to encourage the submission of pediatric studies

IV. Description of the Proposed Rule

The proposed rule is designed to ensure that new drugs and biological products that are likely to be commonly used in children or that represent a meaningful therapeutic benefit over existing treatments for children contain adequate pediatric labeling for the approved indications at the time of, or soon after, approval. The rule would therefor require a manufacturer of a drug classified as a "new chemical entity" (a drug that contains no previously approved active moiety which is the molecule or ion that is responsible for the physiological or pharmacological action of the drug) or new biological product to submit, before approval, safety and effectiveness information on relevant pediatric age groups for the claimed indications.

The requirement would be waived if:

1. the product did not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and was unlikely to be used in a "substantial number" (100,000 or more pediatric patients constitutes a substantial number) of pediatric patients

2. studies on the product were impossible or highly impractical

3. the product were likely to be unsafe or ineffective in pediatric patients

4. reasonable efforts to develop a pediatric formulation had failed

The rule would also require that manufacturers of already marketed drugs and biological products conduct studies to support pediatric use labeling for the claimed indications.

The Federal Food, Drug, and Cosmetic Act authorizes the FDA to grant periods of exclusive marketing to manufacturers who obtain approval of labeling supplements adding pediatric use information to a drug's label. A manufacturer is entitled to 3 years of market exclusivity for obtaining approval of pediatric use labeling based on clinical studies. Also, a manufacturer may be entitled to 7 years of exclusive marketing under the Orphan Drug Act for obtaining approval of an application for use of a drug to treat a disease or condition affecting a pediatric population of less than 200,000.

Washington Times

ngton Times 8/13/97 BUSINESS

Government to insist on tests for drugs children might take

By Lauran Neergaard
ASSOCIATED PRESS

The Clinton administration is preparing to force drug manufacturers to test whether the medicines they sell to adults are safe and effective for children to use, too.

About 80 percent of the nation's prescription drugs are not labeled for child use because they never were tested on children. Pediatricians often must guess a safe dose when they have to use adult drugs such as asthma and AIDS medications on their smallest patients.

The drug industry has largely ignored Food and Drug Administration efforts dating back to 1994 designed to spur more children's prescription information.

Now, President Clinton is set to propose regulations today that would require manufacturers to provide that information for new drugs promptly — or face the FDA in court.

Officials familiar with the rules, who spoke on condition of anonymity, say that when a company seeks FDA permission to test an experimental drug on adults, the agency would decide whether it has potential for children. If so, the company would be ordered to provide a plan for determining the safe child dose.

The FDA would not delay approving a drug for adults, stressed one administration official. Pediatric labeling could be added soon after sales to adults begin, as long as the move is timely, the official said.

The proposed rules do not require massive, expensive clinical trials on children. Instead, if a drug is considered safe for adults, companies could do simple dosage testing — studies that take three to six months to perform — to show the dose that gets a therapeutic level of the medicine into a child's bloodstream.

"People assume any drug that is prescribed for their children has been tested, and that's not the case," said Susan DeLaurentis of the Pediatric AIDS Foundation. "This will now be a requirement."

The proposed rules also would require existing adult drugs that are widely prescribed to children — such as bronchodilators for asthma patients and the antidepressant Prozac — to have the pediatric dose added to the label. But a deadline on that was not immediately set.

Of 183 drugs approved in the past five years, only 44 were quickly labeled to include child prescription information. The FDA targeted 64 more drugs that offered promise for children, but only two ultimately were labeled for children, the AIDS foundation said.

Clinton Wants Drug-Safety Tests for Children

By Laurie McGinley
Staff Reporter of The Wall Street Journal

In a major change in the nation's drug-approval policy, President Clinton will propose today that new drugs likely to be prescribed for children should first be

PHARMACEUTICALS

tested on kids for safety, dosage and, in some cases, effectiveness.

The policy could pose a quandary for the drug industry, which would face new research costs but can't afford to appear insensitive to children's needs. Alan Holmer, president of the Pharmaceutical Research and Manufacturers of America, the industry's Washington-based trade group, said manufacturers are committed to increasing their pediatric testing but questioned whether a government mandate is needed.

The drug-testing proposal follows an increasing clamor from children's health experts about what they see as a growing problem: Drugs commonly used for kids often don't – and, indeed, aren't required to – undergo pediatric testing. In the case of new AIDS drugs, doctors have been reluctant to prescribe them to children because they don't know how the drugs, which have severe side effects, will work.

Only about 40% of drugs considered highly beneficial for young patients undergo pediatric testing, including medications for such common childhood ailments as asthma, allergic reactions and ear infections, administration officials say. Only about 20% of the drugs on the market have been tested on children.

While pediatricians often prescribe drugs that haven't been studied in children, they frequently lack important information on precisely how much medication to use and how it will affect their patients.

As a result, physicians are sometimes forced to choose between "prescribing drugs without well-founded dosing and safety information or utilizing other potentially less effective therapy," says a copy of a draft Food and Drug Administration rule. In fact, administration officials say, the percentage of drugs tested on children is decreasing, and is largely absent for children under two years of age. In the case of AIDS, only five of the 11 approved drugs have been tested in children.

The administration estimates the plan

THE POLICY CHANGE, to be proposed today, could raise costs for drug makers.

would cost the drug industry between $13.5 million and $20.9 million a year. Part of that reflects a requirement that manufacturers develop drug formulations, such as liquids, that could be used by children.

Mr. Holmer of the drug makers' group called the administration's cost estimate too low. "It widely misses the mark and fails to reflect the enormous scientific difficulties that are often involved" in conducting pediatric tests and developing formulations for children, he said.

Industry officials say that pediatric trials are particularly challenging because parents are often reluctant to enroll their children. Another problem: The tests may have to be repeated in children of different ages to get enough useful information.

But health groups and administration officials note that drug companies have been conducting safe clinical trials involving children for years. "Safety isn't a concern," says Susan DeLaurentis, co-founder of the Pediatric AIDS Foundation, a Santa Monica, Calif., group that has pushed hard for increased pediatric testing. She notes that both the American Academy of Pediatrics and the federal government have issued guidelines on how to conduct such tests ethically. And other AIDS activists say the regulation virtually ensures that manufacturers developing the next generation of AIDS drugs conduct pediatric testing before seeking FDA approval.

The Clinton administration's plan would require prescription drug makers to submit pediatric data to the FDA when they apply for approval to sell the drugs to adults, or shortly after approval is granted. The rule would cover drugs that are expected to be a significant advance for children and medications likely to be taken by more than 100,000 children a year. The FDA expects 12 of the new drugs it approves each year to trigger the requirements, and it would decide which they were.

While manufacturers that don't comply would face court action and fines, they

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Drug-Safety Tests Sought for Kids

Continued From Page B1

wouldn't be threatened with drug-approval delays or product recalls—enforcement actions the administration rejected as unethical.

For drugs already on the market, manufacturers would be required to submit pediatric information if there were "compelling circumstances" – for example, if the drugs could help children but weren't being used because of a dearth of data. In cases where children and adults are affected similarly by a disease, companies would have to test a drug for safety and dosage but not perform more elaborate effectiveness testing.

Some drug companies are already testing their drugs in children. A **Glaxo Wellcome PLC** spokeswoman says the company includes pediatric studies for its HIV drugs, among others. Glaxo also tested its drug Ultiva, an analgesic used in anesthesia procedures, in children two and older, and it is now testing the drug in children ranging in age from newborn through 18. Various forms of Glaxo's asthma drug, Ventolin, are approved for children as young as two, she adds.

SmithKline Beecham PLC is testing its antidepressant, Paxil, in young people, a spokesman says. He also notes that the company conducted pediatric trials for its leading antibiotic, Augmentin.

A spokesman for **Novartis AG**, the company that makes Ritalin, says the drug to treat attention deficit disorder has pediatric approval but isn't recommended for children under six years of age. He declined to comment on the proposed requirement to test drugs in children because the company hasn't seen the proposal.

The new rule, which is still subject to change, will become effective sometime after the close of a 90-day public-comment period. Manufacturers submitting new drug applications would have between 15 and 21 months to hand in kids' studies, depending on when they filed their FDA application.

—Elyse Tanouye contributed to this article.

President to Order Drug Makers to Conduct Pediatric Studies

By ROBERT PEAR

WASHINGTON, Aug. 12 — President Clinton will order changes in the testing of prescription drugs to insure that manufacturers specifically examine the drugs' effects on children if the medications are to be used by any significant number of young patients, White House officials said today.

The officials said they decided to require such studies because drug companies were not doing enough pediatric studies on their own.

Mr. Clinton will announce the new policy on Wednesday at the White House, the officials said.

Chris Jennings, a White House aide who coordinates health policy, said: "Medications used for pediatric populations have been woefully and inadequately tested to date. Only 42 percent of drugs that have proved highly useful in pediatric populations have been tested on children."

The order is the latest example of the Clinton Administration's emphasis on protecting children. Mr. Clinton recently persuaded Congress to create a health insurance program for children. Under his direction, Federal agencies are trying to halt the sale of tobacco to minors and to protect children from environmental health hazards, sex and violence on television, and liquor advertising.

Under a rule to be issued on Wednesday by the Food and Drug Administration, Mr. Jennings said, "we will require drug manufacturers to conduct studies to determine the safety and appropriate dosage levels for any prescription drugs used widely by children."

In addition, he said, "we will require appropriate labeling" to reflect the results of those studies.

Alan F. Holmer, president of the Pharmaceutical Research and Manufacturers of America, a trade association for drug companies, said the industry would work with the Government in a cooperative spirit.

"I would expect that there would be some increase in testing of drugs in children as a result of this regulation," he said, "but it's hard to determine the precise magnitude until we have a chance to see the text of the regulation."

Dr. John D. Siegfried, deputy vice president of the association, said it might be difficult for drug makers to recruit children for clinical trials.

"F.D.A. assumes that thousands of children are willing to be tested and that their parents are willing to have them tested," Dr. Siegfried said. "But in reality, there are not a lot of parents who want their kids to be in clinical tests just for the sake of satisfying the Government."

In addition, he said, children of different ages may react differently to the same dose of a particular drug. So the studies will be difficult to design.

Under the proposed regulation, drug companies would not have to evaluate a new drug in children if it was "impossible or highly impractical" to do so.

Explaining why the White House had decided to act now, Mr. Jennings said: "In the last few years, we have requested the pharmaceutical industry to provide this information and to put it on drug labels. Unfortunately, we have had a fairly low success rate in getting the companies to do it voluntarily."

Many drugs used by children, including asthma medications and antibiotics, have not been specifically studied in children or approved for use in children. They are approved for adults and prescribed for children, for uses not specifically recognized on the labels.

Mr. Holmer said drug trials for children must not delay the development, approval and marketing of drugs for adults.

But Donna E. Shalala, the Secretary of Health and Human Services, said: "Children are not simply small adults. Under the new rule, manufacturers of drugs likely to be used by children will be required to complete

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studies and place information on drug labels to help physicians make scientifically based decisions when prescribing drugs for children."

In addition, Mr. Holmer said, drug companies will have to conduct new studies of some drugs already in wide use among children.

Dr. Robert M. Ward, a professor of pediatrics at the University of Utah and chairman of the American Academy of Pediatrics' committee on drugs, welcomed the President's initiative.

"This is one of the most important advances for pediatric drug therapy in several decades," Dr. Ward said in an interview. "It will improve the information that doctors have available to them when they select and prescribe medications for children."

For example, Dr. Ward said: "Patients with asthma are often treated with steroids taken through an inhaler. These are among the most effective treatments available for asthma. But drug companies have not spent the money or the time to study these drugs in large groups of children and to submit the data to the F.D.A."

Susan DeLaurentis, a co-founder of the Pediatric AIDS Foundation, praised the new rule.

"Drug companies will be required to evaluate the safety and dosing of drugs that will be used in children," she said. "They are not required to do that now. This is a huge change. It's fantastic."

Prescription Drugs and Children

Clinton Announces Action to Force New Studies, Different Labeling

By Peter Baker
Washington Post Staff Writer

More than a half-century after requiring that new medications be proven safe and effective for adults, the federal government for the first time plans to force drug manufacturers to conduct separate studies on how their products will affect children.

Under new rules announced by President Clinton at the White House yesterday, pharmaceutical companies beginning next year would be obligated to test the safety of their prescription drugs for children, determine the proper dosages and then label them accordingly.

"The executive action that I take today simply is designed to ensure that parents and pediatricians have the safety information they need," Clinton said. Without such tests, he said, "the pediatricians' other alternative is to guess—with potentially grave consequences."

Currently just 20 percent of drugs marketed in the United States are labeled for use by children, often forcing pediatricians to make judgments about prescribing medications based on incomplete information or to simply refrain rather than risk causing more harm than good. The decisions on how much and how often to give drugs to infants, toddlers and adolescents are far more complicated than simply cutting adult dosages in half, according to physicians.

Each year, more than 5 million children under age 6 are given commonly used drugs such as Prozac, Ritalin and others that treat asthma, allergies and ear infections even though they have not been adequately tested, according to the administration. About half of the drugs used to treat adults with the AIDS virus have not been tested for children.

"Children are not little adults," said Joseph R. Zanga, vice president of the American Academy of Pediatrics. "At every age and stage of their development, they respond to things, drugs included, in different ways than adults."

In having Clinton announce the rule rather than the Food and Drug Administration, the White House continued its strategy of promoting relatively modest initiatives that, while important in the everyday lives of some Americans, traditionally have not merited presidential attention.

It also fit into the Clinton approach to restructuring the health care system one piece at a time, a strategy adopted after the failure of the comprehensive overhaul crafted by first lady Hillary Rodham Clinton, who was on hand for yesterday's event. The most recent and prominent example of that was the $24 billion expansion of health coverage for indigent children included in the balanced budget plan signed into law by Clinton last week.

Joined by Vice President Gore and Health and Human Services Secretary Donna E. Shalala, the Clintons unveiled the pediatric drug rule at a White House ceremony that featured Regan Ralph, a Washington lawyer whose son was treated for asthma with drugs not labeled specifically for children.

> ***"I consider it a national scandal that 80 percent of the drugs have not been fully tested for kids."***
>
> —Sen. Mike DeWine (R-Ohio)

Her son, 21-month-old Sam Hanoura, stole the show by wandering around stage and ultimately plopping down in the chair between the president and first lady. "Drugs can be good, but it's scary not knowing exactly what's going to happen," his mother said afterward.

The same sentiment prompted Sens. Mike DeWine (R-Ohio) and Christopher J. Dodd (D-Conn.) to introduce legislation last spring providing incentives to drug makers to conduct pediatric tests. "I consider it a national scandal that 80 percent of the drugs have not been fully tested for kids," DeWine said in a telephone interview.

Clinton aides said they decided to impose the regulation after a voluntary system launched in 1994 failed to win much industry cooperation. "We have not had good success in increasing the number of new drugs that are tested in kids," said FDA Deputy Commissioner William B. Schultz. The estimated $20 million cost to industry, he said, would be "relatively modest" out of hundreds of millions of dollars already spent on drug development.

The proposed regulation would take effect in six months and focus first on 10 commonly used drugs already on the market.

Industry leaders yesterday said they shared Clinton's goal, but disputed the notion that they have not made progress on their own. Alan F. Holmer, president of the Pharmaceutical Research Manufacturers of America, said the "vast majority" of the 10 drugs singled cited have been approved for children's labels or have been tested and have label revisions pending.

"We question whether a government mandate is needed because of all the progress that has been made and is being made," Holmer said, "but we pledge to work with the president on a collaborative and constructive basis."

Staff writer John Schwartz contributed to this report.

Washington Post
8/14/97

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PAGES INCLUDING COVER SHEET: 3

COMMENTS:

National Association of
Children's Hospitals

LAWRENCE A. McANDREWS, FACHE
President & Chief Executive Officer

N · A · C · H

Statement

Lawrence A. McAndrews

CHILDREN'S HOSPITALS URGE FEDERAL ACTION TO STIMULATE MANUFACTURERS' TESTING OF PHARMACEUTICAL PRODUCTS FOR CHILDREN'S USE

August 13, 1997

The National Association of Children's Hospitals (N.A.C.H.), representing more than 100 children's hospitals across the country, strongly commends the Clinton administration's recognition of a serious failing of the health care market place – the absence of adequate market incentives or requirements for testing and labeling of pharmaceutical products for use by children.

The proposal for public comment of new regulations mandating testing of pharmaceuticals for pediatric use by the Food and Drug Administration (FDA) reflects the strong, ongoing personal commitment of President Clinton and the First Lady to public policy that helps every family meet its children's needs for health, education, safety, and security. Certainly a serious concern for any parent whose child requires medication is the realization that only about 20 percent of all of the drugs marketed in the United States have been tested and labeled specifically for use by children.

Three weeks ago, in a hearing before the Senate Public Health and Safety Subcommittee, a number of the nation's leading pediatric researchers cited the serious lack of pharmaceutical products tested for children's use as one of the most important challenges facing the pediatric health care community in its efforts to convince the nation of the need for increased investment in research devoted to children's illnesses and conditions.

These researchers included academic leaders from Children's Hospital in Boston and Le Bonheur Children's Medical Center in Memphis. They recognize that the market's failure would not be a problem if children's health care needs were identical to those of adults. But that, of course, is not the case. As both parents and pediatric providers understand all too well, children are not miniature adults. Their health care needs are not appropriately met by providing either adult-sized treatments or even miniature versions of them.

All too often, our children's care givers must rely only on their personal judgment in deciding which drugs and which dosages are best suited for their patients. Because they devote such a large share of their services to children with complex conditions requiring specialized care, children's hospitals are very aware of the limited extent of testing and labeling of pharmaceuticals for children.

N.A.C.H. believes the Administration's new initiative to develop the most appropriate ways to stimulate product testing through regulation can complement the important legislation proposed by Senators Christopher Dodd (D-CT) and Mike DeWine (R-OH) plus Representative Jim Greenwood (R-PA) and Henry Waxman (D-CA) to create market incentives for manufacturers to undertake pediatric studies of new and FDA-approved pharmaceuticals. Their legislation, which has strong bipartisan support, continues the effort begun in 1991 by former Senator Nancy Kassebaum (R-KS) to persuade the Congress of the need to address the lack of pharmaceutical testing for children.

Because they represent only about 30 percent of the nation's population, less than 15 percent of health care spending, and the poorest segment of the population, children do not command the attention of the health care market for investment in research and development (R&D). This is true not just for R&D for children's health care in particular, but for all R&D related to children.

According to the National Science and Technology Council's April 1997 prepublication report on "A National Research Initiative for America's Children for the 21st Century,"

> "...(T)he share of total national R&D toward children is less than 1.2 percent. Unlike other areas of research, the Federal Government bears almost total responsibility for children. For example, the private sector provides over 50 percent of health and energy R&D funding and over 90 percent of transportation R&D. In contrast, the Federal Government provides approximately 90 percent of children's R&D."

Clearly, strengthening the federal investment in research devoted to children remains critical. But children's needs will not be fully met if the federal government alone shoulders the responsibility for pediatric research and development. Through a balanced commitment to market incentives and regulation, the federal government can stimulate manufacturers' investment in product testing to meet children's unique health care needs more fully.

Just last week, Congressional and White House commitment to bipartisanship in budget policy helped to launch the most important new federal commitment to strengthening children's health insurance coverage in a generation. We are confident that the same spirit of bipartisanship can lead to effective federal policy combining appropriate incentives and regulations to ensure the necessary testing of pharmaceutical products for pediatric use, which both children and their parents deserve.

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 announced a proposed regulation that would create important protections for children by requiring manufacturers to provide pediatric-use information for medicines used to treat children. The rule would also require companies to submit information that would be placed on drug labels to help pediatricians and other health care providers make treatment decisions based on scientific information specific to children. This rule is designed to ensure that important drugs are available for use in children and to reduce avoidable adverse drug reactions and under-treatments by better informing physicians about whether -- and in what dosages -- drugs are safe and effective for use in children.

Continuing a Comprehensive Effort

The proposed rule is part of a comprehensive effort by the Department of Health and Human Services' Food and Drug Administration (FDA) to increase the number of drugs and biologic products with adequate labeling for safe and effective use in children. In 1994, the FDA issued a regulation to encourage drug manufacturers to submit pediatric-use data for review. The FDA has also implemented a "Pediatric Plan" designed to improve pediatric-use information for marketed drugs and to encourage voluntary development of pediatric-use data during the drug development process.

Ensuring Children's Safety

Despite these efforts, many new drugs are still being approved without information on how they should be used to treat children. In addition, there is extensive evidence that drugs for conditions that affect both adults and children are routinely used to treat pediatric patients despite the absence of pediatric labeling, and even in the face of disclaimers stating that safety and effectiveness have not been established in children. The absence of pediatric labeling information may require physicians caring for children to choose between prescribing drugs without well-founded dosing and safety information, or utilizing other, potentially less effective therapies. As a result, inadequate pediatric labeling puts children at risk for unexpected adverse reactions or lack of optimal treatment. Even after a drug has been used in children for some time, and there has been substantial clinical experience with a drug, directions for safe and effective use in children are often not provided on drug labels. Under the proposed rule announced today, manufacturers of new and marketed drugs or biologic products likely to be used to treat children will be required to provide sufficient data and information to support directions for safe pediatric use, with few exceptions.

Building on the President's Commitment to Children's Health

Since taking office, protecting the health of America's children has been one of President Clinton's primary objectives. Since 1993, the Clinton Administration has significantly increased investments in priority areas for children, and results have followed. For example, in large part due to President Clinton's comprehensive Childhood Immunization Initiative, a record number of 2-year-olds are now properly vaccinated, and most vaccine-preventable diseases are at record lows. In addition, infant mortality is at an all time low, and the numbers of women receiving prenatal care in their first trimester is at an all-time high. President Clinton has also expanded health coverage to more children by signing the Kassebaum-Kennedy legislation into law, and by ensuring inclusion of provisions in the new balanced budget that will expand health coverage to up to 5 million uninsured children.