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5 HIV TESTING OF WOMEN AND]

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7 Thursday, May 11, 1995

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9 House of Representatives,

10 Committee on Commerce,

11 Subcommittee on Health an(

12 Washington, D.C.

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14 The subcommittee met

15 Room 2322, Rayburn House (

16 Bilirakis [chairman of th(

17 Present: Representa

18 Burr, Bilbray, Ganske, No...

19 Towns and Studds.

20 Staff Present: Melody J. Harned, Majority Counsel; Kay

21 Holcombe, Minority Staff Member.

DO NOT DETACH

HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
ROOM B-334, RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

MANUSCRIPT FOR CORRECTION AND RETURN TO COMMITTEE

Subject HIV Testing of Women and Infants

Hearing date May 11/95

Referred to Hon. Tom Coburn

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GPO: 1994 76-923 (m)

491 discuss testing issues.

492 I do want to assure Mr. Ackerman in his absence and other
493 Members that if there is an interest in having Federal--that
494 if there is interest in having Federal legislation in this
495 area I certainly will work with you all in drafting separate
496 legislation.

497 And now I will call upon any other Members who are here,
498 none of which are here, for their opening statements.

499 I am sorry. I guess I may as well break at this point.
500 Again, I apologize, but those of you who are veterans on the
501 Hill understand that this goes on all the time. As soon as
502 we return, we will go into some more opening statements and
503 then the first panel. Thank you.

504 [Recess.]

505 Mr. COBURN. [Presiding.] We are going to start, if we
506 may. And since I don't have an opening statement, I will
507 defer to the Ranking Member, Mr. Waxman from California.

508 Mr. WAXMAN. Thank you very much, Mr. Chairman.

509 It seems to me we ought to step back and look at where we
510 are. And the exciting fact is that with the ability now to
511 treat a pregnant woman who is HIV infected, with AZT we can
512 dramatically lower the number of babies that will be born
513 with pediatric AIDS. That is an exciting reality.

514 Now the question is, how do we make that progress that we
515 have seen a reality in practice? We need to, it seems to

785 Mr. BILIRAKIS. And without any further ado we will go
786 right into our second panel.
787 Dr. Coburn, you had no opening statement?
788 Mr. COBURN. I have no opening statement, Mr. Chairman.
789 Mr. BILIRAKIS. Thank you.
790 Our second panel consists of Dr. Helene Gayle, the Acting
791 Director of the National Center for Prevention Services at
792 the Centers for Disease Control; and Dr. James Balsley, the
793 Chief of the Pediatric Medicine Branch in the Division of
794 AIDS at the National Institute of Allergy and Infectious
795 Diseases. Dr. Balsley was also the Chief Medical Officer for
796 the 076 protocol, which demonstrated that pregnant women who
797 take AZT significantly reduce the risk of transmitting HIV
798 to their babies.
799 I ask you both to please limit your testimony to five
800 minutes. I will turn on the light but certainly won't cut
801 you off if you go just a few seconds over. And, of course,
802 without objection your entire written statements will be
803 made a part of the record.
804
805 STATEMENTS OF HELENE D. GAYLE, M.D., MPH, ASSOCIATE
806 DIRECTOR, CENTERS FOR DISEASE CONTROL--WASHINGTON, ACTING
807 DIRECTOR, NATIONAL CENTER FOR PREVENTION SERVICES;
808 ACCOMPANIED BY ERIC GOOSBY, DIRECTOR OF THE OFFICE OF
809 HIV/AIDS POLICY FOR THE PUBLIC HEALTH SERVICE; AND JIM

1380 Mr. BILIRAKIS. Dr. Coburn.

1381 Mr. COBURN. Thank you.

1382 Let me thank each of you for being here, and I appreciate
1383 that.

1384 I might just ask a couple of questions, because I am not
1385 familiar with all the members of the panel. You all have
1386 cared for people with HIV; is that correct?

1387 Ms. GAYLE. Yes.

1388 Mr. COBURN. You all have had hands-on caring for people,
1389 and mothers as well?

1390 Ms. GAYLE. Yes.

1391 Mr. COBURN. Okay. I want to follow up, Dr. Gayle, if I
1392 might for a minute, right now we are not going to track
1393 newborns, right? We are not going to track this disease in
1394 newborns?

1395 Ms. GAYLE. Well, we are--we are talking about having a
1396 fairly rapid consultation process that will discuss this.
1397 There are a variety of different surveillance mechanisms.
1398 This is one.

1399 Mr. COBURN. The point is, are you tracking this disease
1400 in newborns with the suspension of this study?

1401 Ms. GAYLE. In others ways, yes.

1402 Mr. COBURN. Would you explain those to me?

1403 Ms. GAYLE. For instance, we have a surveillance system
1404 that collects all AIDS cases throughout the country. That

1405 gives us good information about the picture. It doesn't
1406 give you exactly the same picture.
1407 And let me back up for a minute. The childbearing--the
1408 survey of childbearing women does not track HIV infection in
1409 newborns. It tracks HIV infection in women. We have
1410 multiple other surveys that, in fact, between AIDS case
1411 surveillance as well as other surveys that we have in other
1412 clinics, public clinics and otherwise, we can use other
1413 information to put together some information on women. We
1414 feel this particular survey gave us an extremely good, broad
1415 picture of where the epidemic is going in women.
1416 Mr. COBURN. Okay. I am still having some understanding
1417 of why you discontinued the study.
1418 Ms. GAYLE. As I stated before, we are at a point in time
1419 where there are a lot of different changes going on and we
1420 felt it was useful to step back, take a look, see where we
1421 are with our perinatal prevention activities overall. That
1422 is one piece of it. And we would like to look at that in
1423 the context of the broader picture.
1424 Mr. COBURN. Okay.
1425 Would you give me just a short synopsis of where we are
1426 right now with this epidemic? What is our increasing rate,
1427 what is our total numbers, are we seeing a slowdown in the
1428 number of identified seropositive people?
1429 Ms. GAYLE. Dr. Curran will probably want to add something

1430 as well. Dr. Curran is in charge of all of our surveillance
1431 activities.
1432 The HIV epidemic is, obviously, a very heterogeneous
1433 epidemic and is growing at different rates in different
1434 populations.
1435 Mr. COBURN. Overall, I am speaking.
1436 Ms. GAYLE. The rate of new cases continue to increase at
1437 about 3 percent per year. We are having the fastest-growing
1438 new cases of AIDS in women, in heterosexual populations and
1439 minority populations.
1440 Mr. COBURN. Of childbearing age?
1441 Ms. GAYLE. Yes, and minority populations. And continuing
1442 to have spread in new parts of the country, more spread to
1443 rural areas, continued growth of the epidemic throughout.
1444 And, Jim, I don't know if you want to add any.
1445 Mr. CURRAN. Well, HIV has, in 1993, became the leading
1446 cause of death in adults between 25 and 44 years of age. It
1447 is the fourth leading cause of death in women in that age
1448 group, and the first leading cause of death in men in that
1449 age group. Pediatric AIDS increased 8 percent from 1993 to
1450 1994, and the increase in women adjusted for the case
1451 definition change in adults was approximately the same.
1452 Pediatric AIDS parallels AIDS in women rather predictably,
1453 as you might guess.
1454 Mr. COBURN. Right. So we do--you have established that we

1455 have an at-risk group of reproductive women in this country
1456 that are the largest-growing segment of this disease? Is
1457 that true?

1458 Mr. CURRAN. Yes. We think HIV infection in women is
1459 particularly important.

1460 Mr. COBURN. Dr. Gayle, let me follow up with one other
1461 question to you, if I may. You said it makes sense that
1462 women in this group should be tested. Can you tell me what
1463 group in this country should not be tested on a voluntary
1464 basis, what group should not be tested for HIV at this time
1465 that would not make sense?

1466 Ms. GAYLE. Yes, no, that is what I prefaced my comments
1467 to your colleague, by saying that at this point in time,
1468 given where we are in our prevention strategies and where we
1469 are in our ability to improve the quality of life for anyone
1470 with HIV, probably makes sense for most people to--we are
1471 focusing today on what is the best strategy to prevent HIV
1472 infection in children, so that is why I particularly focused
1473 on that, but I would agree.

1474 Mr. COBURN. Did you just say that most people should be
1475 checked for that? Did I hear you say that, most people
1476 should be checked for HIV status?

1477 Ms. GAYLE. What I said is I think that given the fact
1478 that we have very, very good ways now of improving the
1479 quality of life for people, there is really no reason why it

1480 wouldn't be useful information for most people. I think it
1481 is an individual decision. I think most--
1482 Mr. COBURN. That is a different question. But in terms
1483 of--your statement was most people should be checked for HIV.
1484 Ms. GAYLE. I think most people should be provided the
1485 kind of information that they can make that very personal
1486 decision for themselves.
1487 Mr. COBURN. Let me just follow up with--and you or any of
1488 the doctors on the panel can answer this.
1489 Dr. Lee, before this committee, on the Ryan White Act,
1490 when asked certain groups that should be tested, he said
1491 prisoners should be tested, because of the growth in that
1492 group. Are there other areas where the CDC thinks that
1493 specific groups should be tested? Specific targeted groups.
1494 Should health care workers be tested?
1495 Mr. CURRAN. Well, we have recommendations for testing and
1496 counseling for a large number of groups. Our first
1497 recommendation is for pregnant women, for example, were
1498 published in 1985, just a few months after the antibody test
1499 was licensed, and we recommended then that anybody who was
1500 at increased risk for HIV infection who was pregnant be
1501 tested. But we have guidelines for testing all populations
1502 who are at increased risk for HIV.
1503 Mr. COBURN. Okay. Let me ask one other question, and
1504 then I will defer back to the Chairman. And you please

1505 correct me if this is an incorrect statement.

1506 Approximately, we have a 50 percent identification rate on

1507 vectors in this disease. Is that an adequate policy to

1508 control this epidemic? I mean, do we have a policy in place

1509 that is going to control this epidemic by identifying 50

1510 percent of the people that are carrying this disease?

1511 Ms. GAYLE. I think, yes, in our counseling and testing

1512 programs that we have throughout the country, our rates are

1513 a little bit higher than that. It is hard to look at it and

1514 just say that any one figure is right for the whole

1515 population.

1516 Again, this is a fairly heterogeneous epidemic. We think

1517 that given all things, that it is important to put the

1518 greatest emphasis on people who are at greatest risk. And

1519 we clearly know that there are behaviors that put people at

1520 particularly high risk. And so our strategy would be to

1521 make sure that people who are at the highest risk get the

1522 information that would allow them to make that decision

1523 about getting tested.

1524 Clearly, anything that would move in the direction of

1525 saying that the whole population would have to be

1526 mandatorily tested or anything like that--

1527 Mr. COBURN. I am not looking for that.

1528 Ms. GAYLE. I am not saying you are, but I am just saying

1529 that would be the extreme. And clearly, that would not be

1530 the direction. We want to make sure that people have the
1531 kind of information that allows them to know what their
1532 risks are and to have access to testing and counseling.
1533 Mr. COBURN. I understand.
1534 Would you do one other thing for me? Describe untreated
1535 syphilis in a newborn. What happens to a child who has
1536 vertical transmission of syphilis, a newborn that goes
1537 unidentified? What is the outcome of that disease in that
1538 child?
1539 Ms. GAYLE. It can have extremely serious consequences.
1540 Mr. COBURN. Right. And do not by far the vast majority
1541 of the States in this country test for syphilis at birth? I
1542 think it is 47 States.
1543 Ms. GAYLE. Probably, that is probably close to right.
1544 Mr. COBURN. Does the CDC continue to recommend that that
1545 be ongoing?
1546 Ms. GAYLE. Yes. I think that the--there is a real
1547 distinction between syphilis and HIV, though. Clearly, HIV
1548 is a life-threatening disease.
1549 Mr. COBURN. Syphilis in a newborn is a life-threatening
1550 disease.
1551 Ms. GAYLE. Yes, but it is ultimately a simply treated
1552 disease. There is a very clear simple intervention that can
1553 be given. We are talking about a very complicated
1554 intervention that must be given to a woman and her child.

1555 Mr. COBURN. So let me follow up; because of what the
1556 treatment differences are, we should see a difference in
1557 diagnosis, and we are not going to treat from a public
1558 health standpoint because we have a different treatment
1559 pattern. Is that what you are telling me?
1560 Ms. GAYLE. No, not at all. It is not simply treatment. I
1561 think that the whole nature of HIV is very different than
1562 the whole nature of syphilis. And again, one of the reasons
1563 why we feel that voluntary testing is an extremely important
1564 part of this, is that we have seen already in this disease
1565 that mandatory testing drives people underground. That
1566 would be counterproductive and would not be the appropriate
1567 public health strategy.
1568 We are dealing with public health realism, we are dealing
1569 with how to best get people into therapy, how best to make
1570 sure that those people can be followed over a long period of
1571 time for what is an extremely complicated illness. And so I
1572 think it is very different than syphilis, which people have
1573 grown to accept a very simple treatment and a very less
1574 scary overall picture.
1575 Mr. COBURN. I would just say that tertiary and secondary
1576 syphilis are not very simple treatments, if you have ever
1577 administered it to an adolescent.
1578 Mr. BILIRAKIS. I thank the gentleman. Go ahead, by all
1579 means.

1630 baby that is exposed. Everybody will get PCP prophylaxis
1631 because they are already getting zidovudine for the first
1632 six weeks. It is simple to switch from zidovudine to
1633 trimethoprin-sulfamethoxazole. It is a break.

1634 And so, you know, that is the way we are going to get this
1635 done. But it has got to be voluntary or people are going to
1636 get lost. They are going to break the connection. And
1637 there have got to be services made available to the people.
1638 Including substance abuse treatment services, which is never
1639 really talked about anywhere.

1640 Mr. WAXMAN. Substance abuse services, we have got to pay
1641 for those drugs for extended period of time. We can't tell
1642 a woman go get tested, then find out she is HIV positive,
1643 then say you are on your own to find out whether you can
1644 afford to pay for these drugs.

1645 But then she faces other consequences; because HIV and
1646 AIDS has a certain status in our population that could cause
1647 a woman to lose her child if she is considered an improper
1648 mother. And I am sure many of these women are very
1649 frightened of that.

1650 Maybe we will hear from other witnesses about it, the
1651 stigmatization could well be, if she had insurance, she
1652 could lose it.

1653 Mr. COBURN. Would the gentleman yield for a minute?

1654 I would just glean for you my experience of being in a

1655 rural area and offering HIV testing to all my patients, and
1656 I have identified several who are carrying that, and I have
1657 done that since 1985. We have yet to have the first patient
1658 refuse to do that. But we have also been very firm with our
1659 recommendations that you are going to be tested if we are
1660 going to care for you. And so, therefore, when put in that
1661 terms--and we also have been very good about being
1662 confidential as to the results of those testing.

1663 One of the things that is positive, in terms of the
1664 insurance concerns, that everybody has in this country of
1665 losing coverage, because you have it, is that if every
1666 pregnant woman has to be tested, then there is no stigma to
1667 being tested. Right now, when we start testing and it goes
1668 on a report and then somebody that is not, then the
1669 insurance companies have the potential to look at that and
1670 say, well, they didn't want to be tested. And all of a
1671 sudden now we are going to have some selection criteria on
1672 insurance. So I think this is a double-edged sword and
1673 sometimes it is better to have everybody tested, from that
1674 standpoint.

1675 Ms. GAYLE. Just to add to that, I think we don't want to
1676 underestimate what issuing our guidelines will hopefully do.
1677 When CDC issues guidelines, those essentially become the
1678 standard of care. And so that is what we are talking about
1679 with our guidelines, is having that become the standard of

2759 should be offered to every woman and the education for
2760 everyone. Even in my hospital there are 98 women who aren't
2761 infected for every two who are, and it is as important for
2762 them to know their status and to have the educational
2763 reinforcement of good practice as for the other.

2764 Mr. MENNUTI. I think that the issue of cost-effectiveness
2765 is very important here, and I think that it can be moderated
2766 to a certain extent if you said the mandate is to offer
2767 testing, the mandate is not to perform the testing.

2768 Mr. BILIRAKIS. The gentleman's time has expired.

2769 Mr. MENNUTI. How strongly it is encouraged and how
2770 strongly it is offered can vary by area. There may be areas
2771 where the prevalence is so low the dollars would be better
2772 put in prevention; but, in general, offering it should be
2773 across the board.

2774 Mr. BILIRAKIS. Dr. Coburn--excuse me, Greg--Dr. Coburn, why
2775 don't you take your full 10 minutes now, if you would like.

2776 Mr. COBURN. Okay, thank you. A couple questions.

2777 Dr. Cooper, if you care for a baby in New York and you
2778 suspect drug withdrawal in that baby, do you test that baby
2779 for drugs?

2780 Mr. COOPER. New York statutes now are rather clear, and,
2781 yes, we can test if we have reason to test.

2782 Mr. COBURN. Do you get informed consent every time when
2783 you test that baby for drugs?

2784 Mr. COOPER. The issue with drug testing is viewed as one
2785 where there is a compelling State responsibility, and if we
2786 feel testing is required, then we can do it.
2787 Mr. COBURN. Do you feel that there is some difference
2788 between compelling State responsibility on a seropositive
2789 baby and a drug screen positive baby or one that would give
2790 you clinical signs?
2791 Mr. COOPER. Complex issue. In New York State, we still
2792 have 8,000 women who get no prenatal care and 75,000 who get
2793 late prenatal care. Because of the expanded medicaid and
2794 our ability to bring more women in, we have reduced the low
2795 birth weight by a third in New York State.
2796 Mr. COBURN. You are ahead of us in Oklahoma.
2797 Mr. COOPER. By a third. By the same token, we have done
2798 some sensitivity analyses such that if we reduced by 1
2799 percent the number of women coming in for prenatal care, we
2800 would probably have a higher morbidity and mortality from
2801 prematurity than we would achieve the other way around.
2802 Mr. COBURN. I guess what I am trying to get back to, what
2803 I am trying to get to, is how are you as far as feeling that
2804 if you have a child that has been born to somebody who did
2805 not want testing, would you feel that it is an appropriate
2806 thing to test that child?
2807 Mr. COOPER. Who did not want testing?
2808 Mr. COBURN. The mother did not want testing.

2809 Mr. COOPER. Emotionally, I would feel that I want to test
2810 that child. Practically, if we do it right--because it is
2811 remarkable how, when women are told what they can do to
2812 protect their children, they come around, and that is the
2813 real heart of the matter.
2814 And if I had a diehard, I have learned, just as you have,
2815 people don't make decisions without reason. I may not know
2816 what the reason is, but they have a reason. And so that is
2817 a family who I flag, and I try to refine my relationship.
2818 And I would run the risk that I could keep that mother and
2819 that child in care and that the best way to protect that
2820 child and that mother would be to keep them in care.
2821 The alternative is to turn the child over to the State. We
2822 have 50,000 children in foster care in New York City today,
2823 and that is not the kind of care I want for my child.
2824 Mr. COBURN. Let me follow up with one other question for
2825 you, if I may, Dr. Cooper. Were you satisfied with the
2826 answer Dr. Gayle gave for the reason for discontinuing that
2827 study?
2828 Mr. COOPER. Not really.
2829 Mr. COBURN. Would anybody else on that panel like to
2830 comment on the reason given by the CDC for discontinuing
2831 this very valuable study? No takers, huh?
2832 Mr. MENNUTI. Yes, I would like to comment on it.
2833 I think that it probably--I don't know the motivation and

2834 the timing, obviously, which are in question, but I think it
2835 is probably, if we are going to go to a format or if we are
2836 going to get to testing 95 percent of women, we may get the
2837 same information out of that testing as we do out of the
2838 anonymous seroprevalence study of newborns. And so,
2839 clearly, when you are investing that kind of money in doing
2840 it, you should periodically reevaluate it.

2841 The question of whether this is the right time to get rid
2842 of the study, I think she said suspended, and I assume we
2843 are going to reevaluate it and may reinitiate it or may
2844 decide to scrap it. At some point, we should get to testing
2845 enough women where maybe the information comes out of
2846 maternal testing more than newborn.

2847 Mr. COBURN. We talked just a moment ago that probably the
2848 ACOG--for those of you who are not familiar with ACOG
2849 guidelines in this room, when ACOG issues a guideline, that
2850 becomes, whether they like it or not, in courts of this
2851 country the standard of care and to violate against that is
2852 going to have a major impact on the testing of women for
2853 HIV. It will change many practices that are not presently
2854 doing it, and they will do that. I applaud ACOG for doing
2855 that. I am not sure right now that that is enough.

2856 I want to just comment on one other thing in terms of the
2857 rise in syphilis. You and I both know that the rise in
2858 syphilis is because of the multiple partners and the

2859 increased sexual promiscuity of our society, and we wouldn't
2860 know of that rise if we didn't have a method of testing for
2861 it right now. And so I think it is important for us to be
2862 aware of that.

2863 Not that it is a like or similar issue or disease, but I
2864 think it is important for us to all realize that we would
2865 have no awareness of that were that not in place at this
2866 time, even though maybe in some States that syphilis has
2867 gone down, but in many States we are at a 40-year high
2868 nationally for syphilis in this country. And the reason for
2869 that--the reason for that is multiple partners.

2870 And when we have teenagers who start at 15, 60 to 70
2871 percent of them will have four or more partners by the time
2872 they are 19. So the thing that is not discussed in this
2873 whole issue all the time, and we continue, is we have a
2874 sexually transmitted disease epidemic in this country that
2875 the national leadership is ignoring. And until we train our
2876 doctors to become aware and to get up to date on the fact
2877 that we do have this epidemic, we are not going to control
2878 it, regardless of what the government policy is.

2879 But the government should be leading the standard, and we
2880 should have people like you standing out and saying, let's
2881 get up to grade and attack this issue. Because this is
2882 just--HIV is just one symptom of the many other diseases that
2883 are being transmitted now that we are kind of covering up

2884 and not wanting to address.

2885 Mr. VAN DER HORST. I can't agree with you more,

2886 Congressman. I think if you wanted to have one piece of

2887 legislation come out of all our discussion it would be to

2888 mandate that physicians be reaccredited every five years

2889 through an exam so they know what the hell they are doing.

2890 I mean, I think it is nuts that we can go to a--

2891 Mr. COBURN. The American College of Family Practice

2892 requires that and so does ACOG.

2893 Mr. VAN DER HORST. I know, but as an internist, we do not

2894 require it, and I think that is nuts.