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Joan Claybrook, President

November 18, 1996

Harold Varmus, MD
Director
National Institutes of Health
Building 1, Room 126
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Varmus:

Because of our ongoing concern about the NIH-funded research project to randomize people who are injection drug users (IDUs) to receive or not receive sterile syringes from needle exchange programs (NEPs), we have completed a study to determine the actual availability of syringes through pharmacies in Anchorage, Alaska for those people who, through the process of randomization, are excluded from using the NEP. The results give lie to the claim of the study's Principal Investigator, Dennis Fisher, that the pharmacy condition represents an ethical alternative to NEPs because syringes are easily available through pharmacies in Anchorage. Even though the state has no requirement for a doctor's prescription in order to purchase syringes in pharmacies, our results demonstrate that only 14% of pharmacies in Anchorage consistently sell sterile syringes to people who may be IDUs in an unencumbered fashion. It is of particular concern that an African American woman was denied syringes at all five pharmacies she surveyed, including two that had sold syringes to non-African Americans the previous day. These data further demonstrate the unethical nature of the proposed research and underscore the need for it to be canceled immediately before the lives of IDUs are endangered.

Methods

Our study method was similar to that utilized in a previous study of syringe availability in St. Louis, Missouri (Compton W, Cottler L, Decker S, Mager D, Stringfellow R. Legal needle buying in St. Louis. American Journal of Public Health 1992; 82:595-6.), in which research assistants were sent in to pharmacies and attempted to purchase syringes. We used the list of

29 pharmacies attached to Dr. Fisher's NIH proposal. Two pharmacies in Eagle River, about 25 miles from Anchorage, and one hospital pharmacy were excluded from the study. Four independent pharmacies were closed on the weekend the study was conducted and an additional pharmacy on Dr. Fisher's list could not be located. This left 21 pharmacies for study.

Three volunteers (one white male, one African American female and one female of mixed white and Alaskan native descent, all in their mid-40s) were trained to participate in the study. Each was assigned pharmacies to visit and trained to approach the pharmacist or clerk and say verbatim: "I need a pack of ten 28-gauge, 100-unit insulin syringes, please." If the pharmacist or clerk refused to sell syringes, the volunteers were instructed to engage in casual conversation to determine why they could not purchase the syringes. The volunteers, none of whom are active IDUs, were dressed casually. They did not carry the survey instrument (questionnaire) into the pharmacy, but filled it out immediately upon leaving the pharmacy. The instrument also included questions addressing whether the pharmacist or clerk asked for a prescription for the syringes, whether they inquired about the volunteer's medical condition and whether the volunteer was required to sign a list of people purchasing syringes, all of which represent obstacles to syringe purchase. The volunteers also obtained receipts from those pharmacies willing to sell syringes. Pharmacies were visited once, except for two pharmacies that were visited twice.

Results

Seventeen of the 21 pharmacies were visited by the volunteers. Of these, only six (35%) agreed to sell syringes. However, two of these six refused to sell syringes to the African American woman the next day. (The African American woman was refused syringes at all five pharmacies she visited.) Of the six that agreed to sell syringes, three required the volunteers to sign a list of syringe purchasers, and one of these inquired into the medical need for purchasing syringes. A fourth pharmacy was located in a membership store (Costco) and required membership identification, which the volunteer happened to have. Thus, only two pharmacies, both from the Fred Meyers chain, provided unrestricted syringe sales. A call to corporate headquarters confirmed that this was corporate policy and so the third Fred Meyers in Anchorage was not visited and was counted as having syringes available. The average price for 10 syringes at the six pharmacies was $3.38, almost double what Dennis Fisher has publicly stated.

Six of the 11 pharmacies that refused syringe sales asked for a physician's prescription, even though Alaska has no prescription law. In addition, four

of the 17 pharmacies required the volunteer to sign a list of syringe purchasers and eight asked questions about the volunteer's medical condition. After being refused syringes at five Carr's pharmacies, a call to Carr's corporate headquarters confirmed that it was corporate policy not to sell syringes and thus three additional Carr's were not visited. Thus, including the four pharmacies that were not visited, only seven of 21 pharmacies (33%) sold syringes under any circumstances, two of which subsequently refused the African American volunteer and four of which had additional obstacles to syringe purchase. Therefore, in only the three Fred Meyers pharmacies (14% of the 21 pharmacies studied) is there consistent and unencumbered syringe access.

Discussion

These data underline the difficulty of obtaining sterile syringes in Anchorage (explaining in part the high hepatitis B and C prevalences there), and make the pharmacy condition in the University of Alaska randomized trial an unacceptable alternative to the NEP.

Three observations are in order. First, it should be noted that Anchorage is one of the few cities in the United States that has a municipal paraphernalia law (most states, although not Alaska, have state paraphernalia laws), which effectively gives the pharmacist the responsibility of determining whether the syringe will be used for a legitimate medical purpose. This in part explains the reluctance of pharmacies to sell syringes to IDUs. And, despite Dr. Fisher's claim that those assigned to the pharmacy condition will be given vouchers for free syringes in pharmacies (Beswick T. NIH freezes needle exchange study: UCSF researcher requests ethics review. Bay Area Reporter, October 24, 1996, p. 23), there is no mention of vouchers (for either syringes in pharmacies or for hepatitis B vaccination) in his NIH protocol.

Second, despite Dr. Fisher's claim that IDUs are not willing to take the three-injection hepatitis B vaccine, those who have made a real effort to accomplish this have met with notable success. For example, in Italy 91% of IDUs recruited and retained in an hepatitis B vaccination program completed all three injections (Lugoboni F, Mezzelani P, Venturini L, Fibbia GC, Des Jarlais DC. An HBV vaccination program from street injecting drug users: implications for testing an HIV vaccine. Presented at VIIIth International Conference on AIDS, Amsterdam, 1992 (PoC 4796)). The difficulty of vaccinating IDUs is therefore a self-serving excuse by Dr. Fisher to avoid obliterating hepatitis B as a study endpoint in his study.

Third, IDUs prevented from attending the NEP will be losing more than free access to sterile syringes. They will also be losing access to the following additional free services that, according to Dr. Fisher's protocol,

are to be provided by the Anchorage NEP, but are not available at pharmacies: condoms, bleach for the disinfection of injecting equipment, alcohol wipes, sterile water and HIV prevention literature.

Interestingly, the question of conducting a randomized controlled trial of NEPs was considered by the National Academy of Sciences panel in its landmark review of the efficacy of NEPs. The panel's report did not even discuss the possibility of randomizing by individual, the method proposed by Dr. Fisher, presumably because the National Academy of Sciences panel believed that community randomization is a preferable method for assessing community-based interventions like NEPs. The report stated: "Furthermore, given the results of two recent government-sponsored reports that concluded that these programs have positive effects and do not appear to have negative effects [the same conclusion ultimately reached by the National Academy of Sciences in its report], it may not be ethical to withhold treatment from communities willing to initiate such programs ... The panel recommends adopting strong observational epidemiologic designs rather than attempting to conduct large-scale randomized experiments to evaluate needle exchange and bleach distribution programs" (Normand J, Vlahov D, Moses LE. Preventing HIV Transmission: The Role of Sterile Needles and Bleach. National Academy Press, Washington, DC, 1995).

Our data from Anchorage document the multiple obstacles to syringe purchase in pharmacies and demonstrate the inadequacy of pharmacy syringe sales as an alternative to NEPs. Indeed, to follow the researchers' logic, if existing pharmacy sales practices in states without prescription laws were indeed an ethical alternative to NEPs, there would be no need for NEPs in any state without a prescription law. Not one of the six federally funded reviews referred to in our previous letter to you (or any other study to our knowledge) made the recommendation that NEPs are only necessary in states with prescription laws; instead most endorsed the combination of pharmacies and NEPs as the optimal national approach to providing sterile syringes to IDUs. As has been demonstrated throughout the world, given access to both NEPs and pharmacies, some IDUs will choose to use NEPs, some will choose pharmacies, and a significant proportion will use both. It is precisely that choice that IDUs who are enrolled in the Anchorage study will be denied. It is time for the NIH to admit its error and put an end to this highly unethical and exploitative study.

Sincerely,

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Research Associate

Sidney M. Wolfe, M.D.
Director