



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

Amy Gutmann, Ph.D., Introductory Remarks

The Honorable Kathleen Sebelius
Secretary of the Department of Health and Human Services

Meeting 9, Distinguished Speaker
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1 DR. GUTMANN: So it is my honor and privilege and pleasure
2 to welcome the 21st Secretary of Health and Human Services,
3 the Honorable Kathleen Sebelius. I want to say a few words
4 about the Secretary before she says a few words to us.

5 In each phase of her career, Kathleen Sebelius has
6 embodied the motto of the Sunflower State, leading
7 Americans to the stars through difficulties. The
8 difficulties have been tremendously numerous and diverse.
9 Time and again she's triumphed to benefit citizens across
10 this country.

11 Since assuming office in 2009, Secretary Sebelius
12 has presided over momentous changes at HHS. The passage of
13 the Affordable Care Act has lead to a new focus on wellness
14 and prevention, increased access to primary care health
15 providers and a more efficient medical records system to
16 the benefit of millions of Americans.

17 Public officials from both parties have praised
18 her as an expert collaborator and as a consensus builder.
19 I needn't tell members of our Commission how important that
20 is and members of the American public recognize how
21 important those talents put to work for the public good
22 are.

23 In her two terms as Governor of the State of
24 Kansas, Secretary Sebelius boosted state education

1 spending, fought to create jobs and increased affordable
2 health care. In 2005, Time Magazine called her "One of the
3 nation's five best governors."

4 Prior to that, Secretary Sebelius served eight
5 years as Kansas Insurance Commissioner earning a reputation
6 for standing up for consumers and proposing visionary
7 changes to the health care system.

8 In recognition of her many accomplishments,
9 Governing Magazine selected her as its public official of
10 the year for 2000.

11 Secretary Sebelius leads the nation's emergency
12 health response to crises and natural disasters, including
13 the Haiti earthquake, the Gulf oil spill and the Joplin,
14 Missouri tornado. She is no stranger to how to respond
15 effectively to the nation's greatest crises. It is in this
16 role that Secretary Sebelius has asked us, the Presidential
17 Commission for the Study of Bioethical Issues, for ethical
18 advice on the development of medical countermeasures for
19 children.

20 We're honored, Madame Secretary, to have you in
21 our presence and to be entrusted with such a task. Welcome
22 on all our behalves.

23 (Applause)

24 SECRETARY SEBELIUS: Well, thank you so much to

1 Amy Gutmann, not only for that very kind introduction -- my
2 mother would be very proud -- but for your leadership on
3 this really important endeavor. I want to also thank the
4 Commission members and recognize my old friend, Barbara
5 Atkinson, who comes from the Sunflower State and has done
6 great work. But the job that you're doing is just
7 incredibly important and it's one of the reasons I wanted
8 to spend a little time with you today.

9 I know that we have Dr. Skip Nelson here from the
10 FDA, Major General Parker with the National Biodefense
11 Science Board, Lisa Kaplowitz is here from ASPR. I want to
12 recognize the great, new Executive Director of the
13 Commission, Dr. Lisa Lee, who spent over a decade at CDC
14 and now is here. I can tell you that Amy lost no time in
15 saying, "We have to get her on board quickly, move quickly,
16 we need Lisa," so we're delighted that you're here doing
17 this important work.

18 I really do recognize that all of you have busy
19 lives and lots to do, but the work of this Commission is
20 critical. It's critical to us at the Department and it's
21 critical to the President. I think that you have
22 volunteered your time and effort to make sure that we get
23 these very important issues right.

24 The work that you did looking at the public health

1 service experiments in Guatemala was critical to get us
2 through a situation that could have provoked, really,
3 international crises and yet you helped us navigate that
4 difficult terrain. Assessing the rules that protect human
5 subjects and research today are really important framework
6 going forward and clearly need that kind of balanced look.

7 I think that the effort to bring transparent
8 deliberations to some of the most difficult issues also
9 serves a real role in educating the public about what has
10 to be regarded as important and brings that dialogue
11 forward.

12 So I think there's serious ethical issues around
13 the development of medical countermeasures for children.
14 We are very concerned that as we look at our responsibility
15 to protect the health and safety of the American public, we
16 have the responsibility at HHS for developing and stock
17 piling safe and effective medical countermeasures to
18 protect the nation from bioterror attacks or naturally
19 occurring issues. The work that is done in our various
20 departments on this issue is ongoing; continually assessing
21 what's out there trying to be informed by the newer science
22 looking at what's available.

23 One of the things that I did -- because many of
24 you might know I was sworn in in the midst of the first

1 pandemic in 70 years in this country. I had done a lot of
2 things in Kansas, but we'd never had a pandemic -- thank
3 God. But I learned very quickly about some of the
4 challenging issues around medical countermeasures; what we
5 knew and what we didn't know, how long it might take to
6 develop effective responses.

7 So one of the after action items in that situation
8 was to have a review of our entire medical countermeasure
9 system. The President asked us to conduct that and I was
10 pleased to do it. It was clear, among other things, that
11 we needed to improve our capacity to produce medical
12 countermeasures more rapidly in the face of any attack or
13 threat. We were in a situation in the United States, and
14 that is being changed over time, but that we really could
15 only produce less than a third of whatever was needed.

16 So we relied on contracts; international
17 contracts, that might or might not have been fulfilled. We
18 have little control. It was a situation which we have
19 identified as one that we need to fix.

20 So we've made some progress toward goals for
21 adults. We know that the development of appropriate
22 countermeasures for children is really slower, but
23 critically important. It's due in part to the challenges
24 of collecting appropriate scientific information about

1 pediatric populations. We know we've got to address that
2 problem. You can't just assume that what we have for
3 adults works for children, but we have to do it
4 thoughtfully and carefully and with children's safety as
5 the highest priority.

6 We know that the best science has to be available
7 but that's really only part of the job. We have to look at
8 all of the costs and benefits, risks and opportunity and
9 then proceed in a way that really reflects our best values
10 as a nation as we go down this path.

11 So we are relying on you at the Department from
12 the Office of the President, because we know that the work
13 that you have done delivers rational, independent
14 evidence-based advice on a wide variety of issues. I can
15 think of no issue really more important, and really more
16 urgent, then helping us develop a pathway to figure out how
17 to keep our children safe and secure in the event that
18 something occurs.

19 So I just wanted to come and say, thank you.
20 Thank you for the work you have done. We seem to have no
21 lack of work for you to do. I wish we would run out of
22 issues to bring your way, but I don't think that's likely
23 to happen any time soon, but your work is critically
24 important and to the 300 million people or so who can't be

1 in the room today, I want to say, thank you, on their
2 behalf because the problems that you're helping to solve
3 and sort through are really affecting the lives of a lot of
4 Americans, whether they know it or not. So thank you very,
5 very much, and thank you, again, Dr. Gutmann, for your
6 leadership and your willingness to take on these
7 challenges.

8 (Applause)

9 DR. GUTMANN: I think you'll all recognize, so I
10 would normally apologize, but I think no apologies are
11 necessary for this particular interruption, right? We all
12 know how busy the Secretary's schedule is, so really I have
13 to say personally, and I know Jim feels the same way, it's
14 really very good of her to take the time. I have no doubt
15 of her sincerity in how important it is for us to continue
16 the deliberations from where your board left off.